UNIVERSITE DU QUEBEC A MONTREAL

CONSUMER SAFETY LAW ON GLOBAL AND REGIONAL MARKETS

THESIS
PRESENTED
AS A PARTIAL REQUIREMENT
OF THE DOCTORATE IN LAW

BY
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JULY 2017

UNIVERSITE DU QUEBEC A MONTREAL

LA PROTECTION JURIDIQUE DE LA SECURITE DU CONSOMMATEUR AU SEIN DE MARCHES GLOBALISES ET REGIONALISES

THESE
PRESENTE EN COTUTELLE
COMME EXIGENCE PARTIELLE
DU DOCTORAT EN DROIT

PAR
STANISLAV LOVETSKI

Juillet 2017

ACKNOWLEDGEMENTS

I am grateful to all the people who gave me the possibility to complete this thesis.

Most importantly, I would like to thank my supervisor, Dr. Thierry Bourgoignie of the Department of Juridical Sciences, Université du Québec à Montréal (UQÀM). Mr. Bourgoignie has been a valuable source of motivation and insightful comments. I also wish to thank all my professors for the knowledge they have passed on to me.

I would also like to express my regards to everyone from the Department of Juridical Sciences and especially Mme Guylaine Mireault for all the administrative work regarding my academic file.

I would further like to thank Donald MacKeigan (Montreal) for his linguistic advice and his expert opinion.

Finally, I would like to very much thank Paul Chamberlain (Mexico), Denis Champagne (Montreal), and Alain Dagenais (Montreal) for all indispensable support and help throughout my studies.

DEDICATION

To my mother, Tamara.

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ABBREVIATIONS

AHJWG	Ad Hoc Joint Working Groups on Enhancing Cooperation and Coordination among the Basel, Rotterdam, and Stockholm Conventions
API	Active Pharmaceutical Ingredients
AQSIQ	General Administration of Quality Supervision, Inspection and Quarantine of China (RAPEX)
ATP	Adaptation to Technical Progress [CLP regulation] (European Union)
AUHM	Appropriate Use of Herbal Medicines (Guidelines)
BAuA	Federal Institute for Occupational Safety and Health Federal Office for Chemicals (Germany)
CARREX	Rapid Alert System for Exchange of Information on Dangerous (non-food) Consumer Goods in CARICOM countries
CARICOM	Caribbean Community
CCPSA	Canada Consumer Product Safety Act
CE	Critical Element (U.S.A.)
CEC	Commission for Environmental Cooperation (U.S.A.)
CEPA	Canada Environment Protection Act
CETA	Comprehensive and Economic Trade Agreement between Canada and the European Union
CI	Consumers International
CiP	Chemicals in Products
CIS	Commonwealth of Independent States
CMP	Chemicals Management Plan (Canada)
CSA	Canada Shipping Act

CSHN	Consumer Safety and Health Network (OAS)
CLIA	Cruise Lines International Association
CLP	Classification, Labelling and Packaging of Substances [regulation] (European Union)
COP	Conference of the Parties (Rotterdam Convention)
COTED	Council for Trade and Economic Development (CARICOM)
CPC	Consumer Protection Code (Brazil)
CPSA	Consumer Product Safety Act (USA)
CPSC	Consumer Safety Commission (USA)
CPSIA	Consumer Product Safety Improvement Act (USA)
CRC	Chemical Review Committee (Rotterdam Convention)
CRP	Consumer Rights Protection [Committee] (EAEU)
CSHN	Consumer Safety and Health Network
DFATD	Department of Foreign Affairs, Trade and Development (Canada)
DSHEA	Dietary Supplement Health and Education Act (U.S.A.)
DGD	Decision Guidance Document (Rotterdam Convention)
DG SANCO	European Commission's Directorate General for Health and Consumer Policy
DIN	Drug Identification Number (Canada)
DNA	Designated National Authority (Rotterdam Convention)
DOT	Department of Transportation (U.A.S.)
DSB	Dispute Settlement Body (WTO)
EAEC	Eurasian Economic Community
EAEU	Euro Asian Economic Union
EC	European Commission
ECJ	Court of Justice of the European Union
ECHA	European Chemicals Agency (European Union)
ECLN	European Constitutional Law Network
EDB	Eurasian Development Bank (EAEU)

EDEXIM	European Database of Export and Import of Dangerous Chemicals (European Union)
EEA	European Economic Area
EEC	Eurasian Economic Commission (EAEU)
EFTA	European Free Trade Association
EI	[State on] Effective Implementation (ICAO)
EIHWHRMR	Export and Import of Hazardous Waste and Hazardous Recyclable Material Regulations (Canada)
EIHWR	Export and Import of Hazardous Waste Regulations (Canada)
EMSA	European Maritime Safety Agency (European Union)
EP	Environmental Programme (UN)
EPA	Environmental Protection Agency (U.S.A)
ESM	Environmentally Sound Management
EU	European Union
FAA	Federal Aviation Administration (U.S.A.)
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration (U.S.A.)
FDCA	Food, Drug, and Cosmetic Act (U.S.A.)
FHSA	Federal Hazardous Substances Act (U.S.A.)
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act (U.S.A)
FSPTC	Family Smoking Prevention and Tobacco Control (Act)
GASP	Global Aviation Safety Plan (ICAO)
GATT	General Agreement on Tariffs and Trade
GDP	Good Distribution Certificates (European Union)
GMDSS	Global Maritime Distress and Safety System (IMO)
GMO	Genetically Modified Organism
GMPs	Good Manufacturing Practices
GOST	State Standard (Russia)
GPSD	General Product Safety Directive (European Union)

GREDICC	Groupe de Recherche en Droit International et Comparé de la Consommation
HPR	Hazardous Products Regulations (Canada)
ICAO	Civil Aviation Organization
ICCM	International Conference on Chemicals Management (Chemicals in Products Project)
ICPEN	International Consumer Protection and Enforcement Network
ICTI	International Council of Toy Industries
IEHK	Interagency Emergency Health Kit
IGE	Intergovernmental Group of Experts (on Consumer Protection Law and Policy)
IHCP	Institute for Health and Consumer Protection (European Union)
IMDG	International Maritime Dangerous Goods Code (IMO)
INN	Non-proprietary Name (Pharmaceuticals)
IRPTC	International Registry for Potentially Toxic Chemicals
ISM	International Safety Management [Code] (IMO)
IASA	International Aviation Safety Assessment [program] (FAA)
ISO	International Organization for Standardization
MERCOSUR	Southern Common Market
MoU	Memorandum of Understanding (IMO)
NAPRA	National Association of Pharmacy Regulatory Authorities (Canada)
NCCIH	National Center for Complementary and Integrative Health (U.S.A.)
NHPs	Natural Health Products (Canada)
NIP	National Implementation Plan (Stockholm Convention)
NNHPD	Natural and Non-prescription Health Products Directorate (Canada)
NRER	Ministry of Natural Resources and Environment of the Russian Federation
OAS	Organization of American States
OCP	Official Contact Point (Rotterdam Convention)

OECD	Organization for Economic Co-operation and Development
PIC	Prior Informed Consent
POP(s)	Persistent Organic Pollutant(s) (Stockholm Convention)
PQMD	Partnership for Quality Medical Donations (U.S.A)
PSC	Post State Control (IMO)
OSHA	Occupational Safety and Health Administration (U.S.A.)
RAPEX	European Union Rapid Exchange Information System on Dangerous Goods
RASFF	Rapid Alert System for Food and Feed (European Union)
RCC	Canada-U.S. Regulatory Cooperation Council
RCRA	Resource Conservation and Recovery Act (U.S.A.)
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (European Union)
REIO	Regional Economic Integration Organizations (Stockholm Convention)
SARPs	International Standards and Recommended Practices (ICAO)
SAICM	Strategic Approach to International Chemicals Management
SDR	Special Drawing Right (Athens Convention)
SIAR	Inter-American Rapid Alert System (SIAR [for its Spanish acronym])
SOLAS	Safety of Life at Sea (Convention)
SPS	Sanitary and Phytosanitary (SPS Agreement)
SSC	Significant Safety Concern (ICAO)
STCW	Standards of Training, Certification and Watchkeeping for Seafarers [Convention] (IMO)
STC	Specific Trade Concern
TBT	Technical Barriers to Trade [Agreement]
TFEU	Treaty on the Functioning of the European Union
TMSP	Third Maritime Safety Package (European Union)

TSB	Transportation Safety Board (Canada)
TSCA	Toxic Substances Control Act (U.S.A.)
TTIP	Transatlantic Trade and Investment Partnership
UNCTAD	United Nations Conference on Trade and Development
UNECE	United Nations Economic Commission for Europe
USOAP	Universal Safety Oversight Audit Program (ICAO)
WHA	World Health Assembly
WHO	World Health Organization
WSSD	World Summit on Sustainable Development
WTO	World Trade Organization

SUMMARY

While national consumer protection measures may have been sufficient to protect the safety of consumers in past decades, this is not the case anymore under contemporary market conditions. Free-trade rules make consumers more vulnerable in the marketplace since they may have the effect of dismantling or reducing national consumer protection measures. The regionalization and internationalization of markets has become one of the main challenges of modern consumer law and policy.

Recent headlines have suggested that we are in middle of a global consumer safety crisis. An ever-increasing number of dangerous non-food products are being recalled from the global market on a regular basis. Despite the fact that safety is a priority need for consumers and the quest for safety is shared by all consumers worldwide, few or no attempts have yet been made by legal scholars to identify the key features of an adequate legal and institutional framework for the safety of non-food consumer products and services on global and regional markets.

This work intends to contribute to the design of such an international response. The purpose thereof is not to set out all conditions and requirements under which an effective protective framework for consumers could be put in place and made operational at the international level. The objective is less ambitious. The attempt is to identify, systemize and evaluate the existing international initiatives most likely to have an impact on consumer safety for non-food products and services.

This research evaluates whether and to what extent globalized or regionalized consumer markets do internalize the need for consumer protection against unsafe products and services made available to consumers. Most relevant developments taking place in the area of consumer safety at the international and regional levels will be identified and their impact assessed. The goal is to explore how far initiatives taken by international and/or regional institutions in the area of consumer safety contribute to ensuring a high level of protection of consumers against unsafe products and services on global or regional markets.

The research reveals that the existing policy approach has remained dispersed, sector-specific, slow moving and limited in scope. To date, thousands of potentially dangerous consumer products and services remain unregulated under international and regional safety schemes. A horizontal and comprehensive vision of consumer safety, including general safety legislation applicable to all products (and eventually all services) available on consumer markets has emerged only recently in some

countries, among which is Canada and regions such as the European Union. Such a global safety net remains unknown or undeveloped in most regions as well as at the international level. This lack of global vision has three main causes: the absence of an international institutional framework on consumer safety; conflicts between free trade rules and the consumer safety agenda; and the lack of common ground among countries for assessing safety hazards and risks.

This review suggests, in a conclusive part, initiatives that could enhance in a realistic manner the protection of consumers against unsafe products and services circulating on global markets. The following four recommendations are formulated: to designate one international institution as competent to deal with consumer safety maters; to work on a new generation of trade agreements, whether multilateral or bilateral ones, that would formally include consumer protection as one of their policy objectives and hence admit consumer protection as a legitimate exception from the application of the agreement free trade rules; to promote a global and common understanding of product safety parameters through a mix of hard-law and soft-law initiatives; to design a worldwide knowledge-based policy tool in the area of product safety and make it operational.

CONSUMER PROTECTION- CONSUMER SAFETY – INTERNATIONAL CONSUMER LAW – REGIONAL INTEGRATION- HARMONISATION OF LAWS – CONSUMER PRODUCTS- INTERNATIONAL CARRIAGE- CHEMICALS - PHARMACEUTICALS -ROTTERDAM CONVENTION- STOCKHOLM CONVENTION- BASEL CONVENTION- SOLAS CONVENTION- CHICAGO CONVENTION

RÉSUMÉ

Si les mesures nationales de protection des consommateurs ont été efficaces au cours des dernières décennies, ce n'est plus le cas dans la présente conjoncture, car les règles du libre-échange pourraient avoir pour effet de les abolir ou de les affaiblir, rendant ainsi les consommateurs plus vulnérables. La régionalisation et la mondialisation des marchés comptent aujourd'hui parmi les principaux problèmes relevant du droit et des politiques qui régissent la consommation.

Récemment, les gros titres de la presse ont pu faire croire à une crise mondiale de la sécurité des consommateurs. En effet, le nombre de biens non alimentaires dangereux rappelés par les fabricants est en constante augmentation. Or, alors que la sécurité des biens est un besoin prioritaire pour les consommateurs de tous les pays, peu de juristes, voire aucun, ont entrepris à ce jour de recenser ce qui constituerait les paramètres essentiels d'un cadre légal et institutionnel suffisant pour assurer la sécurité des biens et des services de consommation non alimentaires sur les marchés mondiaux et régionaux.

Cette recherche a pour but de contribuer à définir cette réponse internationale. Cependant, elle ne consiste pas à dresser la liste exhaustive des conditions essentielles à l'établissement d'un cadre de protection des consommateurs et à son bon fonctionnement à l'échelle internationale. Moins ambitieux, son objectif est de recenser, de systématiser et d'évaluer celles des initiatives internationales actuelles qui sont le plus à même d'améliorer la sécurité des biens et des services de consommation non alimentaires.

Cette étude cherche à déterminer si les marchés de consommation mondialisés ou régionalisés tiennent compte de la nécessité de protéger les consommateurs contre les biens et les services dangereux et, le cas échéant, la mesure dans laquelle ce besoin est respecté. Le but est de recenser les actions les plus pertinentes menées pour protéger les consommateurs à l'échelle internationale et régionale et d'en évaluer les effets. On entend ainsi mesurer le degré de protection que les initiatives prises par les instances internationales et régionales compétentes offrent aux consommateurs contre les biens et les services dangereux dans les marchés mondiaux et régionaux.

L'étude révèle que l'approche stratégique employée à l'heure actuelle reste lente, limitée, dispersée et adaptée seulement à des secteurs d'activité précis. Aussi des milliers de biens et de services de consommation potentiellement dangereux échappent-ils encore aux régimes de réglementation internationaux et régionaux. L'idée d'un système de protection des consommateurs exhaustif et horizontal, qui

engloberait l'application de lois générales visant tous les biens (et, à terme, tous les services) offerts dans les marchés de consommation, n'a vu le jour que récemment, et ce, uniquement dans certains pays (dont le Canada) et certaines régions (dont l'Union européenne). Ce type de mécanisme, appliqué à l'échelle mondiale, demeure inconnu ou embryonnaire dans la plupart des régions, de même qu'à l'échelle internationale. Ce manque de vision globale est attribuable à trois facteurs : l'absence de cadre institutionnel international en matière de protection des consommateurs ; le conflit qui oppose les règles du libre-échange et les principes de la protection des consommateurs ; et le fait que les pays ne s'entendent pas sur la question de l'évaluation des risques.

Dans sa conclusion, l'étude met de l'avant des initiatives réalistes qui pourraient améliorer la protection des consommateurs contre les biens et les services dangereux en circulation dans les marchés mondiaux. Les quatre recommandations suivantes sont formulées : donner à une instance internationale le pouvoir de régir la question de la protection des consommateurs ; concevoir des accords de libre-échange multilatéraux et bilatéraux de nouvelle génération dont la protection des consommateurs constitue l'un des objectifs stratégiques et, partant, une exception légitime à l'application des règles de libre-échange ; promouvoir l'adoption, à l'échelle internationale, d'une vision commune de ce qui constitue un bien sûr en mettant en œuvre des initiatives relevant du droit dur et du droit mou ; concevoir et mettre en œuvre un système stratégique mondial de gestion des connaissances dans le domaine de la sécurité des biens.

PROTECTION DES CONSOMMATEURS- SÉCURITÉ DES CONSOMMATEURS – DROIT INTERNATIONAL DE LA CONSOMMATION – INTÉGRATION RÉGIONALE- HARMONISATION DES LOIS – BIENS DE CONSOMMATION- TRANSPORT INTERNATIONAL- PRODUITS CHIMIQUES - PRODUITS PHARMACEUTIQUES -CONVENTION DE ROTTERDAM- CONVENTION DE STOCKHOLM – CONVENTION DE BÂLE- CONVENTION SOLAS- CONVENTION DE CHICAGO

INTRODUCTION

Although consumption has existed forever, it has more recently reached new heights as one result of market globalization. Today, almost every aspect of our existence depends on consumption, from quality of everyday life to health and security. Thus, any failure or shortcoming in the good functioning of the market will affect consumers, especially when it comes to the safety of products and services made available to them.

Safety is the foundation of our existence and wellbeing. The *Oxford Dictionary* defines "safety" as "being protected from or unlikely to cause danger, risk, or injury".[1] Accordingly, some scholars tend to link the concept of safety with accident prevention. They consider "safety" as meaning "no (avoidable) accidents", or more realistically, "as few accidents as possible".[2] In relation to consumers, safety means that only products or services with hazardless properties should be in circulation in the market.

Yet, the concept of safety for consumer products and services is not as simple as it appears at first sight. In theory, any consumer product or service, under certain circumstances, could be hazardous or even deadly. Nevertheless, society has willingly tolerated a certain degree of risk in products and services, especially when the risks

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[1] *Oxford Dictionary*, online: Oxford Dictionary <http://www.oxforddictionaries.com>.
[2] Jiefang Huang, *Aviation Safety and ICAO* (Alphen aan den Rijn: Kluwer Law International, 2009) at 4, online: Leiden University <https://openaccess.leidenuniv.nl/bitstream/handle/1887/13688/000-huang-diss-28-01-09.pdf?sequence=1>.

are understood to be inherent in their use. For example, alcohol and "junk" foods by their very nature pose risks to consumers' health if consumed in excess albeit only over time. Other products like a kitchen knife or a bike might cause instant grave injuries and even death if used without proper instructions or training. Consumers have been willing to accept such risks. However, when two similar products or services are on the market and one of them is safe and the other not, the public has right to ask: Why is a hazardous product/service allowed to be in the market place?[3]

The problem of unsafe consumer products and services coexisting with goods the public assumes to be safe has recently become more acute as one consequence of market globalization.[4] The surge in global trade has given to consumers an unprecedented variety of products at bargain prices, but at the cost of diminished effectiveness of national safety rules. Well-established domestic consumer safety schemes have little or no impact on overseas product design or manufacturing processes. Government institutions established to guard product safety, such as customs or national standards boards, simply do not have enough work force or financial recourses to verify and test every consumer product crossing the border daily. Moreover, under World Trade Organization (WTO) rules governments have limited options when it comes to product safety. Import restrictions related to consumer safety may be regarded as trade barriers that must be dismantled. Under such circumstances national consumer safety legislation is in persistent jeopardy.

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[3]Cary Coglianese, Adam Finkel & David Zaring, *Import Safety: Regulatory Governance in the Global Economy* (Philadelphia: University of Pennsylvania Press, 2009), at 10&11.

[4]*Ibid.* at 11 & also in Thierry Bourgoignie, "Un droit de la consommation est-il encore nécessaire en 2006? ", in *Regards croisés sur les enjeux contemporains du droit de la consommation*, ed. by Thierry Bourgoignie (Cowansville, Quebec: Yvon Blais Inc, 2006), at 20-26.

Recent headlines have suggested that we are in middle of a global consumer safety crisis. In the US alone, deaths, injuries, and property damage from consumer product incidents cost the nation more than $1 trillion annually.[5]

An ever-increasing number of dangerous products have been recalled from the global market on a regular basis. For instance, a problem with hazardous batteries overheating is persistent for numerous electronic devices. In two of the best-known cases, only a miracle has saved consumers' lives. In 2008, Sony globally recalled more than 10,000,000 batteries because of notebook computer cells overheating, causing property damage and burns ending up with a staggering 429 million in overall costs.[6] In 2016, the newest Samsung smartphone - Galaxy 7 - has had similar problems. After 92 reports in the United States alone of the batteries overheating, containing 26 reports of injuries and 55 reports of property damage including fires in cars and a garage, the US authorities ordered a recall of one million units.[7]

Multinational toy manufacturers withdrew from the market millions of toys in response to the discovery of lead paint or unsafe magnetic parts on many popular toys brands such as Barbie that were produced in China and sold worldwide.[8] After seven

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[5]CPSC, *Port Surveillance News: CPSC Stops More Than 12.5 Million Units of Violative Products from Reaching Homes in Fiscal Year 2013* (5 May 2014), online: CPSC <http://www.cpsc.gov/en/Newsroom/News-Releases/2014/Port-Surveillance-News-CPSC-Stops-More-Than-125-Million-Units-of-Violative-Products-from-Reaching-Homes-in-Fiscal-Year-2013/>.

[6]Mark Hachman "Sony's Latest Battery Recall", *PC Mag* (31 October 2008), online: PC Mag <http://www.pcmag.com/article2/0,2817,2333692,00.asp> & Susan Arendt, "Sony Battery Recall Costs $429 Million", *PC Mag* (26 October 2006), online: PC Mag <http://www.pcmag.com/article2/0,2817,2040936,00.asp> & CPSC, *Sony Recalls Notebook Computer Batteries Due to Previous Fires* (23 October 2006), online: CPSC <https://www.cpsc.gov/en/Recalls/2007/Sony-Recalls-Notebook-Computer-Batteries-Due-to-Previous-Fires/>.

[7]Anita Balakrishnan, "Samsung, Safety Regulators Officially Recall about 1 Million Galaxy Note 7 phones", *CNBC* (15 September 2016), online: CNBC <http://www.cnbc.com/2016/09/15/consumer-safety-agency-plans-recall-of-samsung-galaxy-note-7-dj-citing-official.html> & CPSC, *Samsung Recalls Galaxy Note7 Smartphones Due to Serious Fire and Burn Hazards* (15 September 2016), online: CPSC <http://www.cpsc.gov/en/Recalls/2016/Samsung-Recalls-Galaxy-Note7-Smartphones/>.

[8]Louise Story, "Putting Playthings to the Test", *New York Times*, (22 August 2007), online: New York Times

fatalities and more than 100 injuries worldwide were linked to faulty airbags produced by the Takata Corp.,[9] the company initiated one of largest auto recall in history, replacing more then 30 million defective airbags on vehicles made by ten different automakers.[10] The list goes on. Needless to say that only extraordinary consumer product recalls have made their ways to headlines. Smaller scale crises with consumer product safety have not been covered by the news outlets.

On the regional level, safety problems related to imported consumer products have demonstrated similar tendencies. The 2015 Annual Report released by the European Union (EU) Commission shows that the number of notifications sent through the European Union Rapid Exchange Information System on Dangerous Goods (RAPEX) in recent years has been increasing dramatically, from four in 1984 to 2125 in 2015. Only 15% of all notifications sent through RAPEX concerned products originating from the 28 EU Member States and three European Free Trade Association (EFTA) countries. More than 80% of unsafe consumer products originated outside of Europe Union; predominately, in 62% of cases, in China and Hong Kong.[11]

Without a doubt, hazardous product recall is one essential and useful instrument to protect consumers. Yet, recall is a mechanism to correct or ease the problem with dangerous products already in stores or in consumer hands. It does not prevent such

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<http://query.nytimes.com/gst/fullpage.html?res=9D0CE1DE1E3AF93AA1575BC0A9619C8B63&pagewanted=all>.

[9]The chemical that inflates the air bags could explode with too much force, blowing apart a metal inflator and sending shrapnel into the passenger compartment.

[10]*Everything You Need to Know about the Takata Airbag Recall* (23 December 2015), online: Consumer Reports <http://www.consumerreports.org/cro/news/2014/10/everything-you-need-to-know-about-the-takata-air-bag-recall/index.htm> & Marcy Gordon & Tom Krishner "Largest Auto Recall in U.S. History: Takata says 34 Million Airbags Defective", *Associated Press* (19 May 2015), online: CTV News <http://www.ctvnews.ca/autos/largest-auto-recall-in-u-s-history-takata-says-34-million-airbags-defective-1.2380824>.

[11]EC, *EU RAPEX Annual Report 2015* (2016), online: EC <http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/reports/docs/rapex_annual_report_2015_en.pdf>.

products from entering the market in the first place. Often recalls have been done unforgivingly late; by then many consumers have already died and been injured. Moreover, producers have frequently refused to admit that their products are unsafe. For instance, after initial reports on injuries and deaths were filed, the airbag maker Takata Corp. refused to declare the inflators defective and even questioned the US agency's authority to order it to conduct a recall. Only after pressure and legal actions from U.S. safety regulators the company agreed to replace faulty airbags.[12]

The regulatory landscape in many developing countries, where the majority of consumer products are made today, is uneven and unpredictable. When product safety crises have occurred local authorities have often refused to cooperate. In cases of consumer death or injury, legal or criminal ramifications for foreign producers are questionable. Even the US government, with its almost unlimited resources, has little power to punish offending manufacturers abroad. After at least eighty-one Americans died from contaminated heparin produced in China, local authorities did not permit the US Food and Drug Administration (FDA) to conduct an investigation or press any charges against a Chinese manufacturer.[13]

The crisis with ready-to-use merchandise produced overseas is only one side of the global consumer safety problem. The safety of domestically made products is in question as well. *Per se,* the logo "Made in Canada" does not necessary indicate that the entire product and its components are manufactured somewhere between British Columbia and Newfoundland. In many instances, it would be more accurate to label products as "Assembled (Put Together) in Canada", perhaps.[14] Nowadays, the supply chains for manufacturing, especially technically complex products such as cars and

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[12]*Op. cit.* 10 (*Everything you Need to Know About the Takata Airbag Recall*)
[13]More on heparin crises see CHAPTER II at 2.2.2.
[14]In fact, Canada does not have a regulation regarding labeling standards for "Made in Canada" logo. The existing guidelines are not legally binding. The guidelines suggest that the logo "Made in Canada" should be put on products when more than 51% of value is originated in Canada.

electronics, are vast and multilevel, counting hundreds or even thousands of contractors from around the globe. Any, even the smallest, faulty part or substandard ingredient imported from overseas might make the entire product assembled domestically unsafe and deadly; as it happened in cars using airbags from Takata Corp. Hence, ongoing global consumer safety crises affects both imports and domestically made products.

In this era of globalization, the importing country has only a few limited options to protect its national market from hazardous products. It may simply rely on the safety standards in force in the exporting country. In theory, this approach would work if safety standards in the exporting country were equal or more protective than in the importing country. In majority of cases, however, product safety standards in developing countries, where mass production is concentrated, are significantly less protective or absent at all.

Alternatively, the importing nation may screen products when they cross the border and enter its jurisdiction. Of course, in an era of expanding global trade, the task of inspecting and testing each product entering from international trade is just a "mission impossible". Even an ambitious US Government plan to X-ray all shipping containers for nuclear weapons only before they entered the United States has been put on hold after US customs officials admitted that the goal was unachievable.[15] The most realistic and practical option would be for exporting and importing countries to harmonize their standards, production and quality control protocols, and legal and regulatory frameworks for consumer safety. Subsequently, by developing cooperation in informational exchange and mutual inspections, both parties could

[15]Customs and border protection officials scanned with X-ray or gamma-ray machines only 473,380, or 4.1 percent, of the 11.5 million containers shipped in 2012; roughly the same amount as in 2007. (Jeff Bliss, "U.S. Backs Off All-Cargo Scanning Goal With Inspections at 4%" *Bloomberg* (13 August 2012), online: Bloomberg <http://www.bloomberg.com/news/articles/2012-08-13/u-s-backs-off-all-cargo-scanning-goal-with-inspections-at-4->.

enforce shared standards and regulations bringing product safety to an adequate and common level. Such harmonization could be done on a bilateral or multilateral basis.

However, bilateral agreements or multilateral agreements with a limited number of contracting parties do not sufficiently protect consumers from hazardous products due to their limited geographical scope of application. On global markets, imports come from a multitude of exporting countries. Existing production processes and distribution channels for consumer products are complex and multilevel, involving multiple suppliers and importers from different parts of the world. Hence, only a global partnership would set up a comprehensive legal and technical framework to protect universally consumers' life and health.

Furthermore, bilateral or multilateral agreements on consumer safety create discriminatory business conditions. Higher regulated geographical areas will suffer from unfair competition from less regulated ones. Undoubtedly, it will also create barriers to trade, providing grounds for future litigations under the WTO. Needless to say that a geographically spotty regulatory pattern might further jeopardize global safety as without comprehensive multilateral harmonization products that have been prohibited or restricted in higher regulated areas are more likely to be dumped into less regulated parts of the world. Hence, only global implementation of safety policies and market surveillance activities would set up conditions to facilitate international business, to promote healthy global competition, and to ensure that every consumer in every part of the world is safe.

In this research, the intent is to evaluate whether and to what extent globalized or regionalized consumer markets do internalize the need for consumer protection against unsafe products and services made available to consumers. Most relevant developments taking place in the area of consumer safety at the international and regional levels will be identified and their impact assessed. The goal is to explore

how far initiatives taken by international and/or regional institutions in the area of consumer safety do contribute to ensuring a high level of protection of consumers against unsafe products and services on global or regional markets.
Within the broad range of categories of products, only non-food products will be considered. Indeed, well developed international legal and institutional frameworks on food safety have been put in place for decades.[16] On the contrary, international initiatives targeted at non-food consumer products, and at services as well, have developed at an unforgivably slow pace. Furthermore, these measures have remained sectoral and limited to particular groups of non-food consumer products, such as chemicals and pharmaceuticals, and to a few services, such as passenger carriage.

Few or no attempts have yet been made by legal scholars to look at the global picture to better understand the roots of existing problems with global consumer safety for non-food consumer products and services.

The conduct of the study has been organized to develop three main theses.

1. THESIS ONE. Proclaiming and confirming the need for supra-national responses: for many years initiatives in the area of consumer safety have remained mostly national; but recently developed open-borders policies or market regionalization and globalization call for international responses (CHAPTER I).

[16]Since 1963, consumer health and life have been protected through the harmonization of the international safety standards for all foods under umbrella the *Codex Alimentarius*. Over the decades, the 188 Codex members have negotiated science-based recommendations in all areas related to food safety: food hygiene; maximum limits for food additives; residues of pesticides and veterinary drugs; and maximum limits and codes for the prevention of chemical and microbiological contamination. While being recommendations for voluntary application by members, Codex standards serve in many cases as a basis for national legislation. More on *Codex Alimentarius* see: *Codex Alimentarius,* online: FAO <http://www.fao.org/fao-who-codexalimentarius/codex-home/en/>.

2. THESIS TWO. Assessing the existing international sources of consumer safety in the non-food sector: although more numerous than for other consumer protection subject matters, international responses to the need for increased consumer safety on global markets remain few and sectoral, mix often conflicting goals and lack effectiveness (CHAPTER II).

3. THESIS THREE. A new input from economically integrated regions: initiatives taken by regional institutions in the consumer safety area prove to be more comprehensive and far-reaching; however, their actual impact will depend upon a set of conditions or parameters that few regional systems actually meet (CHAPTER III).

The above described review and assessment will lead us to draw some general conclusions and formulate suggestions for new initiatives that could contribute in a realistic manner to the protection of consumers against unsafe products and services circulating on global markets.

CHAPTER I

CONSUMER SAFETY IN OPEN BORDERS MARKETS: THE NEED FOR INTERNATIONAL RESPONSES

The right of consumers to receive protection against unsafe products and services made available in the market place has been confirmed and given actual implementation under national consumer laws worldwide (1.1). It has also been proclaimed by the United Nations as one of the basic "consumer needs" to be satisfied by governments. This international recognition of consumer safety as a basic concern significantly helped in building adequate legislation throughout the world (1.2). Indeed, the development of open-border consumer markets in the context of market globalization and regionalization creates new challenges for the safety of consumers and urgently calls for international or regional responses (1.3).

1.1 Consumer' right to safety under national consumer legislation

Until the second part of the last century, the general belief was that the free market economic model in line with Adam Smith's "invisible hand" concept[17] was sufficient to ensure consumer welfare. As a result, specific protection of the weaker party in the market place was considered unnecessary.[18]

The situation began to change towards the end of the 1950s, when mass production and wide access to credit spurred an unprecedented consumer boom in Europe and North America. Unfortunately, the lack of consumer voices in the legal and policy decision-making spheres led to constant abuses of consumers. Spontaneously or under pressure from civil society, the political establishment quickly came to admit that the gross imbalance of powers, resources and rights between economic operators and consumers had serious economic and social impacts that needed to be prevented or at least mitigated.

Despite consumers mobilizing and consumer-association movements spreading widely throughout the world, consumers remained poorly organized and represented in comparison to business interests. Nevertheless, because every citizen/constituent is a consumer, in democratic societies the political elite is constantly under pressure

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[17]Adam Smith introduced the "invisible hand" concept in his book the *Wealth of Nations* in 1776. He assumed that an economy functions well in a free market scenario where everyone works for his/her own interest. He assumed that an economy comparatively works and functions well if the government leaves people alone to buy and sell freely among themselves. He suggested that if people were allowed to trade freely, self-interested traders present in the market would compete with each other, leading markets towards the positive output with the help of an "invisible hand". Today, the invisible-hand theory is often presented in terms of a natural phenomenon that guides free markets and capitalism in the direction of efficiency, through supply and demand and competition for scarce resources, rather than as something that results in the well-being of individuals. See more on the "invisible hand" theory: Joy Blenman, *Adam Smith: The Father Of Economics*, (7 September 2016), online: Investopedia <http://www.investopedia.com/articles/economics/08/adam-smith-economics.asp>.

[18]Iris Benohr, *EU Consumer Law and Human Rights*, (Oxford, U.K.: Oxford University Press 2013), at 12.

from public frustration and outcry if government institutions fail to provide effective consumer protection. Needless to say, the detrimental effects of an inconsistent consumer protection agenda propagate to all levels of the society. It weakens the foundation of democratic and economic institutions by aggravating unfair and unequal distribution of justice between social groups (consumers vs. businesses) and undermining consumer confidence in the way the market operates.

To correct the patent failures of the legal and economic foundations of the free market, governments must allow consumer interests to use countervailing power to rectify the inherent imbalances between consumers and economic operators.[19] This rationale for third-party intervention is especially relevant when safety is at stake and damages are caused to consumers' health and life. Indeed, lack of individual safety has a cost for society as a whole.[20] In particular, the problem crystalized in the aftermath of health scandals during the 1950s, such as the thalidomide crisis.[21] A series of actions were carried out to make consumers a competent free-market player with a set of rights to be confirmed and given effective protection.[22]

Many recognize March 15, 1962, as one of the most important days in the history of consumer protection, as it was on this date that the Bill for Consumer Rights was introduced in the US Congress and President J.F. Kennedy gave a speech during which he stated:

> "If a consumer is offered inferior products, if prices are exorbitant, if

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[19]John Goldring, *Consumer Protection, the National-State, Law, Globalization, and Democracy,* at 1 to 5, online: School of law: University of Wollongong <http://jcmc.indiana.edu/vol2/issue2/goldring.html >.

[20]Guido Calabresi, *The Cost of Accidents: A Legal and Economic Analysis*, (Yale University Press, 2008), at 131 to 135 & at 289 to 309.

[21]*Op. cit.* 18 (Iris Benohr) at 12&13. For information on Thalidomide health crises see CHAPTER III at 3.2.7.

[22]*Ibid.* (Iris Benohr).

> drugs are unsafe or worthless, if the consumer is unable to choose on an informed basis, then his dollar is wasted, his health and safety may be threatened, and national interest suffers".

The speech was the first high-level political message to recognize consumers as the only players in the national economy who were not organized to defend their interests. In this landmark message, J.F. Kennedy proclaimed four basic consumer rights. The right to safety - protection against product hazards to life or health - came first; then the right to choose - consumer access to a variety of products and services at fair prices; the right to information - protection against dishonest or misleading information or practices which could affect consumers' ability to make the right choice; and the right to be heard - adequate recognition of consumer needs in government policy and legislation. In 1975, President G. Ford added the right of consumers to be educated, so as to prevent unfair exploitation of uninformed consumers.[23] Thus, since 1962, consumers have been recognized as an important group in society with the right to seek government protection.

Although consumer rights have been proclaimed now for 55 years and certain steps have been taken on different levels of government toward development and implementation of comprehensive consumer policies, consumers are still faced with an overwhelming number of everyday practices and behavior that are detrimental to their interests. The consequences may be just frustration or material losses, but they may also include physical harm or even death.

Still today, there are strong economic and social considerations which call for the consolidation by national policy-makers of active consumer protection programs and

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[23] *Consumer Rights and its Expansion,* Centre for Consumer Action Research and Training, online: Centre for Consumer Action Research and Training <http://www.cuts-international.org/Consumer-Rights.htm>.

for further development of consumer protection legislation[24], especially in the area of consumer safety.

There is also significant opposition or obstacles to such a move.

First, a highly significant and sensitive issue is the economic impact of consumer protection regulations on business. Governments strike a balance between consumer interests and the possible negative effects of consumer protection policy and law on the economy. The greatest disadvantage for economic operators is the extra cost of consumer protection measures, which can affect profit margins if product prices remain the same or lead to decreased sales as prices rise to reflect the additional extra measures. Market competitiveness is also at stake. Consumer protection regulations can also have economic implications for consumers if the extra cost of safety measures makes products too expensive to buy.[25]

Second, policy-makers and legal scholars may regard consumer law and policy as an unnecessary luxury.[26] Some believe that it is not necessary to have specific consumer protection regulations since competition law should eliminate dishonest producers from the market and an effective legal system should protect consumers' economic interests and physical safety by using existing legislation such as a civil code. In other words, a free market can self-regulate all consumer-related problems and government should just maintain fair competition between producers. This approach would work only if all producers in a market voluntarily institute and accept a code of operations

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[24]Thierry Bourgoignie, "Consumer Law and Policy Today: Everything Fine or Can We Do Better?", International Association of Consumer Law Conference, (2 July 2016), University of Amsterdam (The Netherlands), available on GREDICC website: <www.gredicc.uqam.ca> & *Op. cit.* 3 (Thierry Bourgoignie), at 1 to 18.

[25]*Op. cit.* 20 (Guido Calabresi), at 17 to 35.

[26]Ejan Mackaay, *L'analyse économique du droit de la consommation, dans Propos autour de l'effectivité du droit de la consommation*, ed. by Thierry Bourgoignie, (Cowansville, Quebec: Yvon Blais Inc, 2008) at 215-237.

and meticulously follow it. However, it is not likely that this scenario will ever work, since we do not live in an ideal world, and dishonest producers will always have an economic edge over honest producers.

While competition law and contract law may bring protection to consumers, their goals are much broader and consumer protection is not their dominant concern. For example, contract law assumes "that the parties to contract are legally equal in terms of power and information."[27] This concept works well for commercial contracts where parties exercise comparable powers, but it does not work for business-to-consumer relationships, as consumers do not have the same bargaining power and do not benefit from the same information and experience as economic operators. Contrary to contract law, consumer law presumes unequal relations between consumers and professionals, with the latter enjoying a superior position.[28]

While contract law can help in restoring more balance and fairness in consumer contracts, it cannot help in preventing, regulating and solving all types of market failures and imbalances, which do affect the position of consumers on the market place.[29] Many aspects of consumer protection go far beyond the application of contract law provisions, such as consumer information and education, product labeling and marketing, pre-market quality and safety controls, conformity assessment with voluntary or mandatory standards, corrective measures in case of product-related accident or increased risk of hazard, market surveillance, enforcement and redress procedures.

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[27]*Op. cit.* 19 (John Goldring), at 3 to 5.

[28]Denis Mazeaud, "Droit commun du contrat et droit de la consommation. Nouvelles frontières?", in *Études de droit de la consommation*, ed. Liber Amicorum & Jean Calais-Auloy (Paris: Dalloz, 2004), at 701.

[29]For detail analyses on such market failures, see Iain Ramsay, *Consumer Law and Policy: Text and Materials on Regulating Consumer Markets*, (Oxford and Portland, Oregon; Bloomsbury Publishing, 2012).

Hence, the argument is made by consumer lawyers for admitting the specificity, if not autonomy, of consumer law because of its specific nature, goals and instruments.[30] Such specificity is especially confirmed in the safety area, where indeed the following principles and tools give their imprint to consumer safety policy while departing from traditional private law principles:

1. *Safety as a collective interest.* Safety concerns are pertinent to all consumers and not only individual buyers or users. To protect such a collective interest calls for collective responses. Under contract law, the individual interests of the contracting parties will prevail.
2. *Prevention rather than compensation actions.* Measures must be taken to allow only safe products to be placed on the market in order to reduce the costs of individual, collective and external costs of product-related accidents.
3. *Social justice and solidarity in spreading safety risks.* Product-related risks are spread throughout society as a whole. Hence, liability rules based on individual producer negligence should be replaced by strict liability schemes.
4. *Specific administrative arrangements for consumer market surveillance.* Administrative law, rather than contract law, will provide for adequate and efficient institutions, powers and corrective actions.

Despite controversies about the status of consumer law, all countries throughout the world have put in place key elements of consumer regulations.[31] In most states,

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[30]Thierry Bourgoignie, "Lois générales sur la protection du consommateur et codes de la consommation en Europe", in *Pour une réforme du droit de la consommation au Québec*, ed. by François Maniet, (Cowansville, Qc.: Yvon Blais Inc., 2005), at 228; Thierry Bourgoignie, "La protection des consommateurs économiquement faibles ou le consommateur oublié", in *Droits des pauvres. Pauvre droit ?*, ed. Jeune Barreau Cabay, (Louvain-la-Neuve, 1984), at 149 à 162 & Gunther Teubner, "Substantive and Reflexive Elements in Modern Law", Law and Society Rev., 17:2, (1983), at 239 to 285.

[31]We must also bear in mind that in addition to laws and regulations, there are other factors that also affect just how well consumers are protected, such as cultural traditions, economic realities, effective

consumer law exists as a mandatory legislative framework that is reinforced and implemented through a system of state institutions. Even if legal and technical aspects of consumer law vary from state to state, the ultimate goal is the same, i.e. providing consumers with effective and adequate protection. The trend is universal, and it does not really matter what kind of background or social or economic structure the state may have: developed, as in the case of France;[32] in transition, as in Russia;[33] developing, as in Brazil;[34] or communist, as in China.[35] Every state confirms the need

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work of authorities, presence of active consumer movements, business practices and customs, etc. However, not all of these are included in this research.

[32]Consumer protection in France has a very long history dating back to 1804. However, the main avalanche of legislation related to consumer protection was developed between the 1970s and 1990s. Although consumer legislation in the early 1980s covered all crucial aspects of consumer protection, it was a vast mosaic of many unrelated and often incoherent pieces of law with which it was very difficult to work. The next important step in the evolution of French consumer law was made in 1982, when the Commission on reform of consumer protection law was set up with a mandate to incorporate all aspects of consumer legislation into one coherent and easy-to-work-with manuscript. As a result, in 1997, all documents related to consumer protection were integrated into the Consumer Code. The Code comprises five parts 1) consumer and contract information; 2) conformity and security of products and services; 3) indebtedness; 4) consumer associations; 5) institutions. The authors of the code tried to select and assemble the pieces of different laws into a framework of five focal points without making any amendments, and accordingly the code is still somewhat of a puzzle. As for consumer institutions, from 1976 to 1991 the French government had a department or ministry (1981-1983) responsible for consumer protection. Since 1991, consumer protection has fallen under the responsibility of a minister or state secretary as a supplementary assignment.

[33]In contrast with France, consumer protection in Russia has developed in a somewhat revolutionary manner. Before 1991, in Russia and throughout the former Soviet Union, consumers did not exist as a class, and the government was not required to protect individuals who did not subscribe to Soviet ideology. The situation changed dramatically after Russia became an independent state and moved toward a free-market economy. Consumer protection law was developed and adopted just a few months after the fall of the Soviet system. Because nothing existed before 1991, the Russian government had the opportunity to design a very structured and logical document that covers all aspects of consumer protection, from consumer safety and education to consumer unions and protection of consumers' economic interests. The law is very compact and easy to understand, even for people with only basic education, and so all consumers can know their rights. As for institutions responsible for consumer protection, after 1991, consumer protection was a prerogative of the anti-trust committee, and since 2004, consumer protection has been the responsibility of the State Service for Consumer Protection and Well-being, a Health and Social Development department.

[34]Consumer protection law was created in Brazil because of a constitutional amendment. Art. 5 of Chapter 1 of the Federal Constitution of 1988 refers to consumer rights and state responsibility to promote these rights. Two years later on September 11, 1990, the National Congress adopted law 8.078, better known as the Consumer Protection Code (CPC). The CPC gives consumers adequate and strong preventive protection against possible abuse. In parallel, the government established consumer protection institutions, such as consumer protection specialized prosecution offices, consumer stations, special civil courts, etc. For more on consumer protection in Brazil, see Luciano Pinto, *Consumer*

to protect consumers to some degree. Despite obstacles and reluctance by governments to act, consumer law has emerged and developed in all countries worldwide.

Provisions on consumer safety are one main element of consumer legislation. Such provisions can be found either as a specific chapter of comprehensive consumer protection laws (Brazil, Russia, China, France) or in separate consumer/product safety acts (Canada, the US).

The Brazilian *Código Brasileiro de Defesa do Consumidor*, recognizes consumers' rights on "safeguard of life, health and safety against risks caused by practices in supply of product and services considered hazardous or harmful". The code includes dozens of provisions on consumer safety which embrace all aspects of the matter from safety prevention measures to suppliers' liability.[36] Similarly, *Law of the People's Republic of China on Protection of the Rights and Interests of the*

Protection in Brazil, A General View, (2002), online: George Washington University, Institute of Business and Public Management Issues <http://www.gwu.edu/~ibi/minerva/Fall2002/Luciano.Maia.pdf>.

[35]In 1993, the People's Republic of China adopted the Act Respecting the Protection of Consumer Rights and Interests. The act came into force on January 1, 1994. The act, *inter alia*, enumerates in general terms consumer rights and the obligations of business dealers, and it enjoins state organizations to punish the criminal offences of business dealers who violate consumers' legal rights and interests. No new agency or redress mechanism was provided for, but the People's Courts are required to adopt measures to make it convenient for consumers to take legal proceedings and accept, hear, and try disputes over consumer rights and interests in conformity with Art. 30 of *Civil Procedural Law of the People's Republic of China*. (*Law of the People's Republic of China on the Protection of Consumer Rights and Interests*), online: Lehman law <http://www.lehmanlaw.com/resource-centre/laws-and-regulations/consumer-protection/law-of-the-peoples-republic-of-china-on-protection-of-the-rights-and-interests-of-the-consumers-1994.html>). In 2014, the Law was revised introducing new higher penalties for fraud and false advertising. The Law also clarified merchandise return policies. Finally, class-action lawsuits against retailer malfeasance were made easier to file. More information on law revision see: *Amendments to Consumer Protection Law Allows for Public Interest Lawsuits With Limitations*, online: Congressional Executive Committee on China <http://www.cecc.gov/publications/commission-analysis/amendments-to-consumer-protection-law-allows-for-public-interest>.

[36]*Código Brasileiro de Defesa do Consumidor,* at Art.6.1, online: Biblioteca do Senado Federal <<https://www2.senado.leg.br/bdsf/bitstream/handle/id/496457/000970346.pdf?sequence=1>.

Consumers,[37] French *Code de la Consummation*,[38] or Russian *Закон РФ О защите прав потребителей*[39], are all all-purpose consumer protection laws with specific stipulations regarding consumer safety. It is important to note that in addition to general consumer protection laws, several sectors of industry are subject to specific product safety legislation. This is the case, for example, with food, toys, household appliances, motor vehicles, pharmaceuticals and cosmetics.[40]

Canada and the US adopted a different approach to consumer safety regulation. While general consumer protection legislation lies in the hands of state or provincial governments, consumer safety remains a prerogative of the federal authority.
In the United States, the 1972 *Consumer Product Safety Act* (CPSA)[41] established an independent federal government agency - the Consumer Safety Commission (CPSC). The act gives CPSC the power to develop safety standards and pursue recalls or bans for products that present unreasonable or substantial risks of injury or death to consumers. In 2008, the *Consumer Product Safety Improvement Act* (CPSIA) amended CPSA to provide CPSC with significant new regulatory and enforcement tools as part of amending and enhancing several CPSC statutes on, among other things, lead, phthalates, toy safety, durable infant or toddler products, third-party

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[37]*Op. cit.* 35 (*Law of the People's Republic of China on Protection of the Rights and Interests of the Consumers*), at Art.7, 18, 27, 50.
[38]*Code de la consommation*, Art. L221-1 to L221-11, online: Legifrance <http://www.legifrance.gouv.fr/affichCode.do;jsessionid=14D18F0AE4A372668F5BE9F55FB08FC6.tpdjo03v_1?cidTexte=LEGITEXT000006069565&dateTexte=20130728>.
[39]*Закон РФ "О защите прав потребителей"*, [The Consumer Protection Act of the Russian Federation], art. 7, online: Общество Защиты Прав Потребителей <http://ozpp.ru/laws/zpp.php>.
[40]For example, toy safety requirements in Brazil are regulated by MERCOSUR Resolution N 23/04 - *Technical Standard on Toy Safety*. This regulation establishes requirements for physical and mechanical hazards, restricted substances, and flammability of toys. (MERCOSUR Resolution N 23/04 - *Technical Standard on Toy Safety*: NM 300.1: 2002 Safety of toys Part 1: General, mechanical and physical properties; Part 2: Flammability; Part 3: Migration of certain elements; Part 4: Experimental sets for chemistry and related activities; Part 6: Security of electric toys. See more on toy' standards: International Council of Toy Industries (ICTI), online: ICTI <http://www.toy-icti.org/info/toysafetystandards.html>).
[41]CPSC, *Consumer Product Safety Act,* online: CPSC<http://www.cpsc.gov//PageFiles/105435/cpsa.pdf>.

testing and certification, tracking labels, imports, ATVs, civil and criminal penalties and SaferProducts.gov, a publically-searchable database of reports of harm.[42]

In Canada, a major reform took place recently with the adoption of the federal *Canada Consumer Product Safety Act* (CCPSA) in 2010.[43] The key purpose of the CCPSA is to protect the public by addressing or preventing dangers to human health or safety that are posed by consumer products in Canada. This federal law lists prohibited products, sets protocols for incident reporting and product recall, and includes priority elements to make the market place safe. In addition to the Safety Act, sector specific regulations have been put in place.

1.2 Safety as one of the basic "consumer needs" proclaimed by the United Nations

In the early development of consumer protection law, pressures from international sources on national governments to develop a comprehensive consumer protection system that would include consumer safety remained sporadic and sectorial. For example, the *Convention for the Unification of Certain Rules Relating to International Carriage by Air, the Warsaw Convention,* was signed as early as 1929.[44] By regulating some terms of the passenger's contract and in particular liability matters, the Warsaw Convention was the first international document that explicitly set out consumer rights.

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[42]See more on CPSA, CPSC, and CPSIA, online: *United States Consumer Safety Commission* <http://www.cpsc.gov/en/>.

[43]*Canada Consumer Product Safety Act 2011* (S.C. 2010, c. 21), online: Department of Justice Canada <http://laws-lois.justice.gc.ca/eng/acts/C-1.68/index.html>.

[44]*Convention for the Unification of Certain Rules Relating to International Carriage by Air, Signed at Warsaw on 12 October 1929 (Warsaw Convention)*, online: McGill, <https://www.mcgill.ca/iasl/files/iasl/warsaw1929.pdf>.

Another initiative was the creation of the Codex Alimentarius Commission in 1963 by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) to develop food standards and guidelines.[45] Also relevant was the adoption by the WHO in 1981 of the *International Code of Marketing of Breastmilk Substitutes.*[46]

Nevertheless, for many years the international community did not formally recognize the full range of consumer rights, nor did consumer safety both in the food and non-food sectors receive a specific endorsement.

The first universal initiative that intended to reflect the view of international policy-makers on the need for consumer protection was the resolution 39/248 on consumer protection adopted by the UN General Assembly on April 9, 1985[47] and the appended *Guidelines for Consumer Protection* (Guidelines). This resolution sets out guidelines for national governments to introduce or further develop a comprehensive consumer protection system that would include, among other priority needs, consumer safety.

The Guidelines suggest a universal model framework for consumer protection policy. With one of the objectives being "to assist countries in achieving or maintaining adequate protection for their population as consumers", the guidelines prioritize six basic consumer needs: a) the protection of consumers from hazards to their health and safety; b) the promotion and protection of the economic interests of consumers; c) access by consumers to adequate information to enable them to make informed

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[45]*Codex Alimentarius*, FAO, online: Codex Alimentarius net < http://www.fao.org/fao-who-codexalimentarius/en/ >.

[46]WHO, *International Code of Marketing of Breastmilk Substitutes*, online: WHO <http://www.who.int/nutrition/publications/code_english.pdf>.

[47]*Consumer Protection (Guidelines for Consumer Protection)*, GA Res.39/248, UN GAOR, 1985, UN Doc. A/RES/39/248, online: UN <http://www.un.org/documents/ga/res/39/a39r248.htm>.

choices according to individual wishes and needs; d) consumer education; e) availability of effective consumer redress; and f) freedom to form consumer and other relevant groups or organizations, and the opportunity for such organizations to present their views and the decision-making processes affecting them.

1.2.1 History of the UN Guidelines for Consumer Protection

The *Guidelines for Consumer Protection* were in process at the UN at the same time as the *Code of Conduct for Transnational Corporations* (TNCs).[48] This Code had started out as a proposed instrument to contain the excesses of TNCs in the developing world.[49] However, provisions aiming to protect business interests, especially from nationalization, were added and provisions to protect the interests of developing countries and their citizens were watered down. The Guidelines then emerged and, in part, became the vehicle for some of the business regulatory elements lost from the TNC Code. [50] Not surprisingly, they faced strong opposition from business. The industry lobby pushed for the Code and strongly against the

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[48]UN Commission on Transnational Corporations, "Informational Paper on the Negotiations to Complete the Code of Conduct on Transnational Corporations", *International Legal Materials* 22:1, (January 1983), at 177 to 191, online: JSTOR <https://www.jstor.org/stable/20692548?seq=1#page_scan_tab_contents>.

[49]More on history of TNCs Code see: Karl P. Sauvant, "The Negotiations of the United Nations Code of Conduct on Transnational Corporations", *The Journal of World Investment & Trade*, 16 (2015), at 11 to 87, online: Columbia Center on Sustainable Investment, Columbia Law School <http://ccsi.columbia.edu/files/2015/03/KPS-UN-Code-proof-2-Journal-of-World-Investment-and-Trade-March-2015.pdf>.

[50]The Code of Conduct ultimately did not itself get anywhere.

Guidelines.[51] As well, in both the socialist and capitalist camps the Guidelines were seen as a potential threat to their respective ideological doctrines.

The history of the *Guidelines for Consumer Protection* began in 1978 when the Secretary-General reported on the possibility of certain actions aimed at developing consumer protection legislation. This report was submitted to the Economic and Social Council, which decided to pursue "the elaboration of a set of general guidelines, taking particularly into account the needs of developing countries."[52] The first draft of the *Guidelines for Consumer Protection* was ready in 1982. A broad range of stakeholders from government to industry and NGOs engaged in the heated discussions. At one point, it seemed that the draft would never become a final document. The dogma is that it is a very difficult job to develop international documents capable of satisfying all members of the United Nations, but the process becomes totally overwhelming when a document touches on such sensitive issues as economy and international trade. This was especially true during a time of antagonistic political contradictions between the socialist and capitalist blocs. For example, the Soviet bloc was categorically against the omission from the final draft of remarks concerning transnational corporations. In keeping with its Marxist ideology, the Soviet bloc expressed its deep disagreement and underlined that the *Guidelines for Consumer Protection* "virtually lost their initial significance," believing that transnationals are responsible for most consumption-related problems.[53] However, if some disagreements about the Guidelines were based on different ideological approaches and could find support on only one side of the Iron

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[51]Jeremy Malcolm, *Updating the UN Guidelines for Consumer Protection for the Digital Age,* Kuala Lumpur: Consumers International, (2013), online: Consumers International, <http://www.consumersinternational.org/media/1353300/updating-ungcp.pdf>.
[52]David Harland, *The United Nations Guidelines for Consumer Protection: Their Impact in the First Decade* in *Consumer Law in the Global Economy—National and International Dimensions* ed. by Iain Ramsay, (Aldershot: Ashgate, 1997), at 2.
[53]*Ibid.*at 3.

Curtain, others were even more antagonistic by virtue of global disagreement with the United Nations position.

Many members of the United Nations, from both the socialist and capitalist camps, refused to allow the UN to intrude upon such sacred national priorities as economic regulation. The soviet bloc, with its fully planned economy, "believed that the interrelationship between consumers and manufacturers of goods and services is an internal matter for states and becomes international in character only when it comes to matters of international trade in the context of protecting the interests of developing countries as collective importers and consumers of goods and services."[54] The capitalist bloc had a fairly similar vision in that members believed that free market economy had all necessary mechanisms of self-adjustment to meet consumer needs and should not be regulated, especially at the international level.

Despite the many difficulties encountered during elaboration and discussion, and strong opposition on the both sides of the Iron Curtain, the *Guidelines for Consumer Protection* were finally adopted, although the final Resolution 39/248 was significantly different from the initial draft, having become more abstract in certain aspects. The international community used consensus, a procedure involving the adoption of a text without a formal vote but with no objections, as a procedure of adoption.

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[54] *Ibid.*

1.2.2 The UN Guidelines for Consumer Protection

Resolution 39/248 is a compact document that includes four parts and spans less than three pages. In the introduction, the authors list consumer needs that are addressed by the Guidelines and which are believed to apply in all countries, especially in the developing world.

The Guidelines note that consumers are often faced with economic disparities, educational levels, and bargaining power, and they reassert the right of consumers to have access to non-hazardous products. The Guidelines also underline the requirement of governments to: (i) facilitate production and distribution in accordance with consumer needs and desires; (ii) encourage maintenance of a high level of ethical conduct in the production and distribution of goods and services; (iii) help combat abusive business practices at the national and international levels; (iv) facilitate the creation of independent consumer groups; (v) encourage international cooperation in consumer protection; and (vi) develop market conditions which give rise to a wide range of choices and low prices.

Most of the objectives related to consumer protection also enter the sphere of economic interests, to which many UN members are so sensitive. Moreover, even if governments were to elaborate consumer protection policy, such policy would vary greatly, not only from country to country, but also from region to region, and in keeping with economic, social, cultural, and religious circumstances and needs. Indeed, in some places consumers are overwhelmed with choice and accessibility to luxury goods and services, while in other places consumers struggle on a daily basis with malnutrition and a lack of potable water.

In order to avoid any tensions and make the Guidelines a truly universal document suitable for any economic situation, the authors included in Article 2 a provision to affirm that "each government must set its own priorities for the protection of consumers in accordance with the economic and social circumstances of the country, and the needs of its population, and bearing in mind the cost and benefits of the proposed measures."

Government is also responsible for establishing and maintaining institutions that are able to implement and monitor consumer protection policy that encompasses the entire population.[55] As for business operators, the Guidelines appeal to them to follow the laws and regulations in countries where they operate. However, even though the Guidelines ask them to follow international consumer protection standards, businesses are only obliged to do so when the competent state authority adopts such standards.[56]

From a positive point of view, the Guidelines possess the necessary flexibility to be universal. The Guidelines provide optimal mechanisms for the adjustment of national consumer protection policy according to the current situation and the needs of the population. Moreover, the Guidelines specify that policy implemented by government must be balanced between costs and benefits. This is particularly important for developing countries. The Guidelines provide the freedom needed for governments to act according to their financial ability while ensuring that their actions regarding consumer protection do not exceed reasonable cost, especially costs related to safety measures.

Standards of safety vary greatly from state to state. Merchandise considered unsafe and banned for use in Canada or the EU, might be permitted in less developed

[55]Art. 4.
[56]Art. 5.

countries for economic and other reasons. For example, the formerly widely used pesticide is now completely banned in the developed world but is still permitted in African countries where it is an inexpensive product to fight malaria. An unaffordable extra cost of safety measures (mandating an alternative and less harmful but more expensive pesticide) would put the population in an immediately life threatening condition.[57] Hence, governments in the developing world have to strike a balance between safety measures and urgent necessities. The Guidelines provide such opportunity.

Governments must also take into account certain sectors of the population that have limited access to protection and justice, such as in rural areas. In other words, the Guidelines ensure that consumers have adequate and equal rights that are not dependent upon location or social status. This provision is also very important for developing countries, where consumers in remote locations often have less choice with higher prices and little protection as a result of certain circumstances, such as level of education, access to justice, etc.

A point of interest is how the Guidelines approach business, a key element of consumer protection. Although any mention of transnational corporations was omitted during editing, the authors found a different way to include them in the Guidelines by making the latter applicable to "all enterprises." According to the Article 7 of the Guidelines, all businesses "should obey the relevant laws and regulations of the countries in which they do business." On the one hand, this formula forces businesses "to play" according to national regulations; however, on the other hand, if national regulations are weak or do not exist, what basic rules should a company follow? How low can safety standards go if the competent authorities of the country of operation disagree with the international standards? The key point is that

[57]More on the matter see CHAPTER II at 2.2.1.2.

even though the Guidelines initially insist upon a high level of ethical conduct for production and distribution of consumer goods, they later give businesses the authority to operate in accordance with local standards, which can be very low. This ambiguous situation may not benefit the consumer, especially in developing countries where legislation and government control are usually limited or entirely absent.

Furthermore, transnational corporations can find themselves in a more privileged position than local businesses, since the international consumer safety standards under which transnational corporations already operate may be higher than local ones so that only local business is forced to make additional investments to meet new national consumer regulations.

As for import safety, the Guidelines apply both to home-produced goods and to imports. Hence, imported products should have adequate safety features.[58] The Resolution also clarifies the relation between consumer protective measures and free-trade rules: "in applying any procedures or regulations for consumer protection, due regard should be given to ensuring that they do not become barriers to international trade and that they are consistent with international trade obligations".[59]

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[58]Art.9.
[59]Art.8.

1.2.3 Basic principles of consumer protection

The Guidelines set out six basic principles of consumer protection:

(i) Physical integrity and product safety

The Guidelines fully embrace all aspects of safety from manufacturing and distribution to safety standards and product recall. Under the Guidelines, government is responsible for adopting the complete package of legislation regarding consumer safety, including legal systems, safety regulations, national or international standards, voluntary standards and the maintenance of safety records to ensure that products are safe for either intended or normally foreseeable use. As for business operators, both manufactures and distributors[60] must ensure that all products, including imports, are safe and suitable for use when they reach consumers, even after handling and storage.

As well, business operators are responsible for providing proper, easy-to-understand instructions on using products safely, including information on risks associated with normally foreseeable use. Vital safety information should be conveyed to consumers by internationally understandable symbols wherever possible.

As for product recall, in the event an unsafe product (or a product that could become unsafe) is distributed to the public, business operators, together with the authorities, must take all necessary steps to recall the product and replace or modify it within a reasonable period of time, or compensate consumers for

[60]In accordance with the Guidelines, distributors are those who responsible for bringing goods to the market: suppliers, exporters, importers, retailers and the like.

the purchase price. Governments should develop appropriate policies concerning product recall protocols as well as ensure that consumers are properly informed of hazardous products.[61]

A specific part of the Guidelines is dedicated to standards for the safety and quality of consumer goods. Four key points regarding safety standards might be underlined:

i. the state is responsible to formulate or promote the elaboration and implementation of safety standards for consumer goods, including voluntary, at the national and international levels;
ii. national standards and regulations for product safety should be reviewed from time to time to ensure that they conform to international standards;
iii. if, due to local economic conditions, national safety standards are lower than the generally accepted international standards, every effort should be made to raise that standards as soon as possible;
iv. the state should encourage and ensure the availability of facilities to test and certify the safety and quality of essential consumer goods.[62]

Finally, the document endorses international cooperation and the exchange of information on hazardous consumer products as a key component of global consumer safety. In order to enable countries to protect themselves adequately against the harmful effects from imported consumer merchandise, an information network should be set up to strengthen the exchange of information regarding products that have been banned, withdrawn or severely restricted. Evidently, such information exchange benefits all states, especially

[61]Art. 10 -12.
[62]Art. 24 -26.

developing countries. However, since information related to banned and severely restricted products may vary greatly from country to country in a way that it might have detrimental effects on consumers, it is imperative that national authorities develop adequate local mechanisms to minimize potential harmful effects from such products.[63]

(ii) Promotion and protection of consumers' economic interests

Under the Guidelines, government is responsible for effective policy to ensure that consumers derive maximum benefit from their financial capacity, through adequate and fair production, distribution, and marketing practices.

Government, in close cooperation with consumer organizations has the responsibility to develop relevant legislation for marketing, advertising, business practices, etc., especially with respect to one-sided standard contracts that limit consumer rights and to business practices related to credit and promotion marketing.

The government sphere of responsibility also includes control over how products and services respond to demand and how they are suitable for consumer use, as well as opportunities for consumers for easy access to after-sales service and repair.[64]

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[63]Art. 44-45.
[64]Art. 13-23.

(iii) *Information and education*

Under the UN Guidelines, information and education programs should be developed according to cultural traditions, paying special attention to disadvantaged consumers, such as low-income or poorly educated consumers.

Ideally, consumer education should become a part of the public education system and should include the following aspects of consumer protection: a) health and nutrition; b) products hazards; c) product labeling; d) relevant legislation on how to obtain redress; e) information on weights and measurements, prices, quality, credit conditions, etc.; and f) pollution and the environment. Government should work in close contact with consumer organizations and businesses and through educational programs and mass media to educate the population. The aim of such programs should be to enable people to act as discriminating consumers, capable of making an informed choice about goods and services, and conscious of their rights and responsibilities.

(iv) *Consumer redress*

Under the Guidelines, consumers must be able to obtain effective redress through legal and/or administrative systems established by government, using formal or informal procedures that are expeditious, fair, inexpensive, and accessible to everyone, including low-income consumers. For their part, business operators should, on a voluntary basis, help consumers to receive fair and effective redress.

(v) *Freedom of consumers to form consumer groups or organizations and the opportunity for such organizations to present their views and the decision-making processes affecting them.*

The Guidelines do not include a separate paragraph for this principle; however, they do state that such organizations must take part in the consumer decision-making process.

In addition to the six main principles of the *UN Guidelines for Consumer Protection*, this document also includes some specific provisions related to developing countries and their needs. The first key point is effective distribution of essential consumer goods and services. The Guidelines force governments, as required by the situation, to create effective logistics and infrastructure that must embrace all regions, in particular rural areas, and ensure that the entire population has easy access to essential goods and services. The second key point pertains to government responsibility in areas related to consumer safety and health, such as food, water, pharmaceuticals, and chemicals. As for food, government should adopt and apply international food standards, such as the standards of the Food and Agriculture Organization of the United Nations, the World Health Organization's *Codex Alimentarius,* or other similar standards. Moreover, government should develop or improve and maintain the necessary instruments and institutions to ensure food safety through standards, inspections, monitoring, etc. With regard to water, government should have and maintain an adequate and safe nation-wide drinking water supply and distribution system. Concerning pharmaceuticals, government should have an adequate regulatory system to ensure that distributed drugs are safe and used in accordance with international recommendations. Finally, the Guidelines call to adopt appropriate measures concerning pesticides and chemicals in regard to their use, production and storage, taking into account such relevant health (safety) and environmental information as governments may require producers to provide and

include in the labeling of products.

1.2.4 The UN Guidelines amended

The fast-growing world economy and global concerns for environmental matters pushed the international community towards amending the Guidelines. "The *United Nations Guidelines* were not intended to be a static document. They need to be revised in the light of changes in social, political, and economic systems. Extending the *United Nations Guidelines* to include sustainable consumption patterns was an important step in this direction."[65]

Steps towards amending the *United Nations Guidelines for Consumer Protection* were made at the Conference on Environment and Development, more commonly known as the Earth Summit in June 1992 and Earth Summit+5 in July 1997. Both meetings addressed urgent issues facing the international community at the close of the second millennium, such as poverty, hunger, disease, illiteracy, and the continuing deterioration of the ecosystem.

Agenda 21, one of the many documents produced during the Earth Summit, noted that poverty, deterioration of the environment, and consumption and production patterns have very high levels of interrelation. As a result, the international

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[65]Commission on Sustainable Development, *Consumer Protection and Sustainable Consumption: New Guidelines for the Global Consumer, Background Paper for the United Nations Inter-Regional Expert Group Meeting on Consumer Protection and Sustainable Consumption*, UN ECOSOCOR, 1998, online: UN <http://www.un.org/documents/ecosoc/cn17/1998/background/ecn171998-consumer.htm>.

community underlined the urgency of a shift toward sustainable patterns of consumption and production.[66]

Two objectives were introduced in Agenda 21: a) to promote consumption and production patterns that reduce environmental stress and meet the basic needs of humanity; and b) to develop a better understanding of the role of consumption and how to bring about more sustainable consumption patterns in everyday life. In light of these two objectives, Agenda 21 urged the international community to undertake actions on a broad range of sustainable consumption topics.[67] Afterward, Resolution 1995/53 of the Economic and Social Council called upon the Secretary-General to develop guidelines on sustainable consumption.[68]

Later the Earth Summit+5 documents reported that "the state of the global environment had continued to deteriorate," in spite of some progress in material and energy efficiency.[69] As a result, the Earth Summit+5 Resolution included quite a bit on sustainable consumption in the chapter on Implementation of Agenda 21 in Areas Requiring Urgent Action.

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[66]UN Department of Economic and Social Affairs, Division for Sustainable Development, *Agenda 21*, ECOSOCOR, 1992, online: UNEP <http://www.unep.org/documents.multilingual/default.asp?documentid=52>.

[67]a) all countries should strive to promote sustainable consumption patterns, and developed countries should take the lead in achieving this objective; b) state and/or private researchers and regional and international financial and environmental organizations should make a concerted effort to examine and analyze production and consumption and the impact on the environment and financial development, as well as to develop a balanced pattern of consumption with optimization of resource use and minimization of waste; c) governments should develop a domestic framework that will encourage a shift toward sustainable patterns of consumption and production; d) governments and industry should shift their efforts towards use of energy and resources in a financially efficient and environmentally friendly manner: 1) minimize waste, 2) assist individual households to make environmentally sound purchase decisions, 3) encourage leadership through government purchasing, 4) exercise environmentally friendly price policy, and 5) educate and inform the general public about becoming conscientious consumers.

[68]UN Economic and Social Council, *Consumer Protection*, ECOSOC Res. 1995/53, UN ECOSOCOR, 1995, online: UN <http://www.un.org/documents/ecosoc/res/1995/eres1995-53.htm>.

[69]UNGA, *Nineteenth Special Session, the Earth Summit+5*, GA, UN GAOR, online: UN <http://www.un.org/esa/earthsummit/>.

The most important outcome of the Earth Summit+5 were the provisions of the Rio Declaration on the environment and development, contained in the chapter on international legal instruments, which called for additional revision of the *United Nations Guidelines for Consumer Protection*. "It is necessary to continue the progressive development and, as when appropriate, codification of international law related to sustainable development. Related bodies in which such tasks have been undertaken should cooperate and coordinate in this regard."[70] This time, the United Nations expressed quite explicitly its concern about the slow process of revising and shaping international law regarding sustainable consumption and urged all parties to do everything possible to continue this process.

As a result, just six months later, an inter-regional expert group meeting on the extension of the *United Nations Guidelines for Consumer Protection* took place in Sao Paulo from January 28-30, 1998, under the auspices of the UN Department of Economic and Social Affairs. The main goal of this summit was to develop recommendations and suggestions "for extension of the guidelines related to sustainable consumption and production patterns."[71] In the documents from the Sao Paulo meeting, the UN experts agreed that since 1985, the international community had shown considerable concern for the interconnection between the environment and financial and social development. Sustainable consumption was the key element

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[70]UN GAOR, *Programme for the Further Implementation of Agenda 21*, GA Res19/2, UN GAOR, 1997, UN Doc. A/RES/S-19/2, online: UN <http://www.un.org/documents/ga/res/spec/aress19-2.htm>.
[71]UN Commission on Sustainable Development, *Consumer Protection and Sustainable Consumption, New Guidelines for the Global Consumer: Background Paper for the United Nations Inter-Regional Expert Group Meeting on Consumer Protection and Sustainable Consumption*, UN Commission on Sustainable Development OR, 1998, online: UN <http://www.un.org/documents/ecosoc/cn17/1998/background/ecn171998-consumer.htm>.

having tremendous impact on the environment, and it was time to match the *UN Guidelines for Consumer Protection* to the requirements dictated by reality.[72]

Consumers International (CI),[73] at the request of the UN Economic and Social Council and through a series of consultations among international consumer institutions, prepared draft amendments regarding sustainable consumption. The main aim of all of these amendments was to shift wasteful patterns of consumption towards a sustainable one.[74] The next step was a report by the Secretary-General submitted just three weeks after the meeting in Sao Paulo, which included a final proposal of revisions to the *United Nations Guidelines for Consumer Protection.* [75] This final draft incorporated the UN Guidelines and proposals developed at the Sao Paulo meeting. With all these amendments, the Guidelines had expanded significantly, and the new section on sustainable consumption was longer than the original Guidelines.

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[72]The draft proposal was submitted to the Ad-Hoc Inter-Sessional Working Group of the UN Commission on Sustainable Development meeting, to the sixth session of the UN Commission on Sustainable Development, and to the Economic and Social Council session, all of which were scheduled for spring/summer 1998.

[73]Consumers International is the world federation of consumer groups that serves as the only independent and authoritative global organization for consumers. Founded in 1960, CI comprises over 240 Member in 120 countries. More on CI see: *Consumers International,* online: <http://www.consumersinternational.org>.

[74]The key elements of these amendments are government's support for and promotion of consumer education, consumer organizations, eco-testing, eco-labeling, public services which have less impact on the environment, energy efficiency, recycling and waste reduction, and sustainable consumption. Moreover, governments should develop codes and standards that help avoid misleading information about environmental claims, ban or severely restrict the production and use of products and substances that are harmful to the environment, and use pricing and other financial instruments in order to make consumers act sustainably.

[75]In this report, the Secretary-General admitted that "sustainable consumption is an essential part of sustainable development and is closely tied to sustainable production (...). Sustainable consumption requires that consumers, communities, businesses, and organizations of civil society be aware of the potential environmental effects of products and services regarding local and global impact (...). A review and revision mechanism for these guidelines should be established under the aegis of the United Nations so as to assess progress in their implementation by Member States and to revise them as necessary." (Commission on Sustainable Development, *Consumer Protection: Guidelines for Sustainable Consumption, Report of the Secretary-General*, ECOSOC, UN ECOSOCOR, 1998, UN Doc. E/CN.17/1998/5, online: UN <http://www.un.org/esa/documents/ecosoc/cn17/1998/ecn171998-5.htm>.)

In July 1999, the Economic and Social Council endorsed the Guidelines, and later the same year the General Assembly adopted the amendments under Decision 54/449.[76]

However, large sections of the original draft were omitted; for example, the proposed amendments on pricing and economic stimuli policies, legal sanctions, support of education in developing countries by international agencies, education of consumers regarding advertising and marketing, product improvement strategies, as well as promotion by government of issues such as the innovation effect of small enterprises, conservation of energy, environmental testing, and environmental friendly materials.

The Guidelines include a set of avenues that should guide government action towards sustainable consumption: a) promotion of access to non-misleading information about the environmental impact of products and measures against misleading practices; b) cooperation between governments and organizations involved in consumer education, as well as consumer education about pollution and proper use of materials, energy, and water; c) collective responsibility of all parts of society to implement sustainable consumption patterns; d) promotion of sustainable consumption through a mix of government policies that could include regulations, economic and social instruments, etc.; e) restrictions and bans on products and substances that are harmful to the environment; f) promotion of the health-related benefits of sustainable consumption; g) Government's leading role in sustainable practices; h) research on consumer behaviour and damage to the environment; i) promotion of sustainable agriculture; j) international cooperation on sustainable consumption.

Despite the fact that a large portion of the proposed amendments were deleted, the *United Nations Guidelines for Consumer Protection* nonetheless underwent major

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[76] *United Nations Guidelines for Consumer Protection,* GA Dec. 54/449, UN GAOR, 1999, online: UN <http://www.un.org/esa/sustdev/sdissues/consumption/cpp14.htm#54-449>.

changes and became a document which better reflects reality and meets the objectives specified in Agenda 21 and the Earth Summit.

Most recently, the United Nations Conference on Trade and Development (UNCTAD) did undertake a consultation on the revision of the *United Nations Guidelines on Consumer Protection.* This task was mandated by the First Ad Hoc Expert Meeting on Consumer Protection (July 2012) and later developed in the Second Ad Hoc Expert Meeting on Consumer Protection (July 2013).

During the First Ad Hoc Expert Meeting on Consumer Protection delegates concluded that since 1985 the Guidelines have been widely implemented by Member States of United Nations and that all areas of the current Guidelines remain valid and useful. Nevertheless, the following two new challenges to consumer protection were pointed out: e-commerce and financial services. In addition, data protection, abusive advertisement, energy and cross-border trade were also singled out as particular issues to be dealt with. Finally, interest was raised on the implementation and monitoring of the Guidelines.

In the course of the Second Ad Hoc Expert Meeting on Consumer Protection, several areas were identified for incorporation into any future revisions, especially those where substantive progress had been made in other organizations, such as the Organization for Economic Co-operation and Development (OECD), and where there was consensus among United Nations members, particularly: e-commerce[77] and financial services.[78] Additionally, the following key issues were identified for further

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[77]OECD, *Guidelines for Consumer Protection in the Context of e-commerce* (1999), OECD OR, online: OECD <http://www.oecd.org/fr/sti/consommateurs/oecdguidelinesforconsumerprotectioninthecontextofelectroniccommerce1999.htm>.

[78]OECD, *G-20 High-level Principles on Financial Consumer Protection* (2012), OECD OR, online: OECD <http://www.oecd.org/regreform/sectors/48892010.pdf>.

discussion: data protection, misleading advertising, energy, cross-border trade, transport, universal services, access to knowledge, tourism, class actions, and housing.

Participating parties also called for an implementation and control mechanism of the Guidelines. As a mechanism to explore these issues, a proposal was accepted to institute Working Groups in order to produce the first draft of the *Implementation Report*. The objective of this report was to establish a benchmark on the use and adoption of the Guidelines, to highlight the emerging issues for consumer protection and to identify a number of areas for their improvement.

Meanwhile, Consumers International was pushing for a more substantiated revision of the Guidelines. CI emphasized the fact that existing Guidelines are now in need of amendment due to changes in the external environment as well as a consumer agenda that has moved on from many of the issues prevalent in 1985 and even in 1999 when they were last revised. To advocate a broad array of topics to be included in the resolution draft, CI published a 110-page report titled *Updating the UN Guidelines for Consumer Protection for the Digital Age*[79], which details proposals for new measures covering e-commerce and related areas of importance to consumers in the digital age:

(i) a*ccess to knowledge*. Proposed provisions prohibit intellectual property rights from being enforced in ways that override consumers' human rights. For example, consumers of digital content products (such as e-books) should be treated on a level footing with consumers of equivalent analogue products (such as printed books);[80]

[79] *Updating the UN Guidelines for Consumer Protection for the Digital Age*, Consumers International, (2013) online: CI <http://a2knetwork.org/sites/default/files/updating-ungcp.pdf>.
[80] *Ibid.* at 18-20.

(ii) *internet and telecommunications*. Proposed provisions address the dangers for consumers of loss of control over their personal information online, remedies against such loss[81], and promote affordable access to the Internet;[82]

(iii) *e-commerce and digital products*. Extra attention needs to be paid to consumer contracts on-line, information disclosure, payment security, redress, as well as consumer education.[83]

(iv) *financial services*. Recommended provisions endorse better information design and disclosure, clearer contracts and charges (including abusive business practices and contractual abuses) as well as universal access to basic financial services and responsible lending.[84]

Four groups (Financial Services, e-Commerce, Cluster Issues and Implementation of the UN Guidelines for Consumer Protection) were formed to assist the secretariat in preparing a report to the Seventh UN Review Conference in July 2015. Working groups identified areas and issues on which there was some consensus to progress the update of the Guidelines. The *Draft Resolution on Consumer Protection for Consideration by the General Assembly, June 2015*, echoed the proposed amendments related to electronic commerce, financial services, dispute resolution, redress, and protecting consumer privacy. The Seventh UN Review Conference in November 2015 approved the draft resolution to be submitted to the UN General Assembly for adoption.[85] Formal adoption took place on 22nd December 2015 [86].

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[81] *Ibid.* at 34-36.
[82] *Ibid.* at 39-41.
[83] *Ibid.* at 47-53.
[84] *Ibid.* Annex A at 82-85.
[85] UNCTAD, *The Revision of the United Nations Guidelines on Consumer Protection* (November 2015), online: UNCTAD <http://unctad.org/en/Pages/DITC/CompetitionLaw/UN-Guidelines-on-Consumer-Protection.aspx>.
[86] UN, *Macroeconomic Policy Questions: International Trade and Development*, A/70/470/Add.1, online: UN <http://www.un.org/ga/search/view_doc.asp?symbol=A/70/470/Add.1>.

The revised *UN Guidelines for Consumer Protection* extend their scope to state-owned enterprises[87] and introduce four new "legitimate needs":

(i) access by consumers to essential goods and services;
(ii) the protection of vulnerable and disadvantaged consumers;
(iii) a level of protection for consumers using electronic commerce that is not less than that afforded in other forms of commerce; and
(iv) the protection of consumer privacy and the global free flow of information.[88]

Totally new sections have been inserted on Principles for Good Business Practices,[89] National Policies for Consumer Protection,[90] Electronic Commerce,[91] and Financial Services.[92]

The section on Dispute Resolution and Redress was expanded and renamed to reflect the rapid evolution of such consumer disputes handling mechanisms and now includes reference to debt and bankruptcy.[93] The Specific Areas section was also revised and now includes Energy,[94] Public Utilities[95] and Tourism.[96] Section VI, on

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[87]These guidelines apply to business-to-consumer transactions, including the provision of goods and services by state-owned enterprises to consumers. (Guideline 2). UNCTAD, the *United Nations Guidelines on Consumer Protection*, 2015, online: UNCTAD <http://unctad.org/en/PublicationsLibrary/ditccplpmisc2016d1_en.pdf>.
[88]Guideline 5.
[89]a) fair and equitable treatment; b) commercial behaviour; c) disclosure and transparency; d) education and awareness-raising; e) protection of privacy; f) consumer complaints and disputes. (Guideline 11).
[90]Guidelines 14-15.
[91]Guidelines 63-65.
[92]Guidelines 66-68.
[93]Guidelines 37-41.
[94]Guideline 76.
[95]Guideline 77.
[96]Guideline 78.

International Cooperation, has been significantly enlarged to cover enforcement cooperation mechanisms at the cross-border level.[97]

Finally, the new section VII, International Institutional Machinery, addressed the review of the application and implementation of the Guidelines at national and international levels and the further review of the guidelines themselves by a newly created Intergovernmental Group of Experts on Consumer Protection Law and Policy (IGE)[98].

IGE is a standing body to monitor the application and implementation of the guidelines, provide an annual forum for consultations, produce research and studies, provide technical assistance, undertake voluntary peer reviews, and periodically update the guidelines.[99] Nevertheless, the Guidelines specify that the IGE is an institution with purely consultative power and should refrain from passing any judgments on the activities or conduct of individual Member States or of individual enterprises in connection with a specific business transaction.[100]

During its first session on 17 - 18 October 2016, the IGE on Consumer Protection established its method of work and agenda for the period 2016-2020.[101]

As seen from the above comments, the process of amending the Guidelines since 1985 never included any consideration on consumer safety. Consumer safety did not receive any further endorsement in the document.[102] No such amendments were

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[97]Guidelines 82-90.
[98]Guidelines 95-99.
[99]Guideline 97.
[100]Guideline 98.
[101]*Intergovernmental Group of Experts on Consumer Protection Law and Policy: First Session*, online: <http://unctad.org/en/pages/MeetingDetails.aspx?meetingid=1060>.
[102]UNCTAD, *Draft Resolution on Consumer Protection for Consideration by the General Assembly* (June 2015), online: UNCTAD <http://unctad.org/Sections/ditc_ccpb/docs/UNGCP_DraftResolution2015_en.pdf>.

proposed by Consumers International either.[103]

1.2.5 Assessing the impact of the Guidelines

Immediately after their adoption, the Guidelines found as many supporters as opponents. Both sides formulated comments on the Guidelines. Supporters referred to the Guidelines as the consumer protection equivalent of the *Universal Declaration of Human Rights*. "International guidelines can serve as a Charter of Human Rights in the consumer area. That did not mean that every nation would scrupulously obey and implement the principles. Many would, and many would not. But the existence of a UN-sponsored Charter of Consumer Rights simply cannot be ignored by any nation that wishes to be considered civilized."[104]

Opponents warned that some provisions of the Guidelines could aggravate the situation, especially in developing countries, where, for example, the additional cost of safety measures can make products less affordable to consumers with low income.[105]

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[103] *Proposals for Amendments to the UN Guidelines for Consumer Protection* does not suggest any explicit amendments on consumer safety. The only visible recommendation on the matter is product safety for consumers with disabilities. CI suggests that Guidelines should ensure that "products are safe for intended or normally foreseeable use for all consumers, including those with different abilities" (Consumers International, *Consumers International: Proposals for Amendments to the UN Guidelines for Consumer Protection: In Advance of the Ad Hoc Expert Meeting on Consumer Protection*, Geneva, (July 2013), online: Consumer International <http://www.consumersinternational.org/media/1362222/ci_proposal_annex_a_eng.pdf>).

[104] Esther Peterson, *The United Nations and Consumer Guidelines* in *Consumers, Transnational Corporations and Development,* ed. by T. Wheelwright, (Sydney: Transnational Corporations Research Project, University of Sydney, 1986) at 343 to 347.

[105] Murry Weidenbaum, "The Case Against the UN Guidelines for Consumer Protection" (1987) 10 Journal of Consumer Policy, at 425 to 432.

It would take far too long to list all of the pros and cons of the Guidelines, but without a doubt, the Guidelines play a major positive role on the international level in that they force governments, businesses, and international organizations to develop and implement measures regarding consumer protection, in particular with respect to the six main principles.

Since their adoption, the *United Nations Guidelines for Consumer Protection* have had a significant influence on consumer policy actions by both governments and consumer organizations in many countries with widely varying social, cultural, and political traditions.[106] The UN Guidelines have played an important role in providing a clear and comprehensible set of reference points.[107] They provide explicitly stated aims while allowing governments and consumer activists operating in different social, cultural, and historical contexts to build governmental structures, legal systems, and social policies that are appropriate to their own conditions.[108] Governments of both developed and developing countries and of those in transition have reported that the Guidelines continue to play an important role in their work and have had a significant impact on the development of national consumer policies. The Guidelines have also been used actively by the consumer movement.[109]

The *Implementation Report on the United Nations Guidelines on Consumer*

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[106]*Op. cit.* 52 (David Harland), at 6.
[107]For more on the impact of the *UN Guidelines for Consumer Protection* see: ECOSOC, *Consumer Protection. Report of the Secretary-General*, UN ECOSOCOR (1995) UN Doc.E/1995/70, online: UN <http://www.un.org/documents/ecosoc/docs/1995/e1995-70.htm> & ECOSOC, *Co-ordination Questions: Consumer Protection: Report of Secretary-General*, UN ECOSOCOR (1992) UN Doc.E/1992/48.
[108]M. Andruszkiewcz, "Central and Eastern Europe: A Reference Point in Changing Times" *Consumer International*, 1 (1995), at 2 to 3.
[109]*Op. cit.* 52 (David Harland), at 6 to 10.

Protection 1985–2013[110] (the *Implementation Report*) stresses that the Guidelines remain a valid and relevant document for consumer protection policy and have inspired a significant number of national consumer protection laws through the world.

In general, Member States have adopted the core objectives of the *United Nations Guidelines on Consumer Protection.* In many cases, consumer protection has been constitutionally enshrined and some countries have recognized consumer rights as human rights.[111] All Member States carry out consumer protection policies through governmental agencies, largely adhering to the six principles of the current Guidelines. The right of access to safe products and the right to just, equitable and sustainable economic and social development and environmental protection are contained either in consumer protection laws or other national sectorial norms. As for the government institutions, most Member State consumer protection agencies are competent on issues of health and safety protection, promotion and protection of consumer's economic interests, access to adequate information, consumer education, consumer redress and the right to association.

Numerous intergovernmental regional organizations have embraced the objectives of the Guidelines and developed tools to help their Member States achieve them. International Consumer Protection and Enforcement Network (ICPEN)[112] and OECD have drafted policy instruments and guidelines in relation to all core principles of the Guidelines. At the Pan-American level, members of the Organization of American

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[110]UNCTAD, *The Implementation Report on the United Nations Guidelines on Consumer Protection 1985–2013*, TD/B/C.I/CLP/23 (29 April 2013), online: UNCTAD <http://unctad.org/meetings/en/SessionalDocuments/ciclpd23_en.pdf>.

[111]For example, El Salvador (Constitución de la República de El Salvador, artículo 101), Egypt (Constitution, article 14), Poland (Constitution of the Republic of Poland, article 76), and Switzerland (Federal Constitution of the Swiss Confederation, articles 2, 23, 97).

[112]International Consumer Protection and Enforcement Network (ICPEN) – an organization composed of consumer protection authorities from over 50 countries, whose aim is to protect consumers' economic interests around the world; share information about cross-border commercial activities that may affect consumer welfare; encourage global cooperation among law enforcement agencies. More on ICPEN see online: ICPEN <https://www.icpen.org>.

States (OAS) have recognized some principles through the Charter of the OAS[113]. Similarly, the European Commission has developed a comprehensive policy framework for consumer protection.[114]

The *Implementation Report* reconfirms that safety has always been the pinnacle of the consumer agenda throughout the world. Most Members States have adopted laws and regulations regarding product safety, which are usually contained in consumer protection laws and/or sectoral laws.[115] This legislative framework typically engages consumer protection agencies along with other relevant sectoral authorities.[116] In some countries, such as Canada,[117] this topic is entirely assigned to the health authority while others, such as the United States of America,[118] have created an autonomous body for consumer product safety.

On the issue of hazard notification, most national laws grant monitoring and

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[113]Art. 39b, Charter of the Organization of American States, online: Organization of American States <http://www.oas.org/dil/treaties_A-41_Charter_of_the_Organization_of_American_States.htm#ch3>.
[114]More on regional policy frameworks for consumer protection see CHAPTER III.
[115] For example, Chile (Ley de protección al consumidor (Ley 19496): artículo 3° d) párrafoV y artículos 44 a 49; Ley 20.096; Ley 19.300; Ley 18.302), China (People's Republic of China Law of Product Safety, enacted in 1994 and amended in 2000, Food Safety Law 2009), Costa Rica (Ley N° 8279, artículo 29; Ley N° 8228, artículo 05; Ley N° 8279, artículo 46), the Dominican Republic (Ley General de Protección de los Derechos del Consumidor o Usuario No. 358-05, artículo 33; Resolución No. 04- 2007 and Resolución No. 07-2007), France (article L.221, Code de la Consommation), Mexico (Ley Federal Sobre Metrología y Normalización), Peru (Ley No 29571, artículos 25 a 29; Ley No 28405, Ley de Rotulado de Productos Industriales Manufacturados; Ley No 28376, Ley que Prohíbe y Sanciona la Fabricación, Importación, Distribución y Comercialización de Juguetes y Utiles de Escritorio Tóxicos o Peligrosos), Poland (Act of General Product Safety 2003), Switzerland (Loi fédérale du 12 juin 2009 sur la sécurité des produits).
[116] For example, Chile (Instituto de Salud Pública), Costa Rica (Ministerio de Salud y Ministerio de Agricultura y Ganadería (Servicio Nacional de Salud Animal)), France (Commission de la Sécurité des Consommateurs), El Salvador (Organismo Salvadoreño de Reglamentación Técnica, Organismo Salvadoreño de Normalización), Egypt (Organization of Standardization and Quality), Poland (Polish Standardization Committee), Switzerland (Office Fédéral de la Santé Publique, Office Fédéral des Transports, Office Fédéral de l'Energie, Office Fédéral de la Communication, Office Fédéral des Construction et de la Logistique, Swissmedic – Institut Suisse des Produits Thérapeutiques, Office Fédéral de la Police, Office Fédéral des Routes).
[117]Health Canada holds the mandate to manage the health risks and safety hazards associated with consumer products. (Health Canada, online: Health Canada <http://www.hc-sc.gc.ca/index-eng.php>).
[118]United States Consumer Product Safety Commission, online: CPSC <http://www.cpsc.gov>.

communication powers to consumer protection agencies and other market surveillance authorities. In all legislation, economic operators are responsible for notifying governments and the public when products become hazardous. The means of public communication are varied, comprising announcements in official and private media.[119] The European Union has established a rapid alert system for dangerous consumer products – except food, pharmaceutical and medical devices, which are covered by other mechanisms.[120]

All nations (except India) include obligations to recall hazardous products by manufacturers and/or distributions. Generally, consumer protection agencies are responsible for monitoring such obligations, although some reserve compensation procedures to the judicial branch[121] or alternative dispute settlement mechanisms.[122]

As for safety and quality of consumer goods and services, most countries have integrated the postulates of the Guidelines on this matter into state laws and regulations. In many cases, national consumer protection agencies share these responsibilities with other authorities such as standard/normalization organizations and ministries of the environment and/or health.

Finally, the *Implementation Report* underlines that the rapidly growing global economy and fast-changing trade characteristics have made international cooperation fundamental for preventing unsafe and hazardous consumer goods from entering national markets and for recalling them if they have entered. In this regard, OECD has recently created a Working Party on Consumer Product Safety.[123] In addition, the

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[119]For example, the Dominican Republic has used on-line news outlets to alert consumer regarding unsafe products; El Salvador mass media; and Egypt Facebook as a resource.
[120]RAPEX, online: European Commission, <http://ec.europa.eu/consumers/archive/safety/rapex/index_en.htm>.
[121]For example, Chile, Colombia.
[122]For example, Bhutan (Dispute Settlement Body), Indonesia (Ministry of Trade).
[123]Examples of OECD work in this area can be also seen in several OECD Recommendations of the Council: i.e. *Recommendation of the Council Concerning Safety Measures Taken in the Interest of Children*; *Recommendation of the Council Concerning Risk Management and Cost-Benefit Analysis in*

multi-lingual *GlobalRecalls* data portal has been recently established by the OECD for sharing information on products recalls with the public.[124]

The OAS member States, allied with the Pan-American Health Organization, established the first specialized hemispheric forum on consumer product safety with the objective of advancing towards the design and creation of an Inter-American Rapid Alerts System on consumer product safety.[125]

In respond to challenges associated with globalization, the OAS member states supported the creation of the Consumer Safety and Health Network (CSHN) in 2009. The CSHN is the inter-American interdisciplinary institution with a mandate to strengthen national capacities and regional cooperation with the aim of enabling early detection of unsafe consumer products and the adoption of coordinated actions among the competent agencies. The CSHN offers Member States technical cooperation and training to administrate the only existing regional safety alert portal in the Americas. As a central element of the CSHN, the Inter-American Rapid Alert System (SIAR [for its Spanish acronym]) was launched on December 10th, 2014.[126] SIAR is the first hemispheric integrated system for the generation, management and

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the Product Safety Field; *Recommendation of the Council on the OECD Notification System on Consumer Safety Measures*; *Recommendation of the Council Concerning the Establishment of Data Collection Systems Related to Injuries Involving Consumer Products*; *Recommendation of the Council Concerning Recall Procedures for Unsafe Products Sold to the Public* and the *OECD Guidelines for Multinational Enterprises* (Chapter 8). For more information on OECD and Consumer Safety see: OECD, Consumer Product Safety, online: OECD <http://www.oecd.org/sti/consumer/consumer-product-safety.htm>.

[124]The *GlobalRecalls* portal brings together information on product recalls being issued around the world, on a regular basis. The portal includes information on mandatory and voluntary consumer product recalls which were issued by a governmental body and were made publicly available. OECD, *Global Recalls*, online: OECD <http://globalrecalls.oecd.org>.

[125]The OAS Consumer Safety and Health Network's objective is to contribute to the construction of market surveillance systems on consumer product safety in OAS member States. For that purpose, the OAS contributes to strengthening the institutional capacity at the national and regional levels through the organization of training activities and the promotion of the exchange of good practices. The Consumer Safety and Health Network's web portal contains alerts on unsafe consumer products with an advanced search tool. (OAS, *The Consumer Safety and Health Network* (CSHN), online: OAS <https://www.sites.oas.org/rcss/en/pages/about/default.aspx>).

[126]*Ibid.*

rapid and secure exchange of information on consumer safety alerts, based on agreed criteria on principles, general concepts and relevant terminology for regional alerts. SIAR allows Member States to identify consumer product safety alerts issued on agreed criteria and to take the necessary measures to prevent or stop a product from being sold, in conformity with the country's domestic procedures.[127] Since the inauguration of SIAR, thousands of alert notifications on dangerous consumer product have been sent. The only downside of the system is that no translation to English is provided for the alerts sent in Spanish or Portuguese.[128]

Furthermore, the Caribbean Community (CARICOM) Rapid Alert System for Exchange of Information on Dangerous (non-food) Consumer Goods (CARREX) was introduced on January 3, 2012 in response to concerns expressed over the years by consumer representatives of the need to protect consumers from unsafe products.[129] The system functions as a general alert and surveillance structure intended to cope with emergency situations.[130] It aims essentially to permit the rapid exchange of information between the Member States and the CARICOM Secretariat when a dangerous product[131] has been detected in circulation on the market.[132] CARREX operates its Consumer Product Incident Reporting System through a website on which consumers in any CARICOM country can alert their national

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[127]OAS, *Inter-American Rapid Alerts System* (SIAR), online: OAS <https://www.sites.oas.org/rcss/en/Pages/about/siar.aspx>.
[128]More on SIAR' alert notifications see: online: OAS <https://www.sites.oas.org/rcss/EN/Pages/alerts/default.aspx>.
[129]CARREX was developed with the assistance of the European Development Fund.
[130]National contact points have been created in all CARICOM Member States - except the Bahamas, which is not participating in the scheme.
[131]CARREX system does not cover food safety, which is monitored by the Suriname-based Caribbean Agricultural Health and Food Safety Agency (CAHFSA).
[132]CARICOM, Consumer Product Incident Reporting System, online: CARICOM <carrex.caricom.org>.

contact point about a product which they have found to cause harm or pose a safety hazard.[133]

To summarize, since their adoption the UN Guidelines have played a vital role in shaping the consumer protection agenda at national, regional and international levels. Particularly, outstanding results have been achieved in the field of consumer safety. Consumer safety has become *de facto* a universal right, recognized by all Member States.

1.3 Market globalization and national consumer safety measures

While national measures may have been sufficient to protect consumers in past decades, this is not the case anymore under contemporary market conditions.

The regionalization and internationalization of consumer markets has become one of the main challenges of modern consumer law and policy[134]. The effectiveness of national rules appears more and more limited, and a global approach to consumer policy is now needed. In the era of globalization, States must endorse both cross border free movement of products and adequate national safety standards.

Under such circumstances, only the harmonization of interstate laws and regulations on consumer safety and effective interstate exchange of information regarding

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[133]CARICOM, *Rapid Alert System for Exchange of Information on Dangerous (non-food) Consumer Goods* (CARREX) (23 May 2015), online: CARICOM <http://caricom.org/projects/detail/caricom-rapid-exchange-system-for-dangerous-non-food-consumer-goods-carrex>.
[134]*Op. cit.* 3 (Thierry Bourgoignie) at 26-34.

dangerous consumer products on the regional or global market will ensure adequate protection of consumer life and health at national and international levels.

Market globalization is affecting all aspects of consumer life. New and exotic products from foreign countries have flooded consumer markets. This gives consumers unprecedented opportunity to enjoy freedom of choice, but at the same time makes the need for consumer information and consumer protection even more urgent. Consumers are often faced with dangerous and unfamiliar products that do not have proper manuals or labeling in comprehensible language and which are sold by overseas distributors who often resort to new and unfair marketing practices. Globalization has brought about new means of production, marketing, and commerce that have radically affected how countries can impose control on the marketplace. Many mechanisms of control for trade and distribution traditionally used by countries, such as customs, cannot be used or no longer work effectively for consumer protection as one result of open-borders policies and free-trade agreements. Electronic commerce makes any control or protection by the state almost impossible or at least very limited in scope.

The millions who travel outside their home countries and the billions who use the internet are exposing themselves to major redress problems and uncertainties regarding applicable law and competent jurisdiction. International instruments have been adopted which intend to provide consumers with increased protection in trans-border shopping,[135] but the impact thereof remains limited. Many countries, including Canada, have not ratified these international conventions, the scope of which exclude

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[135] *Brussels Convention on Jurisdiction and the Enforcement of Judgments in Civil and Commercial Matters,* 1968, Section 4: *Jurisdiction over consumer contracts*, at Art. 13 to15, online: Oslo University <http://www.jus.uio.no/lm/brussels.jurisdiction.and.enforcement.of.judgments.in.civil.and.commercial.matters.convention.1968/doc.html> & *Convention on the Law Applicable to Contractual Obligations Opened for Signature in Rome on 19 June 1980*, 1980, at Art. 5: *Certain Consumer Contracts*, online: Eur-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV%3Al33109>.

several contracts and give protection only to certain groups of consumers (the so-called passive consumers).[136] Trans-border litigation remains for individual consumers an unaffordable, uncertain, and much too risky move.[137] Currently, the use of international private rules in the consumer field does not lead to the application of international law but rather declares national protective schemes applicable, as consumer protection is regarded as a matter of public order and hence imperative.[138] Consumer legislation commonly holds as being unfair a contract clause by the effect of which the consumer would be deprived of the protection he would be granted under national law.[139]

The paradox is that on the one hand, in order to be part of an international free market community and enjoy all benefits thereof, the state must follow international rules of commerce. On the other hand, those rules require that the state gives up certain powers to regional or international authorities, with the result being to limit the state's authority to set up national schemes conferring on their consumers a high or higher level of protection. International trade and open-borders policies may threaten national consumer protection measures as these could be regarded as an obstacle to

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[136]For more, see Elisabetta Bergamini, "Sale of goods to consumers--evolution of consumer's role in international private law", online: Ministry for Competitiveness and Communications of Malta <http://www.mcmp.gov.mt/pdfs/consumers/Mar05Seminar/Elisabetta_Bergamini.pdf>.

[137]*Op. cit.* 3 (Thierry Bourgoignie) at 26-34.

[138]"The choice by the parties of the law applicable to a consumer contract does not result in depriving the consumer of the protection to which he is entitled under the mandatory provisions of the law of the country where he has his residence....". Civil Code of Québec (S.Q., 1991, c. 64.) at Art. 3117, online: Justice Québec <http://www.justice.gouv.qc.ca/English/sujets/glossaire/code-civil-a.htm>. Also according to the EC directive on unfair terms in consumer contracts, "Member States shall take the necessary measures to ensure that the consumer does not lose the protection granted by this Directive by virtue of the choice of the law of a non-Member country as the law applicable to the contract if the latter has a close connection with the territory of the Member States." (EC, *Commission Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contract*, [1993] O.J. L 095/29, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0013:EN:HTML>).

[139]"Any stipulation in a contract that such contract is wholly or partly governed by a law other than an Act of the Parliament of Canada or of the Parliament of Québec is prohibited." *Consumer Protection Act*, (R.S.Q. c. P-40.1, 1978), at Art. 19, online: Legis Quebec <http://legisquebec.gouv.qc.ca/en/showdoc/cs/P-40.1>.

the free circulation of goods and services, thus calling for the dismantling of national consumer protection frameworks.[140] The irony is that most international free trade agreements are signed by states for the consumer's sake, since they intend to provide greater choice and lower prices on national markets. However, they also play the role of a Trojan horse by bringing into national markets new and additional consumer protection deficits and even threatening the legal framework in place.

Open-borders policies have shifted control over national consumer markets from the national level to the regional or international realm. In internationally or regionally integrated markets, national consumer protection measures are no longer sufficient to effectively protect consumer interests. Some consider that the survival itself of consumer protection at the national level requires that initiatives be taken for consumers at the international or regional level.[141] Hence, consumer law should truly become international.

From the viewpoint of consumers, two main concerns must guide this quest for internationalization of consumer protection and in particular consumer safety. The first is to admit consumer safety as a legitimate exemption from the strict application of free trade rules. The second is to ensure that the positive law harmonization initiatives taken by regional or international policy-makers bring actual benefits to consumers by guaranteeing them a high level of safety in the integrated or common marketplace.

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[140]Thierry Bourgoignie & David Trubek, *Consumer Law, Common Markets and Federalism* (Berlin: Walter de Gruyter, 1987) at 1 to14.

[141]*Ibid.* See also Thierry Bourgoignie & Julie St-Pierre, "Le statut de politique de protection du consommateur dans les systèmes régionaux économiquement intégrés. Une première évaluation comparative" (2007) 20:1 *Quebec Journal of International Law*, at 53 to 56, online: Revue Québécoise de Droit International <http://www.sqdi.org/wp-content/uploads/20.1_bourgoignie.pdf>.

The need to reconcile free trade goals with consumer protection interests is especially acute when safety is at stake. The matter of health and safety is so natural and fundamental to human well-being that all levels of governance in any society must take this issue very seriously. No politician would dare to deny fundamental human/consumer rights of health and safety. Also, health and safety are universal values shared by society as a whole. In spite of differences in cultural and social habits between nations, safety is a relatively universal civil concept. Consumers from any social group in any part of the world want only safe products, and this puts global pressure on political leaders to guarantee this right. Besides, since this right is of dogmatic nature, regional and international organizations may persuade their members to develop, adopt, and implement documents regarding this issue more easily than on other matters of more controversial nature.

Despite this universal consensus on the need for safety, the international community and regional institutions face two major challenges. The first one is to find a balance between legitimate measures taken by national governments in order to protect the safety of their consumers and the free flow of products and services across borders. This has been referred to by legal scholars as the need to protect consumer interests under negative harmonization schemes.[142] Safety, more than any other consumer concern, deserves such a balanced evaluation of conflicting interests.

The second derives from the need to define a commonly acceptable level of protection when taking positive harmonization initiatives aimed at the elimination of distortions of competition resulting from discrepancies in national safety rules and standards due to cultural traditions, stage of economic development, general public

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[142] *Op. cit.* 140 (Thierry Bourgoignie & David Trubek), at 1 to14 & Pedro Caro de Sousa, "Negative and Positive Integration in EU Economic Law: Between Strategic Denial and Cognitive Dissonance?" 13:8 (2012), *German Law Journal* at 979-1012, online: German Law Journal <http://static1.squarespace.com/static/56330ad3e4b0733dcc0c8495/t/56b29e6586db4396b83ffdf3/1454546534135/GLJ_Vol_13_No_08_de+Sousa.pdf>.

educational level or financial ability of the state to implement safety related measures. Evidently, the level of consumer safety is quite different between Canada and Mexico, even though both are Member States of the NAFTA. Such discrepancy in safety matters crystalizes more dramatically on the international realm, especially between developed and developing nations.

To meet this second challenge, the international or regional authorities shall choose the approximation method that is politically acceptable by the member countries and at the same time brings the expected result in terms of law approximation.

Harmonization may be optional, total or minimum.[143]

(i) Optional harmonization leaves the choice to manufacturers to follow the harmonized international/regional rules, hence ensuring free movement, or to follow national legislation, without a guarantee of free movement. Thus, in optional harmonization, there are two sets of rules: one for the domestic market and one for cross-border trade.[144]

(ii) Total harmonization[145] will lead to uniform rules and standards: while positive in terms of free trade, consensus on uniformity may be difficult to reach and

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[143]Catherine Barnard, *The Substantive Law of the EU: The Four Freedoms* (Oxford University Press, 2007) at 599.

[144]Optional Harmonization has been little used; therefore, it will be disregarded in this work. More on optional harmonization see: *Ibid* & Thomas Papadopoulos, *EU Law and the Harmonization of Takeovers in the Internal Market*, (Kluwer Law International, 2010) at 61 to 64.

[145]Total harmonization means the approval system for a product requiring that the product complies with all interstate technical requirements specified on a mandatory basis (in the framework directive or regulation). Thus, the product can be marketed everywhere on regional/ international level.

the risk may exist that legitimate consumer interests will be sacrificed on the altar of uniformity[146].

(iii) Minimum harmonization offers the advantages, but also the disadvantages, of flexibility. Its scope is limited to the definition of a so-called uniform floor or minimum level of protection, below which national legislation is not allowed to fall.[147] National legislators remain allowed to introduce or maintain safety rules granting to consumers a higher level of protection. Hence all distortions of competition and barriers to trade are not eliminated, but an optimal compromise is more likely to be reached between free trade objectives and legitimate consumer expectations.

While total/minimum harmonization categorizes the technical aspects of legal approximation regarding consumer safety standards, the concept of positive/negative harmonization indicates the type of adopted political agenda to achieve consumer safety goals on regional or international open markets.

Positive harmonization is where common rules are provided by international or regional institutions to serve as an interstate mechanism to eradicate legal disparities between member States through endorsing common rules regarding consumer safety. Under this type of harmonization it is crucial to ensure that both effective protection and open borders goals are achieved.[148] Keeping a delicate balance between free market rules and consumer safety requirements might be a difficult task, especially when policy and economic considerations will push for total harmonization.

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[146]EC, *Green Paper on Consumer Protection in the European Union*, Brussels, (COM (2001) 531 (final)), at 10&11, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52001DC0531&from=EN>.

[147]Even the EU with its predilection to uniformity, takes an exceptional approach to consumer matter and allows the Member States to use minimum harmonization to "maintain or introduce more stringent protective measures". (*Op. cit.* 143 (Catherine Barnard), at 600).

[148]*Op. cit.* 140 (Thierry Bourgoignie & David Trubek), at 99 to 110.

On the global scene, examples of positive harmonization in the consumer safety area are the *Codex Alimentarius*, the International Organization for Standardization (ISO) standards[149] and international treaties on dangerous chemicals.[150] At the regional level, explicit initiatives of the EU institutions to develop a detailed legal framework for consumer safety can be seen as a good example of such positive harmonization attempts. From 1975, when the *Council Resolution on a Preliminary program consumer protection and information policy*[151] was adopted, until today, the EU has showed its determination to develop a robust and comprehensive approach to consumer safety.

Nowadays, the EU has completed a broad package of legislation on consumer safety, which consists of the framework within the *General Product Safety Directive* (GPSD)[152]; sector-specific safety legislation applicable to sensitive categories of consumer products, such as toys, chemicals, cosmetics, textiles, electrical appliances and motor vehicles; rules on the marketing of products, including conformity assessment and accreditation procedures[153]; detailed provisions and guidelines on market surveillance systems and practices[154]; and common rules for the liability of

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[149]Since ISO is commercial body, without direct affiliation to the UN, it will not be a part of scrutiny in this work. Only the UN institutions initiatives and international agreements elaborated under auspice of the UN bodies are being reviewed for the purpose of this research.

[150]Detailed analyses of the international instruments on chemical safety, such as Rotterdam, Basel and Stockholm conventions, are presented below in CHAPTER II.

[151]Council of Europe, *Council Resolution of 14 April 1975 on a Preliminary Programme of the European Economic Community for a Consumer Protection and Information Policy,* OJ C 92, 25.4.1975, online: Eur-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:1975:092:0001:0001:EN:PDF>.

[152]*Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety*, OJ L 11, 15.1.2002, p. 4–17, online: Eur-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0095:EN:NOT>.

[153]EC, *Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 Setting out the Requirements for Accreditation and Market Surveillance Relating to the Marketing of Products and Repealing Regulation (EEC) No 339/93*, OJ L 218 of 13.8.2008, online: Eur-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV%3Al33248>.

[154]*Op. cit.* 152 (*Directive 2001/95/EC*), at art. 9, 10 & 19 & EC, *The Blue Guide on the Implementation of EU Product Rules*, 2016, J.O. 2016/C 272/01, online: EC <http://ec.europa.eu/DocsRoom/documents/18027>. The European Union's "Blue Guide" describes general rules for placing electronic products on the market within the EU. It sets rules on how the EU

producers in case of damage caused by a defective product[155]. In March 2013, new proposals for EU legislation, the so-called New Package, have been sent to the European Parliament and the Council of Ministers with the purpose to strengthen the EU regulatory framework on general product safety and market surveillance.[156]

On the other hand, negative harmonization refers to the removal of trade barriers between countries under international or regional open border policies.[157] Obviously, the ultimate goal of such an approach is to promote free trade between member

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regulates the free movement of goods, when the harmonization rules apply, the product supply chain and their obligations, product requirements, conformity assessment, and accreditation.

[155]EC, *Council Directive 85/374/EEC of 25 July 1985 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products*, OJ L 210, 7.8.1985, p. 29–33, online: Eur-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:31985L0374>.

[156]With the New Package, the European Commission wants to improve consumer product safety and to strengthen market surveillance in the EU. The Package is currently under discussion in front of the European Parliament and the Council of the EU. The Package includes the following proposals and documents: EC, *Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, More Product Safety and Better Market Surveillance in the Single Market for Products*, COM/2013/074 final, online: Eur-Lex < http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013DC0074>; EC, *Proposal for a Regulation of the European Parliament and of the Council on Consumer Product Safety and Repealing Council Directive 87/357/EEC and Directive 2001/95/EC, COM/2013/078 final* - 2013/0049 (COD), online: Eur-Lex <http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:52013PC0078>; EC, *Proposal for a Regulation of the European Parliament and of the Council on Market Surveillance of Products and Amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EU) No 305/2011, Regulation (EC) No 764/2008 and Regulation (EC) No 765/2008 of the European Parliament and of the Council, COM/2013/075 final* - 2013/0048 (COD), online: Eur-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52013PC0075>; EC, *Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee:20 Actions for Safer and Compliant Products for Europe: a Multi-annual Action Plan for the Surveillance of Products in the EU, COM/2013/076 final*, online: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013DC0076>; EC, *Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the Implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 Setting out the Requirements for Accreditation and Market Surveillance Relating to the Marketing of Products and Repealing Regulation (EEC) No 339/93, COM/2013/077 (final)*, online: Eur-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013DC0077>. More on New Package see: EC, *Product Safety and Market Surveillance Package*, online: EC <http://ec.europa.eu/consumers/consumers_safety/product_safety_legislation/product_safety_and_market_surveillance_package/index_en.htm>.

[157]*Op. cit.* 142 (Pedro Caro de Sousa) at 979-1012.

countries, not consumer protection. Nevertheless, consumer safety has never been completely overlooked under international or regional free trade rules. The universal concept of safety has always compelled politicians to take into consideration the safety issue despite its potential conflict with the free circulation of goods. Hence, free trade rules included in international and regional agreements most commonly provide for some exemptions from the strict application of the rules in case of specific legitimate interests and under certain conditions.

As an example, under the WTO rules members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health.[158] Similarly, under the regional NAFTA agreement, "each Party may (…) adopt, maintain or apply any standards-related measure, including any such measure relating to safety, the protection of human, animal or plant life or health, the environment or consumers, and any measure to ensure its enforcement or implementation".[159]

On the other side of Atlantic, Article 36 of the Treaty on the functioning of the European Union does confirm the long-standing rule according to which public health and safety are explicitly admitted as legitimate exemptions from the strict application of the treaty free trade rules[160]

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[158]"(…) such measures have to be based on scientific principles and evidence; do not arbitrarily or unjustifiably discriminate between members; and not be applied in a manner which would constitute a disguised restriction on international trade" (Art.2). (WTO, *The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)*, online: WTO <http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm>). More on the WTO and consumer protection and safety see : Emilie Conway, *La protection du consommateur à l'épreuve de l'Organisation mondiale du commerce*, (Cowansville, Qc.: Yvon Blais Inc., 2012). On the WTO and consumer safety, also see below CHAPTER II.

[159]*North American Free Trade Agreement*, at Art. 904, online: Foreign Trade Information System <http://www.sice.oas.org/trade/nafta/chap-091.asp>. More on NAFTA regime for consumer protection and safety see: James P. Nehf, "Principles of Consumer Protection in the North American Free Trade Agreement" in Thierry Bourgoignie dir., *Integration économique régionale et politique de protection du consommateur* (Cowansville (Québec): Yvon Blais, 2009).

[160]In the original Treaty establishing the European Economic Community, signed March 25, 1957, in Rome (*Treaty on the Functioning of the European Union*), Art 36 granted the state-member right to

Negative harmonization still allows for national non-quantitative measures equivalent to barriers to trade, such as consumer safety rules, to be maintained or adopted, but under exceptional circumstances. These circumstances, under WTO, NAFTA and EU agreements, will be discussed in more detail later in this work.

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impose "prohibitions or restrictions in respect of importation, exportation or transit which are justified on grounds of public safety (and) the protection of human (...) life or health". Following Maastricht (*Treaty on European Union*) 1992, Amsterdam 1997, Nice 2001, and latest Lisbon 2007 treaties reconfirmed this right (art. 30). This right has also been endorsed by the ECJ in legal disputes over the years. Regarding case law cases on quantitative restrictions between Member States and consumer protection see: Geraint Howells & Stephen Weatherill, *Consumer protection law*, (Aldershot: Ashgate, 2005) & Hans-W Micklitz, Jules Stuyck & Evelyn Terryn, *Consumer Law: Ius Commune Casebooks for a Common Law of Europe*, (Bloomsbury Publishing, 2010).

CHAPTER II

INTERNATIONAL LEGAL SOURCES OF CONSUMER SAFETY

World Trade Organization (WTO) rules have had a tremendous impact on consumer safety. Not only do the WTO statutes have a direct effect on national and international consumer safety schemes, but this international institution also possesses an effective mechanism of enforcement to dismantle any unjustified trade-barriers erected under the guise of consumer safety. Hence, all consumer protective measures, whether on national, regional or international realms have to follow the WTO praxes. This is why it is logical to look at consumer safety through the prism of the WTO polices before scrutinizing other sources of international law on the matter (2.1). In this part, the WTO's existing agenda on consumer protection will be analyzed first. Next, existing WTO principles explicitly linked to consumer safety will be put under scrutiny. The only two existing cases related to safety of non-food commodities in the scope of WTO will be examined thereafter.

Then sectoral international agreements and initiatives having a direct impact on consumer safety and developed under the umbrella of the UN network will be

assessed (2.2). Four main sectors will receive attention: chemicals (2.2.1), pharmaceuticals (2.2.2), traditional medicine (2.2.3) and transport of passengers at sea and air (2.2.4). This review of the selected international sources of consumer safety will allow us to draw a few conclusive remarks that will contribute to our overall assessment of consumer safety on global markets (2.2.5).[161]

2.1 Consumer safety under WTO rules

The actions of the WTO have been a key impetus of market globalization processes over the last few decades. Its decisions have had a tremendous impact on consumer health and safety throughout the world, due to the supremacy of the WTO free-trade rules over national consumer protection frameworks. The dominance of the WTO policies over the consumer agenda can be unmistakably observed even in the *UN Guidelines for Consumer Protection.* Article 10 of the Guidelines plainly accentuates that "in applying any procedures or regulations for consumer protection, due regard should be given to ensuring that they do not become barriers to international trade and that they are consistent with international trade obligations". A similar statement can be found in Article 46 on the Promotion of Sustainable Consumption: "Governments should promote the development and use of national and international environmental health and safety standards for products and services; such standards should not result in disguised barriers to trade"; and also in Article 49 on International Cooperation: "Governments should work to ensure that policies and measures for consumer protection are implemented with due regard to their not

[161]For details on how regional and national authorities have implemented the international agreements on consumer safety see CHAPTER III.

becoming barriers to international trade, and that they are consistent with international trade obligations".

The WTO does not have consumer protection policy in its mandate and no specific treaty on consumer protection has been adopted under the umbrella of the organization. The clear purpose of the WTO is to endorse free trade by removing tariff and non-tariff barriers to trade.[162] In line with such doctrine, consumer protection is seen only as a potential threat to a free market. Little or nothing has been done by the WTO regarding such a "sensitive" matter. A few treaties adopted under the auspices of the WTO include only scant notions of consumer protection and deal with the matter only to a very limited extent. References to consumer protection can be found as a part of horizontal policies on environment, sanitary measures and product labeling. Nevertheless, such attention to the area of consumer protection remains strictly sporadic and consumer protection has never been outlined during ministerial meetings under the WTO auspice.[163]

While some fundamental consumer rights, such as the right to safety, the right to information, the right to a healthy environment and the right to choice have received greater acceptance as part of the multilateral trading system,[164] the consumer

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[162]*General Agreement on Tariffs and Trade* (GATT) Article III prohibits WTO members from imposing taxes (Article III:2) or other regulations (Article III:4) that treat imports, after passage through customs, "less favorably" than domestic like products. This Article embodies the important principle of national treatment, which holds that all goods and services, regardless of origin, must be treated equally after they enter into a domestic market. Article III:4 applies the national treatment principle explicitly to a nation's enforcement of laws, regulations, and other requirements. More on WTO free trade rules and consumer protection see: Lucas Ballet, "Losing Flavor: Indonesia's WTO Complaint Against the U.S. Ban on Clove Cigarettes", *American University International Law Review* 26: 2 (2011) at 518-522 online: Digital Commons (American University Washington College of Law) <http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1706&context=auilr>. Also, Emilie Conway, *La protection du consommateur à l'épreuve de l'Organisation mondiale du commerce*, (Cowansville, Qc.: Yvon Blais Inc., 2012)

[163]*Ibid.* (Emilie Conway) at 64.

[164]Eight WTO Multilateral Agreements on Trade in Goods were screened on pertinence to consumer protection in Emilie Conway' work, namely: the *Agreement on the Application of Sanitary and Phytosanitary Measures the Agreement on Agriculture*; the *Agreement on Technical Barriers to Trade*;

protection agenda has never been an integral part of the WTO documents. The notion of a consumer has not been given autonomous status nor has a designated body for consumer protection ever been inaugurated under the umbrella of the WTO. All WTO agreements, including the *Marrakesh Agreement Establishing the World Trade Organization*,[165] benefit consumer protection only indirectly.[166] Nothing indicates that this situation will change in the near future.

Evidently, consumer safety could not be completely overlooked by the WTO. Potential conflicts between the application of WTO rules and national laws pursuing other public purposes, such as consumer safety, called for a compromise solution to be found.[167]

GATT Article XX on General Exceptions lays out a number of specific instances in which WTO members may be exempted from free-trade rules.[168] One exception is of

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the *Agreement on Textiles and Clothing*, the *Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994 (Anti-Dumping Agreement)*; the *WTO Agreement on Subsidies and Countervailing Measures*; the *WTO Safeguards Agreement*; the *Agreement on Trade-Related Investment Measures*; the *General Agreement on Trade in Services*; the *Agreement on Trade-Related Aspects of Intellectual Property Rights*. *Ibid.* at 65 to 88.

[165]WTO, *Marrakesh Agreement Establishing the World Trade Organization*, 1994, online: WTO <https://www.wto.org/english/docs_e/legal_e/04-wto_e.htm>.

[166]*Op. cit.*162 (Emilie Conway) at 93-94.

[167]Bernard Hoekman & Michel Kostecki, *The Political Economy of the World Trading System: WTO and Beyond,* 2d ed (OUP Oxford, 2001) at 339, online: Oxford Scholarship <http://www.oxfordscholarship.com/view/10.1093/019829431X.001.0001/acprof-9780198294313>.

[168]Article XX: General Exceptions. Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: (a) necessary to protect public morals; (b) necessary to protect human, animal or plant life or health; (c) relating to the importations or exportations of gold or silver; (d) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Article II and Article XVII, the protection of patents, trademarks and copyrights, and the prevention of deceptive practices; (e) relating to the products of prison labour; (f) imposed for the protection of national treasures of artistic, historic or archaeological value; (g) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption; (h) undertaken in pursuance of obligations under any intergovernmental commodity agreement which conforms to criteria submitted to the Contracting

particular relevance to consumer safety: paragraphs (b) of Article XX. Pursuant to this paragraph, WTO members may adopt policy measures that are inconsistent with GATT disciplines, but necessary to protect human (...) life or health. Should a member pursue a policy that falls under the scope of Article XX, it does not have to preemptively defend the policy unless challenged by another member through the GATT's Dispute Resolution Mechanism. The burden of proof falls on the member invoking the Article XX exception.

To date, two WTO agreements adopted under the provisions of Article XX (b) explicitly include consumer protection measures with direct impact to consumer safety: the *Agreement on the Application of Sanitary and Phytosanitary Measures* and the *Agreement on Technical Barriers to Trade*. It is important to underline that while these two specific WTO agreements were originally adopted to deal predominantly with the field of food safety, the concept has been expended to consumer product safety in general. Both treaties try to identify how to meet the need to apply consumer products safety standards while avoiding protectionism in disguise.[169]

First, with the purpose to harmonize sanitary and phytosanitary measures between members on the basis of international standards, guidelines and recommendations, the *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement)[170] recognizes the governments' right to take sanitary and phytosanitary measures but only to the extent necessary to protect human life or health.[171]

Parties not disapproved by them or which is itself so submitted and not so disapproved; (i) involving restrictions on exports of domestic materials necessary to ensure essential quantities of such materials to a domestic processing industry during periods when the domestic price of such materials is held below the world price as part of a governmental stabilization plan; (j) essential to the acquisition or distribution of products in general or local short supply.

[169]WTO, *Standards and Safety*, online: WTO <https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm4_e.htm#TRS>.

[170]WTO, *Agreement on the Application of Sanitary and Phytosanitary Measures*, online: WTO <https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm>.

[171]The SPS Agreement entered into force with the establishment of the World Trade Organization on 1 January 1995.

However, measures taken should be based on scientific principles, not be maintained without sufficient scientific evidence and be consistent with international standards, guidelines and recommendations. As well, they should not arbitrarily or unjustifiably discriminate between members where identical or similar conditions prevail. In addition, sanitary and phytosanitary measures should not be applied in a manner that would constitute a disguised restriction on international trade and should be based on an assessment, as appropriate to the circumstances, of the risks to human life or health.[172]

If there is a scientific justification, the state reserves the right to introduce or maintain sanitary or phytosanitary measures more protective than the relevant international standards. To some extent, members may apply the "precautionary principle" or so-called "safety first" approach to deal with scientific uncertainty. In cases where relevant scientific evidence is insufficient, Article 5 of the SPS Agreement allows temporary "precautionary" measures on the basis of available pertinent information.

Second, with the aim to create a predictable trading environment, the *Agreement on Technical Barriers to Trade* (TBT Agreement)[173] seeks to ensure that regulations, standards, testing, and certification procedures varying from country to country, do not create unnecessary obstacles to trade. The agreement recognizes the countries' right to adopt technical regulations necessary to fulfill the legitimate objective of protecting human life or health.[174] Yet, under the treaty, governments should harmonize technical regulations on as wide a basis as possible to facilitate the conduct of international trade.[175]

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[172]*Op. cit.* 170 (*Agreement on the Application of Sanitary and Phytosanitary Measures*), at Art. 2.
[173]WTO, *Agreement on Technical Barriers to Trade*, online: WTO <https://www.wto.org/english/docs_e/legal_e/17-tbt.pdf>.
[174]*Ibid.* at Art. 2.2.
[175]TBT postulates also echo in the Guidelines for Consumer protection. Namely, Article 28 of the Guidelines underline that Governments should, as appropriate, formulate or promote the elaboration and implementation of standards, voluntary and other, at the national and international levels for the

Even if the ultimate aim of WTO agreements is to maintain a proper balance between the right of governments to protect the public from unsafe products and prevent taken measures from being unjustified trade barriers, both documents benefit consumer safety. In spite of a long list of stipulations, the SPS Agreement may still be used as an efficient instrument, with which a government, if it has the political will, may impose effective measures to protect consumer health and life. And while the provision regarding precautionary measures may be a panacea for consumer safety related trade problems, it makes the agreement a Pandora's box for international commerce. One need only recall the endless US-EU hormone-treated beef and Genetically Modified Organism (GMO) disputes.[176]

As for the TBT Agreement, it also benefits consumer safety in three ways. First, the treaty forces governments to adopt international standards and as a result provides consumers with a minimum internationally recognizable level of safety. Second, if circumstances require it, the authorities are allowed to establish national standards to protect consumer health and life. Third, as such national standards will themselves create barriers to trade, an incentive will exist to approximate consumer safety regulations at the international level.

Another benefit of the WTO agreements is to promote international standards on safety as developed by other institutions of the UN network, such as these developed by the Codex Alimentarius Commission. The TBT Agreement asks members to play

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safety and quality of goods and services and give them appropriate publicity. National standards and regulations for product safety and quality should be reviewed from time to time, in order to ensure that they conform, where possible, to generally accepted international standards.

[176] *European Communities — Measures Affecting the Approval and Marketing of Biotech Products (Complaint by Argentina)*, (2006), WTO Doc. DS293, (Dispute Settlement) online: WTO <http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds293_e.htm>; *European Communities — Measures Concerning Meat and Meat Products (Hormones) (Complaint by the United States),* (1999), WTO Doc. DS26, (Dispute Settlement), online: WTO <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds26_e.htm>.

a full role in the preparation by appropriate bodies of international standards for products for which they either have adopted, or expect to adopt, technical regulations.[177] For its part, the SPS Agreement calls on countries to base their sanitary or phytosanitary measures on international standards, guidelines, or recommendations.[178]

To oversee its implementation, the SPS Agreement established the SPS Committee. The Committee has developed guidelines to assist governments in ensuring a consistent approach in determining their acceptable risk levels and in selecting measures to achieve an appropriate level of consumer safety.[179] Meanwhile, TBT Committee' work[180] involves two broad areas: review of specific measures[181] and strengthening the implementation of the TBT Agreement.[182]

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[177]*Op. cit.* 173 (*Agreement on Technical Barriers to Trade*), at Art. 2.
[178]*Op. cit.* 170 (*Agreement on the Application of Sanitary and Phytosanitary Measures*), at Art. 3.
[179]WTO, *Guidelines to Further the Practical Implementation of Article 5.5'*, WTO Doc.G/SPS/15, online: WTO <https://www.wto.org/english/tratop_e/sps_e/decisions06_e.htm>. The SPS Committee has also developed guidelines to assist governments implement "equivalence" - the recognition that different methods of production or treatment by another country may provide the same level of health protection as that resulting from the importing country's measures. For more information see: WTO, *Decision on the Implementation of Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures'*, WTO Doc. G/SPS/19/Rev.2., online: WTO <https://www.wto.org/english/tratop_e/sps_e/decisions06_e.htm>.
[180]Equally, the TBT Committee holds three formal meetings per year. More on SPS Committee work see: WTO, *Sanitary and Phytosanitary Measures*, online: WTO <https://www.wto.org/english/tratop_e/sps_e/sps_e.htm#work>.
[181]WTO members discuss specific trade concerns (STCs) — specific laws, regulations or procedures that affect their trade to find out more about the scope and implementation of each other's regulations in light of the core TBT obligations.
[182]Members exchange experiences on the implementation of the Agreement with a view to making implementation more effective and efficient. Over the years, the Committee has developed a series of decisions and recommendations intended to facilitate implementation of the TBT Agreement. More on TBT Committee work see: WTO, *Technical Barriers to Trade*, online: WTO <https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm>. For the latest decisions and recommendations adopted by the Committee see: WTO, *Decisions and Recommendations Adopted by the WTO Committee on Technical Barriers to Trade Since 1 January 1995*, Doc. G/TBT/1/Rev.11, (December 2013), online: WTO <https://www.wto.org/english/tratop_e/tbt_e/tbt_work_docs_e.htm>.

Implementation

The WTO implementation report of 2010[183] makes it clear that the SPS and TBT Agreements have provided an effective framework of rules regarding trade measures taken to protect food safety and plant and animal health. Many governments have enshrined key obligations of the Agreements in their national regulations. They first consider whether the use of one of the relevant international standards could provide the level of health protection that the country considers appropriate and, if not, base their requirement on an assessment of the health risks involved with the trade of the product.[184]

The SPS Committee meets three times a year (occasionally jointly with the TBT Committee) offering an opportunity for WTO members to raise specific trade concerns regarding the SPS requirements of trading partners. Approximately 400 specific trade concerns have been raised between 1995 and today. Overall, most trade concerns are related to animal health (39%), food safety (31%) and plant health (24%).[185] Both developed and developing member countries participate actively in the SPS Committee meetings raising equal number of trade concerns.[186] Noticeably, trade concerns related to non-food consumer products have rarely been procured under the SPS Agreement.

Article 11 of the SPS Agreement offers a mechanism for Trade Dispute Settlement that refers to the consultation of experts when a dispute involves scientific or

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[183]WTO, *Review of the Operation and Implementation of the Agreement on the Application of SPS Measures*, WTO Doc. G/SPS/53, (May 2010), online: WTO <https://www.wto.org/english/tratop_e/sps_e/decisions06_e.htm>.
[184]Oretchen H. Stanton, "The SPS Agreement: WTO Agreement on the Application of Sanitary and Phytosanitary Measures", *International Trade Forum Magazine*, 3 (2010) at 24.
[185]The 6% of concerns are attributed to other issues such as certification requirements or translation. (WTO, *Review of the Operation and Implementation of the SPS Agreement*, WTO Doc. G/SPS/W/273, at 2, online: WTO <http://www.wtocenter.org.tw/SmartKMS/fileviewer?id=138112>).
[186]*Ibid.* at 3.

technical issues.[187] So far, more than 500 disputes had formally been brought under the WTO's dispute settlement system. Of these, 43 alleged violation of the SPS and TBT Agreements and 24 resulted in the establishment of a dispute settlement panel. Such panels were established to look at a variety of issues. Predominately, Disputes Panels have been held on issues associated with agricultural products safety.[188] Only in two instances were Disputes Panels established to examine safety of non-food commodities, i.e. Asbestos[189] and Clove Cigarettes.[190]

These two cases are further described here below.

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[187]More on procedure of trade disputes settlement see: WTO, *Understanding on rules and procedures governing the settlement of disputes*, online: WTO <https://www.wto.org/english/tratop_e/dispu_e/dsu_e.htm#11>.

[188]Since 1995, dispute settlement panels have addressed to following emerging SPS issues: the United States' and Canada's complaints regarding the European Commission (EC) ban on meat treated with growth-promoting hormones; complaints by Canada and the United States against Australia's restrictions on imports of fresh, chilled or frozen salmon; one at the request of the United States to examine Japan's requirement that each variety of certain fruits be tested with regard to the efficacy of fumigation treatment; Japan's restrictions on apples due to fire blight requested by the United States; the Philippines complaints against Australia's quarantine procedures; complaints by the European Communities against Australia's quarantine procedures; complaints by the United States, Canada and Argentina concerning EC measures affecting the approval and marketing of biotech products; complaints of the European Communities against the United States and Canada on their continued suspension of obligations relating to the EC-Hormones dispute; New Zealand's complaint against Australia's restrictions on apples; Canada's and Mexico's complaints regarding against the United States on the Certain Country Labeling (COOL) Requirements; China's complaint against certain United States measures affecting imports of poultry; and Canada's complaint against Korea's measures affecting the importation of bovine meat and meat products from Canada.

[189]Canada complained regarding EC measures affecting asbestos import (*European Communities – Measures Affecting Asbestos and Asbestos – Containing Products (Complaint by Canada)*, (2000), WTO Doc. WT/DS135/R (Report of the Panel) at 10), online: WTO <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds135_e.htm>).

[190]Indonesia complained against the US ban on clove cigarettes import (*United States—Measures Affecting the Production and Sale of Clove Cigarettes (Complaint by Indonesia),* (2014), WTO Doc. WT/DS406/12, (Dispute Settlement), online: WTO <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds406_e.htm>).

European Communities – Measures Affecting Asbestos and Asbestos – Containing Products

Canada, the second largest producer of asbestos in the world, filed a complaint in response to a French decree[191] banning imports of asbestos and products containing asbestos.[192] The EC claimed that the ban on asbestos was necessary to protect consumer health from the inherent toxic properties of asbestos. While recognizing the dangers associated with asbestos, Canada argued that modern products containing asbestos pose no threat to health.[193] After hearing arguments from both sides the WTO Panel ruled in favor of the EC, by declaring that the ban was justified in the light of the exception included in Article XX (b) of the GATT 1994 to protect the life and health.[194]

The Asbestos Dispute is significant because in its ruling the Panel Body explicitly reconfirmed the WTO members' right to determine an appropriate level of health protection. Hence, any Member State has an unconditional right to apply a "safety-first" rule when it is necessary to protect consumer health or life. Nevertheless, it would be important to emphasize that in the Asbestos Dispute, concerns regarding

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[191]On 24 December 1996, the French Government adopted Decree No. 96-1133 banning asbestos, issued pursuant to the Labour Code and the Consumer Code (Décret no. 96-1133 relatif à l'interdiction de l'amiante, pris en application du code de travail et du code de la consummation, (Journal officiel of 26 December 1996)). Article 1 provides for a ban on asbestos in the following terms: "For the purpose of protecting consumers, [...] the manufacture, import, domestic marketing, exportation, possession for sale, offer, sale and transfer under any title whatsoever of all varieties of asbestos fibres or product containing asbestos fibres shall be prohibited [...]".

[192]The Asbestos dispute in the light of consumer protection was comprehensively scrutinized by Émilie Conway; hence, only a short synopsis is provided hereafter. (*Op. cit.*162 (Emilie Conway), at 123-128.)

[193]Canada explained that modern asbestos products are not brittle and fiber emissions during their transportation, installation and use (including subsequent losses due to alteration and abrasion) have been reduced to an absolute minimum, unlike earlier products which released much larger amounts of fibers into the environment.

[194]For full information on EC-Asbestos dispute see: *European Communities – Measures Affecting Asbestos and Asbestos – Containing Products (Complaint by Canada)*, (2000), WTO Doc. WT/DS135/R (Report of the Panel), at 10, online: WTO <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds135_e.htm>.

consumer safety were interpreted mostly via environmental hazards, since adverse effects on public health came through environmental exposure to this toxic chemical.[195]

On the contrary, the Clove Cigarettes dispute had a more direct and broader impact on consumer safety.

United States—Measures Affecting the Production and Sale of Clove Cigarettes

Historically, cigarettes and other tobacco products were exempt from the health and safety standards governing contents and designs that are typically applied to other consumer products, including foods, beverages and drugs.[196] However, in recent days, domestic tobacco control measures have become stricter through the world. Tobacco companies have responded, as ever, with whatever policy and legal arguments they can muster. Tobacco lobbyists routinely claim that tobacco control measures violate international trade and investment law.[197] Lately, the tobacco industry has begun a new wave of international litigation. Outside of the WTO, Philip Morris has also been active in using trade and investment agreements to challenge tobacco control measures directly.[198] As for WTO, the recent dispute launched by Indonesia against a United States "flavoring measure" has crystalized various

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[195]Asbestos has been mostly used in constriction as an inexpensive material with fireproof and insulating proprieties.

[196]WHO, *The Scientific Basis of Tobacco Product Regulation: Report of a WHO Study Group*, (WHO technical report series; no. 945), 2007, at 7, online: WHO <http://www.who.int/tobacco/global_interaction/tobreg/9789241209458.pdf>.

[197]Andrew Mitchell & Tania Voon, "Regulating Tobacco Flavors: Implications of WTO Law", *Boston University International Law Journal*, 29:2 (2011), at 384&385, online: Boston University School of Law <http://www.bu.edu/ilj/files/2014/05/MitchellVoon-finalpdf.pdf>.

[198]Benn McGrady & Alexandra Jones, "Tobacco Control and Beyond: The Broader Implications of United States— Clove Cigarettes for Non-Communicable Diseases", *American Journal of Law & Medicine* [American Society of Law, Medicine & Ethics Boston University School of Law] 39 (2013), at 265&266, online: Georgetown University <http://www.law.georgetown.edu/oneillinstitute/documents/SSRN-id2263270.pdf>.

implications of the International free-trade law for regulatory measures by Member States that restrict "flavoring" of tobacco products.

In recent years, tobacco manufacturers have found it profitable to market flavored tobacco products that are particularly attractive to youth. Some studies estimate that up to 20% of youth smokers (between ages 17 to 19) in the U.S. reported using flavored tobacco products, compared to 6% of adult smokers.[199]

On June 22, 2009, President Obama signed into law the *Family Smoking Prevention and Tobacco Control Act* (FSPTC Act).[200] Section 101 of the FSPTC Act adds chapter IX, section 907(a)(1)(A) to the *Federal Food, Drug, and Cosmetic Act*, which bans the sale of cigarettes that contain an herb or spice that is a "characterizing flavor of the tobacco product", such as clove. The ban contends that flavored cigarettes appeal primarily to children and encourage them to start smoking. Nevertheless, the ban was not extended to menthol cigarettes.

On 7 April 2010, Indonesia requested consultations with the United States with respect to the provisions of Section 907(a)(1)(A) of the FSPTC Act that ban clove cigarettes. Indonesia is the world's main producer of clove cigarettes, and the vast majority of clove cigarettes consumed in the United States prior to the ban were imported from Indonesia.[201] Indonesia's main claims were that the ban on clove cigarettes was both discriminatory and unnecessary. Indonesia further claimed that the United States acted inconsistently with a number of procedural and/or other

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[199] *Op. cit.* 196 (*The Scientific Basis of Tobacco Product Regulation: Report of a WHO Study Group*), at 36.

[200] *Family Smoking Prevention and Tobacco Control Act*, Pub. L. No. 111-31, 123 Stat. 1776 (codified in scattered sections of 21 U.S.C.).

[201] Prior the ban the United States imported $15.2 million worth of clove cigarettes, of which 99 percent came from Indonesia. Clove cigarettes accounted for less than 0.05 percent of cigarettes smoked by young people, and 0.09 percent of all consumption. ("US Rejects WTO Panel on Clove Cigarette Ban", *Reuters* (June 22, 2010) online: Reuters <http://uk.reuters.com/article/2010/06/22/trade-cigarettes-idUKLDE65L1O920100622>).

requirements under Article III: 4 of the GATT 1994,[202] Article 2 of the TBT Agreement, and various provisions of the SPS Agreement in the context of preparing and implementing Section 907(a)(1)(A).[203] On request from Indonesia, a Panel was established in June 2010.[204]

In one of its key findings, the Panel determined that the ban was inconsistent with the national treatment obligation in Article 2.1 of the TBT Agreement because it accords clove cigarettes less favorable treatment than that accorded to menthol-flavored cigarettes. The Panel found that clove and menthol-flavored cigarettes are "like products"[205] within the meaning of Article 2.1 of the TBT Agreement, based in part on its factual findings that both types of cigarettes are flavored and appeal to youth. Prior the dispute, the approach to be used in determining whether products are like under the TBT Agreement was not clear. On appeal, the Appellate Body clarified that whether product categories are to be considered like is a determination about the nature and extent of a competitive relationship between and among the products at issue. Under this approach, the fact that products may pose divergent risks to health will not in and of itself mean that they are not like products, but may be relevant to

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[202]More on GATT provisions relevant to the trade dispute under Article XX see: *Op. cit.* 162 (Lucas Ballet), at 518 to 520.

[203]Indonesia did not argue its claims under the SPS Agreement.

[204]*United States—Measures Affecting the Production and Sale of Clove Cigarettes (Complaint by Indonesia),* (2014), WTO Doc. WT/DS406/12, (Dispute Settlement), online: WTO <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds406_e.htm>.
For detail analysis of the Panel and Appellate Body procedures and findings see: Jonathan Carlone, "An Added Exception to the TBT Agreement After Clove, Tuna II, and Cool" *Boston College International and Comparative Law Review*, 37:1, (February 2014) at 108&109, 112-138, online: Law Digital Commons <http://lawdigitalcommons.bc.edu/cgi/viewcontent.cgi?article=1707&context=iclr> & *Op. cit.* 197 (Andrew Mitchell & Tania Voon), at 392 to 422 & Todd Tucker, "Summarizing WTO Appellate Body Decision on U.S. Flavored Tobacco Ban", (April 2012), online: Citizen <http://www.citizen.org/documents/memo-appellate-body-clove-ruling-04-12.pdf> & *Op. cit.* 198 (Benn McGrady & Alexandra Jones) at 268 to 272 & Joshua Meltzer & Amelia Porges, "Case Notes, Beyond Discrimination? The WTO Passes the TBT Agreement in US-Clove Cigarettes, US-Tuna II and US –COOL", *Melbourne Journal of International Law*, 14:2, (December 2013), at 2&3, online: Melbourne Law School <https://www.law.unimelb.edu.au/files/dmfile/11MeltzerPorges-Depaginated.pdf>.

[205]More on concept of "like products" or competitive relationship see: *Op. cit.* 162 (Lucas Ballet), at 523-528.

the question of competitiveness.[206]

However, the Panel rejected Indonesia's second main claim, which was that the ban was unnecessary. In this regard, the Panel found that Indonesia had failed to demonstrate that the ban is more trade-restrictive than necessary to fulfill a legitimate objective (in this case, reducing youth smoking) within the meaning of Article 2.2 of the TBT Agreement. The Panel's conclusion was based, in part, on its finding that there is extensive scientific evidence supporting the conclusion that banning clove and other flavored cigarettes could contribute to reducing youth smoking.

In January 2012, the United States appealed certain issues covered in the panel report and certain legal interpretations developed by the Panel. However, in April 2012, the Appellate Body ultimately upheld the key Panel' findings.[207]

In July 2013 the U.S. laid out its plan to come into compliance with the WTO dispute settlement panel finding. In a status report to the WTO Dispute Settlement Body (DSB), the U.S. claimed that it was implementing the recommendations and rulings of the DSB by publishing an *Advanced Noticed of Proposed Rulemaking* relating to menthol in cigarettes by the U.S. Food Drug Administration (FDA), releasing a scientific evaluation of menthol in cigarettes by the FDA, announcing a youth education campaign targeting menthol cigarettes, sharing cessation tools and educating the public about menthol cigarettes through the SmokeFree.gov webpage. In addition, the U.S. noted that the "statement today was quite clear in that we have taken measures to come into compliance," and that "our view is that we will not need to revert to this item." Finally, the status report underlined that in light of the

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[206] *Op. cit.* 198 (Benn McGrady & Alexandra Jones), at 269.

[207] Would be important to notice that the Appellate Body disagreed with the Panel' interpretation of "likeness" criteria based on the regulatory purpose of the technical regulation at issue, namely, physical characteristics, end-uses, consumer tastes and habits, and tariff classification. The Appellate Body considered that the regulatory concerns underlying a measure, such as the health risks associated with a product, may be relevant to the determination of "likeness" to the extent they have an impact on the competitive relationship between the products.

significant public health challenges posed by menthol cigarettes, these actions by U.S. health authorities bring the United States into compliance with the DSB's recommendations and rulings in this dispute.[208]

Indonesia was not satisfied with the U.S. actions and on August 12, 2013, asked the DSB to allow Indonesia to impose trade sanctions on the U.S.[209] The U.S. objected to Indonesia's request for sanctions and the matter was referred to arbitration on August 23, 2013. However, in June 2014, the United States and Indonesia jointly requested the Arbitrator to suspend the circulation of its decision. The decision will remain confidential indefinitely until one of the parties terminates the agreement to suspend the arbitration proceedings.[210]

A few remarks about this dispute should be emphasized. First, it is important to note that the present case can be distinguished from *EC-Asbestos* because France imposed a total ban on asbestos products, prohibiting the use of asbestos from manufacture to sales in the French domestic marketplace, whereas U.S. outlawed clove and other flavored tobacco products, mostly imported, leaving U.S. menthol producers with a monopoly on legally-available flavored cigarettes. Therefore, even though United States argued that the ban is defensible under an XX(b) exemption, because the ban on flavored cigarettes protects U.S. children from the harms of smoking cigarettes, it

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[208]*Surveillance of Implementation of Recommendations Adopted by the DSB: United States-Measures Affecting the Production and Sale of Clove Cigarettes: Status Report by the United States*, WT/DS406/11/ADD.4, 2013, at 7&8, online: <http://geneva.usmission.gov/wp-content/uploads/2013/07/July23-DSB.pdf>.

[209]Recourse to Article 22.2 of the DSU by Indonesia, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, WTO Doc. WT/DS406/12 (2013).

[210]Recourse to Article 22.2 of the DSU by Indonesia, Communication from the Arbitrator, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, WTO Doc. WT/DS406/16, (24 June 2014), online: WTO <https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=125508,122599,119011,118886,118743,118023,117359,116708,116125,115577&CurrentCatalogueIdIndex=0&FullTextSearch=>.

clearly violates the GATT art. XX because it is unjustifiably discriminatory between countries where the same conditions prevail.[211]

Second, while the WTO's decision might be seen as a threat to the ability of Member States to introduce consumer health protective regulations, the Appellate Body reconfirmed the importance of members' efforts in tobacco control and clarified the implications of its decision should not to be interpreted as preventing WTO member nations from devising and implementing public health policies generally, and tobacco-control policies in particular, through the regulation of the content of tobacco products, including the prohibition or restriction on the use of ingredients that increase the attractiveness and palatability of cigarettes for young and potential smokers. However, measures adopted to pursue legitimate health objectives have to be done consistently with the national treatment obligation in Article 2.1 of the TBT Agreement.[212]

Third, this case, along with others,[213] is of particular importance, not only for the effect it has on domestic consumer protection regulations but also because it helps in interpreting the TBT Agreement which left its scope ambiguous. This new

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[211]Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures. (GATT Article XX).

[212]Although Section 907(a)(1)(A) of FSPTC Act pursues the legitimate objective of reducing youth smoking by banning cigarettes containing flavors and ingredients that increase the attractiveness of tobacco to youth, it does so in a manner that is inconsistent with the national treatment obligation in Article 2.1 of the TBT Agreement as a result of the exemption of menthol cigarettes, which similarly contain flavors and ingredients that increase the attractiveness of tobacco to youth, from the ban on flavored cigarettes. (Appellate Body Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes (Complainet by Indonasia)*, (2012), WTO Doc. WT/DS406/AB/R at paragraph 235&236, online: WTO <https://www.wto.org/english/tratop_e/dispu_e/406abr_e.pdf>).

[213]Other similar disputes: *United States–Certain Country of Origin Labeling (Complaint Canada)*, (2012) WTO Doc. WT/DS384/24 & WT/DS386/23 (Dispute Settlement), online: WTO <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds384_e.htm>; *Agreement Under Article 21.3(b) of the DSU, United States–Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products (Complaint by Mexico)*, (2008), WTO Doc. WT/DS381, (Dispute Settlement), online: WTO <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds381_e.htm>.

jurisprudence comes at an appropriate time because WTO members are increasingly using technical barriers to trade as mechanism of consumer protection from unsafe and dangerous products on the domestic market. Therefore, more disputes will likely be brought under the TBT Agreement.[214] For instance, a number of WTO members within the context of TBT committee have already expressed varying degrees of concern about the consistency of the Canada's *Cracking Down on Tobacco Marketing Aimed at Youth Act 2009*[215] with some substantive and procedural TBT provisions.[216]

Fourth, the U.S. could have complied with DSB ruling either by rescinding the ban on clove cigarettes or extending the ban to cover menthol cigarettes. Nevertheless, neither has been done. The U.S. action plan presented to comply with the WTO Dispute Settlement Panel finding was nothing but a deceiving hoax since it did not impose any restrictions on menthol cigarettes marketing.

Fifth, the goal of the FSPTC Act's flavorings ban was clear: to remove clove cigarettes from the market and nothing else. It did not shut down the sales of other sweet-flavored cigarettes since there were no such cigarettes on the market at the time of the law's enactment. In fact, not a single major U.S. tobacco company had a chocolate, strawberry, or other sweet-flavored cigarette on the market at the time the FSPTC Act came into an effect. The only flavored cigarettes actually smoked by a

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[214]*Op. cit.* 204 (Jonathan Carlone), at 103.

[215]Similarly, to the FSPTC Act, Canada *Cracking Down on Tobacco Marketing Aimed at Youth Act* was designed to address public health concerns by reducing the incentives for young people to smoke. (*Cracking Down on Tobacco Marketing Aimed at Youth Act* (S.C. 2009, c. 27), online: Justice Law Website <http://laws.justice.gc.ca/eng/AnnualStatutes/2009_27/page-1.html>).

[216]WTO Committee on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 5-6 November 2009*, G/TBT/M/49, (22 December 2009), online: WTO <https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=99791,89598,81738,80313,94266,103378,106242,104442,87898,62393&CurrentCatalogueIdIndex=5&FullTextSearch=>.

few youths that were taken off the market were clove cigarettes.[217]

Sixth, WTO rules do not distinguish between "good" and "bad" consumer products. Products detrimental to health, like tobacco, have the same legal status under international free-trade agreements as products that are beneficial to health such as sport equipment. To exclude tobacco and other unhealthy consumer products from free-trade rules would give WTO Member States the power to protect public health avoiding meanwhile similar disputes in the future.[218]

Finally, Indonesia had more than a legitimate argument. It had a strong and compelling argument. The FSPTC Act did not intend to protect the health of children and teens. The flavored cigarettes that youth actually smoke - menthol ones - were exempt from the law. The clear intent of the Congress was to make it look like it was doing something to protect youths but without actually endangering domestic cigarette sales. In other words, the FSPTC Act was an intentional effort to discriminate against foreign-made cigarettes under the guise of being a legitimate public health policy.[219]

Lastly, the FSPTC Act's flavoring ban for all intents and purposes was a selective ban on clove cigarettes, with no other cigarette brands affected. The arguments brought by Indonesia during WTO dispute have manifested deceitful U.S. polices. Under the pretext of consumer protection the U.S. tobacco lobby tried to restrict the competition on the flavored cigarettes market, and nothing else.

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[217]Michael Siegel, *The Rest of the Story: Tobacco News Analysis and Commentary: U.S. Thumbs Nose at World; Public Citizen Defends Ban on Clove Cigarettes* (29 July 2013) online: Tobacco Analysis <http://tobaccoanalysis.blogspot.ca/2013/07/us-thumbs-nose-at-world-public-citizen.html>.
[218]Geert Van Calster & Denise Prevost, *Research Handbook on Environment, Health and the WTO*, (Edward Elgar Publishing Limited, 2013), at 393&394.
[219]*Op. cit.* 217 (Michael Siegel).

To put it simply, the WTO law intended to protect public health and safety has been used to control the market of flavored cigarettes. And even if consumer health and safety have not been completely overlooked during the dispute between U.S. and Indonesian tobacco lobbies, regrettably, they have been held hostage to multinational tobacco company interests.

The unexpected positive effect of the *United States—Clove Cigarettes* dispute is that, to some extent, the U.S. government was forced to change its domestic policies on smoking. Obviously, the U.S. Action plan on menthol cigarettes, due to its pure education and informational nature, will have a little effect on smoking reduction amongst youth, who already are well enlightened about the detrimental effects of cigarettes on health. Nevertheless, the precedent when one of the most powerful Member State had to submit to a DSB ruling and firm up its domestic antismoking polices confers an optimism regarding the future of the consumer safety in the scope of WTO.

To conclude, the impact of WTO provisions on consumer protection policies is characterized by the principle of tolerance and encouragement to the extent that they do not constitute disguised restrictions on trade. Existing free trade rules contain enough flexibility to provide WTO members with an array of instruments for the protection of consumer health and safety as long as any measures taken properly target their objectives and comply with WTO agreements.

The interaction between free trade law and domestic regulation on consumer safety is often couched in terms of the conflict between the freedom to regulate and the constraints imposed through trade treaties. Consumer protection regulation finds its origin in a different set of concerns to disciplines on regulation that apply via trade law. WTO rules are one of many factors that enter into play when crafting domestic consumer safety legislation, and whether they are determinative or not, depends on

the magnitude of the interaction between consumer and free trade laws.[220]

Since the inception of the WTO, the supremacy of consumer safety national policies over the free trade rules has been reconfirmed multiple times.[221] In recent years, the SPS and TBT agreements have been used often to protect consumer health and life. In most cases Member States exercised their rights to protect consumers from unsafe foods or environmental threats. Safety of non-foods commodities is still a rare case in the scope of the WTO. Nevertheless, in recent disputes on Asbestos and Flavoured Cigarettes the WTO explicitly reconfirmed the right of Member States to protect consumer health and life from dangerous non-food products.

2.2 Sectoral agreements and initiatives

Over the years, the international community has shown steady progress in developing several effective instruments for non-food products and services to protect consumers around the globe. Nevertheless, upon preliminary review the fields most developed are contained only within four particular areas: chemicals, pharmaceuticals, traditional, complementary and alternative medicine, and international carriage. The main international law instruments applicable to these product categories and services are presented in the following four sections.[222]

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[220]"Necessary Complications? Observations on the Nexus between Trade Law and Domestic Regulation", *Frontier Economics*, (April 2015), at 3 to 12, online: Frontier Economics <http://www.frontier-economics.com/documents/2015/04/regulation-trade_frontier-report-april-2015.pdf>.

[221]*Op. cit.* 3 (Cary Coglianese, Adam Finkel & David Zaring) at 208.

[222]On how these instruments have been actually implemented on regional and national level see CHAPTER III

2.2.1 Chemicals

Nowadays, the chemicals industry – which includes industrial chemicals, pharmaceuticals, pesticides, biocides, food and feed additives, and cosmetics – is one of the world's largest industrial sectors and many chemicals are produced and traded internationally. Every year, global sales amount to over USD 3.5 trillion, with exports approximately USD 1.5 trillion.[223] Hence, chemicals are crucial ingredients of our everyday life and wellbeing.

Almost all consumer products are composed of one or several chemical ingredients. Without chemicals consumers would not afford to maintain some of their basic needs. In fact, we would not be able to sustain the existence of the seven billion people in the world. Only with the help of pesticides and fertilizers can we protect and support our food chain. Simply put, it would not be possible to feed everyone on this planet only with organically grown crops.[224] At the same time, almost all chemicals can be harmful and even deadly if they are not used or applied properly. A key element to protecting human health and the environment is to share adequate and relevant information on chemicals in manufactured products throughout the production chain and further down the value chain and to ensure that the necessary information for safe handling and use, recycling and disposal of products is available, accessible and transferred to the relevant stakeholders in a timely and understandable manner throughout the product life cycle.[225]

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[223]Richard Sigman, "Chemical safety" in OECD, *International Regulatory Co-operation: Case Studies*, Vol. 1: *Chemicals, Consumer Products, Tax and Competition*, (OECD: April 2013), at 16, online: OECD iLibrary <http://www.oecd-ilibrary.org/governance/international-regulatory-co-operation-case-studies-vol-1_9789264200487-en>.
[224]Dan Charles, "Our Fertilized World", *National Geographic*, (May 2013) at 94-111.
[225]*Progress Report on the Chemicals in Products Project, Including Proposed Recommendations for Further International Cooperative Action: Implementation of the Strategic Approach to International Chemicals Management: Emerging Policy Issues*, (International Conference on Chemicals

To prevent and minimize the consumer's health and life risks, governments throughout the globe have put in place significant and comprehensive regulatory frameworks. The objective of these frameworks is to ensure that chemical products already on the market are safe or managed in a safe way, and that new ones are properly assessed before being placed on the market. This is done by testing the chemicals, assessing the results, and taking appropriate action.

There are a few considerations why national measures aiming to ensure chemical safety sake should be implemented unambiguously at the international level. First, any framework on safety, while rigorous and comprehensive when implemented, is very resource-intensive and time-consuming for both governments and industry. For instance, the cost for a pesticide company to test one new active ingredient for health and environmental effects is approximately 21 million US$. This amount is astronomical even for the wealthy states. Obviously, most governments in developing part of the world just do not have such resources. As many of the same chemicals are produced in more than one country (or are traded across countries), different national chemical control policies can lead to duplication in testing and government assessment, thereby wasting the resources of industry and government alike. Sharing the cost and testing facilities under the umbrella of international chemical frameworks eliminates unnecessary expenses.[226]

Second, since consumer safety is one the few exceptions under the free market rules, different national policies on the matter create non-tariff or technical barriers to trade (TBT) in chemicals. The World Trade Organization has estimated that since 1998,

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Management Third session, Nairobi, 17–21 September 2012), online: SAICM <http://www.saicm.org/images/saicm_documents/iccm/ICCM3/Meeting%20documents/iccm3%2015/ICCM3_15_EN.pdf>.

[226]OECD, *International Regulatory Co-operation: Case Studies*, Vol. 1: *Chemicals, Consumer Products, Tax and Competition*, (OECD: April 2013), at 10, online: OECD iLibrary <http://www.oecd-ilibrary.org/governance/international-regulatory-co-operation-case-studies-vol-1_9789264200487-en>.

there have been approximately 32 safety-related TBT specific trade concerns: ten deal with control of hazardous substances, chemicals and heavy metals. Hence, legal approximation toward internationally recognized safety standards and protocols prevents free market disruption.[227]

Finally, differences in regulations and test standards discourage research, innovation and growth – as new research and products may only be accepted in the country or countries which apply the same test standards – and they increase the time it takes to introduce new and sounder products onto the market. They can also lead to inefficiencies for governments, because authorities cannot take full advantage of the work of others which would help reduce the resources needed for chemicals control.[228] Therefore, interstate cooperation in the field of chemical safety is not only beneficial for consumer protection against harmful or deadly substances but it also encourages the industry to develop new sounder products, provides the governments with low-cost consumer safety schemes, and prevents international trade from halting.

To date, the international community has developed a few comprehensive legal instruments to target most dangerous chemicals during different stages of their life cycle. Adopted tools come in the form of conventions, guidelines and regulations. For the purpose of this research, the following key international instruments are scrutinized: the *Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal* (adopted on 31 April 1989, entered into force on 5 May 1992); the *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade* (adopted on 10 September 1998, entered into force on 24 February 2004); the *Stockholm Convention on Persistent Organic Pollutants* (adopted on 23 May 2001,

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[227] *Ibid.*
[228] *Ibid.*

entered into force on 17 May 2004); the *Globally Harmonized System of Classification and Labeling of Chemicals* (GHS), 2002; a *Strategic Approach to International Chemicals Management*, 2006; the *Minamata Convention* (adopted on 19 January 2013, not entered into force yet).

2.2.1.1 Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (adopted on 10 September 1998, entered into force on 24 February 2004)

For years, the international community has tried to deal with the notorious practice of exporting products, in particular chemicals and pharmaceuticals that have been banned, severely restricted, or never approved in the country of origin, as well as the dumping of hazardous products in low or less regulated areas.[229] Such exports obviously have a detrimental effect on consumers in the importing country, but they may also return in the form of residues to the country of origin in agricultural products, creating the so-called "Circle of Poison".[230]

Developing countries have been a favoured destination of hazardous chemicals, since they are less aware of the risks involved and they depend on low-priced pesticides and fertilizers to sustain agriculture or to control vector-borne diseases (e.g. malaria

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[229]David Harland, "Legal Aspects of the Export of Hazardous Products" *Journal of Consumer Policy* 8:3, (September 1985), at 209 to 238, online: Springer Link <http://link.springer.com/article/10.1007/BF00380383> & Hanse W. Micklitz, "EC Regulation on the Export of Pharmaceuticals in Third World Countries", *Journal of Consumer Policy* 11:1 (March 1988) at 29 to 53, online: Springer Link <http://link.springer.com/article/10.1007/BF00411519>.

[230]For more on "Circle of Poison", see Paula Barrios, *The Rotterdam Convention on Hazardous Chemicals: A Meaningful Step Toward Environmental Protection?* (University of British Colombia, 2004), online: University of British Colombia <https://open.library.ubc.ca/cIRcle/collections/ubctheses/831/items/1.0077646>.

and yellow fever). Additionally, these countries usually lack appropriate regulations to deal with hazardous chemicals and when these regulations do exist there is very limited capacity to enforce them. Developing countries also generally are short of the ability and the infrastructure to handle these materials in a safe manner to protect human health from their negative effects. The WHO statistics, which record only the gravest cases, indicate that there are about 1 million accidental poisonings and 200, 000 deaths due to pesticides every year, primarily in developing countries.[231]

Pesticide poisoning in developed countries generally is an occupational hazard for agriculture workers.[232] In the developing world, pesticide poisoning mostly is a consumer problem since harmful chemicals are often used by households without proper training or protection and with little or no knowledge of their toxic effects.

Seventy-three percent of the chemicals covered by the Rotterdam Convention are pesticides, hence it can be seen as a major international instrument with which importing nations can obtain a certain level of protection for their consumers. However, the road to the Rotterdam Convention was not easy. With US$ 3.5 trillion in sales annually,[233] the chemical lobby has virtually unlimited resources to influence politicians at any level of government. No wonder it took 30 years for the international community to eradicate numerous obstacles and to find various compromises before the convention took on its current form.

In spite of the fact that most industrial nations had adopted safety regulations on goods for domestic use in the 70s/80s, only a few had extended the same rules to exports. Most countries "do either explicitly or tacitly exclude exported goods from

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[231] *Ibid.* at 1&2.

[232] As a rule, agriculture workers are properly trained and wear protecting gear when handling dangerous substances.

[233] European Chemical Industry Consul, *European Chemical Industry: Facts and Figures 2016*, at 4, online: European Chemical Industry Consul <http://asp.zone-secure.net/v2/index.jsp?id=598/765/42548&startPage=4>. Just pesticide sales are valued at about US$35 billion a year. Also *Op. cit.* 230 (Paula Barrios), at 1&2.

the requirement to comply with national safety regulation."[234] The main arguments of such exclusion were that no country has a right to impose on others its own standards and judgments on safety matter, as well as that an exporting country, which has higher standards, may jeopardize its competitive position on the international market.[235] Even within a single nation, various groups of experts often have very different opinions regarding the safety of some products, especially in the case of complex chemical substances such as drugs or pesticides. This discord becomes even more antagonistic on the interstate level when the assessment of risk often has political, economic, cultural, and other applications. As a result, many see little or no reason why an exporting country should ban the export of a product if the importing country allows it to be marketed. Moreover, developing nations, which know about the potential risk of some products, are faced with the dilemma of accepting certain harmful effects because the population could be in greater danger without certain products.[236]

Hence, the following approaches to minimize the possible harmful effects of importing dangerous products could be chosen:

(i) Products that have been banned, severely restricted, or never approved in the country of origin may continue to be exported (double-standard rule);
(ii) Products may be exported only after the importing country receives notification of the intention to export;
(iii) Products may be exported only upon obtaining official permission or formal consent from the importing country;

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[234]OECD, *Safety of Consumer Products - Policy and Legislation in OECD Member Countries* (Paris: OECD, 1980) at 36 to 37.
[235]*Op.cit.* 229 (David Harland) at 209 to 238.
[236]For example, some developing nations have to use cheap and health harmful malaria-control substances, which have numerous side effects but can prevent deadly disease, others has to use unsafe pesticides in the order to protect life-depending crop.

(iv) No such products should be allowed to be exported.

A consensus has emerged at the international level on a combination of the second and third scenarios: there is no absolute ban on exporting products that have been banned from domestic markets, and hence double standards will be tolerated, but due notification must be given and formal consent must be obtained from the importing country before the exports are made.

Concern related to the export of products that have been banned, severely restricted, or never approved in the country of origin was first recognized at the international level in the 70s/80s. From 1979 to 1982, the General Assembly of the UN adopted four resolutions on the exchange of information regarding banned hazardous chemicals and unsafe pharmaceutical products. In 1979 Resolution 34/173 recognized the urgent need to take concrete measure to prevent adverse effects on health in the importing countries from the importation of banned hazardous chemicals and unsafe pharmaceutical products.[237] In 1980, Resolution 35/186 requested a study on the ways and means to improve the exchange of information on banned hazardous chemicals and unsafe pharmaceutical products.[238]

In 1981, the UN General Assembly Resolution 36/166, urged the Member States and transnational corporations to exchange information on banned hazardous chemical and unsafe pharmaceutical products, and "to deal with this subject through

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[237]UN GAOR, *Exchange of Information on Banned Hazardous Chemicals and Unsafe Pharmaceutical Products*, GA Res. 34/173, UN GAOR, 1979, UN Doc. A/RES/34/173, online: UN <http://www.un.org/documents/ga/res/34/a34res173.pdf>.

[238]UN GAOR, *Exchange of Information on Banned Hazardous Chemicals and Unsafe Pharmaceutical Products*, GA Res. 35/186, UN GAOR, 1980, UN Doc. A/RES/ 35/186, online: UN <http://www.un.org/documents/ga/res/35/a35r186e.pdf>.

appropriate means including possible legislation on the national level".[239] One year later, the General Assembly adopted Resolution 37/137, in which the international community agrees that products that have been banned from domestic consumption and/or sale because they have been judged to endanger health and the environment should be sold abroad only when a request for such products is received from an importing country or when the consumption of such products is officially permitted in the importing country; the Resolution also requires that the exporting country make full information available on those products for safe use in comprehensible language. Finally, it mandates the UN Secretary-General to elaborate within a year an easy-to-read and understand consolidated list of products whose consumption and/or sale have been banned, severely restricted, or not approved by government and to update the list on a regular basis.[240]

Such a Consolidated List[241] helps state authorities to keep current with regulatory decisions taken by other governments and assists them in considering the scope for their own regulatory action. Hence, government agencies, which review applications for product registration, easily ascertain restrictive regulatory decisions made in other countries. It aims at disseminating information on products harmful to health and the environment, complementing and consolidating other information on dangerous chemicals within the United Nations system, including data received from United Nations Environment Programme (UNEP) and Food and Agriculture Organization of the United Nations (FAO).

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[239]UN GAOR, *Exchange of Information on Banned Hazardous Chemicals and Unsafe Pharmaceutical Products*, GA Res. 36/166, UN GAOR, 1981, UN Doc. A/RES/36/166, online: UN <http://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/36/166>.

[240]UN GAOR, *Protection Against Products Harmful to Health and the Environment*, GA Res.37/137, UN GAOR, 1982, UN Doc. Res. 37/137, online: UN <http://daccessdds.un.org/doc/RESOLUTION/GEN/NR0/426/15/IMG/NR042615.pdf?OpenElement>.

[241]UN, *Consolidated List of Products whose Consumption and/or Sale have been Banned, Withdrawn, Severely Restricted or not Approved by Governments*, online: UN <http://www.un.org/esa/coordination/CL11.pdf>.

In 1984, by its resolution 39/229, the Assembly decided to update the List annually, and to make the data available to governments and other users through direct computer access to it. In accordance with this resolution, the format of the List has been kept under continued review in cooperation with the relevant organs, organizations and bodies of the United Nations system, with a view to its improvement, taking into account its complementary nature.[242]

The 1000 page-long list presents, in a unified manner, information on restrictive regulatory decisions taken by governments on a range of agricultural and industrial chemicals. It is a source of valuable information for state authorities to take appropriate regulatory measures on chemicals in the light of their particular national circumstances. Furthermore, the provision of information on trade names, under which these products are marketed, adds value to the Consolidated List and makes it easier for national authorities and others monitoring such activities to identify a restricted product available in the local market. The identification of the chemical product with its manufacturer also provides access to safety data sheets and other information available from the manufacturers. Additionally, commercial data provides an easy method to cross-reference trade names with recognized common scientific names under which most regulatory information is available.

Other international responses to Resolution 37/137 were the adoption by the Food and Agriculture Organization (FAO) of the *Code of Conduct on Distribution and Use of Pesticides* in 1985,[243] the elaboration under the auspices of the United Nations Environmental Program (UNEP) of the *London Guidelines for the Exchange of*

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[242]UN GAOR, *Protection against Products Harmful to Health and the Environment,* GA Res.39/229, UN GAOR, 1984, UN Doc. A/RES/39/229, online: UN <http://www.un.org/documents/ga/res/39/a39r229.htm>.

[243]The Code was updated in 1989 and 2012. During last revision, its name was changed to *International Code of Conduct on Pesticide Management.* (FAO, *International Code of Conduct on Pesticide Management,* (2012), online: FAO <www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/code/en>).

Information on Chemicals in International Trade in 1987 and the introduction of the Prior Informed Consent (PIC) procedure in both documents in 1989. Prior Informed Consent (PIC) refers to the principle that an international shipment of a chemical that is banned or severely restricted in order to protect human life and the environment should not proceed without the agreement or decision of the designated national authority in the importing country.

The Code was one of the first voluntary codes of conduct in support of increased food safety, while at the same time protecting human health and the environment. The key objectives of the Code of Conduct are: the establishment of voluntary standards of conduct for all entities engaged in the distribution and use of pesticides and the promotion of safe pesticide handling to minimize the adverse effect on humans and the environment. The core of the Code consists of the following provisions: 1) pesticide management; 2) pesticide testing; 3) information exchange; 4) action to reduce health and environmental risks; 5) regulatory and technical requirements; 6) availability and use; 7) distribution and trade; 8) information exchange; 9) labeling, packaging, storage, and disposal; 10) advertising; 11) monitoring and observance of the Code.

The London Guidelines are aimed at enhancing the sound management of chemicals through the exchange of scientific, technical, economical, and legal information.[244] The London Guidelines include three voluntary procedures: information exchange, export notification, and the Prior Informed Consent (PIC) procedure.

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[244]Although the London Guidelines were primarily designed to control world commerce of hazardous chemicals, they openly call for application of the Guidelines to pharmaceuticals and food additives if they wish to do so. (UNEP, *The London Guidelines for the Exchange of Information on Chemicals in International Trade,* (1987), at art. 3, online: UNEP <http://www.chem.unep.ch/ethics/english/longuien.htm>).

Regarding information exchange, states that have taken action to ban or severely restrict chemicals must notify the International Registry for Potentially Toxic Chemicals (IRPTC). The Registry than disseminates the notification to the competent authorities in the other states to give them an opportunity to assess the risk associated with the chemical. To the extent practicable, the Designated National Authority (DNA) issuing the notification should provide information concerning alternative measures, such as integrated pest management techniques, non-chemical alternatives, and mitigation measures (Art. 6).

When an export of banned or severely restricted chemicals in the state of export occurs, the state of export must ensure that necessary steps are taken to provide the designated national authority of the state of import with relevant information such as an estimation of the quantity to be exported annually. (Art. 8)

As for the PIC procedure, those countries which elect to participate must record their decisions regarding future imports of banned or severely restricted chemicals in a formal way by informing IRPTC, and all exporting countries are expected to respect those decisions (Art. 7). Under Annex 2, the PIC procedure should be applied to all chemicals banned or severely restricted by ten or more countries. Those chemicals that are banned or severely restricted by five or more states should be submitted to an informal consultation to determine whether they meet the definition of banned and severely restricted for human health or environment.

It is important to notice that the Code reiterates the postulates of the London Guidelines, e.g., the section regarding global management of the pesticides trade[245]

[245]Prior to revision, both the Code and the Guidelines referred to information exchange, export notification, and prior information consent.

and the part on information exchange.[246] However, while the Guidelines are aimed only at the authorities, the Code addresses a more diverse spectrum of entities from governments and international organizations to food industry and consumer groups. Some parts regarding labeling, packaging, storage and disposal, advertising, and reducing health and environmental risks have direct bearing on consumer protection. This symbiosis makes the Code a unique and all-encompassing manual for all entities involved in the distribution and use of pesticides.

Both the Code and the Guidelines established a voluntary framework based on three components: information exchange, export notification, and the PIC procedure. The international community thus obtained a fairly adequate mechanism of protection against the dumping of banned and severely restricted products. However, since both documents were only of a voluntary nature, they could not guarantee total eradication of notorious practices. Only the transformation of voluntary measures into a solid and obligatory instrument would ensure effective implementation of the recommended mechanisms.

Through negotiations during the 90s initiated by the Joint Programme of FAQ and UN Environmental Programme (EP), by the first part of 1996 the international community had elaborated a document where PIC was introduced as a binding mechanism, and later the same year in Rotterdam, the Netherlands, 73 states signed the *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade* (the Rotterdam Convention).[247]

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[246]The information to be exchanged should include: action to ban or severely restrict a pesticide; legal, technical, scientific, and other relevant data; and the availability of resources and expertise associated with pesticide regulatory activities.

[247]The *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade*, 1996, online: Rotterdam Convention <http://www.pic.int/TheConvention/Overview/TextoftheConvention/tabid/1048/language/en-US/Default.aspx >. The text was subsequently amended (new chemicals were added) by the First

Since coming into force on February 24, 2004, the Rotterdam Convention has become the first international instrument that creates binding obligations for the implementation of the PIC procedure and under the auspices of which every nation may seek protection from dangerous exports in the international trade of chemicals.

The principal objective of the Convention is to promote shared responsibility and cooperative efforts among signatory parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm (Art. 1). The Rotterdam Convention reintroduces the same features as in the London Guidelines, including provisions on export notification, prior informed consent, and information exchange. But it also goes far beyond in consolidating the system and establishing executive bodies: the Conference of the Parties, the Secretariat, and the Chemical Review Committee. It also places a clear obligation upon the parties to designate a national authority that must perform the administrative functions required by the Convention.

Amongst other things, the Conference of the Parties (COP) shall keep the implementation of the convention under continuous review and evaluation, and undertake any action that may be required for the achievement of the objectives of the convention (Art. 18). The key functions of the Secretariat are to make arrangements for the meetings of the COP and its subsidiary bodies and to provide them with service as required, to facilitate assistance to the parties in implementation of the convention, to ensure the necessary coordination with the secretariats of the other relevant international bodies, and to perform the other secretariat functions specified in the convention and such other functions as may be determined by the COP (Art.

Meeting of the Conference of the Parties (Geneva, 20 - 24 September 2004), the Fourth Meeting of the Conference of the Parties (Rome, 27 – 31 October 2008) and the Fifth Meeting of the Conference of the Parties (Geneva, 20 - 24 June 2011).

19).[248] The members of the Chemical Review Committee (CRC) are a limited number of government-designated experts in chemicals management who are appointed by the COP on the basis of equitable geographical distribution. The main functions of the CRC are to review information received from Parties regarding banned and severely restricted chemicals and to recommend that the COP list or remove a chemical under the PIC procedure if certain criteria are met.[249]

The information exchange procedure includes a few steps. First, each party that has adopted a final regulatory action such as a ban or severe restriction on a chemical shall notify the Secretariat in writing of such action. The Secretariat shall communicate a synopsis of the received information to the parties every six months. Second, as soon as the Conference of the Parties has decided to make a certain chemical the subject of the PIC procedure and list it in Annex III, the Secretariat has to disseminate such information in the form of a *Decision Guidance Document* (DGD) filled with germane information regarding such decision. This information should include the following: common or trade names and names of preparations; information on hazard classification; use or uses of the chemical, physico-chemical, toxicological, and ecotoxicological properties; summary of the hazards and risks presented by the chemical to human health, including the health of consumers and workers; reasons for the final regulatory action relevant to human health including the health of consumers and workers, or the environment (Annex 1). Finally, each party shall exchange either directly or through the Secretariat any scientific, technical, economic, and other information to facilitate implementation of the convention.

For all chemicals listed in Annex III, the parties are obliged to apply a PIC procedure. After receiving a DGD, which advises that a certain chemical has been listed in

[248]The Secretariat functions are performed jointly by the Executive Director of UNEP and the Director-General of FAO.
[249]Art. 5 to 7 & art. 9.

Annex III, each Party has no more than nine months to transmit a response to the Secretariat concerning the future import of the chemical. A response could consist of consent, no consent, or consent to import under specific conditions or enclose an interim response. Moreover, a response must be accompanied by a description of any legislative or administrative measures upon which it is based. The Secretariat shall then inform all parties of the responses it has received. Each party has to transmit responses to the Secretariat with respect to each chemical listed in Annex III.

In order to prevent possible use of the convention as an instrument of restriction for international commerce, the authors have included a special provision according to which a party that has decided not to import a chemical will apply the same conditions of use for domestically-produced identical substances. (Art. 10)

In the event an importing party has failed to provide a response regarding a chemical listed in Annex III, no export should take place unless the chemical to be exported is registered by the importing party, or in case there is evidence that it has previously been used or imported by the importing party and there is no regulation to prohibit its use, or explicit consent to the import has been received from Designated National Authority (DNA) of the importing party by the exporter (Art. 11).[250]

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[250]DNA should not be confused with Official Contact Point (OCP) of a Party. OCP of a Party is used as a communication link with the Secretariat of the Convention on official issues such as: a) notices regarding participation in meetings of the Conference of the Parties; b) circulation of the reports of these meetings; c) proposals for the addition of chemicals to Annex III of the Convention; d) inclusion in the PIC procedure; e) nomination of experts to subsidiary bodies such as the Chemical Review Committee. The functions of an OCP are clearly distinguished from those of a *Designated National Authority* (DNA). Responsibilities of the DNA for a Party include: a) notifying the Secretariat of final regulatory actions (Article 5); b) submitting proposals for severely hazardous pesticide formulations (Article 6); c) providing import responses to chemicals subject to the PIC procedure (Article 10); d) communicating import responses to stakeholders in the country (Articles 10 and 11) e) sending and acknowledging export notifications (Article 12); f) information exchange (the Convention has a number of information exchange provisions, including information to accompany exported chemicals and general information exchange). More on the OCP functions, online: Rotterdam Convention <http://www.pic.int/Procedures/OfficialContactPoints/tabid/3285/language/en-US/Default.aspx>. More on the DNA functions, online: Rotterdam Convention <http://www.pic.int/Procedures/DesignatedNationalAuthorities/tabid/1366/language/en-

In the event a chemical that has been banned or severely restricted by a party is exported from its territory but the chemical is not listed in Annex III and as a result is not subject to the PIC procedure, the convention stipulates that an export notification (EN) procedure is required. Under this procedure, an exporting party must provide an EN to the importing party before the first shipment and annually subsequently, after a final regulatory action on a ban or restriction of such chemical takes place. Providing an EN is not necessary if the importing party has provided a response for the chemical to the Secretariat and the latter has distributed the response to the parties (Art. 12).

The convention also states specific requirements for labeling. In accordance with Article 13, in addition to the labeling requirements imposed by the importing party, all chemicals which are part of the PIC procedure and all banned or severely restricted chemicals in the country of origin are, when exported, subject to labeling requirements that ensure adequate availability of information with regard to risk and/or hazard to human health or the environment, taking into account relevant international standards. For all chemicals used by an end consumer, the exporting party must send a so-called Material Safety Data Sheet (MSDS) to each importer, in one or more of the official languages of the importing party. The MSDS has to follow an international recognized format, setting out the most up-to-date information available.

US/Default.aspx>. Diverse government bodies might be used as DNA or OCP of a Party. In France, Direction générale de la mondialisation, du développement et des partenariats of the Ministère des Affaires étrangères, Direction des Nations Unies, des Organisations Internationales, des Droits de l'Homme et de la Francophonie / Sous-Direction des Affaires Institutionelles et des Contributions of the Ministère des Affaires Etrangères et Européennes and Direction Générale de l'Alimentation / Service de la prévention des risques sanitaires de la production primaire / Sous-Direction de la Qualité et de la Protection des Végétaux of the Ministère de l'Agriculture, de l'Alimentation et de la Pêche serve as OCP; and Bureau des Substances et Préparations Chimiques of the Ministère de l'Ecologie, du Développement Durable et de l'Energie has functions as DNA and OCP.

The major achievement is that the Rotterdam Convention has transformed the voluntary PIC system, which had been introduced in the London Guidelines, into an obligation. It thereby ensures implementation by the international community, and as a result it offers vigorous protection of human health and the environment from hazardous chemicals. To date, there are a total of 47 chemicals listed in Annex III, among which 33 are pesticides (including 4 severely hazardous pesticide formulations) and 14 industrial chemicals.

Nevertheless, a few points do weaken and jeopardize the Convention's positive effect. First, even though the preamble to the convention emphasizes the importance of taking into account the particular circumstances and needs of developing countries and countries with economies in transition, in particular the need for technology transfer and financial and technical assistance, the text of the Convention remains silent and vague on the matter.

One of the basic conditions for proper operation of the convention is the ability of the importing party to have the adequate technical and administrative capacity to evaluate potential risks for its population and the environment from hazardous chemicals and make appropriate decisions. Without such capacity and proper financing, its ability to perform is limited or in question. Even during the negotiations leading up to the Rotterdam Convention, the financial issue was one of the most controversial matters. While developing countries asked for financial assistance to implement the convention, developed countries wanted to provide such assistance based only on voluntary contributions. This forced the removal of all proposals related to a financial mechanism from the final draft of the Convention, which does not include any provision regarding monetary assistance.

Another weakness of the convention is the absence of concrete obligations for technical assistance. The stipulation in the initial draft whereby the developed

country parties were obliged to provide technical assistance to the other parties was transformed into a declaration whereby the parties shall cooperate in promoting technical assistance for development of the infrastructure and the capacity necessary to manage chemicals to enable implementation of the convention. Furthermore, the parties with more advanced programs for regulating chemicals should provide technical assistance to the other parties in developing their infrastructure and capacity to manage chemicals throughout their lifecycle (Art. 16). Such broad and insubstantial language of the Convention requiring technical assistance on only a voluntary basis jeopardizes the ability of developing countries to implement their obligations under the convention.

Finally, the convention does not include any procedure or institutional mechanism to determine non-compliance with the provisions of the convention or for treatment of parties found to be in non-compliance (Art. 17). One crucial point for any binding system is the existence of provisions regarding compliance.[251]

How successful is the Rotterdam Convention? Even prior to the convention, the voluntary PIC system worked quite effectively as part of the London Guidelines. With a list of 38 chemicals and DNA in 147 countries, by 1997 the PIC had provided significant controls in the international trade of hazardous chemicals, as the key exporters acted in accordance with it.[252] Since the PIC has become a binding scheme under the Rotterdam Convention, it has shared similar success. Annex III currently lists 47 chemicals subject to the PIC procedure,[253] and 154 countries have become parties to the Convention. Hence, most regions or states have translated the Convention's postulates into regional or national laws.

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[251] *Op. cit.* 230 (Paula Barrios), at 1&2.
[252] *Ibid.*
[253] In 1998, the text of the convention was adopted with 27 chemicals in Annex III. Consequently, the Conferences of the Parties in 2004, 2008 & 2011 added a further set of chemicals based on work completed during the interim PIC procedure.

Taking into account the fact that the Convention has been in force for 13 years, it seems quite a good start. Nevertheless, the question must be asked, why to date are only 47 chemicals subject to the PIC procedure? Indeed, chemicals listed in Annex 3 are the most dangerous to consumer health and life. Yet, there are thousands of unsafe formulations trading over the world without any restriction and the international community has done little to protect the consumer, especially in the developing countries, from their harmful and deadly effects. Furthermore, only a few new substances have been added to the Convention over the last 10 years. The inclusion of new chemicals to Annex 3 has been impeded, or at least slowed, by the industrial lobby and the selfish interests of certain Member States, as illustrated by the Chrysotile saga.

Asbestos and all commercial forms of asbestos are known to be carcinogens based on sufficient evidence of carcinogenicity in humans.[254] The UN World Health Organization reports that asbestos-related lung cancer caused by the inhalation or ingestion of asbestos fibers, as well as mesothelioma[255] and asbestosis[256] from occupational exposures resulted in more than 100,000 deaths per annum.[257]

Although asbestos use dates back at least 2,000 years, modern industrial use began only around 1880. In 1950, the United States was the world's largest user of

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[254] Studies in humans have demonstrated that exposure to asbestos causes respiratory-tract cancer, pleural and peritoneal mesothelioma (tumours of the membranes lining the chest and abdominal cavities and surrounding internal organs), and other cancers.

[255]Mesothelioma (or, more precisely, malignant mesothelioma) is form of cancer that develops from cells of the mesothelium, the protective lining that covers many of the internal organs of the body. Mesothelioma is most commonly caused by exposure to asbestos. For more information see, online: National Cancer Institute <http://www.cancer.gov/cancertopics/types/malignantmesothelioma>.

[256] Asbestosis is a lung disease that occurs from breathing in asbestos fibers, causing scar tissue (fibrosis) to form inside the lung. Scarred lung tissue does not expand and contract normally. For more information see, online: Medline Plszus <http://www.nlm.nih.gov/medlineplus/ency/article/000118.htm>.

[257]WHO, *Asbestos Profile*, online: WHO <http://www.who.int/ipcs/assessment/public_health/asbestos/en/>.

asbestos.[258] However, as health and liability issues became apparent, asbestos demand declined rapidly after 1973. To illustrate, in the U.S. production of asbestos decreased considerably from a high of 136,000 metric tons in 1973 to 3,000 metric tons in 2002.[259] Domestic consumption[260] declined from 803,000 metric tons in 1973 to 13,100[261] metric tons in 2000.[262]

Chrysotile is the most abundant form of asbestos and Canada is one of the world biggest producers of this chemical.[263] No wonder that when in 2003 the international community proposed to include Chrysotile in the PIC procedure as an industrial chemical,[264] Canada not only sabotaged any work toward the inclusion, but also built a coalition with other asbestos producing-exporting/importing states[265] to prevent any further action regarding the harmful substance. Both major asbestos exporters such as Canada and importers like India fear that listing asbestos under Annex III will result in new limits on how and where it is used, driving up building costs and causing importers to look for alternate fire-resistant materials.[266]

In September 2004, during the first Conference of the Parties to the Rotterdam Convention (COP1) the listing of Chrysotile again was contested and no consensus

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[258]Use of asbestos peaked in the late 1960s and early 1970s, when more than 3,000 industrial applications or products were listed.

[259]Robert L. Virta, *Worldwide Asbestos Supply and Consumption Trends from 1900 through 2003*, 2013, online: U.S. Geological Survey <http://pubs.usgs.gov/circ/2006/1298/>.

[260]Production plus imports minus exports and adjustments for government and industry stocks.

[261]Most of the asbestos used in the United States is imported from Canada.

[262]*Report on Carcinogens, Eleventh Edition, Substance Profile, Asbestos CAS No. 1332-21-4*, online: United States Department of Health and Human Services <https://web.archive.org/web/20110608211238/http://ntp.niehs.nih.gov/ntp/roc/eleventh/profiles/s016asbe.pdf>.

[263]Canada is the world's fourth largest producer of Chrysotile asbestos, with only Russia, China and Kazakhstan producing more, and is second only to Russia in annual exports of the carcinogenic substance.

[264]Chrysotile is banned or severely restricted for use as by Australia, Chile and the European Community

[265]The countries backed the Canadian opposition: Russia, India, Ukraine, China, Zimbabwe, Indonesia, South Africa and Colombia.

[266]Jake Silver, "Canada blocks UN from declaring asbestos a "hazardous" substance", (21 July 2011), online: WSWS <https://www.wsws.org/en/articles/2011/07/asbe-j21.html>.

was reached due to Canadian-led opposition. The story repeated again and again in October 2006[267] at COP3, in October 2008 at COP4, and in June 2011 at COP5. In the run-up to COP4, a well-worn industry strategy has resurfaced. Asbestos stakeholders in India, Canada and Ukraine have commissioned new "research" on the effects of Chrysotile use despite the global consensus that Chrysotile causes a myriad of debilitating and fatal respiratory diseases and cancers.[268] As all COP decisions must be taken unanimously, the objections by six Parties, representing 5% of the Convention Members, at COP3 prevented the wishes of the 95% majority from being implemented.[269]

Facing rising criticism at home and declining asbestos production,[270] in September 2012, the Canadian Industry Minister made an announcement regarding the government's decision to stop defending asbestos mining in international circles and to no longer oppose adding Chrysotile asbestos to the Rotterdam Convention.[271] Consequently, during COP6 in May 2013 Canada withdraw its objection to listing Chrysotile for PIC procedure.[272] The following month, the Canadian Government came out with the *Canadian Initiative for the Economic Diversification of Communities Reliant on Chrysotile,* which has a budget of $50 million over seven

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[267]During COP3 a sketch of document considering PIC procedure for Chrysotile was outlined. (UNEP/FAO, *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade Chemical Review Committee: Listing of Chemicals in Annex III of the Rotterdam Convention: Consideration of the Draft Decision Guidance Document for Chrysotile Asbestos*, (UNEP/FAO/RC/CRC.2/19), online: Rotterdam Convention <http://www.pic.int/Portals/5/incs/crc2/s19)/English/CRC-2-19.%20chrysotile%20DGD%20rev%201pdf.pdf>).

[268]Laurie Kazan-Allen, *The Rotterdam Convention: Fighting for its Life*, (March 2008), online: International Ban Asbestos Secretariat <http://ibasecretariat.org/lka_rott_conv_fight_life_0308.php#3>.

[269]*Op. cit.* 266 (Jake Silver).

[270]Colin Campbell, *Canada's Chrysotile Business is Dying Out*, (12 September 2103), online: Canadian Encyclopedia <http://www.thecanadianencyclopedia.ca/en/article/canadas-chrysotile-business-is-dying-out/>.

[271]*CPHA Applauds the Government of Canada on Chrysotile Asbestos Decision*, (14 September 2012), online: Canadian Public Health Association <*http://www.cpha.ca/en/about/media/asbestos.aspx*>.

[272]Myron Getman, *United Nations Fails to Add Chrysotile to Rotterdam Convention – Again* (27 May 2013), online: The Mad Skeptic <http://www.themadskeptic.com/2013/05/united-nations-fails-to-add-chrysotile.html>.

years and aims to support communities and businesses economically linked to the asbestos industry in their efforts to make the economic transition to secondary and tertiary sectors.[273] Regrettably, after joining to the Convention in 2012, Russia, the biggest word producer of the substance,[274] took Canada's place in the pro-asbestos coalition[275] and has not been willing to allow Chrysotile to be labeled as a hazardous substance.[276]

Hence, after 10 years of endless attempts, once again no decisions on asbestos were made during COP6. Taking into consideration the implacable disparities on the matter between parties of the Convention, it will take considerable time before Chrysotile appears in Annex III of the Rotterdam Convention.

To conclude, it remains to be seen if the Convention can solve the dilemma faced by many poor nations who are aware of the harmful effects of certain chemicals but still continue using them in order to protect their population from diseases and hunger. In spite of the fact that the Rotterdam Convention confers power to refuse the import of dangerous substances, it does not force the chemical industry to provide cheap and safe products. This catch-22 situation whereby an importer is forced to choose between the bad and the worse must be changed. The international community and in

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[273]*Government of Canada Launches the Canadian Initiative for the Economic Diversification of Communities Reliant on Chrysotile*, (13 June 2013) online: Government of Canada <http://news.gc.ca/web/article-en.do?crtr.sj1D=&crtr.mnthndVl=6&mthd=advSrch&crtr.dpt1D=19&nid=750279&crtr.lc1D=&crtr.tp1D=1&crtr.yrStrtVl=2013&crtr.kw=&crtr.dyStrtVl=13&crtr.aud1D=&crtr.mnthStrtVl=6&crtr.page=1&crtr.yrndVl=2013&crtr.dyndVl=13&_ga=1.262906506.706984300.1398272198>.

[274]Russia annually mines an estimated 1,000,000 tons of asbestos and is responsible for half of the world's Chrysotile asbestos production. (*Seven Countries Opposed the Listing of Chrysotile Asbestos in the Rotterdam Convention* (10 May 2013), online: Asbestos Disease Awareness <http://www.asbestosdiseaseawareness.org/archives/21214>).

[275]The present pro-asbestos coalition includes India, Kazakhstan, Kyrgyzstan, the Russian Federation, Ukraine, Vietnam, and Zimbabwe. (*Ibid.*).

[276]Екатерина Дудина, "Участники Роттердамской конвенции отсрочили вопрос о запрете хризотила" [Ekaterina Dunina, "The Participants of the Rotterdam Convention Conference Postponed Banning Chrysotile"], (20 May 2013). online: РИА Новости <http://ria.ru/economy/20130520/938391658.html>.

particular developed nations should instead phase-out the production and export of chemicals that have been banned or severely restricted domestically, replacing them with safe and economically viable alternatives.

2.2.1.2 Stockholm Convention on Persistent Organic Pollutants (adopted on 23 May 2001, entered into force on 17 May 2004)

The Stockholm Convention entered into force on 17 May 2004 and today 179 parties have joined the treaty. Contrary to the Rotterdam Convention establishing shipment protocols for dangerous formulations, the Stockholm Convention goes much further and calls for the reduction and eventual elimination of the group of chemicals known as Persistent Organic Pollutants (POPs).[277]

Persistent Organic Pollutants are powerful pesticides that serve a range of industrial purposes and pose a significant threat to health and the environment. While the risk level varies from POP to POP, by definition all of these chemicals share four properties: they are highly toxic; they are persistent, lasting for years before degrading; they evaporate, traveling a long distance toward the poles; and they accumulate in the fatty tissue of fish, birds, animals, and human beings. Even at the very low concentrations usually found in the environment, because they bio accumulate in organisms POPs can trigger a range of generally subtle effects on human health, as well as on fish and wildlife at the top of the food chain. One the best-known POPs is DDT. Widely used previously, it continues to be applied against mosquitoes in several countries to control malaria.

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[277] *Stockholm Convention on Persistent Organic Pollutants*, 2001, online: Stockholm Convention <www.pops.int >.

Originally, the Convention listed 12 POPs dividing them into three categories inventoried in Annexes A, B, and C. At its fourth meeting held from 4 to 8 May 2009, the Conference of the Parties adopted amendments to list nine new persistent organic pollutants[278]. At its fifth meeting held from 25 to 29 May 2011, a new amendment added technical Endosulfan and its related isomers, bringing the total POPs number to 22[279].

Parties must take measures: to eliminate the production and use of the chemicals listed under Annex A; to restrict the production and use of the chemicals listed under Annex B; and to reduce the unintentional releases of chemicals listed under Annex C (with the goal of continuing minimization and, where feasible, ultimate elimination).

As an exemption, some nations may use some chemicals for a limited time in accordance with WHO recommendations and guidelines (Annex B), e.g., DDT may only be used locally when a safe, effective, and affordable alternative is not available. Equipment containing POPs, e.g., electrical transformers, must be replaced before 2025 (Annex C). Wastes containing POPs have to be handled, collected, and stored in an environmentally sound manner, and their toxic content has to been destroyed. The convention adopts a precautionary approach which was introduced during the United Nations Conference on Environment and Development in Rio de Janeiro in 1992. Principle 15 of the Rio Declaration states that where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason to prevent environmental degradation.[280]

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[278]*The new POPs under the Stockholm Convention*, online: Stockholm Convention <http://chm.pops.int/TheConvention/ThePOPs/TheNewPOPs/tabid/2511/Default.aspx>.
[279]*Chemicals proposed for listing under the Convention*, online: Stockholm Convention <http://chm.pops.int/TheConvention/ThePOPs/ChemicalsProposedforListing/tabid/2510/Default.asp>.
[280]UNEP, *Rio Declaration on Environment and Development*, 1992, online: UNEP <http://www.unep.org/Documents.Multilingual/Default.asp?DocumentID=78&ArticleID=1163>.

A major part of the Stockholm Convention is dedicated to financial and technical assistance matters. The developed country parties must provide new and additional financial resources as well as appropriate technical assistance to enable developing country parties and parties with economies in transition to meet the agreed full incremental costs of implementing the measures and to develop and strengthen their capacity to fulfill their obligations under the convention (Art. 12-13).

To date, most parties to the Convention have submitted a *National Implementation Plan* (NIP). Article 7 states that each Party must develop a plan for the implementation of its obligations and transmit this plan to the Conference of the Parties within two years of the date the Convention entered into force for that Party.[281] Additionally, the Parties must report regularly on efforts made to implement the treaty and are required to exchange information on best environmental practices and best available technologies.

The success of the Stockholm Convention is undeniable. The treaty has become even more successful than the Rotterdam Convention. 179 States ratified the treaty,[282] and no problems with implementation have been reported. Additionally, certain states that have not joined the Convention have *de facto* implemented its postulates. This is the case with the US, which has introduced equivalent legislation; also with Italy and Malta, which are subject to the EU regulatory scheme.

There are two obvious reasons why the Stockholm Convention has been so successful. First, the effects of POPs on human health and the environment are so evident, destructive, and irreversible that the international community has always agreed on a collective agenda to eliminate those most harmful chemicals from the

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[281]22 parties have not transmitted NIP. For detail information see: *National Implementation Plan Submissions log*, online: Stockholm Convention <http://chm.pops.int/Implementation/NIPs/NIPSubmissions/tabid/253/>.

[282]Compare Rotterdam Convention with 154 parties.

face of the earth.[283] There is no such a consensus on other substances that some states will hold as relatively safe when used with caution.[284] Second, POPs are a global problem. Certain chemicals, such as asbestos, are harmful only locally. That is why some states, like Russia, produce and export those substances putting business interests ahead of overseas consumers' health. It is absolutely immoral. Nevertheless, this business model does not implicate any harmful effects on consumers in the exporting country; hence, on the nation level, producers and exporters as well as politicians feel no or little pressure regarding this unethical practice.

Ironically, most POPs exported from Northern industrial states to the poor nations of the South end up in the countries of origin. The unique property of POPs to travel long distances toward the poles and to accumulate there in the environment and in human and animals tissue puts enormous pressure globally on the political elite to act. The public opinion and political climate shifted dramatically when the population and governments realized that exported toxic substances return back in the form of residues, no less harmful than the original product. No wonder that the international community has worked in unison to eradicate this global problem.

Global Monitoring Report under the Global Monitoring Plan for Effectiveness Evaluation was a first comprehensive analysis of the effectiveness of the Convention. The Report includes baseline information and data on POPs concentrations in core media (air, soil, water, human milk and blood) against which changes over time can be identified. The results are encouraging. For many chemicals listed as persistent organic pollutants under the Convention, concentrations in air have decreased over the past 10–15 years and are now levelling off. Some pesticides are present at such low concentrations that trends cannot be detected. Air concentrations of industrial

[283]In human POPs trigger endocrine disruption, cardiovascular disease, cancer, obesity, and diabetes.
[284]For example, until recently Canada promoted safe use of asbestos. Russia and many other states still believe that harmful effect of asbestos may be avoided through proper usage.

chemicals and unintentionally produced combustion by-products have also shown declining trends.[285]

Regardless of the remarkable achievements over the last 10 years, the Stockholm Convention cannot provide total safety to consumers and the environment from offensive substances. The 22 listed POPs represent much less than even the tip of the toxic iceberg. A closer look reveals that of 93,144 known organic chemicals at least 510 meet the criteria for persistence, bioaccumulation, long-range transport potential, and toxicity[286] and can be considered foreseeable POPs to be banned under the Stockholm Convention.[287] Hence, despite a fruitful decade the Stockholm Convention is still in the beginning of the long journey to a POPs free world.

2.2.1.3 The Basel Convention on the control of transboundary movements of hazardous wastes and their disposal (adopted on 31 April 1989, entered into force on 5 May 1992).

Waste tends to move from developed to less developed countries. A driving force for these transboundary shipments is the difference in treatment and disposal costs

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[285]UNEP, *Global Monitoring Report under the Global Monitoring Plan for Effectiveness Evaluation: Matters for Consideration or Action by the Conference of the Parties: Effectiveness Evaluation*, Conference of the Parties of the Stockholm Convention on Persistent Organic Pollutants Fourth meeting, Geneva, 4–8 May 2009, UNEP/POPS/COP .4/33, (30 January 2009), online: Stockholm Convention <http://chm.pops.int/Implementation/GlobalMonitoringPlan/Overview/tabid/83/Default.aspx>.

[286]Other evaluation suggests that up to 1200 Persistent Organic Pollutants should be banned.

[287]Martin Scheringer *et al, How Many Persistent Organic Pollutants Should We Expect?*, Atmospheric Pollution Research, 3, (2012) at 383-389, online: Atmospheric Pollution Research <http://www.atmospolres.com/articles/Volume3/issue4/APR-12-045.pdf>.

between the North and South, explained by both the disparity in local waste regulations and the labour intensity of waste reuse industries. The North-South movement of waste is also demand-driven. In developed countries, the demand for second-hand goods is often low due to technological obsolescence or regulations.[288] The wealth gap between industrialized and industrializing economies explains the greater demand in developing countries for many types of e-waste,[289] used vehicles,[290] clothing,[291] and etc.[292] And even if the volume of the international trade

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[288]For instance, technical inspections in developed countries ensure that vehicles in poor condition must be taken of the road. Often such vehicles end up in the developing world where technical inspections do not exist or safety requirements are very low.

[289]Nearly 50 million tonnes of e-waste are generated worldwide. These are electronic goods made up of hundreds of different materials and containing toxic substances such as lead, mercury, cadmium, arsenic and flame-retardants. An old-style CRT computer screen can contain up to 3kg of lead, for example. (John Vidal, "Toxic 'e-waste' Dumped in Poor Nations, Says United Nations", the Guardian, (14 December 2013), online: the Guardian <http://www.theguardian.com/global-development/2013/dec/14/toxic-ewaste-illegal-dumping-developing-countries>).

[290]Countries in East and West Africa import more second-hand vehicles than new ones. These cars are of a particularly poor quality, and are often more than 15 years old. (Jorg Janischweski, Mikael P. Henzler, & W. Kahlenborn, *The Export of Second- Hand Goods and the Transfer of Technology: Technical Report*, The German Council for Sustainable Development, (May 2003), at 53, online: German Council for Sustainable Development <https://www.nachhaltigkeitsrat.de/fileadmin/user_upload/English/pdf/pdf/Study_Second-hand_goods_and_transfer_of_technology.pdf >).

[291]Global trade in second-hand clothing has grown dramatically in the past 20 years, from an estimated $400 million in 1980 to $1.4 billion in 2000. Although this may appear relatively small in relation to value, it is large in terms of volume, given that the garments retail for 10-20% of their original selling price. (Simon Fields, *The Beneficial Nature of the Second Hand Clothing Trade in Sub –Saharan Africa*, online: LMB <http://www.lmb.co.uk/images-news/pdf_9c219e8.pdf>). The effect of cheap second hand clothing has been especially harmful to African local clothing manufacture with thousands losing their jobs and plunged deeper into poverty. African countries have also suffered cultural devastation. Instead of colourful traditional outfits, locals now wear T-shirts, football tops, and trainers. In the same time, the merchants ship second hand clothing across the sea to be sold to traders in sub-Saharan Africa for a staggering profit. The clothes costs pennies and can be marked up as much as 3,000 per cent by the time they are sold to African consumer. (Eugene Henderson, "African Countries Ripped off by Rag Trader in Gift Charity Clothing", Express, (22 September 2013), online: Express <http://www.express.co.uk/news/world/431236/African-countries-ripped-off-by-rag-trader-in-gift-charity-clothing>). Finally, second-hand clothing might became unsafe or even deadly if it is contaminated when it is shipped with toxic unsorted waste in the same container. (*Exporting Consumer Goods – Second-Hand Articles or Waste?*, Swiss Confederation, Federal office for the Environment, (April 2016), at 2, online: Federal office for the Environment, <http://www.bafu.admin.ch/publikationen/publikation/01613/?lang=en&download=NHzLpZig7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCGeoJ3hGym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.pdf>).

of second-hand goods is not clear, because it is reported along with newly produced products in trade statistics, it is evident that the international trade of recyclable resource is increasing.[293] Regrettably, countries in Africa and Asia have being flooded with waste items that have been exported as second-hand goods (especially electronic scrap).[294] The Basel Convention is a key international legal instrument with which developing countries protect themselves from hazardous waste export.[295]

The Basel Convention was adopted in 1989 during a diplomatic conference held in Basel, Switzerland,[296] as a response by the international community to the practice of dumping hazardous waste from industrialized nations in developing countries and countries with economies in transition. It entered into force on 5 May 1992.

The key goal of the convention is the protection of human health and the environment by reducing hazardous waste through vigorous control of its life-cycle, from generation and storage to transport and final disposal.

The treaty defines "hazardous waste" as any waste within 45 categories of industrial wastes listed in Annex I of the Convention and possessing one of the hazardous characteristics contained in Annex III (explosive, flammable, toxic, or corrosive) or any waste defined as a hazardous waste under the laws of either the exporting country, the importing country, or any of the countries of transit. For the purposes of

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[292]Sophie Bernard, *Transboundary Movement of Waste: Second-Hand Markets and Illegal Shipments*, Montreal, (December 2011), at 1, {© [as requested the author]}, online: Cirano <http://www.cirano.qc.ca/pdf/publication/2011s-77.pdf>.

[293]Michikazu Kojima, *Towards Appropriate International Recycling and Re-use*, at 3 online: Yumpu <https://www.yumpu.com/en/document/view/37133222/towards-appropriate-international-recycling-and-re-use>.

[294]*Op. cit.* 291 (*Exporting consumer goods – Second-hand articles or waste?*).

[295]*Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal*, online: Basel Convention <http://www.basel.int/Portals/4/Basel%20Convention/docs/text/BaselConventionText-e.pdf>.

[296]The *Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal* was adopted by 116 States on 22 March 1989. It entered into force on 5 May 1992 when 20 States had ratified or acceded to the Convention.

the Convention, all hazardous wastes collected from households (consumer waste) that are subject to transboundary movement are categorized as waste requiring special consideration or "other wastes" (Annex II). Each Party informs the Secretariat of the Convention of the wastes, other than those listed in Annexes I and II, considered or defined as hazardous under its national legislation and of any requirements concerning transboundary movement procedures applicable to such wastes. Consequently, the Secretariat disseminates this information to all parties. (Article 3) The Treaty imposes the following general obligations: a) it is prohibited to export or import hazardous wastes or other wastes to or from a non-party state; b) no wastes may be exported if the state of import has not given its consent in writing to the specific import; c) information about proposed transboundary movements must be communicated to the states concerned, by means of a notification form, so that they may evaluate the effects of the proposed movements on human health and the environment; d) transboundary movements of wastes must only be authorised where there is no danger attaching to their movement and disposal; e) wastes which are to be the subject of a transboundary movement must be packaged, labelled and transported in conformity with international rules, and must be accompanied by a movement document from the point at which a movement commences to the point of disposal; f) any party may impose additional requirements that are consistent with the provisions of the Convention. The Convention establishes notification procedures regarding transboundary movements between parties and transboundary movements from a party through the territory of states, which are not parties.

Transport between the parties is subject to a procedure, whereby the designated authority (DA) of the exporting party must send an export notification to the DA of the importing party, and the latter must consent in writing to such shipments. Any shipment outside this procedure is illegal.[297]

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[297]The shipment can still take place as part of an agreement between the parties outside the convention.

The convention provides technical and education assistance through the Secretariat and 14 regional and coordination centers scattered across the globe and with monetary aid from the parties.[298] In addition, although the parties provide financial support on a voluntary basis, most entities, especially the industrialized nations, have contributed their share.[299]

A majority of members of the international community have ratified the Basel Convention. Up to now, 181 nations have become parties. Nevertheless, the United States of America, one of the key producers of hazardous waste, has not ratified the convention yet, even though the US signed it back in 1990.[300]

One of the crucial aspects of implementation of the convention during the last decades is a minimization of hazardous waste through increased consumer awareness, especially nowadays when more and more developing nations are posting increasingly high levels of consumption. Improved awareness means consumers are more likely to make the right choices and help to lower demand for harmful products. So far, there are no provisions regarding the consumer role or education in the

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[298]For instance in 2013, the total contribution was US$ 2,468,384. The most generous donors were: The EU's Thematic Programme for Environment and Sustainable Management of Natural Resources including Energy (ENRTP), US$ 935,067; Norway, US$322,619; Switzerland, US$796,539; Japan, US$103,566. For more detailed information regarding financial assistance see: Basel Convention, *Trust Fund for the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal*, online: Basel Convention <http://www.basel.int/TheConvention/FinanceBudget/TrustFund(BC)/ContributionsStatus/2014/tabid/3787/Default.aspx>.

[299]In 2013, total contribution was US$ 4,440,292. The most generous donors were: Canada US$178,093: Japan, US$ 695,824; the UK, US$ 366,737; Germany, US$ 445,261; Italy, US$ 277,608; France, US$ 340,026. For more detailed information regarding financial aid for technical assistance see: *Trust Fund to Assist Developing Countries and other Countries in Need of Technical Assistance*, online: Basel Convention <http://www.basel.int/TheConvention/FinanceBudget/TechnicalCooperationTrustFund(BD)/ContributionsStatus/2014/tabid/3788/Default.aspx>.

[300]More on the US ratification see CHAPTER III

convention. However, it seems to be just a matter of time before such stipulations are added. Talks on this matter already have been initiated between the parties.[301]

While hazardous waste is controlled under the Basel Convention, non-hazardous waste and second-hand goods are not controlled by an international regime. An old proverb says, "One man's trash is another man's treasure". Clearly, second-hand usage has been with us forever and reusing goods instead of disposing of them is desirable in terms of a sustainable environmental and resources policy. However, hazardous consumer waste exported to developing countries and marketed as second-hand items might be dangerous or deadly to the final user.

Hence, when dangerous consumer waste is deliberately classified as second-hand goods, they are no longer governed by international waste regulations, and can be traded to developing countries. In fact, the second-hand goods market is used to circumvent the regulations governing waste disposal in order to get rid of waste products cheaply in developing countries, especially to minimize the cost of complying with Extended Producer Responsibility programs.[302] It often happens that goods declared usable are already waste when they leave the country of export. Other times the goods become waste because they are damaged during transport as a result of being inadequately secured or became contaminated when being shipped together with unsorted toxic waste.[303] Furthermore to make the situation even worse,

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[301] *The Goal of Minimizing Hazardous Wastes*, online: Basel Convention <http://www.basel.int/pub/simp-guide.pdf>.

[302] Extended Producer Responsibility (EPR) is a policy approach that requires manufacturers to finance the costs of recycling or safely disposing of products consumers no longer want. In general, EPR programs implemented in rich countries confer a comparative advantage on firms in developing economies, where waste regulations are less stringent. (*Op. cit.* 292 (Sophie Bernard), at 1). More on EPR in North America see: *Extended Producer Responsibility Evaluation: Final Report,* Product Management Alliance, (February 2013), online: Product Management Alliance <http://www.productmanagementalliance.org/images/PMA.SAIC.EPR.Evaluation.pdf>; and OECD, *Extended Producer Responsibility*, online: OECD <http://www.oecd.org/env/tools-evaluation/extendedproducerresponsibility.htm>.

[303] *Op. cit.* 291 (*Exporting consumer goods – Second-hand articles or waste?*).

authorities from developing countries often turn a blind eye to these illegal practices. Reluctant to strengthen monitoring, they prefer to protect the imported waste business and the labour market it generates.[304]

The roots of this growing problem derive from the unclear classification of consumer waste and second-hand products. In the light of the fact that many used goods may be referred to as waste in one part of the world but appreciated as second-hand merchandise in another, the grey area of legal uncertainty has been perceived as a driving force for considerable numbers of illegal shipments.[305] It appears that previously owned goods emerge to be a one-size-fits-all category for recyclable, remanufacturable, and second-hand products. Owing to this institutional ambiguity, authorities and enforcement agencies can misclassify waste as used goods. Such misclassifications have been observed for e-waste, used vehicles as well as used clothes, car tires, and other types of waste. Another outcome of imperfect monitoring is that many used products are traded alongside new products,[306] which makes it hard to keep track.[307]

Certain steps toward stricter regulation of the second-hand goods trade have been done under the umbrella of World Trade Organization (WTO). The US and India, as well as other countries, led the discussions during the Doha Round. They wanted the WTO to undertake initiatives to regulate the movement of used products. Today, the WTO has only a draft version of the proposed legislation, which recommends

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[304]*Op. cit.* 292 (Sophie Bernard), at 3.

[305]Mirina Grosz, *Sustainable Waste Trade under WTO Law: Chances and Risks of the Legal Frameworks' Regulation of Transboundary Movements of Wastes*, (Leiden/Boston: Martinus Nijhoff Publishers, 2011) at 87.

[306]One way to assess the scale of these markets is to compare prices. For instance, the average price for all television sets exported from Europe is 339 Euro, but the price drops to 28 Euro when they are exported to Nigeria, Ghana, or Egypt (where more than 1,000 used television sets arrive daily). This lack of precision makes it difficult to conduct an accurate market analysis on either waste or used goods.

[307]*Op. cit.* 292 (Sophie Bernard), at 2&3.

banning the import of used products. Frankly speaking, it is difficult to believe that the WTO, an international body with a well-defined mandate to promote international trade, will ever produce a document to impede or restrict genuine second-hand goods import/export, causing a shrinking market for used products;[308] especially, with the knowledge that with the appropriate regulations a liberalized trade in used goods would result in potential gains for consumers in both developing and the developed words.[309] It appears that for the time being, the WTO agenda on second-hand goods will remain *status quo.* To correct the situation the international community should draw a clear legal distinguishment between waste and second-hand goods. It is especially important to provide such legal tools to exporting parties.[310]

Addressing the growing problem of e-waste, a set of clear and easy to use guidelines has being developed under the auspices of the Basel Convention.[311] Proposed technical guidelines provide guidance for managing transboundary movements of electronic and electrical waste (e-waste) and used electrical and electronic equipment (used equipment), that may be e-waste, in particular the distinction between used equipment destined for repair, refurbishment or direct reuse and e-waste destined for disposal.

The guidelines specify an array of documents that an exporting side should submit to support its claim that used electronic /electric equipment is not a waste. Where the

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[308]Whereas some countries forbid the import of used goods, others apply prohibitive tariffs. Uganda qualifies used goods as "sensitive", and applies an extra 55% tariff on top of the usual 25% external tariff.

[309]Some studies indicate that import of second-hand products, such as Japanese cars, has a positive outcome for consumers in the EU. (*Op. cit.* 292 (Sophie Bernard), at 2&3).

[310]Predominately, used goods export from developed courtiers where institutional monitoring of waste trade is much more sophisticated than in developing importing states, due to legal discipline, financial and technical abilities.

[311]*Draft Technical Guidelines on Transboundary Movements of Electronic and Electrical Waste and Used Electrical and Electronic Equipment, in Particular Regarding the Distinction Between Waste and Non-waste*, online: Basel Convention <http://www.basel.int/Implementation/TechnicalMatters/DevelopmentofTechnicalGuidelines/Ewaste/tabid/2377/Default.aspx>.

exporters of used equipment claim that this is intended to be or is a movement of used equipment intended for direct reuse and not e-waste, the following should be provided to back up this claim to an authority on its request: a) a copy of the invoice and contract relating to the sale that indicates that the equipment had been tested and is destined for direct reuse and "fully functional" (Equipment or components are "fully functional" when they have been tested and demonstrated to be capable of performing the essential key functions they were designed to perform.); b) evidence of evaluation/testing in the form of a copy of the records on every item within the consignment and a protocol containing all record information; c) a declaration made by the exporter of the equipment that none of the equipment within the consignment is waste as defined by the national law of the countries involved in the movement (countries of export and import, and, if applicable countries of transit); and d) appropriate protection against damage during transportation, loading and unloading, in particular through sufficient packaging and/or stacking of the load.[312]

Additionally, the guidelines stipulate a list of factors suggesting that used equipment is waste. Factors suggesting that used equipment would normally be considered waste include: a) it shows physical damage that impairs its functionality or safety, as defined in relevant standards; b) the protection against damage during transport, loading and unloading operations is inappropriate; c) the appearance is particularly worn or damaged, thus reducing the marketability of the item; d) the item has among its constituent parts hazardous components that are required to be discarded or are prohibited to be exported or used in such equipment under national legislation; e) the equipment is destined for disposal or recycling instead of reuse; f) there is no regular market for the equipment; g) it is destined for cannibalization (to gain spare parts); or

[312]Article 26.

h) the price paid for the items is significantly lower than would be expected from functional equipment intended for reuse.[313]

This proposal appears as a complete and appropriate legal tool to help national authorities eradicate the notorious practice of misrepresentation of e-waste as second-hand goods. Regrettably, it took more than six years to finalise the proposal, after first calls for actions on e-waste problem were sounded during the Ninth Meeting of the Conference of the Parties in June 2008.[314] Another discouraging fact is the limited scope of application of the proposal. Certainly, the e-waste outgoing crisis is an urgent matter. Nevertheless, similar problems associating with used vehicles, clothes, car tires, and other types of consumer waste are equally urgent. To date, little or nothing has been done to address these categories of consumer goods on the international level.

Responses remain national ones. Some countries have taken a proactive position in developing universal guidelines for all categories of waste.

For example, Switzerland elaborated comprehensive guidelines for exporters which provide technical information on wide spectrum of consumer products for distinguishing between waste and second-hand goods.[315] In general, objects are

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[313]Article 28.

[314]The developing of the Guidelines is an inertias process. On 5 February 2014 during teleconference, the Small Intersessional Working Group (SIWG) on E-waste recommended the Secretariat of the Convention to collect more information regarding Article 26. The Secretariat developed a questionnaire to facilitate the collection of information and invited to provide the information requested. Still no specific date for submission the final draft to the Conference of the Parties for approval has been announced. (*Development of Technical Guidelines on e-waste*, online: Basel Convention <http://www.basel.int/Implementation/TechnicalMatters/DevelopmentofTechnicalGuidelines/Ewaste/tabid/2377/Default.aspx>).

[315]*Exporting consumer goods – Second-Hand Articles or Waste?*, Swiss Confederation, Federal office for the Environment, (April 2016), online: Federal office for the Environment, <http://www.bafu.admin.ch/publikationen/publikation/01613/?lang=en&download=NHzLpZig7t,lnp6I

classified as second-hand goods if they fulfill all of the following requirements: a) they are in working order and are permitted for use; b) they are used for their original purpose and ability; c) they are packaged well enough to prevent damage during transit; d) do not contain any substances that are banned by the chemicals legislation (e.g. asbestos, PCBs or mercury etc.); and e) are built to be operated without Chlorofluorocarbons.[316] If one or more of the five criteria are not fulfilled then the goods are waste. Additionally, the guidelines specify details and provide illustrations for the monitoring of trade in most common second-hand goods: textiles, TVs, monitors, computers, refrigerators, compressors, vehicles and tires. Finally, legal obligation and potential criminal charges for illegal waste shipment are stated.

A few other nations, such as Norway,[317] have adopted similar guidelines on second-hand goods. Also, some Asian nations have introduced more restrictive regimes on waste and second-hand goods trade.[318]

The loopholes in the scope of the Basel Convention and its poor enforcement prompted moves to improve the Treaty shortly after ratification. In 1995 at the third meeting of the Conference of Parties to the Basel Convention, the parties adopted a modification called the "Ban Amendment." After ratification, the Amendment outlaws the transboundary movement of hazardous waste designated for disposal from any OECD to a non-OECD country and provides further legal clarity regarding the distinction between wastes and non-wastes for some used equipment and second-

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[316]Chlorofluorocarbons (CFCs) are used in the manufacture of aerosol sprays, blowing agents for foams and packing materials, as solvents, and as refrigerants. CFCs are major contributors to depletion of stratospheric ozone and are scheduled for reduction under the Montreal Protocol to Reduce Substances that Deplete the Ozone Layer 1987.

[317]*A Guide for Exporters of Used Goods 2009*, Norwegian Pollution Control Authority, online: Norwegian Environmental Agency, <http://www.miljodirektoratet.no/old/klif/publikasjoner/2516/ta2516.pdf>.

[318]Takayoshi Shinkuma & Shunsuke Managi, *Waste and Recycling: Theory and Empirics*, (Oxford: Routledge, 2011), at 110 and 119&120.

hand goods and that imports of used and near end-of-life goods that soon become waste.

For some years after, there have been differing views among parties about the interpretation of the provision on amendments to the Convention, with many considering it to be ambiguous. After several meetings without agreement in this regard, the Ninth Conference of the Parties called for the creation of enabling conditions, through, among other measures, country-led initiatives conducive to the attainment of the objectives of the Amendment. Indonesia and Switzerland announced their readiness to organize a country-led initiative to improve the effectiveness of the Basel Convention. The *Decision BC-10/3: Indonesian-Swiss country-led initiative to improve the effectiveness of the Basel Convention* was the first step to address the entry into force of the Ban Amendment. Since a number of the provisions of the Convention are interpreted differently by parties and that the implementation and application of these provisions would benefit from additional legal clarity, the Decision called for the preparation of a study on the interpretation of certain terminology used in the Convention including: a) waste/non-waste; b) hazardous waste/non-hazardous waste; c) re-use; d) direct re-use; e) refurbishment; f) second-hand goods; g) used goods [319] To date the Ban Amendment is still not in force.[320]

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[319] *BC-10/3: Indonesian-Swiss Country-Led Initiative to Improve the Effectiveness of the Basel Convention*, online: Basel Convention <http://www.basel.int/Implementation/LegalMatters/CountryLedInitiative/tabid/1339/Default.aspx>). Recently, the *Decision BC-11/1: Follow-up to the Indonesian-Swiss country-led initiative to improve the effectiveness of the Basel Convention* listed actions that may be considered for the implementation of the framework for the environmentally sound management of hazardous wastes and other wastes in the short and medium term international, regional and national levels. (*BC-11/1: Follow-up to the Indonesian-Swiss country-led initiative to improve the effectiveness of the Basel Convention*, online: Basel Convention: <http://www.basel.int/Implementation/LegalMatters/CountryLedInitiative/tabid/1339/Default.aspx>).

[320] 80 Parties to the Convention ratified the Ban Amendment.

Yet, a close look at the existing problems with the international waste trade reveals that the devil is in the details, deriving from the unclear classification of consumer waste and second-hand products.

Many used goods may be referred to as waste and as second-hand merchandise in different parts of the word. Unfortunately, the Basel convention has not established a clear mechanism of waste classification. Such legal uncertainty is the driving force behind numerous *de facto* illegal shipments of e-waste and used vehicles as well as used clothes, car tires, and other types of waste. International efforts done toward stricter regulation on second-hand goods trade has never materialized into a legal tool.

In the foreseeable future, the only apparent way out from this vicious circle may be through ratification of the Ban Amendment, which outlaws hazardous waste movement from developed countries, where most consumer waste originates, and provides further legal clarity regarding the distinction between wastes and non-wastes. Meanwhile, voluntary guidelines to classify consumer waste and second-hand goods developed by states should be harmonized and given higher legal status.

Synergies among the Basel, Rotterdam and Stockholm Conventions

A few words should be stated about cooperation and coordination of the Basel, Rotterdam, and Stockholm conventions. The idea to put into place a system where all three conventions could perform on a certain level of interconnection has circulated since the late 1990s. In view of the fact that all three conventions share a similar ultimate goal, i.e., the protection of human health and the environment from hazardous chemical substances, it seems logical to cluster them into one single network. During the last 10 years, under the auspices of the UN, the international

community has made a few steps towards the establishment of effective legal, administrative, and technical cooperation and coordination among the three conventions.

The culmination of such actions was the creation of the Ad Hoc Joint Working Groups on Enhancing Cooperation and Coordination Among the Basel, Rotterdam, and Stockholm Conventions (AHJWG) in November 2005. The first meeting of the AHLWG took place in early 2007, when among other things the parties explored the specific areas in which cooperation and coordination among the three conventions at the program level would lead to a mutual advantage of all three conventions and without prejudice to their autonomy. The parties also analyzed the advantages, relevant considerations, and possible disadvantages of each specific area of coordination and cooperation.[321] To date, the three conventions have carried out coordination activities by developing documentation; sharing facilities at the regional and head office level; sharing legal, financial, and logistic expenses; etc.[322] In recent years, cooperation and coordination between the conventions has intensified, especially with respect to sharing the financial and resources burden. By pooling together technical, human and financial resources and by avoiding duplication of efforts and increasing efficiency, parties to the conventions are now in a better position to tackle cost-cutting issues and implement the conventions.[323]

To strengthen further cooperation between the three conventions, the decisions taken by the conferences of the parties to the three conventions give parties general

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[321]UNEP, *Supplementary Report Prepared by the President of the Stockholm Convention Pursuant to Decision SC-2/15 of the Second Meeting of the Conference of the Parties of the Stockholm Convention,* Ad Hoc Joint Working Groups on Enhancing Cooperation and Coordination among the Basel, Rotterdam, and Stockholm Conventions (AHJWG), online: AHJWG <http://ahjwg.chem.unep.ch/index.php?option=com_content&task=section&id=6&Itemid=3>.
[322]For a more detailed list of joint activities between the three conventions see: *Ibid.*
[323]*Synergies Success Stories - Enhancing Cooperation and Coordination among the Basel, Rotterdam and Stockholm Conventions*, at 9 online: Basel Convention <http://www.basel.int/Implementation/Publications/Other/tabid/2470/Default.aspx>.

directions on how to achieve synergies at the national level. Each country has to find its own way, in accordance with national frameworks, structures, processes and stakeholders. National implementation of the synergies process will be a major challenge for parties over the coming years.[324]

2.2.1.4 The Globally Harmonized System of Classification and Labeling of Chemicals (GHS), 2002

In addition to the three international instruments discussed above, there are other UN programs that help to manage chemical safety and thereby contribute to consumer safety.

Thousands of chemical products with dangerous properties are produced, traded and used internationally. These chemicals can be managed safely if appropriately labeled. The label in most cases is likely to be the sole source of information regarding chemical hazards readily available to the consumer.

While existing national laws or regulations on chemical safety are similar in many respects, their differences are significant enough to result in different labels for the same product in different countries.[325] Hence, the same chemical hazards are often

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[324] *Ibid.* at 8.

[325] Description of the toxicity hazard of a substance with LD50 = 257 mg/kg (oral) in different jurisdictions: Globally Harmonized System of Classification and Labeling of Chemicals (GHS): signal word "Danger" and pictogram Skull & Crossbones; the EU: indication of danger "Harmful" and pictogram St. Andrew's cross; the US: toxic; Canada: toxic; Australia: harmful; India: non-toxic; Japan: toxic; Thailand: harmful: New Zeeland: hazardous; China: non-dangerous. (EC, *Analysis of the Potential Effects of the Proposed GHS Regulation on its EU Downstream Legislation*, Commission Services, (August 2006), at 6, online: European Commission

classified and communicated in dissimilar ways. Consequently, consumers are not protected everywhere in like manner. In the light of this fact, only a uniform chemical hazards classification and an internationally recognizable universal labeling system such as the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), sustain consumer safety around the globe. Moreover, inconsistency in hazard classification and communication impedes the international trade and increases the cost of placing consumer products on the international market.[326] The GHS facilitates international trade in chemicals since hazards are identified and communicated on the basis of an internationally consistent criterion. With the GHS, there is reduced need for testing and evaluation against multiple classification systems and through provision of a harmonized system for hazard communication.[327]

The work to develop the Globally Harmonized System of Classification and Labeling of Chemicals[328] began in 1992, when a provision regarding chemicals management was included in Agenda 21: "Globally harmonized hazard classification and labeling systems are not yet available to promote the safe use of chemicals, *inter alia*, at the workplace or in the home. Classification of chemicals can be made for different purposes and is a particularly important tool in establishing labeling systems. There is

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<http://ec.europa.eu/geninfo/query/resultaction.jsp?SMODE=2&ResultCount=10&Collection=EuropaFull&Collection=EuropaSL&Collection=EuropaPR&ResultMaxDocs=200&qtype=simple&DefaultLG=en&ResultTemplate=%2Fresult_fr.jsp&page=1&QueryText=Analysis+of+the+Potential+Effects+of+the+Proposed+GHS+&y=0&x=0>).

[326](UNECE, *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS), Sixth Revised Edition, at Forward, online: UNECE <http://www.unece.org/trans/danger/publi/ghs/ghs_rev06/06files_e.html#c38156>). The need to comply with multiple regulations regarding hazard classification and labeling is costly and time-consuming. Some multinational companies have estimated that there are over 100 diverse hazard communication regulations for their products globally. For small and medium size enterprises regulatory compliance is complex and costly, and it can act as a barrier to international trade in chemicals. Due to differences in national and international legal instruments for hazard classification and communication, often the same product may require multiple labels and safety data sheets, domestically and in international trade. (*National GHS Implementation*, online: United Nations Institute for Training and Research <https://www.unitar.org/cwm/ghs>).

[327]Ibid. (*National GHS Implementation*).

[328]*Op. cit.* 326 (*Globally Harmonized System of Classification and Labelling of Chemicals*).

a need to develop harmonized hazard classification and labeling systems, building on ongoing work."[329] The first version of the GHS was adopted in December 2002 and published in 2003.[330] Since then, the GHS has been updated, revised and improved every two years as needs arise and experience is gained in its implementation.[331] The fifth revised edition of the GHS (GHS Rev.6) was published in 2015.[332]

The Globally Harmonized System of Classification and Labeling of Chemicals is a series of guidelines that provides consistent and appropriate information on chemicals by type of hazard, physical, health, or environmental, through harmonized hazard communication elements: labels and safety data sheets. The GHS also serves as a foundation for the harmonization of rules and regulations on chemicals at the national, regional, and international level. The GHS also contains sufficient context and guidance for industry ultimately responsible for implementation of the requirements. The GHS classification is based on currently available scientific data, including human evidence and expert' judgments, and uses only "neutral test" methods to determinate health and environment hazards. The GHS system includes a definition of hazard class (the nature of the physical, health or environmental hazard)

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[329]UN Department of Economic and Social Affairs, Division for Sustainable Development, *Agenda 21*, 1992, at Chapter 19 (*Harmonization of Classification and Labeling of Chemicals*), online: UN <https://sustainabledevelopment.un.org/index.php?page=view&type=400&nr=23&menu=35>.

[330]Certain steps toward the unification of rules and standards for chemicals had been done even before 1992, mostly in the fields of chemical logistics; however, harmonization had not been achieved in the workplace or consumer sector. From 1992 till 1999, development of the GHS was the responsibility of the Interorganization Programme for the Sound Management of Chemicals (IOMC) Coordinating Group for the Harmonization of Chemical Classification Systems (CG/HCCS), and after 1999, the Sub-Committee of Experts on the Transport of Dangerous Goods (TDG Sub-Committee) and new Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS Sub-Committee). Four existing systems (Requirements of systems in the United States of America for the workplace, consumers and pesticides; Requirements of Canada for the workplace, consumers and pesticides; European Union directives for classification and labeling of substances and preparations; the United Nations Recommendations on the Transport of Dangerous Goods) have been chosen as a basis for development of the GHS.

[331]GHS Rev.1 (2005), GHS Rev.2 (2007), GHS Rev.3 (2009), GHS Rev.4 (2011), GHS Rev.5 (2013). For more details regarding GHS revisions, see: *About the GHS*, online: UNECE <http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html>.

[332]*Op. cit.* 328 (*Globally Harmonized System of Classification and Labelling of Chemicals*).

and hazard category (the division of hazard class according to severity), but not a definition for the process of classification or for the concept of "dangerous". Thus classification under the GHS system is a more neutral process of determining a hazard class, and not one of determining which chemicals should be classified as "dangerous".

The GHS focuses the following objectives: a) enhancing the protection of human health and the environment by providing an internationally comprehensible system for hazard communication; b) providing a recognized framework for those countries without an existing system; c) reducing the need for testing and evaluation of chemicals; and d) facilitating international trade in chemicals whose hazards have been properly assessed and identified on an international basis.[333]

The GHS targets three groups of audiences: consumers, workers (including transport workers), and emergency responders. The GHS is divided into several blocks, e.g., carcinogenicity of chemicals, flammable aerosols, chemicals hazardous to the aquatic environment, etc. The competent authority can apply the whole system or only certain blocks, depending on target groups and primarily needs.

The GHS takes consumer protection very seriously. First, it underlines that consumer education is more complicated and less efficient than the education of professionals, and as result, the label is in most cases likely to be the sole source of information readily available to the consumer. Therefore, the label must be comprehensive, sufficiently detailed, and relevant to the use of the product. Labeling based on the likelihood of injury is considered to be the most effective approach in this respect.[334]

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[333]*Op. cit.* 328 (*Globally Harmonized System of Classification and Labelling of Chemicals*), at Chapter 1.1.

[334]Labels based on this approach provide targeted information on identified risks but may not include certain information on chronic health effects. The competent national authority needs to establish the level of risk when labeling for chronic effects must be implemented.

The GHS introduces an assigned pictogram, signal word, and hazard statement for each hazard category of the hazard class.[335]

The System is now ready to rollout worldwide. In its Plan of Implementation adopted in Johannesburg on 4 September 2002, the World Summit on Sustainable Development (WSSD) encouraged countries to implement the new GHS as soon as possible. To date, parties have taken actions towards development and adoption of the regulation to integrate elements of the GHS nationally. The progress shown in implementation of the GHS requirements indicates that parties are taking the matter of consumer chemical safety very seriously.[336] From this perspective, the future of the GHS looks bright.

To conclude, GHS has received a warm welcome around the word from wide array of stakeholders: governments, regional institutions, industry, and consumers groups. A few factors might explain such development. First, GHS is voluntary legal regime. It does not impose compulsory obligations for any level of governance. National authorities may put GHS into operation only when political willingness together with technical and financial abilities exists. Second, GHS possesses unique flexibility to be adjusted for the existing national circumstances and resources. Divided into several blocks GHS may be applied in the whole or fragmentally, depending on target groups and primarily national/regional needs. Third, no specific mandatory date to make GHS operational has been prescribed. Fourth, moderate monetary investment to set and operate GHS guarantees large savings for the industry. GHS helps reduce operational cost through harmonized safety data exchange and import/export facilitation. Needless to say, that with GHS adoption industry receives unlimited opportunities in new markets as chemical consumer products may be sold worldwide

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[335]*Op. cit.* 328. (*Globally Harmonized System of Classification and Labelling of Chemicals*), at Chapter 1.4.

[336]For more detailed information on implementation of the GHS see: *GHS Implementation*, online: UNECE <http://www.unece.org/trans/danger/publi/ghs/implementation_e.html#c25755>.

provided that GHS labeling and safety sheets are used. Finally, the cost of GHS implementation is modest, since, due to existing national/regional laws, producers already have to provide safety information to consumers. Hence, the costs of printing material or labeling already exist and in most cases will be the same under the GHS regime.

2.2.1.5 Strategic Approach to International Chemicals Management, 2006

Adopted by the International Conference on Chemicals Management in 2006, the Strategic Approach to International Chemicals Management (SAICM)[337] is a policy framework for international action on chemical hazards with the aim of promoting chemical safety and safe management of chemicals globally. The SAICM is a response of the International Community to a challenge made in 2002 during the Johannesburg World Summit on Sustainable Development that by the year 2020 chemicals be produced and used in ways that minimize significant adverse impacts on the environment and human health. The SAICM pays especial attention to the chemical safety of vulnerable groups such as children, pregnant women, fertile populations, etc.

The core of the SAICM consists of three documents: the *Dubai Declaration*, the *Overarching Policy Strategy*, and the *Global Plan of Action.* [338]

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[337]UNEP, *Strategic Approach to International Chemicals Management (SAICM)*, online: SAICM <http://www.saicm.org>.

[338]UNEP, *Strategic Approach to International Chemicals, Management (Comprising the Dubai Declaration on International Chemicals Management, the Overarching Policy Strategy and the Global*

The *Dubai Declaration* expresses the commitment to SAICM by governments, civil society, and the private sector.[339] The *Overarching Policy Strategy* sets out the scope of SAICM and the needs it addresses as well as the following objectives: a) developing measures to support risk reduction; b) strengthening knowledge and information; c) strengthening of institutions, law and policy; d) enhancing capacity-building and technical cooperation; e) illegal international traffic; and f) improving general practices. The document also underlines financial and institutional arrangements.[340] The *Global Plan of Action* sets out proposed "work areas and activities" for implementation of the Strategic Approach.[341]

Among other things related to consumers, such as public health protection, SAICM promotes consumer education and calls on national governments, industry, and NGOs to take action toward awareness-raising among consumers, in particular by educating them on best practices for chemical use and about the risks that the chemicals they use pose to themselves and their environment. The SAICM has also introduced the *Quick Start Program* and a *Trust Fund* to "support initial enabling capacity building and implementation activities in developing countries, least developed countries, the small island developing states, and countries with economies in transition."[342]

Chemicals in Products Project

A key to protecting human health and the environment is sharing adequate and relevant information on chemicals in manufactured products. Producers are central in

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Plan of Action), Dubai, 2006, online:
<http://www.saicm.org/images/saicm_documents/saicm%20texts/standalone_txt.pdf >.
[339]*Ibid.* at 4 to 6.
[340]*Ibid.* at 7 to 18.
[341]*Ibid.* at 19 to 24.
[342]UNEP, *Quick Start Programme*, online: UNEP
<http://www.saicm.org/index.php?option=com_content&view=article&id=104&Itemid=498 >.

collecting and making available such information to consumers so they can make informed choices. The majority of current efforts at international and national levels are aimed at ensuring that harmful chemicals are not present in a product and that legislation and control measures are designed to achieve that. Meanwhile, little has been developed internationally to inform the public on what exactly is in the consumer product. The current lack of information on chemicals in products is one of the key obstacles to achieving a reduction of risks from hazardous chemicals. Avoiding an uncoordinated patchwork of information systems will benefit consumer safety. Current efforts and capacities to provide information to consumers about chemicals in products are insufficient for consumers to understand fully the risks that may occur to human health throughout the life cycle of products and for informed decision-making.[343]

The second session of the International Conference on Chemicals Management (ICCM2) held in May 2009 addressed emerging policy issues (nanotechnology, chemicals in products, lead in paint and electronic waste) and took strategic decisions on the future direction of SAICM. The most significant outcome of this meeting for consumer safety was the recognition of Chemicals in Products (CiP) as an emerging policy issue and the adoption of a resolution which invited UNEP to lead the CiP project.[344] A project was implemented to: a) collect and review existing information

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[343]UNEP, *Progress Report on the Chemicals in Products Project, Including Proposed Recommendations for Further International Cooperative Action*, (SAICM//ICCM.3/15), 2012, at 2, online: SAICM <http://www.saicm.org/images/saicm_documents/iccm/ICCM3/Meeting%20documents/iccm3%2015/ICCM3_15_EN.pdf>.

[344]Resolution recalled the SAICM *Overarching Policy Strategy* goal "that information on chemicals throughout their life cycle, including, where appropriate, chemicals in products, is available, accessible, user-friendly, adequate and appropriate to the needs of all stakeholders" and agreed to "improve the availability of and access to information on chemicals in products in the supply chain and throughout their life cycle". (UNEP, *Implementation of the Strategic Approach to International Chemicals, Management: Emerging Policy Issues*, (SAICM/ICCM.2/10/Add.1), (30 April 2009), online: SAICM <http://www.saicm.org/images/saicm_documents/iccm/ICCM2/meeting%20documents/ICCM2%2010%20Add1%20emerging%20issues%20actions%20E.pdf>).

on information systems pertaining to chemicals in products including but not limited to regulations, standards and industry practices; b) assess that information in relation to the needs of all relevant stakeholders and identify gaps; c) develop specific recommendations for actions to promote implementation of the *Strategic Approach* with regard to such information, incorporating identified priorities and access and delivery mechanisms.[345]

A primary scoping phase of the *Chemicals in Products* determined which priority product sectors should receive first attention. After reviewing existing information systems and collecting views from different stakeholders, participants at a scoping meeting in December 2009 agreed that the product sectors of the highest priority were: children's products/toys, electronics, clothing, construction materials, food packaging and personal care products. Of these sectors, the first four were selected for more in-depth examination.[346]

Following the scoping phase, the project undertook analytical activities, including an overview of existing systems, and concluded that a two-tier approach to information flow on chemicals in products is needed to address the challenges of: a) knowing and transmitting information on what substances are present in the product; and b) interpreting and evaluating that information to serve different stakeholders' needs.[347]

Right now the project is at the development phase, aiming to achieve the SAICM objectives of access to CiP information by 2020. Key elements and tools of the future systems have yet to be identified. A set of crucial questions on the content of information to be communicated and the means of its dissemination have to be

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[345]UNEP, *Progress Report on the Chemicals in Products Project, Including Proposed Recommendations for Further International Cooperative Action*, (SAICM//ICCM.3/15), 2012, at 3, online: SAICM <http://www.saicm.org/images/saicm_documents/iccm/ICCM3/Meeting%20documents/iccm3%2015/ICCM3_15_EN.pdf>.
[346]*Ibid.*
[347]*Ibid.*

answered before the final design of the future system takes shape. These questions include: a) who should exchange information with whom? (stakeholders' roles and responsibilities); b) which chemicals? (all those currently internationally recognized as hazardous or those specifically added according to defined hazard-based criteria); c) what information? (hazards or risks); d) how to adopt information for consumer?; e) how to exchange information? (database, product label, web site); and f) how to protect confidential manufacturer's information? So far no progress on the implementation has been reported.[348]

2.2.1.6 Minamata Convention on Mercury (adopted on 19 January 2013, not entered into force yet)

Mercury has been used in a variety of consumer products[349] because it exhibits properties of both a metal and a liquid at room temperature, is a good conductor of electricity, and reacts precisely to temperature and pressure changes.[350] At the same time, these products are dangerous for consumer health and life when broken or not used properly.[351]

In February 2009, the Governing Council of UNEP adopted Decision 25/5 on the

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[348]Kevin Munn, *The CiP programme - an overview* [Presentation], (March 2014), online: PREZI <https://prezi.com/9pwa5dxpwr6u/the-cip-programme-an-overview/>.

[349]E.g., fluorescent lamps, thermometers and thermostats, batteries, dental amalgam, medical and measuring devices, switches and relays.

[350]*Mercury and Environment*, online: Environment and Climate Change Canada <https://www.ec.gc.ca/mercure-mercury/>.

[351]Exposure to mercury, even small amounts, may cause serious health problems, and is a threat to the development of the child *in utero* and early in life. Mercury has toxic effects on the nervous, digestive and immune systems, and on lungs, kidneys, skin and eyes. It is considered by the WHO as one of the top ten chemicals or groups of chemicals of major public health concern. (WHO, *Mercury and Health*, online: WHO <http://www.who.int/mediacentre/factsheets/fs361/en/>).

development of a global legally binding instrument on mercury.[352] Following the conclusion of negotiations, the text of the Convention was agreed and opened for signature at a Diplomatic Conference held in Minamata and Kumamoto, Japan from 9 to 11 October 2013.

The *Minamata Convention on Mercury* (Minamata Convention) is a global treaty to protect human health and the environment from the adverse effects of mercury. Controlling the anthropogenic releases of mercury throughout its lifecycle has been a key factor in shaping the obligations under the convention.

The major highlights of the Minamata Convention include a ban on new mercury mines, the phase-out of existing ones, control measures on air emissions, and the international regulation of the informal sector for artisanal and small-scale gold mining.[353] As for consumer products, each party should not allow, by taking appropriate measures, the manufacture, import or export of mercury-added consumer products.[354] Additionally, parties to the Convention should exchange information on mercury added consumer products.[355] Meanwhile, parties to the Convention should discourage the manufacture and the distribution in commerce of mercury added products prior to the date of entry into force of the Convention. [356] The Convention will enter into force 90 days after it has been ratified by 50 nations. To date 128 states are signature parties and only 32 have ratified so far

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[352]UNEP, *Proceedings of the Twenty-Fifth Session of Governing Council/ Global Ministerial Environment Forum GC-25/GMEF: Decision 25/5*, (24 February 2011), online: Mercury Convention <http://www.mercuryconvention.org/Negotiations/Mandates/tabid/4223/Default.aspx>.
[353]*Minamata Convention on Mercury*, online: Mercury Convention <http://www.mercuryconvention.org/Portals/11/documents/Booklets/Minamata%20Convention%20on%20Mercury_booklet_English.pdf>.
[354]Ban on manufacture, import and export for most consumers product in effect from 2020. (Article 4 & Appendix).
[355]Article 17.
[356]Article 4.

2.2.2 Pharmaceuticals

Medicines are an essential element of the healthcare system since they are often the only source of treatment against a wide spectrum of mortal and contagious diseases, from trivial colds to deadly cancer. When used appropriately, they save lives, treat diseases, and enhance the quality of wellbeing. New forms of drug therapy are enabling more patients to be treated at home close to their families. By shortening and preventing hospital stays, pharmaceuticals can also ease the burden on health care facilities and services.[357] Worldwide, consumer demand for medicines is simultaneously increasing as a result of innovative financing and distribution schemes in poor countries, Internet distribution, and worldwide demographic shifts toward older populations.[358] With the global market valued at nearly one trillion U.S. dollars,[359] pharmaceuticals constitute one of the biggest expenditures for governments and patients.[360] Every government allocates a substantial proportion of its total health budget to drugs. This proportion tends to be greatest in developing countries, where it may exceed 40%.[361] Nevertheless, counterfeiting, poor quality, unsafe and ineffective

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[357] *National Pharmaceuticals Strategy: Progress Report*, (June 2006), online: Health Canada <http://www.hc-sc.gc.ca/hcs-sss/pubs/pharma/2006-nps-snpp/index-eng.php>.

[358] Laurie Garrett, *Ensuring the Safety and Integrity of the World's Drug, Vaccine, and Medicines Supply*, Policy Innovation Memorandum 21, online: Council on Foreign Relation <http://www.cfr.org/pharmaceuticals-and-vaccines/ensuring-safety-integrity-worlds-drug-vaccine-medicines-supply/p28256>.

[359] *Global Pharmaceutical Sales from 2011 to 2013, by Region*, online: Statista <http://www.statista.com/statistics/272181/world-pharmaceutical-sales-by-region/>.

[360] After hospital care, Canada spends more on drugs than any other major category of the health care system. Since 2000, the total public and private expenditure on prescription drugs has grown by approximately 12 per cent annually. (*Op. cit.* 357 (*National Pharmaceuticals Strategy: Progress Report*)).

[361] WHO, *Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials: Volume 2, (Updated Edition). Good Manufacturing Practices and Inspection*, Geneva (2003), at 1, online: WHO <http://apps.who.int/medicinedocs/pdf/s4900e/s4900e.pdf>.

medicines, and misuse of drugs can sometimes be even more dangerous or mortal than illness itself.

The World Health Organization (WHO) estimates that counterfeiting,[362] substandard formulation, contamination, fakery, and active ingredient substitution[363] constitute a $431 billion illicit market; 83.4 percent of that, or $359 billion, had direct public health impact.[364] Likely an underestimate, in 2013 the Pharmaceutical Security Institute (an organization set up by 24 drug companies in the 1990s) documented 2,193 incidents of illegitimate medicines of all kinds during 2013 (an 8.7% increase over 2012).[365] As much as 50% to 60% of anti-infective medications tested in parts of Asia and Africa have been found to have active ingredients outside of acceptable limits.[366] Seven hundred thousand people are killed annually due to use of substandard medicines for tuberculosis and malaria alone.[367] Recent estimates are that perhaps 15% of the global medicine supply is counterfeit, while in developing

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[362]It is important to underline that statistics on counterfeit medicine, often coming from pharmaceutical companies, are neither reliable not transparent. Estimates on prevalence in various countries range from 1 to 50 percent of the drug supply. (*Op. cit.* 3 (Cary Coglianese, Adam Finkel & David Zaring), at 118&119).

[363]Substandard medicines are products whose composition and ingredients do not meet the correct scientific specifications and which are consequently ineffective and often dangerous to the patient. Substandard products may occur because of negligence, human error, insufficient human and financial resources or counterfeiting. Counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals. The difference is that they are deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients. (WHO, *Substandard and Counterfeit Medicines: Fact Sheet N275*, (January 2016), online: WHO <http://www.who.int/mediacentre/factsheets/fs275/en/>).

[364]*Op. cit.* 358 (Laurie Garrett).

[365]*Incident Trends data*, online: Pharmaceutical Security Institute <http://www.psi-inc.org/incidentTrends.cfm>.

[366]UNODC, *The Globalization of Crime: A Transnational Organized Crime Threat Assessment,* United Nations Office on Drugs and Crime: Vienna, 2010, at 183-184, online: UNODC <http://www.unodc.org/documents/data-and-analysis/tocta/TOCTA_Report_2010_low_res.pdf>.

[367]*Op. cit.* 358 (Laurie Garrett).

regions of Africa, Asia and Latin America over 30% of the medicines on sale may be bogus.[368]

The avalanche of unsafe pharmaceuticals has as well reached the developed world. In the European Union, medicines are now the leading illegitimate product seized at the border, increasing 700% from 2010 to 2011 alone.[369] In 2008 only, the European Customs Union detected over 3,200 attempts to import bogus drugs, involving almost 9 million items, over half of which originated in India.[370] Even the United States, which has probably the world's best-regulated pharmaceutical market, experienced an 800% increase in reported instances of counterfeit drugs between 2000 and 2006.[371] This alarming statistic indicates that counterfeited and substandard medicine is the major ongoing global public health crisis affecting health and life of the consumers around the globe.

Counterfeited and substandard medicine produced in home laboratories and in second-rate factories is only one side of the problem. Many might believe that if they refrain from purchasing cheap pharmaceuticals online and instead purchase from reliable local pharmacies only authentic medicine produced by major companies that they are safe. Unfortunately, a consumer's health and life might be in jeopardy even from genuine medication. In 2008, in the United States, at least eighty-one deaths were linked to contaminated heparin produced by Baxter International[372] and hundreds of patients in the US and Europe suffered allergic reactions after using the

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[368]Amir Attaran, Roger Bate & Megan Kendall, "Why and How to Make an International Crime of Medicine Counterfeiting", *Journal International Criminal Justice*, (February 2011), at 326, online: Social Science Research Network <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1652909>.

[369]The seizures would be even higher, if the EU enforced more than just intellectual property violations. (Amir Attaran, "How to achieve international action on falsified and substandard medicines", *British Medical Journal*, (November 2012) at 2, online: British Medical Journal, <http://www.bmj.com/content/345/bmj.e7381.full.pdf+html>).

[370]*Op. cit.* 366 (*The Globalization of Crime: A Transnational Organized Crime Threat Assessment*), at 184.

[371]*Op. cit.* 368 (Amir Attaran, Roger Bate & Megan Kendall), at 331.

[372]Heparin is a blood thinner that is commonly used in cardiac surgery and dialysis.

drug. Investigation revealed that adulterated Active Pharmaceutical Ingredients (API) supplied by a Chinese producer were used during the production cycle.[373] This tragedy was foreseeable, taking into consideration the fact that 80 percent of the drugs sold in the US are currently produced wholly or in part in India and China.[374]

Increasing costs, high prices for raw ingredients and tremendous competition have forced western pharmaceutical companies to outsource significant elements of their business processes. What was traditionally a domestic industry is now a global one relying on foreign suppliers, contractors, and manufacturers.[375] Where US and EU manufacturers used to supply 90 percent of global API demand 20 years ago, they now produce less than 20 percent. At the same time, while generic medicines accounted for less than five percent 20 years ago, they now make up for over 50 percent, with much of the API coming from Asia. API manufacturing industry is becoming more complex with countries in Asia moving aggressively to supply ingredients to regulated markets such as US and Europe.[376]

API manufacture outsourcing has its challenges, particularly regarding all matters concerning quality assurance and regulatory issues. Quality assurance of pharmaceutical products is important in every phase of development and manufacturing. For outsourcing to be successful, there needs to be a supply of

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[373]The investigators found the contaminated heparin at Changzhou SPL, the Chinese plant that supplies the active ingredient to Baxter. Changzhou in turn buys its heparin from two companies, called consolidators that gather crude heparin from workshops that make it from pig intestines. Many workshops that make crude heparin are unregulated family operations. (Walt Bogdanich, "Heparin Find May Point to Chinese Counterfeiting", *N.Y. Times* (20 March.2008), online <http://www.nytimes.com/2008/03/20/health/20heparin.html?_r=0>).

[374]*Pharmaceutical Outsourcing: Maintaining Quality, Reducing Risk*, online: CAN Canada <http://www.cnacanada.ca/web/wcm/connect/18d377a3-39a6-4d3b-842d-4db4a672eaff/PharmaceuticalOutsourcingMaintainingQualityReducingRisk.pdf?MOD=AJPERES>.

[375]*Outsourcing Excellence in China and India: Close Collaboration Effectively Manages Far-Flung Partnerships*, (12 February 2013), online: Pharma Manufacturing <http://www.pharmamanufacturing.com/articles/2013/018/>.

[376]David Vincent, *API Manufacturing: Product Safety*, online: Pharmaceutical Canada <http://www.pharmaceuticalcanada.ca/article1.asp>.

essential medicines of excellent quality, safety and efficacy. The finished product must be correctly processed, checked, properly stored and handled. Any observed deviation must be reported, investigated and corrected. Absolute confidence in the quality of supply and service is critical.[377] To insure the supreme quality of APIs, a regulatory framework has to be in place and regular inspections have to be conducted on production facilities. Unfortunately, the regulatory landscape in China and India, two major players in the APIs market, is uneven and unpredictable.[378] Government agencies are often not effective and corrupt.[379] Furthermore, authorities from importing states do not have enough legal and human resources to insure through inspections that their manufacturing standards are met. In some cases Asian API manufactures do not cooperate with inspectors or simply refuse them access to the production facilities due to the legal vacuum.[380]

For instance, under the U.S. federal law, refusing a Food and Drug Administration (FDA) inspection may lead to one year imprisonment and a fine of up to $1,000 and forcible actions against inspectors can also lead to criminal punishment. Because of serious punishments for refusing access, most U.S. firms cooperate with FDA inspections. On the contrary, even when a cooperation agreement has been concluded with an exporting State, the FDA is not likely to enjoy the foreign government's assistance in its inspections, especially in times of crisis.[381] Moreover, the FDA has to

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[377]*Op. cit.* 375 (*Outsourcing Excellence in China and India: Close Collaboration Effectively Manages Far-Flung Partnerships*).
[378]*Ibid.*
[379]More on corruption in China and pharmaceuticals safety see: Chenglin Liu "Leaving the FDA Behind: Pharmaceutical Outsourcing and Drug Safety", *Texas International Law Journal*, 48:1, (2012), at 4 & 22-24, online: Texas International Law Journal <http://www.tilj.org/content/journal/48/num1/Liu1.pdf>.
[380]*Ibid.* at 6-17.
[381]For example, during the heparin crisis, a consolidator of the tainted raw heparin ingredient refused to cooperate with FDA inspectors, denying access to its laboratory and records. Additionally, since the victims of the heparin crisis were not Chinese citizens, the Chinese government was not subject to the mounting public pressure that it had seen in previous food and drug scandals that claimed lives in China. The Chinese government did not even initiate its own probe, let alone prosecute anyone. The only public response from the Chinese government after the heparin crisis was its vigorous denial that

stretch its resources[382] and does not have authority to conduct the same inspection pattern abroad as it does for domestically.[383] Although the FDA increased the number of foreign drug establishment inspections, the agency continues to inspect relatively few foreign enterprises compared to its inspection of domestic establishments.[384] In fact, with the current scrutiny rate, it will take the FDA about 8.5 years to inspect all of the 502 establishments in India only once and about 18 years to inspect all of the 920 establishments in China once.[385]

Similar problems with APIs have been observed on the opposite side of the Atlantic. The EU Directive of 2011[386] designed to minimize counterfeit medicines entering the EU market, does not adequately address the APIs quality issue. For example, it allows for preparations and medicines containing APIs to be imported into the EU without checking if the API manufacturer is compliant with EU law. It does not require either mandatory inspection of all global API manufacturers for Good Manufacturing Practices (GMP) compliance, or the traceability of the manufacturing

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the tainted raw heparin had caused deaths in the United States. Thus, the Chinese government's involvement in dealing with the heparin crisis was noticeably absent. More detail information on the heparin crises see *Op. cit.* 379 (Chenglin Liu), at 5&6.

[382]On average, the cost of overseas inspection is double of the domestic one, approximately $52000. (*Op. cit.* 379 (Chenglin Liu), at 9).

[383] FDA cannot conduct foreign inspections without prior notice (as it routinely does in the US); the surprise inspections are crucial for quality control to reveal an accurate picture of the manufacturing process. Unannounced inspections of foreign facilities are almost impossible to conduct because, in some cases, the FDA can only gain access to the facilities by first receiving permission from the foreign government after notifying it months in advance. (*Op. cit.* 379 (Chenglin Liu), at 9).

[384]FDA inspected 11 percent of the total number of foreign establishments in its inventory in fiscal year 2009. In comparison, FDA inspected approximately 40 percent of domestic establishments in same year. (*Drug Safety: FDA Has Conducted More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but More Progress Is Needed*, (GAO-10-961), October 2010, at 15, online: United States Government Accountability Office <http://www.gao.gov/assets/320/310544.pdf>).

[385]*Ibid.* at 16.

[386]EC, *Directive 2011/62/EU of the European Parliament and of the Council Amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, as Regards the Prevention of the Entry into the Legal Supply Chain of Falsified Medicinal Products*, OJ 174.74.2011, online: European Commission, <http://ec.europa.eu/health/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf>.

sites that produce APIs sold in the EU. Therefore, it accepts the continued risk to EU citizens as the normal situation.[387]

To summarize, the problems associated with counterfeited and substandard medicine as well as APIs quality are not only alarming because of scale. The most disturbing fact is that nowadays, no individual state, even with unlimited resources, can guarantee affordable, effective and absolutely safe medicines to its consumers. Governments prohibiting falsified medicines and unsafe APIs under national law remain vulnerable to organized criminals or careless manufacturers doing business in "haven" countries, where laws or enforcement are lax; especially, when 30% of states have little or no regulation regarding medicine.[388]

The globalization of pharmaceutical production, commerce, and trade has reached an excessive level. Existing state mechanisms of safety control for pharmaceuticals and APIs produced overseas are very limited or absent. Thus, only the development and implementation of universal norms and standards for medicines can provide the consumer with adequate protection. This is why the international community has taken numerous steps to make sure that only high quality and genuine medicines pass to the consumer, who must be properly informed on how to use them correctly. The World Health Organization (WHO) plays a key role in this process.

In accordance with its mandate, "the WHO is charged with the task of developing and maintaining global norms, international standards, and guidelines for quality, safety, and efficacy of drugs",[389] as well as helping countries implement them.[390] The WHO

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[387]*To Harmonize the Rules in Order to Guarantee the Safety of Pharmaceutical Products and the Citizen's Health: Why are Mandatory Inspections Needed?*, European Fine Chemicals Group, (12 November 2012), online: European Fine Chemicals Group <http://www.efcg.cefic.org/publications>.
[388]*Op. cit.* 369 (Amir Attaran).
[389]WHO, *Norms, Standards and Guidance for Pharmaceuticals*, online: WHO <http://www.who.int/medicines/areas/quality_safety/quality_assurance/norms_standards/en/>.

provides relevant expertise and technical assistance through such activities as guideline development, workshops and training courses, coordination and promotion of anti-counterfeiting measures, pharmacovigilance for global medicine safety, regulatory and other information exchange.[391] More generally, the WHO's task is to help countries consider the implications of the relevant harmonization agreements.[392]

Over the years, the WHO has developed numerous norms, standards, and guidelines regarding safety, quality, and efficacy of pharmaceuticals and other medical products.[393] Most of them are related to consumer safety. For instance, guidelines on vaccine production make sure that only safe and effective drug pass to consumer. However, there are very technical instructions for producer on manufacturing process and they do not include provisions directly linked to consumer safety topics. In this study we will review only acts where concept of consumer safety is present *per se*: the *WHO Guidelines for Medicine Donations*, 1st edited in 1996; *Good Manufacturing Practices for pharmaceutical products and Certification Scheme*, 1975; *Medical Products and the Internet: a Guide to find reliable information*, 1999; the *Consolidated List of Pharmaceuticals*, 1982; the *WHO Programme for International Drug Monitoring*, 1968.

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[390]WHO, *Essential Medicines and Health Products: Challenges*, online: WHO <http://www.who.int/medicines/areas/quality_safety/challenges/en/>.
[391]*Op. cit.* 389 (*Norms, Standards and Guidance for Pharmaceuticals*).
[392]*Op. cit.* 390 (*Essential Medicines and Health Products: Challenges*).
[393]For list of the WHO publication on medicines see online: WHO <http://www.who.int/medicines/publications/en/>.

2.2.2.1 The WHO Guidelines for Medicine Donations, 1st edited in 1996

During disasters, wars, and pandemics many human lives have been saved only because of donations of drugs. Moreover, medicine donations are continuously welcome in the developing world, since many underprivileged people just do not have enough money to buy life saving pharmaceuticals. As a general rule, medicine donations are neither a long-term solution to underfunded health systems nor a solution to the lack of access to medicines in poor countries – especially for diseases that require lifelong treatment or large numbers of treatments. Donations can be only temporary solutions to defined problems.[394]

Every year the value of drug donations reaches more than US$300 million.[395] Nevertheless, donation without assessment of emergency medical needs and without guidance can cause more problems than help. There are many examples where drug donations have not provided the expected relief because the drugs shipped were irrelevant to emergency situations, inappropriately labeled, of poor quality, etc.[396] In

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[394]WHO, *Guidelines for Medicine Donations*, 2010, at 4, online: WHO <http://whqlibdoc.who.int/publications/2011/9789241501989_eng.pdf?ua=1>.

[395]WHO, *First-Year Experiences with the Interagency Guidelines for Drug Donations*, 2000, (WHO/EDM/PAR/2000.1), Department of Essential Drugs and Medicines Policy, online: WHO <http://whqlibdoc.who.int/hq/2000/WHO_EDM_PAR_2000.1.pdf>.

[396]After the earthquake in Armenia in 1988, of a total of US$55 million in medical supplies, only 42% of drugs were relevant for an emergency situation and only 30% had proper labeling. In donations received in Albania during the Kosovo refugee crisis, only 35% of drugs had adequate expiry dates and only 58% were labeled properly. After 2004 Tsunami on Sri Lanka, of the 56 tons received, only 10% were on the list of requested medications. More than 80% were unsolicited, unexpected and unsorted. Forty-three percent of donated medicines were not essential medicines and 38% were never registered for use in the country. Labeling was inappropriate with 62% labeled in languages not readily understood, 15% without generic names and 81% without package inserts. Fifty percent of donations did not have an expiry date; 6.5% expired on arrival and 67% expired within less than a year. Donations were largely uncoordinated with 50% from collections of unused drugs from private donors and 86% of donations donated by individuals. In contrast, 90% of government donations were relevant. Due to the excess donations, more than 20-30 tons of drugs were inappropriately stored. For more examples of problems with drug donation see: WHO, *Guidelines for Drug Donations*, 1999 (WHO/EDM/PAR/99.4), at 15 & 16, online: WHO <*http://www.who.int/hac/techguidance/guidelines_for_drug_donations.pdf*>; and *Op. cit.* 394 at 19.

some cases, drug donations went absolutely wrong. For example, appetite stimulants were sent to Sudan during the famine.[397] Often already limited resources had to be used getting rid of useless or expired medication. An estimated 17,000 tons of medical donations sent to Bosnia and Herzegovina between 1992 and 1996 were inappropriate and it cost US$34 million to dispose of them.[398]

There are two essential explanations for why medicine donation often goes wrong. First, genuine problems associating with communication, logistic, and management have been observed, especially during natural disasters.[399] Often, due to poor or nonexistent contact with medicine recipients, donors do not have proper information regarding what kind of drugs should be sent to a disaster site. As result, medications are dispatched according to the rule "better something then nothing".[400] Moreover, when disaster strikes and every hour counts for people in urgent need, there is just no time to figure out if certain medications have been approved or banned by the receiving state or if local doctors are familiar with them.[401] Finally, it is just not possible to keep pharmaceutical stocks labeled in official languages for every member state and relabeling and repacking can be time and resources consuming.[402]

Second, drug donations are not sustainable and might be an expensive venture for the developed world. For instance, it costs the public sector of the US over four times as much as other methods of getting medicines to the developing world, namely buying the branded product at a differential price or purchasing the lowest-cost generic drugs available internationally. In fact, donations are the most costly options to the US tax

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[397]Mark Thomas, *Drug Donations: Corporate Charity or Taxpayer Subsidy?*, at 14, online: University of Essex <https://www.essex.ac.uk/armedcon/story_id/000068.pdf>.
[398]*Ibid.* at 13.
[399] For more details on logistical, communication and management problems with drugs donation see: Joep A. Djojodibroto, *An Analysis of WHO Guidelines for Drug Donations for Better Donation Practice in Emergency Situations*, Leeds Institute of Health Sciences, (August 2011), online: WHO <http://apps.who.int/medicinedocs/documents/s19021en/s19021en.pdf>.
[400]*Op. cit.* 396 (*Guidelines for Drug Donations*, 1999) at 8.
[401]*Ibid.* at 8.
[402]*Ibid.* at 7.

payer, whilst being the least effective solution to the global public health crisis.[403]

Finally, the notorious practice so-called "drug dumping" has occurred when useless or dangerous pharmaceutical products are deliberately donated to poor countries. Western governments encourage pharmaceutical companies to make drugs donations, especially to the developing world. Nevertheless, there is significant evidence that this offers incentives for the wrong kind of donations and contains a number of loopholes which are exploited by the pharmaceutical industry to suit their own interests, often at the expense of the health needs of the developing world.[404] When the product is reaching the end of its shelf life or is being discontinued, instead of destroying the product in a regulated and controlled environment a pharmaceutical company donates the drug in question, clearing shelves in warehouse space and saving on disposal operation.[405] Moreover, in most jurisdictions drug donations are considered a charitable act; hence, the company may claim a tax deduction.[406]

While drug donations provide for industries both tax deductions and a very convenient way to get rid of stagnant stocks without having to pay for expensive destruction in their country of origin, medical staff at the receiving end is then forced to spend, sometimes up to 70% of their time sorting medication rather treating patients.[407] Furthermore, received harmful pharmaceuticals cannot be returned to donors, because they are considered hazardous waste and their shipment is subject to the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal.[408] Legal demand for unsafe drugs return involves the existence of consented protocols between exporters and importers, and time-

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[403]*Ibid.* at 11&12.
[404]*Op. cit.* 397 (Mark Thomas) at 2.
[405]*Ibid.*
[406]For instance, under US tax law companies can claim twice the cost of the drug against tax. More on drugs donations and tax benefits see: *Op. cit.* 397 (Mark Thomas).
[407]*Op. cit.* 397 (Mark Thomas) at 2.
[408]More on the Basel Convention regime see 2.2.1.3.

consuming procedures that severely compromise its feasibility.[409] It is a classic Catch 22: rejection of medicine donations jeopardizes the health and lives of people in need; acceptance of medicine from overseas donors brings turmoil with hazardous waste deposal.

To improve safety associated with drug donations practices, the international community has taken certain steps toward meaningful regulation on the matter. The first guideline for drug donations was developed in April 1988, by the Christian Medical Commission (CMC) of the World Council of Churches to address growing problems associated with drug donations in the 1970s and 1980s.[410] In 1996, after reviewing numerous reports on inappropriate drug donations practices, the WHO recognized the existing problem and, together with major international agencies active in humanitarian relief[411], elaborated the *WHO Guidelines for Drug Donations*. The 2nd edition of the guidelines was published in 1999,[412] followed by the 3d edition in 2010. This edition changed the name to the *Guidelines for Medicine Donations*.

The Guidelines are not international regulations; they are intended to serve as a basis for national or institutional guidelines, to be reviewed, adapted and implemented by governments and organizations dealing with drug donations.[413]

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[409]Christina P. Pinheiro, *Drug Donations: what Lies Beneath*, (August 2008), online: National Center for Biotechnology Information <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2649461/>.

[410]Five problems had been identified: a) arrived after or near expiration dates; b) were inappropriate or unsuitable to the recipient country; c) sent without first asking the recipient about their needs; d) sent without prior notification or shipping documents; e) were inadequately packaged or labeled with no prescriber or patient information. (*Op. cit.* 399 (Joep A. Djojodibroto), at 2).

[411]The WHO has conducted several rounds of consultation with numerous humanitarian organizations such as: Churches' Action for Health of the World Council of Churches, the International Committee of the Red Cross, the International Federation of Red Cross and Red Crescent Societies, Médecins Sans Frontières, the Office of the United Nations High Commissioner for Refugees, OXFAM and the United Nations Children's Fund, etc.

[412]*Op. cit.* 396 (*Guidelines for Drug Donations*, 1999) at 1 to 3.

[413]*Ibid* at 6.

The WHO Guidelines identify the following problems related to drug donations: a) donated drugs are often not relevant for the emergency situation or unknown to local health professionals; b) many donated drugs are unsorted, without proper labels; c) the quality of the drugs can be below the standards of the donor country; d) the donor agency sometime ignores local regulations on drugs; e) drugs can be donated in the wrong quantities; f) high declared customs value and the price of logistics can make some drugs too expensive for local drug budgets.

Based on four core principles[414] the Guidelines establish 12 rules for medicine donations.[415] Most of the rules are related to organizational matter, whereas recommendations on quality and labeling are directly linked to consumer safety.

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[414] a) donations of medicines should benefit the recipient to the maximum extent possible; all donations should be based on an expressed need; unsolicited medicine donations are to be discouraged; b) donations should be given with due respect for the wishes and authority of the recipient, and in conformity with the government policies and administrative arrangements of the recipient country; c) there should be effective coordination and collaboration between the donor and the recipient, with all donations made according to a plan formulated by both parties; d) there should be no double standard in quality; if the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation.

[415] a) all medicine donations should be based on an expressed need, should be relevant to the disease pattern in the recipient country, and quantities should be agreed between donor and recipient; b) all donated medicines or their generic equivalents should be approved for use in the recipient country and should appear on the national list of essential medicines or equivalent or in the national standard treatment guidelines; c) the presentation, strength, and formulation of donated medicines should, as far as possible, be similar to those of medicines commonly used in the recipient country; d) all donated medicines should be obtained from a quality-ensured source and should comply with quality standards in both donor and recipient countries; e) no medicines should be donated that have been issued to patients and then returned to a pharmacy or elsewhere, or that have been given to health professionals as free samples; f) after arrival in the recipient country all donated medicines should have a remaining shelf-life of at least one year; g) all medicines should be labeled in a language that is easily understood by health professionals in the recipient country (label should include essential information); h) donated medicines should be presented in pack sizes that are suitable for the recipient and appropriate to the setting in which they will be distributed or dispensed. i) all medicine donations should be packed in accordance with international shipping requirements and should not be mixed with other supplies; j) medicine donations should be jointly planned, and collaboration between donors and recipients should begin early. Medicines should not be sent without prior consent of the recipient; k) in the recipient country the declared value of a medicine donation should be based on the wholesale price of its generic equivalent in the recipient country; l) costs of international and local transport, warehousing, port clearance and (customs) storage, handling and disposal or reverse logistics of expired donated products should be paid for by the donor agency.

The proper labeling of a drug is a key element for safe consumption. Since drugs often arrive with labels in incomprehensible or not easy to understand language, it can lead to mistakes and jeopardize consumer/patient health and life. Moreover, some donated drugs are labeled only with unregistered local trade names and do not have an International Non-Proprietary Name (INN) also know as generic names on the labels.[416] Such situations can confuse health professionals and may be fatal for consumers/patients. To avoid problems related to improper labeling, the Guidelines specify that all drugs should be labeled in a language that is easily understood by health professionals in the recipient country. All drug donations should be packed in accordance with international shipping regulations, and be accompanied by a detailed packing list which specifies the contents of each numbered carton by INN, dosage form, quantity, batch number, expiry date, volume, weight and any special storage conditions. Drugs should not be mixed with other supplies in the same carton.[417]

The WHO Guidelines specify three problems related to the quality of donated drugs. First, double standards should be prevented: medicines of unacceptable quality in the donor country should not be donated to other countries. The WHO Guidelines instruct that all donated medicines should be obtained from a quality-ensured source and should comply with quality standards in both donor and recipient countries. The *WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce*[418] should be used.[419]

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[416]International Non-Proprietary Name (INN), also know as generic names, a unique name that is globally recognized and is public property. For more on INN see: WHO, *International Non-Proprietary Names*, online: WHO <http://www.who.int/medicines/services/inn/en/>.
Improper labeling was creating confusion among the health staff in Sri Lanka after the 2004 tsunami. Many drugs were found without package inserts, inadequate information regarding the substance and use of the medicine, and were labeled in a language which not spoken in recipient country, such as Arabic, Chinese, Danish, French, German, Korean, Spanish, Irish, Turkish. Likewise, 70% of donated medicines that received in Aceh, Indonesia were labeled in a language other than English or Indonesian language. (*Op. cit.* 399 (Joep A. Djojodibroto), at 17&19).
[417]*Op. cit.* 394 (*Guidelines for Medicine Donations*), at art. 7&9 *(Presentation, Packaging, Labeling).*
[418]*More on the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce* please see 2.2.2.2.

Second, patients or health professionals return unused medicines or free samples to a pharmacy to ensure their safe disposal. In most countries it is not permitted to issue returned medicines to other patients, as the quality cannot be guaranteed.[420] In addition, returned medicines are difficult to manage because of broken packages and the small quantities involved. The Guidelines underline that no medicines should be donated that have been issued to patients and then returned to a pharmacy or elsewhere, or that have been given to health professionals as free samples.[421]

Finally, in many recipient countries, especially in emergency situations, logistical problems exist. Regular medicine distribution systems often have limited possibilities for immediate distribution, and distribution through the different storage levels (e.g. central store, provincial store, district hospital) may take a number of months. Donation of medicines just before their expiry should be avoided as in most cases they will reach patients after expiry. The argument that short-dated products can be donated in the case of acute emergencies, because of their immediate use, is incorrect. In emergency situations the systems for receipt, storage and distribution of medicines are often disrupted and overloaded, and donated medicines tend to accumulate. As a

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[419] *Op. cit.* 394 (*Guidelines for Medicine Donations*), at art. 4 *(Quality assurance and shelf-life).*

[420] It's interesting to notice that some domestic drug donations programs do not have similar requirements. Drug donations through recycling seems a more sustainable solution than simply throwing away pharmaceuticals that go unused because patients are cured, die or, for reasons such as undesirable side effects, discontinue their medications. For instance, 38 of the United States adopted regulation on drug recycling or redistribution programs for the estimated 3%–7% of pharmaceutical products that are usually recycled. As a rule, though, the intent is to redistribute unused drugs to needy people who simply cannot afford them. In Canada, by contrast, there are only a few fledgling efforts to recycle drugs and a raft of regulatory or legislative obstacles to creating such programs. However, some pilot projects for recycling drugs are undergoing evaluation. Objections to recycling programs have largely been based on the argument that patient safety would be compromised. Nevertheless, to date, safety problems with recycled drugs have never been reported in the US. More on domestic drug donations and recycling programs in the US and Canada see: Sabrina Doyle, "Canada Lags Behind United States in Drug Return, Reuse and Recycling Programs", Canadian Medical Association Journal, 182:4, (9 March 2010) online: Canadian Medical Association Journal <http://www.cmaj.ca/content/182/4/E197.full>.

[421] *Op. cit.* 394 (*Guidelines for Medicine Donations*) at art. 5 *(Quality Assurance and Shelf-Life).*

general rule the Guidelines suggest that after arrival in the recipient country all donated medicines should have a remaining shelf-life of at least one year. Large quantities of donated medicines become a logistical challenge, even with a long shelf-life. Therefore, based on the national consumption and available quantities in stock or in the supply chain pipeline, all donated quantities should match the needs to be consumed before they are expired.[422]

Although the WHO Guidelines are not a binding document, they have provided a beneficial framework for improved drug donation practices and procedures. As indicated in the report *First-Year Experiences with the Interagency Guidelines for Drug Donations*, the WHO Guidelines have become "useful tools for curtailing inappropriate donations" and enhancing consumer safety.[423] The future of the WHO Guidelines looks quite optimistic, because since their adoption many international humanitarian organizations have noticed an improvement in donation practices. Namely, donations have better met the needs of recipient state and the Guidelines have made it easier to refuse unwanted donations. A positive dynamic in safety for drug donations were notices as well. Especially, clear improvements were reported in shelf-life and in packaging and labeling. [424]

A comprehensive research on drug donations practices during 2000–2008 admits that whereas most long-term medicine donations programs observe the international standards, several donations in response to emergency situations did not comply with the postulates of the Guidelines.[425] The report also suggests that the *WHO Guidelines*

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[422]*Ibid.* at art. 6 *(Quality Assurance and Shelf-Life).*
[423]WHO, *First-Year Experiences with the Interagency Guidelines for Drug Donations*, 2000, (WHO/EDM/PAR/2000.1), Department of Essential Drugs and Medicines Policy, at 21, online: WHO <http://whqlibdoc.who.int/hq/2000/WHO_EDM_PAR_2000.1.pdf>.
[424]*Ibid.* at 21 & 22.
[425]Lisa Bero *et al.*, "To Give is Better than to Receive: Compliance with WHO Guidelines for Drug Donations During 2000–2008", *Bull World Health Organ*, (1 December 2010), 88:12, online: US

for Drug Donations require no substantial changes but that they need to be enforced more strictly. An obvious barrier to enforcing the Guidelines in emergency situations is the lack of an infrastructure for monitoring incoming medicines. To facilitate coordination, monitoring and compliance with the Guidelines, the report calls to establish an independent registry which verifies how donors adhere to each of the 12 Guidelines rules.

Meanwhile, the report advises that recipient countries should formulate their own national drug donation guidelines to avoid receiving unnecessary medicines. A list of needed medicines along with a list of any financial or human resources needed to store, transport or dispense the medicines should be provided to donors.[426]

To improve medicine donations practices during large-scale disasters, UN agencies and NGOs have called for the standardization of medicines needed in emergencies for survival and health of the affected populations. In the 1980s, the WHO initiated work to develop standard, pre-packed kits that could be kept in readiness to meet priority health needs in emergencies. The first WHO Emergency Health Kit was launched in 1990.[427] The Guidelines have promoted the Emergency Kit as an alternative way donors can help.[428] Over the years the concept of the emergency health kit has been adopted by many organizations and national authorities as a safe, standardized, affordable, and quickly available source of the essential medicines and medical devices urgently needed in a disaster situation. Its content is based on the health needs

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National Library on Medicine, National Institutes of Health <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2995193/>.

[426]*Ibid.*

[427]After revision and further harmonization, the contents of the second kit the *New Emergency Health Kit 98* and later the third kit, the *Interagency Emergency Health Kit 2006* were endorsed by the WHO in collaboration with international and nongovernmental agencies.

[428]The kit is permanently stocked by several major international suppliers (e.g. the International Dispensary Association, Médecins Sans Frontières, UNICEF) and can be made available within 48 hours. It is especially relevant when recipients cannot quickly prepare well-defined requests. (*Op. cit.* 394 (*Guidelines for Medicine Donations*) at art. 4.2).

of 10,000 people for a period of three months.[429] The latest kit with improved content, the *Interagency Emergency Health Kit 2011* (IEHK 2011), is designed principally to meet the first primary health care needs of a displaced population without medical facilities. It is important to note that the kit's content is a compromise and there will always be some items which do not completely meet requirements. An ideal kit can only be designed with an exact knowledge of the population characteristics, disease prevalence, morbidity patterns and level of training of those using the kit.[430] Therefore, safe supplemental medicine donations will be always indispensable during the disasters.

Finally, there is a growing body of evidence from large humanitarian emergencies over the last decade[431] which suggests that in many cases cash-based assistance is a more appropriate response to people's needs.[432] Cash donations instead of medicine are the most sustainable way to assist people in needs. For a long time, the WHO has endorsed cash donation to help both people in need as well as local pharmaceutical industries.[433] Another advantage of cash donations is that relief organizations can save, share and distribute funds to other recipients in later crises.[434] Observations also suggest that the risks commonly associated with cash transfer programming, such as security and corruption, can be mitigated through a number of measures. In fact, cash

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[429]WHO, *The Interagency Emergency Health Kit 2011*, at 1, online: WHO <http://whqlibdoc.who.int/publications/2011/9789241502115_eng.pdf?ua=1>.
[430]*Ibid.* at 3.
[431]The 2004 Indian Ocean tsunami, the Pakistan floods of 2010, the 2011 Horn of Africa food crisis, and the 2012 unrest in Yemen.
[432]Anna Brezhneva & Daria Ukhova, *Russia as a Humanitarian Aid Donor*, Oxfam, (July 2013), at 12, online: <http://www.oxfam.org/sites/www.oxfam.org/files/dp-russia-humanitarian-donor-150713-en.pdf> & *Op. cit.* 425 (Lisa Bero *et al)*; also *Op. cit.* 399 (Joep A. Djojodibroto), at 22&27 & *Op. cit.* 397 (Mark Thomas).
[433]Cash donations support both: the activities of the local government and local and regional industries. Moreover, monetary help often is more cost-efficient. Finally, with cash donations, governments may be able to procure local medicine familiar to health professionals and patients. (*Op. cit.* 394 (*Guidelines for Medicine Donations*), at art. 4.2).
[434]Christina P. Pinheiro, "Drug Donations: what Lies Beneath", *Bull World Health Organ*, 86(8): 580, (August 2008), online: National Center for Biotechnology Information <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2649461/>.

transfers are not inherently more risky than any other form of assistance; rather, they entail different risks. At the same time cash transfers have successfully reached beneficiaries in highly insecure areas, including Somalia, Chechnya and Afghanistan.[435]

2.2.2.2 Good Manufacturing Practices for pharmaceutical products and Certification Scheme, 1975

The quality of the pharmaceuticals products circulating on the market has always been a priority for the international community. It is an undeniable fact that only quality medicine can guaranty consumer safety. In theory, poor quality medicine can still be relatively safe for consumers when only harmless compounds, such as starch, are deliberately or erroneously substituted for active ingredients. Nevertheless, consumers cannot through smell, touch, or sight detect that a drug product is safe or if it will work. Moreover, the belief that drug safety can be guaranteed through post manufacture testing is incorrect. Testing alone is not adequate to ensure the safety and efficacy of drug products.[436] It is why only quality medicine must be marketed to consumer. Therefore, it is important that drugs are produced under conditions and practices assuring that quality is built into the design and manufacturing process at every step: facilities that are in good condition, equipment that is properly maintained

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[435] *Op. cit.* 432 (*Russia as a Humanitarian Aid Donor*).

[436] In most instances, testing is done on a small sample of a batch (for example, a drug manufacturer may test 100 tablets from a batch that contains 2 million tablets. (*Facts About the Current Good Manufacturing Practices,* online: FDA <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm>).

and calibrated, employees who are qualified and fully trained, processes that are reliable and reproducible, etc.[437]

Good Manufacturing Practices (GMPs) are a legal codification of sound quality principles applied to the manufacturing and testing of pharmaceutical products. GMPs are intended to assure that: a) raw materials used in the manufacture of drugs are of known, and of possibly standardized, quality and are free from contamination; b) the manufacturing process has been proven to produce a pharmaceutical product meeting its quality attributes; and c) adequate quality control testing measures have been employed to assure that the product meets its quality specifications at time of release to market, and at the end of its shelf life.[438]

The concept of GMPs emerged after the realization that end-point quality testing was insufficient to assure the quality of the individual medication unit (the tablet, the capsule, the vial), but rather quality needed to be assured at each step of the manufacturing process to be certain that each dosage unit met its quality specifications. Prior to GMPs, pharmaceutical product quality was assured by end-point testing.[439]

The first modern code establishing Good Manufacturing Practices, as we recognize them today,[440] were the regulations issued by the Canadian Specifications Board of the Supply and Services Department in 1957 used to assure that drugs supplied to the Canadian Military met quality specifications. Following the success of that regulation, GMPs started being issued by regulatory agencies at a rapid pace first by

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[437] *Ibid.*
[438] Michael H. Anisfeld, *International GMPs*, at Introduction, online: Globepharm <http://www.globepharm.org/what-is-gmp/international-gmps.html>.
[439] *Ibid.*
[440] The first Pharmacopoeia (preparation of drugs in old Greek) book, an ancient version of GMPs, appears to be the Chinese Pên-ts'ao Ching, dating to 4,000 BCE, while in Europe the oldest Pharmacopoeia appears to be that written in the monastery at Lorsch, Germany in 795 CE. (*Ibid.* at *Drug Quality – Pharmacopoeal Testing*).

the U.S. FDA in 1963, followed by the European institutions in 1968.[441] However, it took nearly three decades before GMPs for medicine production became uniformly accepted international standards under the umbrella of the WHO.

The safety and quality of pharmaceuticals has been a concern of the World Health Organization since its inception.[442] The WHO's mandate is to "develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products".[443] The supply of safe and essential drugs was identified by the WHO as one of the prerequisites for the delivery of sustainable health care.[444] The WHO's Revised Drug Strategy, adopted by the World Health Assembly in May 1986, identified the effective functioning of national drug regulation and control systems as the only means to assure the safety and quality of medicines. Over the years, the WHO has developed numerous documents on the matter. Nowadays, Member States rely on the WHO for expertise and guidance in regulation, safety and quality assurance of medicines through development and promotion of international norms, standards, guidelines and nomenclature.[445]

The *Draft Requirements for Good Manufacturing Practice in the Manufacture and Quality Control of Drugs and Pharmaceutical Specialties* (the GMP) was developed at the request of the Twentieth World Health Assembly (WHA) in 1967. Just two years later, the WHA recommended the first version of the *WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce* (the Scheme), and at the same time accepted the GMP text as an integral

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[441] *Ibid.* at *Drug Quality – GMP Implementation.*
[442] WHO, *Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials; Good Manufacturing Practices and Inspection*, Vol. 2, Geneva: WHO, 2003, at 1, online: WHO <http://apps.who.int/medicinedocs/pdf/s4900e/s4900e.pdf>.
[443] WHO, *Constitution of the World Health Organization*, at art. 2, online: WHO <http://www.who.int/governance/eb/who_constitution_en.pdf>.
[444] *Op. cit.* 442 (*Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials; Good Manufacturing Practices and Inspection*).
[445] WHO, *Norms and Standards: Quality, Safety and Efficacy of Medicines*, online: WHO <http://www.who.int/medicines/areas/quality_safety/en/>.

part of the Scheme.

In 1975, after revision, the WHA adopted both the GMP[446] and the Scheme.[447]

The GMP covers a very broad spectrum of technical and administrative topics related to the manufacturing of pharmaceuticals, from equipment and materials used for production to self-inspection and sanitation of production facilities.[448] All these considerations benefit to a certain degree consumer safety. One of the key principals of the manufacturing of medicines is the concept of quality assurance,[449] "a wide-ranging concept covering all matters that individually or collectively influence the quality of a product".[450] In accordance with this concept, the manufacturer must assume responsibility for the quality of the pharmaceutical products to ensure that they are fit for their intended use, comply with the requirements of the marketing authorization, and do not place patients at risk due to inadequate safety, quality, or efficacy. To achieve the quality objective reliably there must be a comprehensively designed and correctly implemented system of quality assurance incorporating GMP and quality control. The system should be adequately staffed with competent personnel, and should have suitable and sufficient premises, equipment, and facilities.[451] Good Manufacturing Practices are a part of a quality assurance concept

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[446]Over the years, the GMP has been revised a few times. Last revision was done in 2014.
[447]WHO, *Good Manufacturing Practices for Pharmaceutical Products: Main Principles*, 2014, online: WHO <http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS986annex2.pdf?ua=1>.
[448]Beside, Main Principle, for products requesting specific conditions of production, such herbal medicine, biological products, etc., WHO has elaborated addition GMP guidelines. The complete list of GMP documents targeting particular products see: WHO, *Essential Medicines and Health Products, Production*, online: WHO <http://www.who.int/medicines/areas/quality_safety/quality_assurance/production/en/>.
[449]The quality assurance concept incorporates not only production but also product design and development.
[450]*Op. cit.* 447 (*Good Manufacturing Practices for Pharmaceutical Products: Main Principles*), at art.1.3.
[451]*Ibid.* at art.1.1.

with an aim to diminish the potential risks[452] inherent to any pharmaceutical production.[453]

Only the provisions having a direct impact on consumer safety are given a more detailed review here below.

Proper labeling

In addition to any supplementary information that may be required by the national authority, labels for pharmaceuticals should include at least the following: a) the name of the drug product; b) a list of the active ingredients (if applicable, with the INN), c) the batch number assigned by the manufacturer; d) the expiry date; e) any special storage conditions or handling precautions; f) directions for use and warnings and precautions that may be necessary; and g) the name and address of the manufacturer or the company or the person responsible for marketing the product. Labels must be clear and unambiguous.[454] Quality of labeling is subject to self-inspection procedures.[455]

Product recalls

In accordance with Article 6.1 of the GMP, there should be a system to recall from the market, promptly and effectively, products known or suspected to be defective.[456] The manufacturer has to appoint an authorized person responsible for the implementation of recalls and support him/her with sufficient staff to handle all

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[452]Essentially, there are two types of risks: cross-contamination (in particular of unexpected contaminants) and mix-ups (confusion) caused by, for example, false labels being put on containers.
[453]*Op. cit.* 447 (*Good Manufacturing Practices for Pharmaceutical Products: Main Principles*), at art. 2.1.
[454]*Ibid.* at art.15.11.
[455]*Ibid.* at art. 8.2 .
[456]*Ibid.* at art. 6.1.

aspects of the recalls with the appropriate degree of urgency.[457] As well, the manufacturer must develop written instructions for its personnel concerning how to handle and monitor recalls, and keep records on action taken.[458] Finally, the manufacturer must inform national authorities promptly of any intention to recall the product because it is, or is suspected of being, defective.[459] From time to time, the product recall procedure must be examined and re-evaluated.[460]

The *WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce* is a voluntary international administrative instrument that assures the quality of pharmaceuticals on the market through a system of licensing and independent analysis of the finished product and through independent inspections, which verify that manufacturing operations are carried out in conformity with the GMP.[461]

Under the Scheme, every member state must attest to the competent authority of another participating Member State that: a) a specific product is authorized to be placed on the market within its jurisdiction or, if the product is not authorized, the reason why that authorization has not been accorded; b) the plant where the product is manufactured is subject to inspections and that the manufacturer conforms to the GMP; and c) all submitted information on the product, including labeling, is currently authorized in the certifying country.[462]

To participate in the scheme, any Member State should have: an effective national

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[457] *Ibid.* at art. 6.2.
[458] *Ibid.* at art. 6.3 & 6.4 & 6.6 & 6.7.
[459] *Ibid.* at art. 6.5.
[460] *Ibid.* at art. 6.8.
[461] WHO, *Guidelines on the Implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce*, online: WHO <http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/guidelines/en/index.html>.
[462] *Ibid.* at art.1.3.

licensing system, legislation on GMP in production of drugs, an effective mechanism of control to monitor the quality of pharmaceutical products, a national pharmaceuticals inspectorate, and administrative capacity to issue the required certificates.[463]

At the request of the importing country, the exporting country must submit three different types of certificates: the Certificate of a Pharmaceutical Product[464] (used if a product is subject to licensing for import and sale),[465] the Statement of Licensing Status[466] (used to confirm license status of a particular product in the exporting country),[467] and the Batch Certificate[468] (used only exceptionally for vaccines, sera and some other biological products).[469] In the case of any quality defect in an exported product, a certifying authority must institute an enquiry.[470]

Both the International Pharmaceutical Federation and the International Federation of Pharmaceutical Manufacturers Associations recognize and stress the important role of the Scheme as a key regulatory safeguard, assisting countries to ensure the quality of imported products.[471]

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[463] *Ibid.* at art. 2.4.

[464] The Certificate of a Pharmaceutical Product includes the following information: name and dosage form of product, name and amount of the active ingredients, name and address of product license holder and/or manufacturing facility, formula (complete composition), and product information for health professionals and for the public (patient information leaflets) as approved in the exporting country.

[465] *Op. cit.* 461 (*Guidelines on the Implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce*), at art. 3.5 & 3.6.

[466] Importing agents use the Statement of Licensing Status to facilitate the screening and preparation of information for an international tender.

[467] *Op. cit.* 461 (*Guidelines on the Implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce*), at art. 3.13.

[468] The Batch Certificate is intended to accompany and provide certification of the quality and expiry date of a specific batch or consignment of a product that has already been licensed in the importing country.

[469] *Op. cit.* 461 (*Guidelines on the Implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce*), at art. 3.14.

[470] *Ibid.* at art. 5.1.

[471] *Joint Statement between: The International Pharmaceutical Federation (FIP) and the International*

Since the beginning, the international community has shown great enthusiasm for implementing GMPs. To date GMPs are in effect in more than 100 countries from Afghanistan to Zimbabwe,[472] either through national codes (Canada, the US, Russia) or adherence to regional codes (the EU, the EAEU).[473] Most developed countries have been using GMPs already for decades,[474] revising and updating them about every five years to keep up with changes in the industry and changes to manufacturing and testing technology.[475] In recent years, the GMPs trend has become universal. More and more developing states and states in transition have adopted GMPs. Others, like Russia, have changed GMPs' legal status from voluntary to compulsory, harmonizing national standards with EU-GMPs. Regardless of legal form (regulation, directive or guidelines), the intent is similar worldwide: consistently assure pharmaceutical product safety and quality.

As this will be further developed in CHAPTER III, the other encouraging fact is that GMPs have been regarded as important drug safety tools on the regional level.

In conclusion, the future of the WHO GMP Guidelines for Pharmaceuticals looks as bright as ever. With the present level of globalization for medicine production, even

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Federation of Pharmaceutical Manufacturers Associations (IFPMA), Ensuring Quality and Safety of Medicinal Products to Protect the Patient: Approved by FIP Council in Barcelona in September 1999, online: FIP <https://www.fip.org/www/uploads/database_file.php?id=237&table_id=>.

[472]Joseph D. Nally, *Good Manufacturing Practices for Pharmaceuticals*, CRC Press (26 December 2006), at 335.

[473]On implementation of GMPs see CHAPTER III.

[474]Till recently, the exception to the almost uniform worldwide concept of the GMPs was Japanese GMPs. Until the 2002 edition, Japanese GMPs were unlike that of any other country. While discussing the same issues as all other GMP codes, the Japanese style of GMPs described the duties and responsibilities of various members of key management staff in the pharmaceutical company. Nevertheless, quality has always been a top priority for Japanese manufactures since the concept of product quality in Japanese culture has deep roots. As result, quality of pharmaceuticals in Japan surpasses any quality standard in America or Europe. (*Op. cit.* 438 (Michael H. Anisfeld), at *GMP Implementation*).

[475]The great exception to global trend is the United States FDA, which has not substantially changed its GMP regulations since issuing them in 1976. (*Ibid.* (Michael H. Anisfeld)).

the most resourceful regulatory agencies such as the FDA cannot fully protect consumers from unsafe drugs. Therefore, the International community has realized that only universal GMPs acceptance to harmonize production protocols and quality control for drug manufacturing can guaranty consumer safety. Work in this direction has accelerated for some time, especially at the regional level. The WHO Guidelines are an indispensable instrument in this endeavour.

Meanwhile, the proposed risk-based approach to GMP compliance may boost both drug safety and effective use of resources. The present system of compliance embraces all pharmaceutical products regardless of their risk-factor to consumers. Nevertheless, consumers are more likely to get sick or die from an injectable product not manufactured in accordance with GMPs than from a cream so manufactured. The approach to GMPs where risk-factors posed by products to consumers are correlated to compliance efforts would be the most logical. Finally, GMP resources should be directed to those elements of operations that most put consumers at risk. For example more effort should be expended in inspecting whether products are properly labeled and less in whether training of personal is fully documented.[476]

[476] *Ibid.* (Michael H. Anisfeld), at *Future Trends – GMPs and Risk Assessment.*

2.2.2.3 Medical Products and the Internet: a Guide to find reliable information, 1999

In recent years, sales of medical products over the Internet have increased substantially.

Currently it is unknown how many pharmacies are doing business over the Internet, but estimates of the industry range from US$50 to 75 billion.[477] There are a few reasons that explain this phenomenon. First, consumers have access to e-pharmacies 24/7 from home. Second, the Internet provides a certain level of anonymity and privacy since consumers do not need to discuss their medical needs in public. Third, the Internet provides a worldwide selection of pharmaceuticals and medical products. Fourth, the consumer can find information fast and easily on any health topic and consult treatment options without paying a visit to a doctor. Finally, the consumer can easily obtain any prescription drugs through the e-pharmacy without a doctor's prescription.[478]

Nevertheless, consumers who buy medical products over the Internet are at risk of suffering adverse events, some of which might be life threatening. These risks include: potential side effects from genuine but inappropriately self-prescribed medications; adverse or no effect from counterfeit copies that contain harmful or inert

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[477]WHO, *Safety and Security on the Internet: Challenges and Advances in Member States: Based on the Findings of the Second Global Survey on eHealth*, WHO, 2011, at 11, online: WHO <http://www.who.int/goe/publications/goe_security_web.pdf>.

[478]Because it provides easy access to controlled drugs, the Internet is becoming an important route for trafficking by online pharmacies. These pharmacies illegally provide prescription drugs to clients worldwide, but without the required prescriptions. They are used as a source by drug addicts and provide the means for large-scale dealing to a practically unlimited number of customers. (INCB, *INCB Targets Illicit Sales of Drugs on Internet Pharmacies International Experts to Meet in Vienna to Discuss Solutions*, (UNIS/NAR/862), (18 October 2004), online: International Narcotics Control Board <https://www.incb.org/documents/Publications/PressRelease/PR2004/press_release_181004.pdf>).

ingredients; adverse or no effect from medical products that are expired, contaminated, poor quality, etc.[479]

Although some Internet pharmacies conduct honest and reliable businesses and provide genuine medical products to the consumer, there are numerous pseudo e-pharmacies that don't play by the rules. Such e-businesses use aggressive marketing techniques to sell poor quality or counterfeit medical products.[480] A 2013 study of approximately 10,000 websites, reported that 97% of them did not meet adequate pharmacy laws and practice standards and 86% of them did not require a valid prescription. An earlier World Health Organization report also estimated that greater than 50% of websites failing to disclose their physical address are engaged in the sale of counterfeit medicines.[481]

Many bogus e-pharmacies have sophisticated tools in place to deceive Internet shoppers. For instance, many sites that list their physical address in Canada or the European Union are in fact located in other third-party countries and have no relation to the regulatory authorities of the countries where they claim to be. They ship sham medicines from multiple locations around the world, making it difficult for authorities in different countries to track them down. Many advertise "no prescription required" and use spam advertising to lure buyers, while online search results list hundreds of fake websites that appear authentic to the average shopper.[482]

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[479]*International Prescription Drug Parity: Statement of William K. Hubbard, Associate Commissioner for Policy and Planning, before the Committee on Government Reform, U.S. House of Representatives, Hearing on Internet Drug Sales, U.S. Food and Drug Administration (FDA)*, (3 April 2004), online: FDA <http://www.fda.gov/NewsEvents/Testimony/ucm161404.htm >.

[480]Such marketing can employ low prices, aggressive advertising, website designs similar to genuine e-pharmacies, etc.

[481]Tim K Mackey & Bryan A Liang, *Pharmaceutical Digital Marketing and Governance: Illicit Actors and Challenges to Global Patient Safety and Public Health*, (16 October 2013), at 3, online: Globalization and Health <http://www.globalizationandhealth.com/content/9/1/45#B36>.

[482]Amy O'Connor, *Tips for Buying Safe Medications On-line*, (21 March 2011), online: Lilly Pad <https://lillypad.lilly.com/entry.php?e=1574>.

A legal vacuum aggravates the problem. A recent survey indicates that many states do not regulate, accredit, or certify Internet pharmacy sites, or do not have rules restricting or prohibiting the online purchasing of pharmaceuticals from other countries, a practice which has already been identified as creating significant and demonstrable health risks.[483]

There are a few weapons in the WHO arsenal to battle such practices, for example the *Guidelines to Fight Counterfeit Drugs*[484] or the *Guidelines on Inspection of Drug Distribution Channels.*[485] However, since most of these documents are destined for national authorities to control illicit practices in international trade, they have little or no effect on Internet sales when the consumer is faced one-on-one with a dishonest e-pharmacy. Realizing that only consumer education on finding reliable health and medical information on the Internet and how to buy medical products through e-pharmacies is the best way to fight wide-scale consumer abuse and to ensure consumer safety, the WHO developed a guide for consumer shopping on the Internet.

In May 1998, the Fifty-first World Health Assembly (WHA) adopted a resolution whereby the international community expressed concerns about the effects of advertising, promotion, and the uncontrolled sale of medical products via the Internet and requested that the Director-General of the WHO develop a guide on medical products and the Internet.[486] A year later, the WHO released *Medical Products and*

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[483]WHO, *Safety and Security on the Internet: Challenges and Advances in Member States: Based on the Findings of the Second Global Survey on eHealth*, WHO, 2011, at 43, online: WHO <http://www.who.int/goe/publications/goe_security_web.pdf>.

[484]WHO, *Guidelines for the Development of* Measures to *Combat Counterfeit Drugs*, (EDM.QSM.99.1), WHO: Department of Essential Drugs and Other Medicines, 1999, online: WHO <http://apps.who.int/iris/bitstream/10665/65892/1/WHO_EDM_QSM_99.1.pdf.>.

[485]WHO, *Guidelines for Inspection of Drug Distribution Channels. WHO: Expert Committee on Specifications for Pharmaceutical Preparations, WHO: Technical Report Series*, No. 885, 1999, online: WHO <http://apps.who.int/prequal/info_general/documents/TRS885/WHO_TRS_885-Annex6.pdf>.

[486]WHA, *Cross-Border Advertising, Promotion and Sale of Medical Products Using the Internet*, Res. WHA51.9 (1998), online: WHO <http://apps.who.int/medicinedocs/en/d/Js21471ru/>.

the Internet: a Guide to Find Reliable Information [487] as a model for Member States to adapt into locally meaningful advice for Internet users to help them obtain reliable, independent, and comparable information on medicinal products.[488] The Guidelines offer practical and easy-to-follow information on what the consumer has to do when buying medical products over the Internet. This eight pages document embraces all aspects of online drug shopping and arms consumers with tools to buy safe and effective medicine.

Although the Internet is a valuable source of information on a wide range of health topics and, when used properly, allows quick and easy access to such information from numerous online databases, it is often difficult for users to determine whether such information posted on the Net is reliable, complete, and up to date.[489] If consumers are not familiar with the source of information, they should take two steps to verify the reliability of the source. First, consult a healthcare professional or other reliable organization regarding the source. Second, scan Net sources for a minimum of information on the source.[490] In addition to evaluating the credibility of Web sites, consumers can also consult national health authorities regarding a list of reliable Internet sources on specific health and medical issues.[491]

When using the Internet, consumers should keep the following considerations in

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[487]WHO, *Medical Products and the Internet: a Guide to Find Reliable Information,* online: WHO <http://apps.who.int/medicinedocs/en/d/Js2277e/>.
[488]*Ibid.* at *Introduction.*
[489]*Ibid.* at art.1.
[490]This information should contain: the name and contact address of the Web site owner; the name of the organization providing funding, services, or other support to the Web site; the source of funding (advertising or sponsorship and how clearly it is stated); targeted audience (consumers, health professionals, or others); and the date of the last update. In addition, the consumer should verify whether the Web site has information on: research and clinical trials; new products approved for a specific disease; general information about diseases and conditions; support groups for people with certain diseases and conditions; and a list of international, national, and local organizations that provide support and information for the disease or condition.
[491]*Op. cit.* 487 (*Medical Products and the Internet: a Guide to Find Reliable Information*), at art. 2.

mind. The information may not be truthful,[492] and identically named products may contain different ingredients in different countries; therefore, the consumer should use only the INN (generic name)[493] to identify the pharmaceutical's composition.[494]

There are many reasons why buying medical products from another country may risk consumers' health and waste their money. The guidelines list at least ten such reasons. First, since every country has specific regulations about approving, licensing, and authorizing medical products, some products on the Internet may not meet the regulations of the consumer's home country and can be subject to special legal procedures for importation. Moreover, if medical products have not undergone studies and evaluation according to the law and regulations of the consumer's home country, there is no assurance of safety and effectiveness for such products. Second, products bought via the Internet may not have a correct, up-to-date, and understandable instructions booklet on use, dosage, and precautions. Third, medical products obtained over the Internet may forfeit quality because of inappropriate production, packaging, and logistics. Fourth, medical products sold over the Internet may circumvent the regulatory protection provided by authorities in the consumer's home country, and the consumer may not be eligible for compensation for any damage resulting from use of the product. Fifth, products promoted and sold on the Internet may be fraudulent, and instead of providing benefits they may cause harm to the consumer's health. Sixth, medical products bought via the Internet may not be covered by medical insurance. Seventh, if medical treatment found on the Internet is

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[492]The information is probably not truthful if it contains: advertisements that use phrases such as scientific breakthrough, miraculous cure, exclusive product, etc.; and/or case histories from cured customers; and/or a list of symptoms and diseases which are claimed to be cured by the product; and/or claims that the product is available from only one source, for a limited time; and/or testimonials from "famous" medical experts; and/or claims that a product is scientifically proven and absolutely safe, etc.

[493]*Op. cit.* (*International Non-proprietary Names).*

[494]Product information should include at least: product name; active ingredient(s); name of other ingredients known to cause problems to some people; what to use the product for; when not to use the product (for example, in pregnancy, allergies, interactions with other medicines or foods); how to use the product; possible undesired effects; how to store the product; manufacturer's name and contact information; last update of the information. *Op. cit.* 487 (*Medical Products and the Internet: a Guide to Find Reliable Information*), at art.3.

not effective, consumers may waste valuable time as well as financial resources and jeopardize their health. Eight, since countries have different laws about what medical products can be imported, it is possible that some products may not be allowed to cross the border and consumers will waste money if they are not entitled to a reimbursement. Ninth, as products with the same name can have different standards and compositions in different counties, consumers may not obtain the exact product they want. And tenth, some Web sites collect personal medical information and may not keep it confidential. Consumers should go through most of such considerations before buying medical products overseas.[495]

The problem remains that the use of the Internet may deprive consumers of the opportunity to seek professional advice. Even if consumers find reliable health and medical information on the Internet, it is still important to discuss their disease or condition with a health professional since not every disease or condition requires medical treatment and medication can cause harm if used improperly. Some medication may be unsuitable for some individuals, for example because of allergy. Mixing medication can be potentially dangerous for the consumer's health and only health professionals can give proper instructions. Patients with particular characteristics, such as pregnant or breast-feeding women, have special concerns and considerations when using medical products. Only healthcare professionals can advise on treatment changes in the event of complications or adverse reaction to medical products. [496]

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[495] *Ibid.* (*Medical Products and the Internet: a Guide to Find Reliable Information*), at art. 4.
[496] *Ibid.* at art. 5.

2.2.2.4 The Consolidated List of Pharmaceuticals, 1982

One of the leading causes of death is believed to be adverse drug reactions. Millions of patients have taken drugs withdrawn from the market. A 2002 study showed that out of the 548 drugs that were approved in the U.S. between 1975-1999, fifty-six (10.2 %) of them subsequently required a new black box warning or were withdrawn. Thus, it is very important that the consumer as well as the practitioner become aware of dangerous drugs.[497]

One of the first international instruments to benefit consumer protection and safety has been the *Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or Not Approved by Governments (Pharmaceuticals)*[498] (the Consolidated List of Pharmaceuticals).[499] In contrast to similar instrument on Chemicals, for obvious reasons this List might be used not only by industry or authorities but also by the common consumer to verify if a certain drug marketed in his/her country has been restricted or banned by other governments and on what ground. First published in 1982, the list has been continuously updated.[500]

The main goal of the Consolidated List of Pharmaceuticals is to inform governments and the public about medicines that are harmful to health. The key sources used to

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[497]Benson Ninan &Albert I Wertheimer, "Withdrawing Drugs in the U.S. Versus Other Countries", *,Innovations in Pharmacy*, 3:3, Article 87, (2012), at 1, online: University of Minnesota: College of Pharmacy <http://pubs.lib.umn.edu/cgi/viewcontent.cgi?article=1089&context=innovations>.

[498]UN ECOSOC, *The Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or Not Approved by Governments (Pharmaceuticals)*, (ST/ESA/322) online: UN ECOSOC <http://www.un.org/esa/coordination/CL-14-Final.for.Printing.pdf>.

[499]On the history of the Consolidated List of banned hazardous chemical and unsafe pharmaceutical products see 2.2.1.1.

[500]WHO, *Pharmaceuticals: Restrictions in Use and Availability* (WHO/EMP/QSM/2010.3), (2010), at iii, online: WHO <http://apps.who.int/medicinedocs/documents/s17126e/s17126e.pdf>.

consolidate the list are the information on restrictive regulatory decisions on a range of pharmaceutical products received from member states as well as the information from drug monitoring programs and certification schemes for drug quality. The collected and organized data is disseminated in the form of WHO Drug Information Circulars and Pharmaceuticals Newsletters[501] to governments and can be used as a guideline in taking appropriate regulatory measures on medicines, in light of their particular national circumstances. Since the Consolidated List of Pharmaceuticals was designed as an easy-to-read and understand document, it also provides valuable information to the general public and to consumer groups about hazardous drugs that are severely restricted and banned in some countries but still on the market in others.[502]

The Consolidated List of Pharmaceuticals consists of two parts. The first part, jointly prepared by the UN and WHO, provides information on restrictive regulatory measures taken by 90 governments on some 500 pharmaceutical products. However, one has to take certain things into consideration when applying the provisions of the Consolidated List of Pharmaceuticals. First, while decisions are taken on some medicines by a limited number of governments, they may not represent the position of other governments, especially in view of different risk-benefits considerations. Second, even if a product is not listed as regulated by a country, most likely it is, and a member state simply has not yet issued a notice on their regulatory decision. Third, although the regulatory text does not address the efficacy of the product, a

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[501]Everyone can automatically receive the electronic version of every new issue of the *WHO Pharmaceuticals Newsletters* after subscription on the WHO website. Newsletters provide easy to understand information on: regulatory government actions regarding certain drugs on the market and reasons for such actions; risks associated with pharmaceuticals; and reports on possible causal relationship between an adverse events and drugs. For more information see: WHO, *WHO Pharmaceuticals Newsletter* online: WHO <http://www.who.int/medicines/publications/newsletter/en/index.html>.

[502]*Op. cit.* 498 (*The Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or Not Approved by Governments* (Pharmaceuticals)), at 4 to 6.

government may nevertheless consider the efficacy as a crucial matter for imposing regulatory measures. Fourth, it is also important to realize that the criterion "severely restricted" can be very widely interpreted by government. As a result, it leads to inconsistency in reporting on national restrictive regulatory measures. Fifth, even though the Consolidated List of Pharmaceuticals does not address psychotropic and narcotic substances, since they are the subject of the international conventions,[503] they can be listed if a government imposes more rigorous control on such substances than the relevant international conventions. Sixth, the Consolidated List of Pharmaceuticals does not cover food additives, since the Codex Alimentarius Commission considers them. Finally, regulatory information on products includes the position of governments on their regulatory actions and national circumstances lead to measures taken, references to legal or statutory documents, and bibliographical references regarding scientific and technical studies on products conducted by international organizations.

Since pharmaceutical companies use different property names for their products, to avoid confusion and to facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients the WHO uses the International Non-Proprietary Name (INN).[504] Whenever possible, all pharmaceuticals products in the Consolidated List are arranged in alphabetical order according to INN and include other scientific and common names and the date when regulation came into force.[505]

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[503]UN Office on Drugs and Crime, *The Single Convention on Narcotic Drugs*, 1961, online: UN Office on Drugs and Crime <http://www.unodc.org/pdf/convention_1961_en.pdf>:
UN Office on Drugs and Crime, *The Convention on Psychotropic Substances*, 1971, online: UN Office on Drugs and Crime <https://www.unodc.org/pdf/convention_1971_en.pdf>;
UN Office on Drugs and Crime, *The United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances*, 1988, online: UN Office on Drugs and Crime <http://www.unodc.org/pdf/convention_1988_en.pdf>.

[504]*Op. cit.* 416 (*International Non-proprietary Names).*

[505]*Op. cit.* 498 (*The Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or Not Approved by Governments (Pharmaceuticals)*), at 6 & 7.

The second part compiled by the UN Secretariat provides, in easy cross-reference manner, information on trade and common scientific names for products covered in part one.[506]

Since the establishment of the List, the dissemination of information on which drugs are banned has become easier. Nevertheless, countries tend to have different policies on which drugs to withdraw and when to withdraw them.[507] Likewise in order for a drug to be withdrawn globally, the side effects usually have to be severe enough to catch the attention of the entire world. In addition most of the time, drugs are kept on the market for many years, possibly due to monetary benefits, before they are found to be more harmful than good.[508] The UN should not only take more proactive position to promote the Consolidated List for consumers use but also standardize among the Member States the mechanism of drugs withdrawal.

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[506]*Op. cit.* 498 (*The Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or Not Approved by Governments (Pharmaceuticals)*) at 7.
[507]Recent research has showed that the U.S., for example, is on its own time course compared to other countries such as UK, Japan, Australia and Sweden and withdraws drugs based on the FDA's decisions. More on different approaches to drugs withdraw please see *Op. cit.* 497 (Benson Ninan &Albert I Wertheimer), at 4.
[508]*Ibid.* (Benson Ninan &Albert I Wertheimer), at 4.

2.2.2.5 The WHO Programme for International Drug Monitoring, 1968

The *WHO Programme for International Drug Monitoring* (the Program) was established in 1968 after the Thalidomide disaster.[509] Under the Program, the WHO Member States work together in the monitoring of drug safety. The Program consists of a network of National Centres for Pharmacovigilance and the WHO Headquarters. Since 1978, the Uppsala Monitoring Centre (UMC) in Sweden has been carrying out the Program. The UMC collects and stores individual cases of suspected adverse drug reaction reported by National Centres and the WHO.

Today, 125 countries take part in the Program,[510] and another 29 countries participate as associate members.[511]

Regulatory agencies, healthcare professionals, researchers, the pharmaceutical industry, and other interested stakeholders use the UMC resources as an essential global database on adverse drug reactions.[512]

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[509]On Thalidomide health crises see 3.2.7. More on *WHO Programme for International Drug Monitoring* see *Uppsala Monitoring Centre*, online: <http://www.who-umc.org/>.
[510]Canada and the US have been members of Program since 1968; all EU state-members have taken part in the program; Russia has been participating since 1998.
[511]For more information on membership see *WHO Programme Members*, online: *Uppsala Monitoring Centre* <http://www.who-umc.org/DynPage.aspx?id=100653&mn1=7347&mn2=7252&mn3=7322&mn4=7442>.
[512]Presently, the UMC database contains over 14 million Adverse Drug Reaction Reports.

2.2.3 Traditional, Complementary and Alternative Medicine

Traditional medicine has always maintained its popularity worldwide.[513] In addition, over the last two decades, we have seen an increasing use of herbal[514] and complementary/alternative medicines[515] in many developed and developing countries.[516] While in the developed world traditional medicine mostly supplements Western-style health care, in developing counties many people do not have this luxury. The WHO estimates that one-third of the world's population has no regular access to essential modern medicines; in some part of Africa, Asia, and Latin America, as much as half the population faces these persistent shortages. However, in these same situations, the rich resources of traditional remedies and practitioners are available and accessible.[517]

Various traditional medicine practices have been developed in different cultures in different regions, but without a parallel development of international standards and

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[513]Traditional medicine is the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness. (WHO, *Traditional Medicine: Definitions*, online: WHO <http://www.who.int/medicines/areas/traditional/definitions/en/>).

[514]Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products that contain as active ingredients parts of plants, or other plant materials, or combinations. (*Ibid. Traditional Medicine: Definition*).

[515]Describing health approaches with non-mainstream roots, often the words alternative and complementary are used interchangeably, but the two terms refer to different concepts: complementary generally refers to using a non-mainstream approach together with conventional medicine, whereas alternative refers to using a non-mainstream approach in place of conventional medicine. Both refer to a broad set of health care practices that are not part of that country's own tradition and are not integrated into the dominant health care system. Acupuncture, massage therapy, relaxation techniques, Tai chi, Yoga are the examples of complementary/alternative medicine. (*Complementary, Alternative, or Integrative Health: What's In a Name?*, National Center for Complementary and Integrative Health, online: NCCIH <https://nccih.nih.gov/health/whatiscam>; and *Ibid. Traditional Medicine: Definition*).

[516]WHO, C.K. Ong *et al., WHO Global Atlas of Traditional, Complementary and Alternative Medicine*, Volume 1, (January 2005), at ix, online: WHO <http://apps.who.int/iris/bitstream/10665/43108/1/9241562862_map.pdf?ua=1>.

[517]*Ibid.* at ix.

appropriate methods for evaluating potential adverse effects on consumer health.[518] In fact, there is not much scientifically backed safety data about traditional medicine. For example, despite the fact that medicinal plants have been used for millennia, to date systematic scientific information on therapeutic effects exists only for a relatively small number of herbs. Data on safety and efficacy is available for an even smaller number of plants and their preparations.[519] Hence, the safety and efficacy of herbal medicine and complementary/alternative medicines, as well as their quality control, have become predominating concerns for both health authorities and the public.[520]

While national authorities through the world have tried to develop and implement the regulation on traditional medicine, they have faced major challenges related to regulatory status, assessment of safety and efficacy, quality control, safety monitoring and lack of knowledge about herbal and complementary/alternative medicines by national drug regulatory authorities.[521]

With the purpose to share existing experience and information and to help in forming harmonized national polices and laws, the WHO has elaborated the following two main documents: the *Guidelines for Appropriate Use of Herbal Medicines* and the *Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine.*

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[518]WHO, *National policy on traditional medicine and regulation of herbal medicines: Report of a WHO Global Survey*, Geneva, (May 2005), at iii, online: WHO <http://apps.who.int/medicinedocs/pdf/s7916e/s7916e.pdf>.

[519]"Законодательство по препаратам на основе лекарственных растений" Провизор 16 (2002) (Legislation on medicinal plants formulations [translated by author]), Провизор, online: Провизор <http://www.provisor.com.ua/archive/2002/N16/art_21.php>.

[520]*Op. cit.* 518 (*National Policy on Traditional Medicine and Regulation of Herbal Medicines Report of a WHO Global Survey*) at iii.

[521]*Ibid.*

2.2.3.1 The WHO Guidelines for Appropriate Use of Herbal Medicines, 1997

For millennia, herbal medicines have played an important role in primary health care in many places around the globe. Nowadays, herbal medicines are still the only affordable remedy for the majority of the world's population in developing countries.[522] In recent years, since official and commercial interest for herbal medicines has extended far beyond the traditional geographical areas of use, primarily to developed countries,[523] more and more governments are considering establishing comprehensive policies on the appropriate use of herbal medicines.[524]

In spite of the stereotypical belief that herbal medicines are safe because of the fact they are natural, some can produce serious adverse reactions and have long-term side effects, especially when mixed with pharmaceutical drugs.[525] The adequate quality of herbal medicine is also a big concern due to less strict regulation than conventional pharmaceutics. As a result, a consumer often does not get what is advertised on the label.[526] In addition, while conventional pharmaceutical products are produced from synthetic materials with precise properties and dosage, herbal medicines are prepared from materials of herbal origin containing small and vague quantities of defined

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[522]For example, in China medicinal plants and their products had a 33.1% share of the pharmaceutical market. (*Infra* 530 (*Guidelines for Appropriate Use of Herbal Medicines*) at art. 1.1).

[523]Just in the United States sales of herbal dietary supplements increased by 7.5% in 2015, reaching a total estimated figure of seven billion dollars. (*Herbal Dietary Supplement Sales in US Increased by 7.5% in 2015*, American Botanical Council, (6 September 2016), online: American Botanical Council <http://cms.herbalgram.org/press/2016/new_1476393283546.html?t=1476393468>).

[524]*Infra* 530 (*Guidelines for Appropriate Use of Herbal Medicines*), at Art.1.3.

[525]*Infra* 530 (*Guidelines for Appropriate Use of Herbal Medicines*), at Art.1.3.

[526]A resent investigation by the New York State Attorney General's Office alleges that some store-brand herbal supplements sold in New York by Wal-Mart, Walgreens, Target and GNC are bogus. In a good number of cases, there was no organic material in the product. Nearly 80% of the state's test results found that the store-brand supplements tested did not contain what is listed on the label. Some of the ingredients that were detected include mustard, powdered rice and sand. (Tom Llamas, "Bogus Herbal Supplements Fail Ingredient Test: Investigation", ABC News, (3 February 2015), online: ABC <http://abcnews.go.com/Health/bogus-herbal-supplements-fail-ingredient-test-investigation/story?id=28684472>).

active ingredients. Moreover, herbal materials are often obtained from diverse unverified geographical and commercial sources so as a result their composition and properties may vary or be contaminated.[527] Thus, only an adequate and effective system of quality control and appropriate treatment protocols can help to avoid dangerous consequences for consumers.

The WHO has always supported the use of herbal medicines. During the 70s and 80s, the World Health Assembly (WHA) adopted numerous resolutions on medicinal plant management, inventory, safe preparation, cultivation, etc.[528] However, with the growing popularity of herbal medicines worldwide, many Member States asked for assistance in developing a legal framework for the safe production, marketing, and use of herbal medicines. In 1989, the WHA adopted the resolution *Traditional Medicine and Modern Health Care* to urge the international community to introduce measures for the regulation and control of medicinal plant products,[529] and, later in 1997, the WHO Regional Office for the Western Pacific Region prepared a set of *Guidelines for the Appropriate Use of Herbal Medicines* (the Guidelines AUHM).[530]

The Guidelines AUNM have four objectives: to provide basic principles and applicable standards to develop a national policy on herbal medicines; to guide interested parties to develop measures for promoting the appropriate use of herbal medicines; to facilitate information exchange; and to ensure the safe and effective use of herbal medicines by practitioners and consumers.[531] The two last objectives should

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[527]WHO, *Supplementary Guidelines on Good Manufacturing Practices for the Manufacture of Herbal Medicines,* WHO Technical Report Series: No. 937, Annex 3, (2006), at 87, online: WHO <http://www.who.int/medicines/areas/quality_safety/quality_assurance/SupplementaryGMPManufactureHerbalMedicinesTRS937Annex3.pdf?ua=1>.

[528]WHO Resolutions on Traditional Medicine (Res. WHA29.72, Res. WHA30.49, Res. WHA40.33); WHO Resolutions on Medicinal Plants (Res. WHA31.33, Res. WHA41.19).

[529]WHA, *Traditional Medicine and Modern Health Care,* Res WHA42.43., (May 1998), online: WHO <http://www.who.int/medicines/areas/traditional/wha4243.pdf?ua=1>.

[530]WHO, *Guidelines for Appropriate Use of Herbal Medicines*, 1997, online: WHO <http://apps.who.int/medicinedocs/en/d/Jh2945e/>.

[531]*Ibid.* at Art. 2.2.

be reviewed in the scope of this work since they directly relate to consumer safety.

The Guidelines AUHM cover a broad range of topics: regulation of practitioners, regulation of the manufacturing and distribution of medicinal herbal products, etc. They have a flexible nature and set out only generic principles.

As the Guidelines AUHM suggest, the international community should collect and exchange information on the safety, efficacy, and quality of herbal medicines, using existing databases.[532] To ensure the quality of herbal medicine services and thus protect the public safety, the state should establish a regulatory framework and a certification scheme for practitioners.[533] In contrast to conventional pharmaceutical products, herbal products are prepared from material of herbal origin, which is more susceptible to contamination and deterioration in comparison to chemically synthesized pharmaceuticals. Furthermore, the techniques and procedures used for production and quality control of conventional pharmaceutical products are often not suitable for herbal products. The Guidelines AUHM therefore call for manufacturing and quality control in accordance with the provisions of both[534] the *Good Manufacturing Practices for Pharmaceutical Products*[535] and the *Good Manufacturing Practices: Supplementary Guidelines for the Manufacture of Herbal Medicinal Products.*[536] To ensure that only good quality herbal medical products

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[532]*Ibid.* at Art. 5.7.
[533]*Ibid.* at Art.6.
[534]*Ibid.* at Art. 7.1 & 7.2.
[535]*Op. cit.* 447 (*Good Manufacturing Practices for Pharmaceutical Products: Main Principles*).
[536]Following the publication of the WHO guidelines on *Good Manufacturing Practices for Pharmaceutical Products: Main Principles*, supporting and supplementary guidelines were developed to address specific issues connected with the manufacture of certain types of pharmaceutical product. As part of this series, the WHO *Supplementary Guidelines for the Manufacture of Herbal Medicinal Products* were issued in 1996 and were updated in 2006. The structure of these supplementary guidelines follows that of the WHO's GMP main principles, complementing them. The supplementary guidelines are intended to provide WHO Member States with general and minimum technical requirements for quality assurance and control in the manufacture of herbal medicines. Each Member State should develop its own national GMP for manufacturing herbal medicines that are appropriate to the country's actual situation. (WHO, *Supplementary Guidelines on Good Manufacturing Practices for the Manufacture of Herbal Medicines,* WHO Technical Report Series: No. 937, Annex 3, 2006, at 1&2, online: WHO

reach international markets, the Guidelines AUNM suggest following the principles of the *WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.*[537]

As for labeling requirements, all herbal medical products should have a "user-friendly" label and package in the official language of the country where the product is marketed with the key information: name of product; the name and quantity of active ingredients; directions for use; warning statements and adverse effects; overdose information when relevant; expiry date; storage conditions; name and address of manufacturers and/or importers; and registration number.[538]

2.2.3.2 The WHO Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine, 2004

In recent years, intercultural exchange, boosted by globalization, has increased the popularity of the use of complementary, traditional, and alternative medicine (CAM) in both developing and developed countries.[539] As many as 4,000 different practice or

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<http://www.who.int/medicines/areas/quality_safety/quality_assurance/SupplementaryGMPManufactureHerbalMedicinesTRS937Annex3.pdf?ua=1>).

[537] *Op. cit.* 530 (*Guidelines for Appropriate Use of Herbal Medicines*), at art. 7.4.

[538] *Op. cit.* 530 (*Guidelines for Appropriate Use of Herbal Medicines*), at art. 8.5.

[539] Consumers in the United States alone spend up to US $34 billion per annum on complementary alternative medicine. CAM accounts for approximately 1.5% of total health care expenditures. Currently, about 38% of Americans are using CAM for health and to treat a variety of issues. Most commonly, this report shows that people actively seek out acupuncture and massage to manage chronic pain. Of the $34 billion people spent for CAM services, an estimated $22 billion was spent on self-care costs such as herbs and natural products like fish oil and Echinacea. Visits to acupuncturists, massage

discipline areas have been catalogued, including chiropractic, therapeutic massage, rolfing, Kanpo medicine, etc.[540] Many consumers consider CAM as a safe and effective approach against a vast array of illnesses. And indeed, those properties of CAM therapies are often supported by empirical evidence on safety and effectiveness.[541] However, as a result of different cultural traditions, local CAM practitioners and consumers may often be unfamiliar with the proper and safe use of techniques and therapeutic products of CAM. As the use of traditional or alternative medicines increases, so do reports of adverse reactions.[542] Finally, CAM products are unregulated in many countries, and therefore many of the concerns about the risks for consumers relate to the safety and quality of CAM medicinal products. Reported problems include sales of incorrect or contaminated plant species and adulteration of CAM medication therapies.[543]

In response to the challenges posed by the widespread use of CAM, the WHO developed the WHO Traditional Medicine Strategy: 2002-2005, where consumer

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therapists, and chiropractors was attributed to more than half of the money spent on self-care - about $11.9 billion. (*Americans Spend 34 Billions Dollars on Alternative Medicine*, Pacific College of Oriental Medicine, (6 May 2015), online: Pacific College of Oriental Medicine <http://www.pacificcollege.edu/acupuncture-massage-news/press-releases/718-americans-spend-34-billion-dollars-on-alternative-medicine-.html>). The WHO estimates that up to 80% of developing country populations rely on traditional medicine for their primary health care, due to cultural tradition or lack of alternatives. In wealthy countries, up to 65% of people seek out various types of natural remedies. For example, 90% of pain clinics in the United Kingdom and 70% in Germany include acupuncture, a popular treatment for relieving pain. (*Infra.* 547 (*Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine*), at 1).

[540] WHO, *New WHO guidelines to promote proper use of alternative medicines*, 2004, online: WHO <http://apps.who.int/medicinedocs/pdf/s5525e/s5525e.pdf/>.

[541] Such evidence is usually based on sources such as traditional scriptures, pharmacopoeias and/ or clinical experience collected over hundreds of years. An increasing number of scientific studies now support the use of certain TM/CAM therapies. (*Ibid.* at 2).

[542] In China, where traditional therapies and products are widely used, a significant increase in adverse reactions has been reported, from 4,000 between 1990 and 1999 to 9,854 in 2002 alone. Norway has reported cases of pneumothorax: collapse of lungs, occurring as a result of disease or injury. (For more on *Pneumothorax* see: Pneumothorax <http://www.pneumothorax.org/>.) This condition is caused by unqualified acupuncturists, and there have also been cases of paralysis caused by unqualified manual therapists. *Infra.* 547 (*Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine*), at 3 to 5.

[543] *Infra.* 547 (*Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine*), at 3&4.

safety was given priority. The Strategy has four major objectives: a) framing policy; b) ensuring safety, efficacy and quality; c) enhancing access; d) promoting proper use of CAM.[544]

In 2003, the WHO adopted a resolution that urges the international community "to provide reliable information on traditional medicine and complementary and alternative medicine to consumers and providers in order to promote their sound use."[545] The best way to avoid possible harmful effects of CAM on consumer health "is to make sure that consumers are better informed and aware of CAM strategies and treatments so as to enable them to make appropriate decisions on how to improve their health."[546]

Just one year later the WHO set up the *Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine* (Guidelines on CAM).[547]

With the primary goal of assisting Member States in developing context-specific and reliable consumer information on the proper and safe use of CAM and to maximize the benefits and minimize the risks of CAM, the Guidelines pursue three objectives: to provide an overview of the key elements directly tied to consumers that must be placed in healthcare systems in order to ensure proper use of CAM; to describe general principles and activities for the development of reliable consumer information about CAM; and to outline the key elements that should be taken into consideration

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[544]*Ibid.* at 1.
[545]WHA, *Traditional Medicine*, Res. WHA56.31 (2003), online: WHO <http://apps.who.int/gb/archive/pdf_files/WHA56/ea56r31.pdf>.
[546]*Supra.* at vi.
[547]WHO, *Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine,* 2004, at 3&4, online: WHO <http://apps.who.int/medicinedocs/en/d/Js5525e/>.

to develop the consumer information on promoting proper use of CAM.[548]

The WHO has identified three different types of healthcare systems in relation to CAM. First, integrative types incorporate CAM into all areas of the healthcare system. In countries with this type of healthcare system,[549] there is a regulatory basis for CAM, CAM doctors must receive a university degree, health insurance covers CAM treatments, and authorities also often provide some consumer education on CAM. The second type, an inclusive healthcare system, recognizes CAM but does not include it in all aspects of healthcare.[550] Most countries, however, have the third or tolerant type of healthcare system, where CAM is not officially recognized within the national healthcare system.

As proper safe use of CAM by consumers is influenced by local culture and primarily depends on the individual's knowledge and ability to minimize the risks and maximize the benefits of CAM, the CAM guidelines set up a consumer checklist to facilitate proper use of CAM.[551] Moreover, consumers need to be aware of the different levels of efficacy and the different legal status of medicinal products, which have a major impact on the safety, efficacy and quality of the products and treatment.[552]

Even though public consumer information on CAM cannot compensate for poor

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[548]*Ibid.* at x.
[549]Countries with an integrative health system: China, the Republic of Korea, and Vietnam.
[550]Countries with an inclusive health system: Canada, Germany, India, United States, Ukraine, etc.
[551]The checklist includes the following questions: Is the therapy suitable for treating the condition? Does the therapy have the potential to prevent and/or cure symptoms or in other ways contribute in other ways to improved health and wellbeing? Is the therapy or herbal medicines provided by a qualified CAM practitioner with an adequate training background, good skills, and knowledge? Are the herbal medicinal products or materials of assured quality? Are the therapies or herbal medicinal products available at a competitive price? *Op. cit.* 547 (*Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine*), at Art. 1.3.
[552]*Ibid.* (*Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine*), at Art. 4.4.1.

CAM products or inadequate CAM practices, it can arm consumers with knowledge about the potential risks or benefits of CAM. Thus, it is important that consumer information on CAM be provided in the form of a well-balanced message containing reliable, well-supported data that is adapted to the specific local context in respect of "cultural influence, health system structure, and utilization pattern".[553] Moreover, to develop adequate consumer information on CAM use, national authorities should take the local type of healthcare system into account.[554]

It is essential that national and/or local authorities take part in the development and dissemination of consumer information on CAM. To develop contextually appropriate CAM information, all levels of governance should collaborate and exchange ideas with local and foreigner manufacturers, suppliers, consumer organizations, and other stakeholders.[555] In order to reach as many CAM consumers as possible, consumer information has to be acceptable, understandable, and in plain and simple language. Education programs on CAM use may be included in school curricula.[556] It would be also useful to introduce pertinent regulations for CAM and

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[553]Each country has its own unique medical knowledge based on local, cultural, and past experience. As a result, domestic consumers often misuse imported CAM, when they apply their own medical concepts to it. To develop consumer information on suitable, local use of CAM, the national authority should take into consideration all aspects of domestic cultural particularities, including social, religious, and spiritual features. *Op. cit.* 547 (*Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine*), at Art. 2.1.

[554]As utilization patterns may vary not only between countries but also between different consumer groups within a country, the development of consumer information on CAM should be in accordance with a specific country's situation. There are three different types of utilization patterns. In countries where some population groups have limited access to conventional medicine (mostly among the poor populations of some developing countries), CAM may be the primary source of health care. The dual utilization pattern (including use of both conventional medicine and CAM) is mostly used in countries with an *integrative* healthcare system. Selective utilization is common in high-income countries with a tolerant type of healthcare system, where CAM is complementary to conventional medicine. *Op. cit.* 547 (*Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine*), at Art. 2.2 & 2.3.

[555]*Ibid.* (*Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine*), at Art. 3.1.

[556]As Guidelines suggest, the information developed on CAM national regulations, safety, benefits, adverse effect, etc., may be disseminated to consumers, the media, and healthcare providers through specially established CAM information centers. The media, which play a key role in informing the

put into place adequate surveillance systems.[557]

Information on CAM varies from country to country and depends on country-specific features. The national authorities have to decide what kind of information is more suitable for local circumstances. Nevertheless, the Guidelines list general topics that should be passed on to consumers.[558]

Although proper and safe use of CAM primarily depends on consumer knowledge, the guidelines specify other elements of the healthcare system which must be put in place to ensure safe use of CAM, notably: safety and quality control of herbal medicines,[559] development of legal frameworks for CAM, training and qualified practice for CAM practitioners, organization of CAM practitioners and CAM surveillance system.

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general public, should have access to truthful, balanced, and accurate information on CAM use. Different forms of media may target different objectives. For example, the mass media targets the broad audience and may raise consumer awareness about CAM, but may not always explore issues in depth. Conversely, print media may provide more in-depth information but reaches fewer consumers. Information on rational use of CAM may also be passed on to consumers through consumer organizations, workshops, seminars, the Internet, etc.

[557]To control the reliability and ethical content of information, to prevent false health claims and misleading advertisements, and to ensure appropriate labeling, adequate regulation must be introduced. To learn more about harmful adverse events, a CAM surveillance system must be put in place. Where possible, the national surveillance system for conventional medicines may be used. All adverse reactions on CAM have to be reported to appropriate regional/national centers or the authorities. (*Op. cit.* 547 (*Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine*), at Art. 3.2 & 3.3).

[558]The information should at least include: the importance of being an informed consumer; the need for all health providers to be aware of major therapies in use; the importance of ensuring the competence of CAM providers; and information on standard charges and possible health insurance coverage for CAM. Consumers also need to know where and how to find and identify reliable CAM information. In addition, the information on herbal medical therapies (herbal medicines) should include the following: therapeutic claims (supported by clinical and other relevant data); the quality of the product; information about product/active ingredients (when possible using both local and Latin names); recognition of quality standards (including GMP standards); storage instructions and expiry date; quality control of raw materials; precautions; and adverse effects and protocol in case of an adverse event. (*Op. cit.* 547 (*Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine*) at Art. 4.1 & 4.4).

[559] More on herbal medicine safety see 2.2.3.1.

In the absence of adequate regulations, some CAM practitioners may not adhere to adequate standards of clinical practice, with obvious implications for safety. One way to eliminate such concerns is to train, regulate and register all practitioners who employ CAM and encourage consumers to seek treatment from competent practitioners who provide high quality services. Preferably CAM practitioners should be educated in the general principles of conventional medicine in order to refer patients to conventional practitioners when appropriate.[560]

Adequate training and the licensing of CAM practitioners will improve safety, promote the credibility of CAM therapies and CAM providers, and enhance consumer trust in their practitioners.[561]

Efforts to strengthen the organization of CAM practitioners will ensure better structures for self-regulated control mechanisms. The development of a professional code of ethics can further contribute to consumer trust and safety.[562]

A surveillance system is essential in order to improve the safety of CAM therapies in general and to learn more about potential harmful adverse events and interactions following CAM use. National surveillance system for conventional medicines, adapted for collecting reports on CAM medication therapies, could be used for the reporting of suspected adverse cases.[563]

In conclusion, the guidelines provide simple, easy-to-follow tips on issues to look out

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[560]*Op. cit.* 547 (*Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine*) at Art. 4.6.
[561]*Op. cit.* 547 (*Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine*), at Art. 1.4 (c).
[562]*Op. cit.* 547 (*Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine*), at Art. 1.4 (f).
[563]*Op. cit.* 547 (*Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine*), at Art. 3.2.2.

for and guide governments, healthcare professionals, consumer organizations and other stakeholders on how to develop and disseminate consumer information on the proper use of traditional, complementary, and alternative medicine.

2.2.4 International carriage

During the past few decades, international travel has seen unprecedented growth, especially in the aviation and cruise industries. Before 1970, only a few could take a flight due to high tickets prices. Nowadays, new aeronautic technologies and low-cost business models have reduced airfare to a price of a taxi ride. In 2013 alone, the number of travelers who preferred plane to other means of transportation reached 3.1 billion. It is expected that more than 6.4 billion passengers will travel by air in 2030.[564]

Similar trends have been observed for the cruise industry. The time when most overseas passengers traveled by sea became history as soon as air travel turned into an affordable service for most consumers. Nevertheless, the industry reincarnated itself into a leisure model of traveling, where the journey is more important than the destination. In recent years, cruising has become ever more popular as, providing holiday options for any taste and wallet. In 2013 almost 21 million people took

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[564]ICAO, *2013 ICAO Air Transport Result Confirm Robust Passenger Demand, Sluggish Cargo Market*, (December 2013), online: ICAO <http://www.icao.int/Newsroom/News%20Doc%202013/COM.43.13.ECON-RESULTS.Final-2.en.pdf>.

nautical vacations.[565] The industry is expecting more than 25 million cruisers by 2020.[566]

As international travel has grown so have global concerns regarding passenger safety.

When booking airline tickets for business or leisure, or reserving a cruise vacation, consumers consider the price of fare, the class of services, the quality of food and drinks, the entertainment options, etc. The last thing that comes to their minds is to look up how safe is a particular air or cruise line. Consumers do believe that by default it is unconditionally safe. And indeed, safety has always been a paramount for aviation and cruise industry. So far, the safest means of transportation are plane and boat. In spite of the fact that a few air disasters occur annually,[567] statistically, there are more chances to get injured or have a deadly accident on our way to the airport or cruise terminal than when we are already on a plane or a boat.[568] And it does not really matter whether consumers embark on an aircraft or cruise liner in Montreal, Cape Town or Mumbai; the merit of safety is universal. This remarkable accomplishment has been achieved through interstate legal harmonization of safety

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[565]Worldwide, the cruise industry has an annual passenger compound annual growth rate of 6.55% from 1990 – 2019; from 3.7 million in 1990 to 25 million passengers by 2020. This growth have been driven by larger capacity new builds and ship diversification, more local ports, more destinations and new on-board/on-shore activities that match demands of consumers.

[566]*Growth of the Cruise Line Industry*, Cruise Market Watch, online: Cruise Market Watch <http://www.cruisemarketwatch.com/growth/>.

[567]As for cruise industry, except the Costa Concordia disaster, there no have been other major accidents at the high seas in recent years.

[568]In 2013, word wide, only 173 fatalities were reported in commercial scheduled air transport, and only a few passengers died cruising (mostly from natural cause or accidents not related to cruise ship safety). In comparison, almost 2000 people die every year on the road only in Canada alone. (ICAO, *Safety Report 2014*, at 5, online: ICAO, <http://www.icao.int/safety/Documents/ICAO_2014%20Safety%20Report_final_02042014_web.pdf> & *Cruise Ship Deaths: Passenger & Crew Cruise Ship Deaths* (2013), online: Cruise Ship Deaths <http://www.cruiseshipdeaths.com/Cruise_Ship_Deaths_2013.html> & *Canadian Motor Vehicle Traffic Collision Statistics 2012*, Transport Canada, 2014, at 3, online: Transport Canada <https://www.tc.gc.ca/media/documents/roadsafety/cmvtcs2012_eng.pdf>).

rules related to all aspect of operations, from boats and planes certification scheme to proper personal training.

Existing international legal instruments have played a decisive role in building universal safety culture to ensure sound travel by air and sea all around the globe.

First, air safety will be analyzed; then the legal framework regarding safety at sea will be put under scrutiny. The following legal instruments will be examined: the *Convention Relating to the Regulation of Aerial Navigation* (Paris, 1919); the *Convention on International Civil Aviation* (Chicago, 1944); *Convention for the Unification of Certain Rules Relating to International Carriage by Air* (Warsaw, 1929 and Montreal, 1999) *International Conventions for the Safety of Life at Sea* (SOLAS,) (1914, 1929, 1948, 1960, and 1974); *Convention Relating to the Carriage of Passengers and their Luggage by Sea* (Athens, 1974).

2.2.4.1 The Convention Relating to the Regulation of Aerial Navigation (Paris, 1919) and the Convention on International Civil Aviation (Chicago Convention 1944)

Flight is inherently a risky venture, carried out in a hostile environment at great speed. Clearly, if aviation need be free from any dangers or risks, it would not exist at all.[569] Nevertheless, billions of passengers take off safely into the sky every year.[570] The global air transport network is able to operate close to 100,000 daily flights, safely, efficiently and securely in every region of the world.[571] With only a few accidents on record world-wide, air traveling nowadays is safer than ever before.[572] In aviation, the notion of safety has been defined as "the state of freedom from unacceptable risk of injury to persons or damage to aircraft and property".[573] And the existing international aviation safety framework has aimed to reduce unacceptable risks to as few as possible.

Aviation safety is not only operational flight safety from a technical point of view.[574] It extends profoundly to many dimensions. From one side, serious threats to aviation

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[569]Jiefang Huang, *Aviation Safety and ICAO,* (The Netherlands: Kluwer Law International BV, 2009), at 4.

[570]Some 3.5 billion passengers used the global air transport network for their business and leisure needs in 2015. The annual passenger total is up approximately 6.4% compared to 2014 and is expected to reach over 6.4 billion by 2030, based on current projections. (ICAO, *Continuing Traffic Growth and Record Airline Profits Highlight 2015 Air Transport Results*, Montreal, (22 December 2015), online: ICAO <http://www.icao.int/Newsroom/Pages/Continuing-Traffic-Growth-and-Record-Airline-Profits-Highlight-2015-Air-Transport-Results.aspx>).

[571]ICAO, *About ICAO*, online: ICAO <http://www.icao.int/about-icao/Pages/default.aspx>.

[572]With an accident rate of 2.8 accidents per million departures, 2013 was the safest year on record since ICAO began tracking the global accident rate. (*Op. cit.* 568 (*Safety Report 2014*) at 8).

[573]ICAO, "Determination of a Definition of Aviation Safety", ICAO Working Paper AN-WP/7699 (11 December 2001) at 2.2.

[574]The technical aspects of the aviation safety include both: "hardware" (planes, navigation and airport equipment, fuel and etc.) and human factors (on board crew, traffic controllers, ground and technical maintenance personal and etc.).

safety[575] come from terrorism,[576] military conflicts,[577] passengers[578] and even crew.[579] From another side, the financial model of aviation safety should be sustainable to be easily implemented even by a state with limited financial resources.[580] Consequently, aviation safety requires a multidisciplinary approach: technical, economic, political, and, obviously, legal.[581]

Civil aviation is virtually international by its nature. Its optimal benefit could not be realized if it were confined to national boundaries. At the same time, its risks are also shared globally. While every State retains its sovereignty within its territory, it is unable to regulate the safety of international civil aviation without the cooperation of other States. Global risks have required concerted international action.[582]

Due to the global nature of aviation, civil aviation safety has been on the radar of the international community for nearly 100 years, beginning with the adoption in October 1919 in Paris of the *Convention relating to the Regulation of Aerial Navigation* (Paris

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[575]Safety also includes security. In accordance with International Civil Aviation Organization (ICAO) terminology, the former is related to the operational safety of aircraft, including personnel licensing and airworthiness, whereas the latter means "safeguarding civil aviation against acts of unlawful interference". (Annex 17 to the *Chicago Convention*, 8th ed., April 2006) In this work aviation security will not be scrutinized.

[576]Passenger planes have always been desirable targets for terrorists; and the tragic event of 11 September 2001 was one of the worst attacks on civil aviation.

[577]For example, Malaysia Airlines Flight 17 with 283 passengers and 15 crewmembers crashed on 17 July 2014 after being shot down over the conflict zone in eastern Ukraine.

[578]Passenger actions in midair might threaten safety of the flight. For instance, in November 2014, a passenger on a Vietnam Airlines plane tried to open the emergency exit during the flight. ("Vietnam Airlines Mid-Air Scare: New Zealander Mark Ansley "Never Thought Twice" about Restraining Man Trying to Open Exit Door on Flight to Sydney", *ABC News*, (6 November 2014), online: ABC News <http://www.abc.net.au/news/2014-11-06/nz-man-restrained-by-passengers-for-trying-to-open-exit-door/5871750>).

[579]On 24 March 2015, Germanwings Flight 9525 co-pilot locked the captain out of the cockpit and intentionally crashed the plane with 144 passengers and six crewmembers.

[580]A particular safety standard is very attractive from a technical point of view, but it may not be cost-effective or may even be economically prohibitive to implement even for developed states. In that case, a careful policy judgment is needed to determine what standard should be imposed.

[581]*Op. cit.* 569 (Jiefang Huang), at 4.

[582]*Op. cit.* 569 (Jiefang Huang), at 6.

Convention).[583] This treaty represented the first successful multilateral endeavour to set up a global regulatory regime for aviation.[584]

The Paris Convention established an international legal framework to ensure the safety of international civil aviation through the following provisions: a) common rules for aircraft registration in order to determine its nationality and the related jurisdiction of the state of registration (Chapter 2); b) regulations for certificates of airworthiness of civil aircraft and mutual recognition of such certificates by contracting states (Chapter 3); c) international rules of the air, including international rules for signals, lights and the prevention of collisions, as well as the undertaking by states to enforce them (Article 24); and d) application to aircraft of the principles of maritime law governing salvage (Article 23).[585] Nevertheless, the Convention made no attempt to develop uniform technical safety standards, nor did it contain any provisions for the creation of an international body exclusively responsible for aviation safety. Consequently, every state developed its own regulatory blueprint on aviation technical safety.[586]

It is important to notice that the Paris Convention did establish a permanent body with its headquarters and secretariat in Paris, the International Commission for Air Navigation (ICAN) which comprised representatives of states parties to the Convention. Its mandate was to oversee, implement and modify the Paris Convention. Officially ICAN did not affiliate with the League of Nations. Nevertheless, the members of the League backed ICAN efforts. Over the years, the Commission

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[583]Originally, 27 nations were parties of the convention. (*The Convention Relating to the Regulation of Aerial Navigation Signed at Paris, October 13, 1919*, online: Space Law <http://www.spacelaw.olemiss.edu/library/aviation/IntAgr/multilateral/1919_Paris_conevention.pdf>).

[584]*Op. cit.* 569 (Jiefang Huang), at 8.

[585]Other subjects relating to aviation safety, such as aeronautical maps and ground markings, logbooks, as well as collection and dissemination of meteorological information, were also covered.

[586]Certain steps toward aviation safety were also done in the Americas. *Pan American Convention on Commercial Aviation Adopted at Havana on 20 February 1928* clarified basic principles and rules for aerial traffic. It was ratified by 11 states: Chile, Costa-Rica, Dominican Republic, Ecuador, Guatemala, Haiti, Honduras, Mexico, Nicaragua, Panama, and United States. (David McClean *et al, Shawcross and Beaumont on Air Law* (London: LexisNexis Butterworths, 2014) at 689).

convened or sponsored many conferences and meetings relating to the safety of air navigation.[587]

Two features weakened the Paris Convention. First, the document did not have a mechanism allowing modifications to update constantly changing rules and standards. Second, the treaty never received universal acceptance. Only 32 states eventually ratified or acceded to the Convention. In particular, two major powers, the United States and the Soviet Union, never became parties. Furthermore, regional agreements undermined the authority of the Paris Treaty. [588]

In spite of its shortcomings, the significance of the Paris Convention for aviation safety should not be underestimated. The basic principles for aviation safety laid down in the treaty were used years later as a foundation for a new treaty on civil aviation – the Chicago Convention. With some modifications, Paris principles of safety are still in use.[589]

The *Convention on International Civil Aviation*, also known as the Chicago Convention,[590] was signed at Chicago on 7 December 1944 and came into force on 4 April 1947.[591] The document establishes certain principles and arrangements in order that international civil aviation may be developed in a safe and orderly manner and

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[587]*Op. cit.* 569 (Jiefang Huang), at 8 & 9 & David MacKenzie, *ICAO: A History of the International Civil Aviation Organization*, (University of Toronto Press, 2010), at 15.
[588]*The Ibero-American Convention Relating to Air Navigation*, (Madrid, 1926) & *the Pan-American Convention on Commercial Aviation* (Habana, 1928). *Op. cit.* 569 (Jiefang Huang), at 9 & 10.
[589]*Op. cit.* 569 (Jiefang Huang), at 8 &9.
[590]ICAO, *Convention on International Civil Aviation*, online: ICAO <http://www.icao.int/publications/Documents/7300_cons.pdf>.
[591]Chicago became one of the largest international conferences to that time with 955 delegates, advisers and members of the conference secretariat. Originally, the Convention had 52 signatory states. It received the requisite 26th ratification on March 5, 1947 and went into effect on April 4, 1947. The same date International Civil Aviation Organization (ICAO) was inaugurated. (For detail history of the Chicago Convention and ICAO see David MacKenzie, *ICAO: A History of the International Civil Aviation Organization*, University of Toronto Press Incorporated, Toronto, 2010).

that international air transport services may be established on the basis of equality of opportunity and operated soundly and economically.[592]

The Agreement did not inherit the drawbacks of its predecessor. From the start, the Convention has been a truly universal treaty. The majority of states, including the US and the USSR, did participate in the Chicago conference and shorty after became parties to the Convention. Today, 191 States have ratified of the Convention.[593] Moreover, the document received needed flexibility through a system of Annexes. Necessary updates have not required making changes to the text of the Treaty itself.

Yet, the most significant outcome of the Convention was the setting-up of an international body exclusively responsible for aviation safety, namely the International Civil Aviation Organization (ICAO).[594] The aims and objectives of the ICAO are to develop the principles and techniques of international air navigation and to foster the planning and development of international air transport. Regarding safety, the mandate of the Organization includes the following measures: a) insure the safe and orderly growth of international civil aviation throughout the world; b) encourage the arts of aircraft design and operation for peaceful purposes; c) encourage the development of airways, airports, and air navigation facilities for International civil aviation; d) meet the needs of the peoples of the world for safe, regular, efficient and economical air transport; e) promote safety of flight in international air navigation; f) promote generally the development of all aspects of international civil aeronautics.[595] The institutional structures of ICAO include a plenary body, the Assembly; a permanent body responsible to the Assembly, the

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[592]*Op. cit.* 590 (*Convention on International Civil Aviation*), at Preamble.
[593]Cook Islands as well as all United Nations members, except for Liechtenstein, Dominica and Tuvalu are party of the Convention (ICAO, *Signatories to the Convention*, online: ICAO <http://www.icao.int/secretariat/legal/List%20of%20Parties/Chicago_EN.pdf>).
[594]Article 43.
[595]Article 44.

Council; and the Secretariat headed by the Chief Executive Officer of the Organization, the Secretary General.[596]

The passenger's safety[597] has been the primary goal of the Convention since inception.[598] Consequently, ICAO has endorsed safety through legal harmonization. International Standards and Recommended Practices (SARPs) are the primary mechanisms used by ICAO for this purpose.[599] They cover all technical and organizational aspects of aviation.[600] Typically, SARPs are drafted by ICAO's Air Navigational Commission, based on research and analysis conducted by one of its subcommittees or subgroups responsible for the issue in question. Some standards are accompanied by Procedures for Air Navigation Services (PANSs), which are highly

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[596]Articles 48, 50 & 54 h). For more details of ICAO's structures and their functions see *Op. cit.* 569 (Jiefang Huang), at 17.

[597]Beside the technical safety portion, the convention also prohibits the use of weapons against civil aircraft in flight: "Every State must refrain from resorting to the use of weapons against civil aircraft in flight and that, in case of interception, the lives of persons on board and the safety of aircraft must not be endangered." (Article 3 bis). Nevertheless, only technical aspects of aviation safety will be review in the scope of this work.

[598]In spite of efforts to include provision on comprehensive economic policy for international civil aviation into original draft of the Treaty, the economic agenda has never become a part of the Chicago Convention. Consequently, ICAO has never become an international economic regulatory body. (*Op. cit.* 569 (Jiefang Huang), at 16. & Aslo Andras Vamos-Goldman, *The Stagnation of Economic Regulation Under Public International Air Law: Examining Its Contribution to the Woeful State of the Airline Industry*, 23 TRANSP.L.J 425, 431 (1996)).

[599]A standard is defined as "any specification for physical characteristics, configuration, material, performance, personnel or procedure, the uniform application of which is recognized as necessary for the safety or regularity of international air navigation and to which contracting states will conform in accordance with the Convention", whereas A recommended practice is defined as "any specification for physical characteristics, configuration, material, performance, personnel or procedure, the uniform application of which is recognized as desirable in the interest of safety, regularity or efficiency of international air navigation and to which contracting states will endeavour to conform in accordance with the Convention". (ICAO, *Resolution A36-13: Consolidated Statement of ICAO Policies and Associated Practices Related Specifically to Air Navigation*, (Doc. 9902), at II-3, online: ICAO <http://www.icao.int/publications/Documents/9902_en.pdf>).

[600]Article 37 of the Chicago Convention calls for inter state collaboration in dealing with: a) communications systems and air navigation aids, including ground marking; b) characteristics of airports and landing areas; c) rules of the air and air traffic control practices; d) licensing of operating and mechanical personnel; e) airworthiness of aircraft; f) registration and identification of aircraft; g) collection and exchange of meteorological information; h) logbooks; i) aeronautical maps and charts; j) customs and immigration procedures; k) aircraft in distress and investigation of accidents; and such other matters concerned with the safety, regularity, and efficiency of air navigation as may from time to time appear appropriate.

detailed instructions for particular technical SARPs.[601] Drafts of SARPs are then submitted to the ICAO Council for adoption. SARPs supported by two-thirds of the Council members are added to the appropriate Annex.[602] There are currently over 10,000 SARPs reflected in the 19 Annexes to the Chicago Convention.[603] The SARPs are constantly reviewed and amended to keep pace with advanced technology and organizational developments.[604] By joining ICAO, States agree to collaborate in order to achieve the highest practicable degree of uniformity in regulations, standards, procedures and organization in relation to aircraft, personnel, airways and auxiliary services in all matters in which such uniformity will facilitate and improve air navigation.[605]

The key policy considerations, which underlie the legislative process within ICAO in the formulation of SARPs, are uniformity, reliability and affordability. Definitely, the uniformity of international standards is the most important criteria governing the ICAO legislative process.[606] Under the Chicago Convention, each contracting State undertakes to keep its own regulations in these respects uniform, to the greatest possible extent, with those established under the Treaty.[607]

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[601]In addition to SARPs and PANSs, ICAO also elaborates Regional Supplemental Procedures (SUPPS), regional air navigation plans, and related manuals, circulars and guidance.
[602]Brian F. Havel, Gabriel S. Sanchez, *The Principles and Practice of International Aviation Law*, (Cambridge University Press, 2014), at 178.
[603]So far, 19 Annexes have been adopted, namely: Annex 1 – Personnel Licensing (Licensing of flight crews, air traffic controllers & aircraft maintenance personnel); Annex 2 – Rules of the Air; Annex 3 – Meteorological Service for International Air Navigation; Annex 4 – Aeronautical Charts; Annex 5 – Units of Measurement to be used in Air and Ground Operations; Annex 6 – Operation of Aircraft; Annex 7 – Aircraft Nationality and Registration Marks; Annex 8 – Airworthiness of Aircraft; Annex 9 – Facilitation; Annex 10 – Aeronautical Telecommunications; Annex 11 – Air Traffic Services – Air Traffic Control Service, Flight Information Service and Alerting Service; Annex 12 – Search and Rescue; Annex 13 – Aircraft Accident and Incident Investigation; Annex 14 – Aerodromes; Annex 15 – Aeronautical Information Services; Annex 16 – Environmental Protection; Annex 17 – Security: Safeguarding International Civil Aviation Against Acts of Unlawful Interference; Annex 18 – The Safe Transport of Dangerous Goods by Air; Annex 19 – Safety Management (Added in November 2013).
[604]ICAO, *About ICAO*, online: ICAO <http://www.icao.int/about-icao/Pages/default.aspx>.
[605]Chicago Convention Art. 37.
[606]*Op. cit.* 569 (Jiefang Huang), at 50.
[607]Chicago Convention Art. 12.

It is also important to emphasize that Article 38 of the Chicago Convention allows the contracting party to retain a certain degree of flexibility in complying with the norms imposed by the Agreement. SARPs become applicable to all member States, unless they notify ICAO that they could not comply with them. Hence, the State has right to refrain from implementing certain SARPs as long as it duly notifies the ICAO within sixty days from the adoption of the amendment to the international standard. The Notification sent by the contracting party regarding discrepancies between SARPs and national regulations and practices is published in the form of Supplements to Annexes.

To ensure that states fulfill their obligations under the Convention, mechanisms for compliance and enforcement have been put in place. Under ICAO auspices, the Universal Safety Oversight Audit Program (USOAP) has been established. ICAO defines Safety Oversight as a function by means of which states ensure effective implementation of the safety-related SARPs and associated procedures contained in the Annexes to the Convention and related ICAO documents. Safety Oversight also ensures that the national aviation industry provides a safety level equal to, or better than, that defined by the SARPs.[608]

The USOAP was created as a response to the alarming situation in 90th, when many developing countries did not have adequate expertise fully to appreciate the contents of the Annexes, let alone the capacity to determine whether there were differences to be filed with ICAO. Consequently, there was no reliable information concerning the implementation of the standards.[609]

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[608]ICAO, *Doc 9734, AN/959, 2nd ed. (2006): Safety Oversight Manual, (Part A): The Establishment and Management of a State's Safety Oversight System*, at 2-1, online: ICAO <http://www.icao.int/WACAF/AFIRAN08_Doc/9734_parta_cons_en.pdf>.

[609]More on USOAP development see *Op. cit.* 569 (Jiefang Huang), at 69 to 71 & *Op. cit.* 602 (Brian F. Havel, Gabriel S. Sanchez), at 180&181.

The USOAP was launched in January 1999 with the objective of promoting global aviation safety through the auditing of ICAO Member States on a regular basis to determine the status of states' establishment of safety oversight measures and resources, as well as relevant ICAO SARPs, associated procedures, guidance material and safety-related practices.[610] The USOAP was expanded in 2005 to cover provisions contained in all safety-related Annexes to the Chicago Convention. Core areas audited by the USOAP are: primary aviation legislation and civil aviation regulations; civil aviation organization; personnel licensing and training; aircraft operations; airworthiness of aircraft; aircraft accident and incident investigation; air navigation services; and aerodromes and ground aids.[611] The Effective Implementation (EI) of each Audit Area is rated from 0% to 100%, with 0% being "Not Implemented" and 100% being "Fully Implemented". The EI score represents the percentage of satisfactory USOAP protocol questions applicable for a given state.[612]

In 2011, the USOAP evolved from periodic audits to a new approach based on the concept of Continuous Monitoring Approach. Under this new approach, cyclical audits are being supplemented with an ongoing process of gathering safety information. This systematic and more proactive risk based approach to the conduct of monitoring activities provides ICAO with the ability to ensure that information on the safety performance of Member States is provided to other Member States and to the travelling public on an ongoing basis.[613]

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[610]The U.S. and EU programs served as the blueprints for ICAO USOAP.
[611]ICAO, *Universal Safety Oversight Audit Programme*, online: ICAO <http://cfapp.icao.int/tools/38thAssyiKit/story_content/external_files/Flyer_US-Letter_ANB-USOAP_2013-08-30.pdff>.
[612]ICAO, *Safety Audit Information*, online: ICAO < http://www.icao.int/safety/Pages/USOAP-Results.aspx>.
[613]More information on USOAP Continuous Monitoring Approach see: ICAO, *USOAP Continuous Monitoring Approach*, online: ICAO <http://www.icao.int/safety/CMAForum/Pages/default.aspx>; Also on ICAO audit procedures see *Op. cit.* 569 (Jiefang Huang), at 70&71.

During the course of an audit, ICAO may identify what is referred to as a Significant Safety Concern (SSC) with respect to the ability of the audited state to properly oversee its airlines (air operators); airports; aircraft; and/or air navigation services provider under its jurisdiction.[614] SSC does not necessarily indicate a particular safety deficiency but, rather, indicates that the state is not providing sufficient safety oversight to ensure the effective implementation of all applicable ICAO Standards.[615]

It is important to emphasize that ICAO has never operated as a police to impose international regulation upon contracting parties. Since its foundation, ICAO's agenda has not been to punish the state for not fulfilling its obligations under the Convention, but rather to provide technical expertise and financial aid to assist the state in the compliance process.[616] ICAO enhances interstate technical and financial collaboration on aviation safety.[617]

As for SARPs enforcement, ICAO does not have a mandate to sanction the state in case of non-conformity. Nevertheless, nothing prevents other Member States from using reports on observance ICAO safety benchmarks to take actions against the state for non-compliance.

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[614]The Council approved a mechanism for the sharing of unresolved SSCs with the public: SSCs have been available on the ICAO public website since January 2014; for new SSCs identified after January 2014, there be a period of 90 days between the time an SSC is posted on the secure site for Member States and the time it is posted on the ICAO public website, in order to give an extra incentive to States to resolve the SSC quickly and to allow a window for assistance activities. (ICAO, *The Council Decision C-DEC 197/4*).

[615]*Op. cit.* 612 (*Safety Audit Information*) & ICAO, *CMA Forum (FAQ)*, online: ICAO <http://www.icao.int/safety/CMAForum/Pages/FAQ.aspx>.

[616]*Op. cit.* 602 (Brian F. Havel, Gabriel S. Sanchez), at 179.

[617]Through the ICAO Technical Cooperation Bureau, Canada participates in the ICAO Co-operative Development of Operation Safety and Continuing Airworthiness Programs (COSCAP) as a financial and in-kind contributor, with its latest efforts focused on North Asia and South East Asia. Since 2005, Transport Canada Civil Aviation (TCCA) has contributed more than 1 million USD to this program. Similarly, the U.S. Trade and Development Agency (USTDA) has entered into bilateral agreements with China, India and Brazil for technical cooperation in the aviation sector, supporting airport expansion, airspace management and safety. (More on Canada international safety programs and USTDA initiatives see: ICAO, *Safety Report 2014*, at 17 to 19 online: ICAO <http://www.icao.int/safety/Documents/ICAO_2014%20Safety%20Report_final_02042014_web.pdf>).

To address foreign air transportation safety concerns, in 1992, the U.S. Federal Aviation Administration (FAA) established the International Aviation Safety Assessment (IASA) program with the purpose of ensuring that all foreign air carriers operating to or from the U.S., or code-sharing with a U.S. carrier, comply with ICAO safety standards. IASA assessments determine compliance with these international standards by focusing on each Critical Element (CE)[618] of an effective aviation safety oversight authority specified in ICAO Safety Oversight Manual.[619]

The IASA Program is conducted under the provisions of Article 6 of the Chicago Convention (Scheduled Air Services), which states "no scheduled international air service may be operated over international or into the territory of a contracting state, except with the special permission or other authorization of that state, and in accordance with the terms of such permission or authorization." Before granting such permission, either party has the right to "request consultations concerning the safety standards maintained by the other party relating to aircrews, aircraft, and operation of airlines of that party."

The U.S. Government maintains and publishes a country-by-country summary listing of the results of its IASA determinations. Countries are listed as either Category 1 - the FAA has found that the country meets ICAO standards for safety oversight of civil aviation, or Category 2 - the FAA has found that the country does not meet those standards. Carriers from Category 1 countries are permitted to operate into the U.S. and/or codeshare with U.S. air carriers in accordance with Department of Transportation (DOT) authorizations. Carriers from Category 2 countries that operate

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[618]These eight critical elements include: (CE-1) Primary aviation legislation; (CE-2) Specific operating regulations; (CE-3) State civil aviation system and safety oversight functions; (CE-4) Technical personnel qualification and training; (CE-5) Technical guidance, tools and the provision of safety critical information; (CE-6) Licensing, certification, authorization, and approval obligations; (CE-7) Surveillance obligations; and (CE-8) Resolution of safety concerns.

[619]*Op. cit.* 608 (*Doc 9734, AN/959, 2nd ed. (2006): Safety Oversight Manual, (Part A): The Establishment and Management of a State's Safety Oversight System*).

into the U.S. and/or codeshare with U.S. air carriers have such services limited to levels that existed at the time of the assessment; or carriers from Category 2 countries that seek to initiate commercial service into the U.S. and/or seek to codeshare with any U.S. air carrier are prohibited from initiating such services.[620] In April 2015, 99 entities were listed of which eight states received a Category 2 rating: Bangladesh, Barbados, Curacao, Ghana, Indonesia, Nicaragua, Sint Maarten, and Uruguay.[621]

Similarly, since 2006 the EU has published a list of carriers banned from access to EU airspace. The list is based on data gathered from ICAO's audits.[622] The list is available to the public and constantly updated. As of June 2016, more than 200 airlines have been banned from operating flights into the EU.[623]

Finally, to ensure continuous safety improvement, since 2007 ICAO has developed a strategic approach that measures progress in the area of safety. The Global Aviation Safety Plan (GASP) specifically establishes targeted safety objectives and initiatives while ensuring the efficient and effective coordination of complementary safety activities among all stakeholders. The timetable for the implementation of ICAO's GASP objectives sets out target dates over the next 15 years applicable to the global aviation community as a whole. There are three target date objectives: Near-Term (by 2017) Implementation of an effective safety oversight system; Mid-Term (by 2022) Full implementation of the ICAO state safety program framework; and Long-Term

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[620]More on IASA Program see *International Aviation Safety Assessment Program*, FAA online: FAA <http://www.faa.gov/about/initiatives/iasa/media/FAA_Initiatives_IASA.pdf>.
[621]*Flight Standard Service: International Aviation Safety Assessment Program*, FAA, online: FAA <http://www.faa.gov/about/initiatives/iasa/media/IASAWS.xlsx>.
[622]EC, *Regulation 2111/2005 of the European Parliament and of the Council of 14 December 2005 on the Establishment of a Community List of Air Carriers Subject to an Operating Ban within the Community and on Informing Air Transport Passengers of the Identity of the Operating Air Carrier, and Repealing Article 9 of Directive 2004/36/EC*, OJ L 344, 27.12.2005, p. 15–22, at Annex, online: Eur-Lex < http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32005R2111>.
[623]EC, *EU Air Safety List*, online: EC <http://ec.europa.eu/transport/modes/air/safety/air-ban/doc/list_en.pdf>.

(by 2027) Advanced safety oversight system including predictive risk management.[624]

2.2.4.2 Convention for the Unification of Certain Rules Relating to International Carriage by Air (Warsaw, 1929 and Montreal, 1999)

The analysis of international instruments on aviation safety would not be complete without a brief examination of an important convention in the sphere of private international air law, namely, the *Convention for the Unification of Certain Rules Relating to International Carriage by Air*, concluded in Warsaw on 12 October 1929 (Warsaw Convention).[625] The Document was amended or modernized in 1955 and 1971. The most recent attempt to modernize the Convention resulted in the conclusion of a convention bearing the same title, signed in Montreal on 28 May 1999, which came into force on 4 November 2003.

It is a unique document in many ways. First, this international convention with binding nature was the first to admit that consumers' interests had to be protected, long before the international community had recognized consumer rights. Second, some provisions of the convention address the protection of the economic interests of the consumer, subjects that rarely found in international sources of consumer

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[624]ICAO, *Global Aviation Safety Plan, 2014-2016*, (Doc.10004), at 4, online: ICAO <http://www.icao.int/NACC/Documents/Meetings/2014/SSPSMSANT/GASP.pdf>. More on the Global Aviation Safety Plan see ICAO, GASP <http://www.icao.int/safety/SafetyManagement/Pages/GASP.aspx>.

[625]*Convention for the Unification of Certain Rules Relating to International Carriage by Air, Signed at Warsaw on 12 October 1929,* (Warsaw Convention), online: McGill <https://www.mcgill.ca/iasl/files/iasl/warsaw1929.pdf>.

protection law. Finally it enhances passengers' safety by presuming automatically airline fault in the case of an accident causing death or injury to a passenger and by imposing burdensome monetary obligations.

The Warsaw Convention primarily deals with the contractual liability of air carriers. The carrier is liable for damages sustained in the event of death or any injury suffered by a passenger if the damage is caused by an accident that takes place on board the aircraft or while embarking/disembarking (Art.17). The liability of the carrier for each passenger is limited to the sum of 125,000 francs (approximately US$10,000),[626] if the carrier and the passenger do not agree to a higher limit of liability. Any provision tending to relieve the carrier of liability or to fix a lower limit shall be null and void (Art. 23). The carrier is, however, not liable in two cases: if the carrier proves that it and its agents have taken all necessary measures to avoid the damage (Art. 20), and if the carrier proves that the damage was caused by or contributed to by the negligence of the injured person (Art. 21).

The Warsaw Convention was modified by the *Hague Protocol 1955*, which doubles the liability of the carrier for each passenger to the sum of 250,000 francs (approximately US$20,000).[627]

During the 1970s, the international community undertook some efforts to further amend the Warsaw Convention. The *Guatemala Protocol* in 1971 introduced some new provisions on airline liability for passenger claims that were later integrated into

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[626]The sums mentioned above shall be deemed to refer to the French franc consisting of ≤ 65 milligrams of gold of millesimal fineness 900. These sums may be converted into any national currency in round figures.

[627]*Protocol to Amend the Convention for the Unification of Certain Rules Relating to International Carriage by Air, Signed at Warsaw on 12 October 1929, Done at The Hague on 28 September 1955* (the Hague Protocol 1955), art. XI, online: McGill <https://www.mcgill.ca/iasl/files/iasl/hague1955.pdf>.

the *Montreal Protocol 3* (1975). However, neither instrument has come into force.[628]

The large-scale development of air transport and use thereof by consumers during 80-90th called for further amendments to the Warsaw Convention. A revolutionary step in the evolution of rules of international carriage by air has become the transformation of the Warsaw Convention into the *Convention for the Unification of Certain Rules for International Carriage by Air,*[629] signed at Montreal on 28 May 1999 (Montreal Convention).[630]

The convention recognizes the importance of ensuring protection of the interests of consumers in international carriage by air and the need for equitable compensation based on the principle of restitution.[631]

While maintaining the core provisions of the Warsaw Convention, the Montreal Convention modified and clarified certain stipulations, in particular regarding the liability of the carrier. The most significant change was the introduction of a two-tier regime in relation to the air carrier's liability for death and injury to passengers. Under the first tier, the carrier is not allowed to exclude or limit its minimum liability, i.e., the carrier is strictly liable for claims up to that limit. The convention increased the minimum limit carrier liability to the sum of 100,000 Special Drawing Rights (SDR)[632] for each passenger in case of death or injury of passengers.[633] Under the

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[628]A certain degree of success was achieved in modernizing the provisions related to the air-cargo industry in 1998, when the Montreal Protocol 4, signed in 1975, finally came into force.

[629]*Convention for the Unification of Certain Rules for International Carriage by Air Signed at Montreal on 28 May 1999*, (Montreal Convention), online: Lex Mercatoria <http://www.jus.uio.no/lm/air.carriage.unification.convention.montreal.1999/>.

[630]This international treaty was adopted by a diplomatic meeting of ICAO member states in 1999. The convention took effect and replaced the Warsaw Convention on 28 June 2004, after 30 parties had ratified it.

[631]*Op. cit.* 629 (*Convention for the Unification of Certain Rules for International Carriage by Air Signed at Montreal on 28 May* 1999), at Preamble.

[632]Approximately US$151,000; Special Drawing Rights (SDR) is an international reserve asset, created by the International Monetary Fund (IMF) in 1969 to supplement the existing official reserves

second tier, the carrier's liability for damages above the 100,000 SDR level is unlimited unless it can prove either that such damage was not due to its negligence or other wrongful act or omission or that it was solely due to the negligence or other wrongful act or omission of a third party.[634]

In addition, a court may award the plaintiff, in accordance with national law, partial or whole legal expenses.[635] The convention has introduced a completely new provision regarding advance payments that the carrier shall make without delay in the case of an aircraft accident resulting in death or injury of passengers to meet the immediate economic needs of the passenger or his/her family. However, such payments shall only be made if required by national law.[636]

The Convention has also set new stipulations regarding jurisdiction, providing easier access to justice for passengers or family in case of damage resulting from death or injury. In accordance with Article 33, an action may be brought either before the court of the domicile of the carrier or of its principal place of business, or where it has a place of business through which the contract has been made or before the court at the place of destination and even in the country in which at the time of the accident the passenger has principal and permanent residence. An action can be taken against both the actual carrier (who performs the carriage) and the contracting carrier (who only executes a contract of carriage).[637]

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of member countries. The SDR also serves as the unit of account of the IMF and some other international organizations. Its value is based on a basket of key international currencies. In September 2016, 1SDR = 1.37 USD. For more on SDR, see online: IMF <http://www.imf.org/external/>.

[633] *Op. cit.* 629 (*Convention for the Unification of Certain Rules for International Carriage by Air Signed at Montreal on 28 May* 1999), at art. 21.1.

[634] *Ibid.* at Art. 21.2.

[635] *Ibid.* at Art. 22.

[636] *Ibid.* at Art. 28.

[637] *Ibid.* at Art. 45.

To date, 121 States and the EU are parties to the Convention.[638] While the primary focus has so far been on the Convention's limits on liability, its historic contribution to the promotion of aviation safety should not be ignored. By imposing a presumption of fault on the carrier in the case of an accident causing death or injury to a passenger, the Convention has placed a heavy responsibility on the carrier to do its utmost to protect the safety of the passengers. Since the pilots and engineers have to testify before the court that they have taken all necessary measures to prevent the accident, this will lead them to exercise more care in their work and to discover and cure mechanical defects and human errors. Consequently, the safety record of the carrier will be improved.[639]

In conclusion, nowadays air travel has become a routine activity for millions around the world. More and more people prefer air travel to other means of transportation because it is the fastest and safest way to get to a destination. One of the key elements in maintaining the existing vitality of civil aviation is safe operation on all levels. Despite the fact that scheduled passenger traffic has significantly increased over the years, accident-related statistics indicate a reduction in the number of accidents as well as the accident rate.[640] Such remarkable success has been achieved through worldwide approximation of the aviation safety rules.

The international nature of civil aviation has called for international action on safety matters for nearly 100 years. The global approach to the safety in the sky was introduced back in 1919 and reconfirmed again in 1944. Today, the uniform international rules on aviation safety, laid down in the Chicago Convention, have become important as ever, considering that international passenger traffic has dramatically multiplied since the adoption of the Treaty.

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[638] *Op. cit.* 629 (*Convention for the Unification of Certain Rules for International Carriage by Air Signed at Montreal on 28 May* 1999), at *Parties*.
[639] *Op. cit.* 569 (Jiefang Huang), at 10.
[640] *Op. cit.* 617 (*Safety Report* 2014), at 5.

The pivotal principles of global air safety have been developed and harmonized under the watchful eye of ICAO. This specialized agency of the United Nations, exclusively responsible for aviation safety, is the universal policymaking body on behalf of 191 Member States. Improving the safety of the global air transport system is ICAO's guiding and most fundamental strategic objective.[641] Ultimately, through continuous modernization of safety standards and technical assistance to Member States, ICAO possesses indispensable institutional mechanisms to fulfill the aims and objectives of the Chicago Convention, making air traveling safer than ever.

Lastly, data on unresolved Significant Safety Concerns have been made available to the public on the ICAO website since January 2014.[642] Therefore, before booking a flight anyone can obtain information on how a particular Member State has implemented ICAO's postulates on safety.

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[641] *Ibid.* at 2.
[642] *Op. cit.* 612 (*Safety Audit Information*).

2.2.4.3 International Conventions for the Safety of Life at Sea (SOLAS) (1914, 1929, 1948, 1960 and 1974)

The time when most long-distance international travel was accomplished by ship is long over,[643] since air traveling has become widely accessible to the general public. Nevertheless, the problem of maritime passenger protection remains current, as in recent years the cruise industry has showed an unprecedented rate of growth. In 2011, the passenger-carrying component of the world fleet totalled 4,131 ships, a combined gross tonnage of 34.8 million.[644] Of this total tonnage, 47 per cent[645] was comprised of cruise ships.[646] The U.S. alone has reported 3,500% growth in this sector over the

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[643]The late 19th and early 20th centuries represented the golden age of passenger travel by sea. Air traveling did now exist or was unaffordable for most people. Emigrants from Europe to the Americas were traveling by boats on a massive scale. Passenger ships were therefore much more common than they are today and accidents frequently led to heavy casualties. The annual loss of lifes from British ships alone averaged between 700 and 800 during this period. (*SOLAS - The International Convention for the safety of life at sea*, online: Metal Safe Sign <http://www.mss-int.com/solas.html>).

[644]Only passenger ships of over 300 Gross Tonnage (GT). (Gross tonnage, was defined by the *International Convention on Tonnage Measurement of Ships*, 1969, adopted by the International Maritime Organization in 1969, and came into force on July 18, 1982. The provision of the Convention were subsequently converted into national laws; for instance, the Canadian regulation Standard for the Tonnage Measurement of Vessels - TP 13430 E. Gross tonnage is calculated based on the moulded volume of all enclosed spaces of the ship and is used to determine ship's manning regulations, safety rules, registration fees, and port dues. (IMO, the *International Convention on Tonnage Measurement of Ships*, 1969, online: Admiralty Law Guide <http://www.admiraltylawguide.com/conven/tonnage1969.html>; *Standard for the Tonnage Measurement of Vessels* (TP 13430 E), Transport Canada, online: Transport Canada <https://www.tc.gc.ca/eng/marinesafety/tp-tp13430-menu-332.htm>).

[645]Nigel S. Greenwood, *Passenger ship safety since 1912*, BC Shipping News, (February 2013), online: BC Shipping News <http://www.bcshippingnews.com/magazine/feature-article/passenger-ship-safety-1912-nigel-s-greenwood>.

[646]All passenger ships roughly could be divided into ocean going ships (cruise ships) and ships operating "short international voyage", such as ferries or ships on cabotage routes. In this work only international safety rules for ocean going ships or cruise ships will be scrutinized. International law defines "short international voyage" as an international voyage in the course of which a ship is not more than 200 miles from a port or place in which the passengers and crew could be placed in safety, and which does not exceed 600 miles in length between the last port of call in the country in which the voyage begins and the final port of destination. (UN, *International Convention for the Safety of Life at Sea*, 1974, at PART A (Regulation 2(a)), online: <https://treaties.un.org/doc/Publication/UNTS/Volume%201184/volume-1184-I-18961-English.pdf>).

last 45 years, with 17.6 million passengers having taken a cruise vacation in 2013[647] versus only 500,000 in 1970.[648] In 2014, annualized total passengers carried worldwide were 22.2 million.[649] Capacity of the cruise industry alone in 2015 is estimated to be over 486,000 berths in 298 ships.[650] With new mega-ships on order[651] this is expected to increase for a projected total annual cruise capacity of over 25 million in 2019.[652]

New passenger ships are significantly larger than a century ago. In April 1912, the White Star liner Titanic carried 2,228 souls on her maiden voyage, whereas, the latest floating-cities like Oasis of the Seas carries up to 8,700 persons.[653] Due to the new holiday business model, the demographics of the passengers have changed as well. Previously, when traveling by sea was only the way to get around, the passengers were from all walks of life and all age groups. Nowadays, cruising attracts mostly older generations and retirees, with 36% aged 45-59, and 35% over 60. Both the size of the ships and the limited mobility of older travelers raise concerns regarding passenger evacuation during emergencies.[654] Especially, such concerns have crystalized in the aftermath of the Costa Concordia disaster.

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[647] *The Contribution of the North American Cruise Industry to the U.S. Economy in 2013,* Business Research & Economic Advisors, (September 2014), at 4, online: Cruise Lines International Association <http://www.cruising.org/docs/default-source/research/us-economic-impact-study-2013.pdf?sfvrsn=2>.

[648] *Cruise Industry Overview – 2013: State of Cruise Industry*, Florida Caribbean Cruise Association, online: Florida Caribbean Cruise Association <http://www.f-cca.com/downloads/2013-cruise-industry-overview.pdf>.

[649] A 3.2% increase over 2013. (*2015 Passenger Capacity*, online: Cruise Market Watch <http://www.cruisemarketwatch.com/capacity/>).

[650] A 7.3% increase over 2014. (*Ibid.*)

[651] From 2015 to 2022, at least 40 new mega-cruise ships with capacity more then 2000 passengers will be delivered. (*Cruise Ship Orderbook*, Cruise Industry News online: Cruise Industry News <http://www.cruiseindustrynews.com/cruise-news/cruise-ship-orderbook.html>).

[652] *Growth of the Cruise Line Industry*, Cruise Market Watch, online: Cruise Market Watch <http://www.cruisemarketwatch.com/growth/>.

[653] "Titanic vs. Oasis Of the Seas: Compare World's Biggest Cruise Ships, Then And Now", Huffington Post, (11 April 2012), online: Huffington Post <http://www.huffingtonpost.ca/2012/04/11/titanic-vs-oasis-compare-cruise-ships_n_1419368.html>.

[654] *Op. cit.* 645 (Nigel S. Greenwood).

The Costa Concordia tragic event has shown that even the most cutting-edge technology cannot completely protect passengers' life and health at sea, especially when the human factor is involved. Captain Francesco Schettino disregarded existing international rules for safe navigation and evacuation procedures, resulting in 32 fatalities.[655] On the positive side, the scale of human losses was not as extensive as 100 years before, due to international safety regulations being introduced after the Titanic disaster.

Needless to say that the passengers and crew of the Titanic had been doomed even before the ship hit the iceberg. The legal vacuum on maritime safety left only a slight chance to survive in the event of a disaster. In 1912, there was little in national regulations specifically for shipping. A few existing national laws on safety were not adequate. International rules were even fewer.[656] The fundamental problem with the safety on Titanic derived from the simple lack of lifeboats for everyone aboard.[657] The twenty lifeboats could accommodate only half of the ships' passengers and crew.[658] Such a delinquent situation was absolutely legal, since the number of lifeboats required by law at that time was based on the gross register tonnage of a ship, not on the passenger capacity![659] The present-day international safety

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[655]More on Costa Concordia disaster see: "Costa Concordia: What happened", BBC, (10 February 2015), online: BBC <http://www.bbc.com/news/world-europe-16563562>).

[656]*Safety and Shipping 1912-2012: From Titanic to Costa Concordia: An Insurer's Perspective from Allianz Global Corporate & Specialty*, Allianz Global Corporate & Specialty AG, 2012, at 28, online: Allianz Global Corporate & Specialty AG <http://www.agcs.allianz.com/assets/PDFs/Reports/AGCS_safety_and_shipping_report.pdf>.

[657]In the original blueprints, the Titanic was set to carry 64 lifeboats (a total well over the number required for the ship's maximum capacity of 3547 people). During construction this number was reduced to 48 lifeboats to make the decks look less cluttered. Actually, only 20 lifeboats were carried aboard during the tragic night.

[658]1,178 - the total capacity, in numbers of people, of the lifeboats carried by the Titanic.

[659]In an emergency, lifeboats at the time were intended only to shuttle passengers off the ship onto a nearby vessel providing assistance. It was therefore commonplace for liners to have far fewer lifeboats than needed to accommodate all their passengers and crew. (David F. Hutchings, & Richard P. de Kerbrech, *RMS* Titanic *1909–12 (*Olympic *Class): Owners' Workshop Manual*, (Sparkford, Yeovil: Haynes 2011), at 116 & Bartlett, W.B., *Titanic: 9 Hours to Hell, the Survivors' Story*, (Stroud,

regulations do not permit a passenger ship to set sail without having lifeboats or inflatable life rafts with capacity to accommodate everyone aboard.

The 1912 drama in the middle of the Atlantic happened because of both bad luck and inadequate safety standards to protect human lives on the high seas.[660] And if, for obvious reasons, the element of bad luck cannot be avoided in any catastrophe, appropriate safety regulations if put in place, could prevent, or at least minimize, potential losses.

The Titanic was by no means the greatest maritime tragedy of the past century.[661] Yet, the Titanic disaster became a wake-up call for mobilizing the international community to act promptly for maritime safety sake. It took also relatively little time for the shipping industry to acknowledge that to truly operate on a global scale, international rules and regulations were needed.[662]

Gloucestershire: Amberley Publishing, 2011), at 30 & *Titanic Lifeboats*, online: Titanic Facts <http://www.titanicfacts.net/titanic-lifeboats.html>).

[660]In theory, the *Titanic* disaster might have been avoided had the ship's officers paid attention to reports regarding the frozen waters they were approaching. Earlier in the evening, neighboring ships in the area had reported that the waters ahead contained numerous masses of solid ice and that approaching ships should proceed with caution. The Titanic, however, thought to be unsinkable, ploughed ahead at full speed. (*Op. cit.* 656 (*Safety and Shipping 1912-2012: From Titanic to Costa Concordia: An Insurer's Perspective from Allianz Global Corporate & Specialty*), at 9).

[661]Even leaving aside wartime losses, the past century is in fact distressingly full of peacetime marine disasters approaching or exceeding the Titanic's losses: the MV Dona Paz disaster near the Philippines in 1987 with 4,341 fatalities easily eclipses the catastrophic event in the Atlantic; the Toya Maru was lost in a typhoon in 1954 with 1,153 persons; the La Joola, a Senegalese ferry, capsized in 2002 with more than 1,800 passengers onboard; and the Al Salaam Boccaccio 98 sank in the Red Sea in 2006, taking with her more than 1,000 souls. (*Op. cit.* 645 (Nigel S. Greenwood)).

[662]The urgent need for international common rules at sea became obvious after the Titanic. For instance, the *International Radio Telegraphic Convention 1906* adopted the distress signal "SOS". However, British wireless operators preferred the older CQD code and rarely used the SOS signal. As a result, initially Titanic radio operator sent "CQD". Eventually, he began to alternate between the two. As an aftermath of the disaster in the Atlantic the SOS signal became standard. (*Sinking Of The Titanic Influences Wireless Radio*, online: Modesto Radio Museum <http://www.modestoradiomuseum.org/titanic.html> & *Op. cit.* 656 (*Safety and Shipping 1912-2012: From Titanic to Costa Concordia: An Insurer's Perspective from Allianz Global Corporate & Specialty*), at 28).

The aftermath was the start for global regulation to protect lives at sea. The oldest international consumer protection instrument was adopted in 1914 at a conference held in London, just two year after the Titanic sinking. Since then, the Safety of Life at Sea Convention (SOLAS)[663] has specified appropriate standards for live-saving equipment, ship construction and survivability, navigation equipment and practices, and communications.[664] Over the following years, numerous international documents regarding safety at sea have been adopted. Consequently, today's maritime industry is regulated by a myriad of codes, conventions and guidelines that set the boundaries for safe and efficient shipping operations.[665] Nonetheless, SOLAS has continuously remained the pivotal international instrument on passenger safety at high seas.

Since 1914, four other SOLAS conventions have been endorsed: the second was adopted in 1929 and entered into force in 1933; the third was adopted in 1948 and entered into force in 1952; the fourth was adopted under the auspices of the newly established UN agency the Inter-Governmental Maritime Consultative

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[663]As the title suggests, the 1914 Convention primarily concern was the safety of human life.

[664]In respond to evolving concern, in 2002, SOLAS was amended with provisions on Ship and Port Facility Security. Similarly to the Air Carriage part, the aspects of security at sea will not be scrutinized in this work. (*Amendments to the Annex to the International Convention for the Safety of Life at sea (SOLAS)*, 1974, [contained in Resolutions 1, 2, 6 and 7 and including International Ship and Port Facility Security (ISPS) Code], London, (12 December 2002), online: Admiralty Law Guide <http://www.admiraltylawguide.com/conven/amendsolas2002.pdf>).

[665]Other conventions relating to maritime safety: *International Convention on Standards of Training, Certification and Watchkeeping for Seafarers* (STCW) *as amended, including the 1995 and 2010 Manila Amendments*; *Convention on the International Regulations for Preventing Collisions at Sea* (COLREG), 1972; Convention on Facilitation of International Maritime Traffic (FAL), 1965; International Convention on Load Lines (LL), 1966; *International Convention on Maritime Search and Rescue* (SAR), 1979; *Convention for the Suppression of Unlawful Acts Against the Safety of Maritime Navigation* (SUA), 1988, and *Protocol for the Suppression of Unlawful Acts Against the Safety of Fixed Platforms located on the Continental Shelf,* 2005; *Convention on the International Maritime Satellite Organization* (IMSO), 1976; *Special Trade Passenger Ships Agreement* (STP), 1971 and *Protocol on Space Requirements for Special Trade Passenger Ships*, 1973. More on international instruments for maritime safety see International Maritime Organization (IMO), online: IMO <http://www.imo.org>.

Organization[666] in 1960 and entered into force in 1965; the present fifth version was adopted in 1974 and entered into force in 1980.[667]

The SOLAS conventions have all covered many aspects of safety at sea. Over the years, new subjects on maritime safety have been added to keep up with technological progress and organizational needs. The 1914 version, for example, included chapters on safety of navigation, construction, radiotelegraphy, life-saving appliances and fire protection. These fundamental subjects on safety are still dealt with in separate chapters in the 1974 version.[668]

SOLAS 1929 echoed postulates from 1914 and introduced international regulations for preventing collisions at sea. SOLAS 1948 followed the already established pattern but covered a wider range of ships and went into considerably greater detail. Important improvements were made in many fields; namely, watertight subdivision in passenger ships; stability standards; the maintenance of essential services in emergencies; structural fire protection. Regulations regarding collision at sea, the safety of navigation, meteorology were revised and brought up to date. New chapters such as dangerous goods and radiotelephony were introduced.

The year 1948 was particularly significant because a conference held in Geneva under the auspices of the United Nations adopted a convention formally establishing the Inter-Governmental Maritime Consultative Organization, a permanent international body capable of adopting legislation on all matters related to maritime

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[666]More on the IMO see below in this CHAPTER.
[667]UN, *International Convention for the Safety of Life at Sea* (SOLAS), 1974, online: UN <https://treaties.un.org/doc/Publication/UNTS/Volume%201184/volume-1184-I-18961-English.pdf>.
[668]More on history of SOLAS Conventions sea *SOLAS - The International Convention for the Safety of Life at Sea*, online: Metal Safe Sign <http://www.mss-int.com/solas.html>.

safety. The name was changed in 1982 to the International Maritime Organization (IMO).[669]

To keep up with fast changing technical developments at sea, SOLAS 1960 incorporated numerous technical improvements. Many safety measures previously applied only to passenger ships were extended to cargo ships. The radio requirements were again revised and, in the chapter dealing with life-saving appliances, provision was made for the carriage of life rafts, which had developed to such an extent that they could be regarded as a partial substitute for lifeboats in some cases. Additionally, regulations dealing with construction, fire protection and collision were revised. Finally, IMO obtained the mandate to keep SOLAS 1960 up to date by means of amendments.[670]

To surmount growing organizational predicaments, a new SOLAS Convention was inaugurated in 1974.[671] SOLAS 1974 is currently in force and it is unlikely to be replaced by a new instrument because its amendment procedure allows updates and

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[669]*Ibid.*

[670]The first set of amendments was adopted in 1966 and from then on amendments were introduced regularly. The essential contents on safety included: 1966: amendments dealing with special fire safety measures for passenger ships; 1967: amendments adopted, dealing with radiotelephony in areas of high traffic density; novel types of craft; and the repair modification and outfitting of ships; 1968: new requirements introduced dealing with shipborne navigational equipment, the use of automatic pilot and the carriage of nautical publications; 1969: various amendments dealing with such matters as specifications for lifebuoys and lifejackets; radio installations and shipborne navigational equipment. 1973: regulations concerning life-saving appliances.

[671]SOLAS 1960 stipulated that amendments would enter into force twelve months after being accepted by two-thirds of contracting parties to the parent Convention. This procedure had been perfectly satisfactory when the Convention encompassed small number of Member States. During the 1960s, however, the membership of the IMO and number of Parties to the SOLAS Convention was growing rapidly. The number of ratifications required meeting the two- thirds target also increased, resulting unacceptable delay to secure entry into force of SOLAS modifications. Consequently, IMO decided to introduce SOLAS 1974 which would not only incorporate all the amendments to the 1960 Convention but would also include a new procedure which would enable future amendments to be brought into force within an acceptable period of time. (*Op. cit.* 668 (*SOLAS - The International Convention for the Safety of Life at Sea*)).

amendments without replacing the entire Convention.[672] The Convention contains many provisions on maritime safety for both cargo and passenger ships. In this work only a synopsis of the most essential regulations for passenger ships safety is provided.

Under the Annex Chapter I, General provisions, all passenger ships are subject to surveys and certification procedures to determine that they meet the requirements of the Convention, including a survey before the ship is put into service, a periodical survey[673] and additional surveys as the occasion arises.[674] After an inspection and survey finds that a passenger ship complies with all requirements of the Convention, the Passenger Ship Safety Certificate is issued.[675] SOLAS 1974 lays down the control procedures that empower port state officers to ensure that foreign ships calling at their ports possess valid certificates. Furthermore, the port state officer is authorized to take further action if there are clear grounds to believe that the condition of the ship or of its equipment does not correspond substantially with the particulars of any of the certificates. The officer can take steps to ensure that the ship does not sail until it can do so without endangering passengers, crew or the ship itself.[676]

To insure safe design of the ship, Annex Chapters II-1 encompasses detailed technical provisions on the ship construction including Subdivision and Stability, Machinery

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[672]SOLAS 1974 reverses the process of amendment adoption assuming that Member States are in favour of proposed modifications unless they take positive action to make their objection known. More specific, Article VIII states that amendments to the chapters which contain the Convention's technical provisions - shall be deemed to have been accepted within two years unless they are rejected within a specified period by one-third of Contracting Governments or by Contracting Governments whose combined merchant fleets represent not less than 50 per cent of world gross tonnage.

[673]In most cases once every 12 months.

[674]Annex Chapter I, Regulation 7.

[675]Annex Chapter I, Regulation 12 (a) (i).

[676]If action of this type is taken, the flag state must be informed of the circumstances and the facts must also be reported to IMO. (Annex Chapter I, Regulation 19).

and Electrical Installations[677] and Annex Chapters II-2 includes regulation on Fire Protection, Fire Detection and Fire Extinction. It details fire safety measures for passenger ship carrying more than 36 passengers.[678]

Chapter III, Life-Saving Appliances, is divided into three parts. Part A contains general requirements, which apply to all ships, describes appliances by type, their equipment, construction specifications, methods of determining their capacity and provisions for maintenance and availability. It also describes procedures for emergency and routine drills. Part B contains additional requirements exclusively for passenger ships.[679]

Chapter IV, Radiotelegraphy and Radiotelephony, prescribes the type of radio installations, the operational requirements for radio watch keeping, details on technical requirements and the radio officer's obligations regarding mandatory logbook entries.[680]

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[677]For instance, the subdivision of passenger ships into watertight compartments must be such that after assumed damage to the ship's hull the vessel will remain afloat in a stable position. The requirements for machinery and electrical installations are designed to ensure that services which are essential for the safety of the ship, passengers and crew are maintained under various emergency conditions.

[678]The key provisions on fire safety are: 1. Division of the ship into main and vertical zones by thermal and structural boundaries. 2. Separation of accommodation spaces from the remainder of the ship by thermal and structural boundaries. 3. Restricted use of combustible materials. 4. Detection of any fire in the zone of origin. 5. Containment and extinction of any fire in the space of origin. 6. Protection of the means of escape or of access for fire-fighting purposes. 7. Ready availability of fire-extinguishing appliances.

[679]Part C includes additional requirements exclusively for cargo ships.

[680]Since its establishment, IMO and its Member States are in co-operation with the International Telecommunication Union (ITU). In fact, many SOLAS Radio Regulations were developed in close collaboration with ITU. More on ITU and SOLAS see: *ITU Guidance for Administrations*, online: International Telecommunication Union <http://www.itu.int/en/ITU-R/terrestrial/mars/Documents/Guidance.pdf> & International Telecommunication Union, online: ITU <http://www.itu.int>.

Chapter V, Safety of Navigation, details operational procedure for all ships on all voyages.[681] The subjects covered include the maintenance of meteorological services for ships; the ice patrol service; routing of ships; search and rescue services; and etc. The chapter also includes a general obligation for contracting governments to ensure that all ships are sufficiently and efficiently manned from a safety point of view. Finally, the same Chapter contains requirements on radar installation and other navigational aids.

Chapter VII, Carriage of Dangerous Goods, prescribes the classification, packing, marking and stowage of dangerous substances in packaged form for all kind of ships. The chapter also limits the dangerous good load for the passenger ships.[682] Additionally, the *International Maritime Dangerous Goods Code* (IMDG) was adopted by IMO in 1965.[683] For many years it has been up-dated periodically to accommodate new substances and to supplement or revise existing provisions to keep pace with developments.[684]

Chapter VIII, Nuclear Ships, provides only for basic requirements which were supplemented by various recommendations contained in an attachment to the Final Act of the 1974 SOLAS Conference.[685]

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[681]Including short international voyage.

[682]For instance, in passenger ships the following explosives only may be carried: safety cartridges and safety fuses; small quantities of explosives not exceeding 9 kilograms (20 pounds) total net weight; distress signals for use in ships or aircraft, if the total weight of such signals does not exceed 1,016 kilograms (2,240 pounds). Notwithstanding, additional quantities or types of explosives may be carried in passenger ships in which there are special safety measures approved by the administration.

[683]The development of the IMDG Code dates back to the 1960 Safety of Life at Sea Conference, when code which covers such matters as packing, container traffic and stowage, particular reference to the segregation of incompatible substances was proposed and later adopted 1965 by the fourth IMO Assembly.

[684]IMO, *International Maritime Dangerous Goods Code*, online: IMO <http://www.imo.org/blast/mainframe.asp?topic_id=158>.

[685]NS Savannah was the first nuclear-powered passenger ship with capacity up to 60 passengers. Built in the late 1950s Savannah was a demonstration project for the potential use of nuclear energy. Launched on 21 July 1959, she was in service between 1962 and 1972. (More on NS Savannah see: *NS Savannah*, online: NS Savannah <http://www.nssavannah.net>). Nowadays, Russian nuclear

Since the *Convention on the International Regulations for Preventing Collisions at Sea* was introduced by an IMO conference in 1972, this Chapter was consequently removed from SOLAS 1974.[686]

Recently, the Maritime Safety Committee of the IMO adopted a package of amendments to SOLAS, the result of a comprehensive review of passenger ship safety initiated in 2000 with the aim of assessing whether the current regulations were adequate, in particular for the large passenger ships now being built. The work in developing the new and amended regulations has based its guiding philosophy on the dual premise that the regulatory framework should place more emphasis on the prevention of an accident from occurring in the first place.[687]

A few words about the IMO, as a specialized agency of the United Nations, IMO is the global standard-setting authority for the safety performance of international shipping. Its main role is to create and maintain a regulatory safety framework for the shipping industry that is fair and effective, universally adopted and universally implemented. In other words, its role is to create a level playing-field so that ship operators cannot address their financial issues by simply cutting corners and

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icebreakers, with capacity up to128 guests, are used as cruise ships for expeditions in the Artic. (More on Artic cruises on nuclear ships please see: *Polar Cruises*, online: Polar Cruises <http://www.polarcruises.com/arctic/ships/icebreaker/50-years-victory>).

[686]The Convention entered into force in 1977. (IMO, *Convention on the International Regulations for Preventing Collisions at Sea*, 1972, online: IMO <http://www.imo.org/About/Conventions/ListOfConventions/Pages/COLREG.aspx>).

[687]The concern was not whether new mega passenger ships complied with the SOLAS requirements applicable to ships of their category, but whether SOLAS and other international regulations drafted before some of the large ships in question had been built duly addressed all the safety aspects of their operation - in particular in emergency situations - and whether the training requirements relating to personnel operating large cruise ships were in need of any review or clarification. What became clear from the initial work was that concern over large passenger-ship safety would be centered on the difficulty in safely evacuating some passengers, such as the elderly and injured, from lifeboats to rescue vessels. (For more information see: IMO, *Passenger ships*, online: IMO <http://www.imo.org/OurWork/Safety/Regulations/Pages/PassengerShips.aspx>).

compromising on safety performance.[688]

The *Convention on the International Maritime Organization* (IMO Convention) was prepared and opened for signature and acceptance at the United Nations Maritime Conference in Geneva in 1948. Originally signed by 24 states, today the IMO Convention has 171 parties.[689]

The purposes of the Organization are to provide a mechanism for cooperation among governments in the field of governmental regulation and practices relating to technical matters of all kinds affecting shipping; to encourage and facilitate the general adoption of the highest practicable standards in matters concerning maritime safety and efficiency of navigation.[690] The Organization is also empowered to deal with administrative and legal matters related to these purposes.

The Organization consists of an Assembly,[691] a Council[692] and five main Committees: the Maritime Safety Committee; the Marine Environment Protection Committee; the Legal Committee; the Technical Cooperation Committee and the Facilitation Committee and a number of Sub-Committees support the work of the main technical

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[688]IMO, *Introduction to IMO*, online: IMO <http://www.imo.org/About/Pages/Default.aspx>.
[689]As of 2014, there are 171 member states of the IMO, which includes 170 of the UN members and the Cook Islands. The most recent member to join was Zambia, which became an IMO member in 2014. Associate members: Faroe Islands, Hong Kong and Macao. UN member states that are not members of IMO are generally landlocked countries, including: Afghanistan, Andorra, Armenia, Belarus, Bhutan, Botswana, Burkina Faso, Burundi, Central African Republic, Chad, Kyrgyzstan, Laos, Lesotho, Liechtenstein, Mali, Federated States of Micronesia, Nauru, Niger, Rwanda, South Sudan, Swaziland, Tajikistan, and Uzbekistan. (IMO, *Member States*, online: IMO <http://www.imo.org/About/Membership/Pages/MemberStates.aspx>).
[690]Article 1(a) of the *IMO Convention*.
[691]The Assembly consists of all Member States and it meets once every two years in regular sessions, but may also meet in an extraordinary session if necessary. The Assembly is responsible for approving the work program, voting the budget and determining the financial arrangements of the Organization.
[692]The Council is elected by the Assembly for two-year terms. The Council, based in London, UK, is the executive organ of IMO and is responsible, under the Assembly, for supervising the work of the Organization. Between sessions of the Assembly the Council performs all the functions of the Assembly, except the function of making recommendations to governments on maritime safety.

committees.[693]

The IMO legislative process is accomplished through specialized committees and sub-committees comprised of representatives from Member States. One of the leading committees of the IMO that carries out the organization's technical work is the Maritime Safety Committee. This committee has a number of subcommittees which deal with a wide variety of maritime safety issues. These subcommittees include: Safety of Navigation; Ship Design and Equipment; Standards of Training and Watchkeeping; Fire Protection; Stability and Load Lines; Communication and Search and Rescue; and Flag State Implementation.[694]

Over the years the IMO has proved to be an effective and indispensable international institution to promote safety at sea. Numerous international agreements on maritime safety have been adopted and globally implemented under the umbrella of the IMO; namely, the latest version of the *International Convention for the Safety of Life at Sea* 1974, the *Global Maritime Distress and Safety System* (GMDSS) 1988,[695] and the *International Safety Management Code* (ISM Code) 1998.[696]

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[693]For more information on IMO structure see: IMO, *Structure of IMO*, online: IMO <http://www.imo.org/About/Pages/Structure.aspx>.

[694]The Maritime Safety Committee (MSC) is the highest technical body of the Organization. It consists of all Member States. The functions of the Maritime Safety Committee are to consider any matter within the scope of the Organization concerned with aids to navigation, construction and equipment of vessels, manning from a safety standpoint, rules for the prevention of collisions, handling of dangerous cargoes, maritime safety procedures and requirements, hydrographic information, log-books and navigational records, marine casualty investigations, salvage and rescue and any other matters directly affecting maritime safety. It also has the responsibility for considering and submitting recommendations and guidelines on safety for possible adoption by the Assembly. The expanded MSC adopts amendments to conventions such as SOLAS and includes all Member States as well as those countries which are party to conventions such as SOLAS even if they are not IMO Member States. (*Ibid.*).

[695]In February 1999, the GMDSS became fully operational, so that now a ship that is in distress anywhere in the world can be virtually guaranteed assistance, even if the ship's crew does not have time to radio for help, as the message will be transmitted automatically. More on GMDSS see: *Inmarsat*, online: Inmarsat <http://www.inmarsat.com/services/safety/gmdss/>.

[696]The purpose of the ISM Code is to provide an international standard for the safe management and operation of ships. The objectives of the Code are to ensure safety at sea, prevention of human injury

The IMO's safety regulations have been primarily enforced by means of Post State Control (PSC). The concept of PSC was introduced by the IMO through its *Standards of Training, Certification and Watchkeeping for Seafarers Convention* (STCW)[697] to apply the STCW requirements to all ships calling at their ports so that there is no competitive disadvantage for ships flagged in states which are not party to the convention.

Port State Control designates the inspection of foreign ships in other national ports by PSC officers for the purpose of verifying that the condition of the ship and its equipment comply with the requirements of international regulations on safety and that the ship is manned and operated in compliance with these rules. This principle now underpins much of the IMO's regulations and PSC has become a crucial element of the international enforcement of regulatory standards.[698] Today, PSC is a very

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or loss of life. For more information see: IMO, *ISM Code and Guidelines on Implementation of the ISM Code 2014*, online: IMO <http://www.imo.org/OurWork/HumanElement/SafetyManagement/Pages/ISMCode.aspx>.

[697]IMO, *International Convention on Standards of Training, Certification and Watchkeeping for Seafarers*, 1978, online: IMO <http://www.imo.org/About/Conventions/ListOfConventions/Pages/International-Convention-on-Standards-of-Training,-Certification-and-Watchkeeping-for-Seafarers-(STCW).aspx.>.

[698]It should be noted that, within the context of the implementation of IMO instruments, Port State Control is a concept of an essentially corrective kind: it aims to correct non-compliance or ineffective flag State enforcement of IMO regulations by foreign ships voluntarily in port and is an incentive for flag State compliance. The exercise of PSC jurisdiction for the purpose of correcting deficiencies in the implementation of safety of navigation rules is established in the main IMO safety conventions, namely, Load Lines 1966, 1988 Load Lines Protocol, TONNAGE 1969, SOLAS 1974, and STCW 1978. These treaties regulate the right of the port State to verify the contents of certificates issued by the flag State attesting compliance with safety provisions. They also entitle the port State to inspect the ship if the certificates are not in order or if there are clear grounds to believe that the condition of the ship or of its equipment does not correspond substantially with the particulars of the certificates or if they are not properly maintained. SOLAS provides that the port State may check operational requirements when there are clear evidences that the master or the crew is not familiar with essential shipboard procedure relating to the safety of the ship or procedures set out in the ship's safety management system. More on PSC jurisdiction see: IMO, *Implications of the United Nations Conventions on the Law of the Sea for the International Maritime Organization*, (LEG/MISC.8), (30 January 2014), at 18&19, online: IMO <http://www.imo.org/ourwork/legal/documents/implications%20of%20unclos%20for%20imo.pdf>.

powerful force which helps maintaining safety standards throughout the industry.[699] Many Port States publish details of ship detentions for noncompliance with international safety regulations on the Internet, which encourages ship-owners to remain proactive in their care of ships safety.[700]

IMO has encouraged the establishment of regional Port State Control organizations and agreements by virtue of Memorandum of Understanding (MoU). MoUs have covered all of the world's oceans: Europe and the North Atlantic (Paris MoU); Asia and the Pacific (Tokyo MoU); Latin America (Acuerdo de Viña del Mar); Caribbean (Caribbean MoU); West and Central Africa (Abuja MoU); the Black Sea region (Black Sea MoU); the Mediterranean (Mediterranean MoU); the Indian Ocean (Indian Ocean MoU); and the Gulf Region (the Riyadh MoU).[701]

Europe and the North Atlantic -Paris MoU consists of 27 participating maritime Administrations and covers the waters of the European coastal States and the North

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For list of Maritime Conventions please see: IMO, *List Of Conventions*, online: IMO <http://www.imo.org/About/Conventions/ListOfConventions/Pages/Default.aspx>.

[699]Port State Controls around the world use sophisticated databases to generate a list of ships to target for inspections on a daily basis. Ships may be targeted as a result of previous inspection findings, on a ship risk profile, or simply on the fact that an inspection is due. Once the ship has been targeted, the Port State Control visit normally begins with examination of documents, followed by a general inspection of the ship to verify that she complies with all relevant regulations. If ship complies, and the statistics suggest that is frequently the case in modern day shipping, the PSC officer issues a "clean" inspection report to the master. If deficiencies are identified, the inspection report includes a "deficiencies found" report, which gives guidance on any follow-up actions that need to be taken to rectify the deficiencies. If deficiencies are found, they are normally required to be rectified before departure of the ship. If more serious deficiencies are found – that might be hazardous to safety – the authorities will make sure that the hazard is rectified before the ship is allowed to proceed to sea and to ensure that outcome, may detain the ship. The operator of a ship does have the right of appeal against a detention, but an appeal does not lead to the immediate lifting of the detention. Whatever the outcome of a PSC inspection, the ship's data and the inspection result are recorded on a central computer database for easy access to any concerned parties.

[700]*Op. cit.* 656 (*Safety and Shipping 1912-2012: From Titanic to Costa Concordia: An Insurer's Perspective from Allianz Global Corporate & Specialty*), at 34 to 36.

[701]More on PSC see: IMO, *Port State Control*, online: IMO <http://www.imo.org/blast/mainframe.asp?topic_id=159>.

Atlantic basin from North America to Europe.[702] With the mission to eliminate the operation of sub-standard ships through a harmonized system of Port State Control, the Organization conducts more than 18,000 inspections annually on board foreign ships in the Paris MoU ports, ensuring that these ships meet international safety and security standards.[703]

2.2.4.4 Convention relating to the Carriage of Passengers and their Luggage by Sea (Athens, 1974)

Similar to the Warsaw and Montreal conventions on civil aviation, the *Athens Convention relating to the Carriage of Passengers and their Luggage by Sea,* 1974 (Athens Convention)[704] has been the only instrument on the international stage establishing a regime of liability for damages suffered by passengers carried on a seagoing vessel.[705] The treaty enhances passengers' safety by presuming automatically the carrier's fault in case of accident causing death or injury to a passenger and by imposing heavy monetary obligations.

The convention applies to any international carriage if: the ship is registered in a state party to the convention, or the contract of carriage is concluded in a state party to the

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[702]The current member States of the Paris MoU are: Belgium, Bulgaria, Canada, Croatia, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Latvia, Lithuania, Malta, the Netherlands, Norway, Poland, Portugal, Romania, the Russian Federation, Slovenia, Spain, Sweden and the United Kingdom.

[703]More on Paris MoU see: *Paris MoU*, online: Paris MoU <https://www.parismou.org>.

[704]*Athens Convention relating to the Carriage of Passengers and their Luggage by Sea*, 1974, online: Admiralty and Maritime Law Guide <http://www.admiraltylawguide.com/conven/passengers1974.html>.

[705]The convention consolidated and harmonized two earlier Brussels conventions (1961 & 1967) dealing with passengers and luggage.

convention, or the place of departure or destination is in a state party to the convention. The convention covers passengers and their luggage[706] during the period on board ship, or during the course of embarkation or disembarkation, or during traveling from land to the ship and vice-versa.[707]

In accordance with Article 3.1, the carrier[708] shall be liable for the damage suffered as a result of the death of or personal injury to a passenger and the loss of or damage to luggage[709] if the incident which caused the damage so suffered occurred in the course of the carriage and was due to the fault or neglect of the carrier or of his servants or agents acting within the scope of their employment. The convention limits the liability of the carrier for the death of or personal injury to a passenger to 700,000 francs.[710] However, Member States are allowed to fix a higher limit of liability for national carriers based on proved negligence.

The passenger may bring action before a court of the state of his/her permanent residence, or the court of the principal place of business of the defendant, or the court of the place of departure/destination, or a court of the state where the contract of carriage was made.[711] Any contractual provision purporting to relieve the carrier of its liability towards the passenger or to prescribe a lower limit of liability than that fixed in the convention is null and void, but the nullity of that provision does not render

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[706]Luggage includes: articles, vehicles, and live animals. (Art. 1.5).
[707]Art. 1.8.
[708]The carrier remains liable even though all or part of the carriage has been entrusted to a performing carrier. (Art. 4).
[709]The carrier is not liable for the loss of or damage to monies, jewellery, ornaments, works of art, or other valuables, except where such valuables have been deposited with the carrier for the agreed purpose of safe-keeping. (Art. 5).
[710]The sums refer to the French franc consisting of ≤ 65 milligrams gold of millesimal fineness 900. These sums may be converted into any national currency. (Art. 7 & 9).
[711]Providing the court is located in a state party to the convention and the defendant has a place of business in and is subject to the jurisdiction of that state. (Art. 17.1).

void the contract of carriage.[712]

The convention was also amended in 1974. The Athens Convention uses the "Poincaré franc", based on the "official" value of gold as the applicable unit of account. The *Protocol to the Athens Convention relating to the Carriage of Passengers and their Luggage by Sea*[713] has made the unit of account the Special Drawing Right (SDR).[714]

Eventually, some 32 countries became party to the Athens Convention, and they represented 40% of world tonnage.[715]

Over the years following the adoption of the Treaty, the international community has made a few significant steps towards modernization of the Athens Convention. The *Protocol of 1990 to Amend the Athens Convention Relating to the Carriage of Passengers and their Luggage by Sea, 1974*[716] (the Protocol 1990) has raised the amount of compensation available in the event of death or injury to 175,000 SDR (around US$224,000).[717] Unfortunately, the Protocol 1990 never attracted enough parties to enter into force. Nevertheless, just 12 years later, a successful attempt was undertaken to improve the Treaty.

The *Protocol of 2002 to Amend the Athens Convention Relating to the Carriage of*

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[712]Art. 18.

[713]*Protocol to the Athens Convention Relating to the Carriage of Passengers and their Luggage by Sea of 13 December 1974*, online: Admiralty and Maritime Law Guide <http://www.admiraltylawguide.com/conven/protopassengers1976.html>.

[714]For the death of, or personal injury to, a passenger, this limit of liability is set at 46,666 Special Drawing Rights (SDR) (about US$70,000) per carriage. (Art. 2).

[715]IMO, *Summary of Conventions*, online: IMO <http://www.imo.org/en/About/Conventions/StatusOfConventions/Pages/Default.aspx>.

[716]*The Protocol of 1990 to Amend the Athens Convention Relating to the Carriage of Passengers and their Luggage by Sea, 1974,* online: Admiralty and Maritime Law Guide <http://www.admiraltylawguide.com/conven/protopassengers1990.html>.

[717]As for loss of or damage to cabin luggage and for loss of or damage to vehicles, the convention sets higher limits at 1,800 SDR (about US$2,700) and at 10,000 SDR (about US$15,000), respectively. (Art. 2).

Passengers and their Luggage by Sea, 1974 (the Protocol 2002), introduced to the convention a few new features on strict liability.[718] A new article (4bis) of the convention requires carriers to have certificates attesting that insurance or other financial security, such as the guarantee of a bank, covers the limits for strict liability under the convention in respect of the death of and personal injury to passengers.[719]

Similar to the Montreal Convention on civil aviation, the 2002 Protocol introduced a two-tier regime for carrier's liability for death and injury to passengers. The limits of minimum strict liability for the death of or personal injury to a passenger are 250,000 SDR, unless the carrier proves that the incident was of *force-majeur* nature or was wholly caused by an act or omission done with the intent to cause the incident by a third party. If and to the extent that the loss exceeds the above limit, the carrier shall be further liable unless the carrier proves that the incident which caused the loss occurred without the fault or neglect of the carrier. [720]

The 2002 Protocol entered into force in April 2014 after being ratified by 17 States.[721] Consequently, the Athens Protocol 2002 renamed the Treaty as the *Athens*

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[718]The *Protocol of 2002 to Amend the Athens Convention Relating to the Carriage of Passengers and their Luggage by Sea, 1974*, online: UK Government <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/261628/Misc.6.2013_Prot_2002_Athens_8760.pdf >.

[719]The limit of the compulsory insurance must not be less than 250,000 SDR (about US$375,000) per passenger on each distinct occasion. (Art. 5 & 7).

[720]The carrier is liable, unless the carrier proves that the incident resulted from an act of war, hostilities, civil war, insurrection or a natural phenomenon of an exceptional, inevitable and irresistible character; or was wholly caused by an act or omission done with the intent to cause the incident by a third party. If the loss exceeds the limit, the carrier is further liable up to a limit of 400,000 SDR (about US$600,000). National law may set higher limits of carrier liability, and if so, the member party must inform the IMO Secretary-General. (Art. 4).

[721]10 parties were required to enter into force. Today the Parties are: the EU and 26 Contracting States: the UK, Albania, Belgium, Belize, Bulgaria, Croatia, Denmark, France, Greece, Ireland, Latvia, Lithuania, Malta, Marshall Islands, Montenegro, Netherlands, Norway, Palau, Panama, Portugal, Saint Kitts and Nevis, Romania, Serbia, Slovak Republic, Spain, and the Syrian Arab Republic. (IMO, *Status of Multilateral Conventions and Instruments in Respect of which the International Maritime Organization or its Secretary-General Performs Depositary or other Functions: As at 28 October 2016*, at 325 to 334 online: IMO

Convention Relating to the Carriage of Passengers and their Luggage by Sea 2002 (Athens Convention 2002).[722]

In conclusion, a presumption of fault on the carrier in the case of an accident causing death or injury, together with serious financial obligations imposed by the Athens Convention 2002 have placed a heavy responsibility on the carrier to do its utmost to protect the safety of the passengers at high seas.

Since the Titanic disaster, maritime passengers' safety has dramatically improved through a combination of factors: technology and crew training enhancements; new construction and design techniques; and of course, tough international regulations on safety.

Total losses of merchant ships are on the decline. Lloyd's Register Casualty Statistics reveal a global pattern of falling losses in the period 1910 to 2010. One ship in every 100 was lost in 1910, a rate which has improved to around one ship in every 670 as at 2010.[723]

Today a passenger cruise-liner is one of the safest means of transportation. In fact, statistically, it is the safest one.[724] And in recent year cruising is just getting safer. A

<http://www.imo.org/en/About/Conventions/StatusOfConventions/Documents/Status%20-%202016.docx.pdf>).

[722]As October 2016, 26 states representing 44.5% of world tonnage are parties to the Convention. States that ratify the 2002 Protocol are required to denounce the 1974 Convention and its Protocols, if they are Party to the 1974 Convention and those Protocols. (*Ibid.*)

[723]Based on Lloyd's Register data for 2000-2010, shipping losses broadly reflect the distribution of ship types in the world fleet, although cargo vessels (general cargo, ro-ro cargo, other dry cargo) make up a disproportionate number of losses (44% of losses, despite representing 20% of the world fleet by number). Conversely, tankers (including LNG/LPG carriers and crude oil tankers) have a relatively low loss rate at 8% of losses despite representing 13% of the total world fleet, as do container vessels (4% of fleet; 1% of losses) and offshore industry ships (5% of fleet; 1% of losses). The cruise ships have the lowest losses rate, approximately 1%. (*Op. cit.* 656 (*Safety and Shipping 1912-2012: From Titanic to Costa Concordia: An Insurer's Perspective from Allianz Global Corporate & Specialty*), at 13).

[724]Fatalities per billion passenger-miles: cruise ships 0,08; commercial air 0,8; passenger cars 3,3; and motorcycles 231,4. (*Report on Operational Incidents 2009 to 2013 for CLIA Global*, G.P. Wild,

comprehensive study of cruise ship emergencies has found that the number of major incidents such as fires, engine failures, and other serious safety problems, has trended downward over the past five years, even as cruise ship capacity has sharply increased.[725] The 55,000 cruise passengers that travel by ship every day do so safely and efficiently in the vast majority of cases.[726]

Because of the international nature of the shipping industry, it has long been recognized that action to improve safety in maritime operations is more effective if carried out at the international level rather than by individual countries acting unilaterally and without co-ordination.[727] Hence, regulations and standards have to be themselves agreed, adopted and implemented on an international basis. And the IMO is the forum at which this process takes place. Today, IMO legal policies cover all aspects of international maritime safety, including ship design, construction, equipment, manning, and operation.[728]

A comprehensive legal framework on maritime safety has been developed for decades under the umbrella of the IMO. And for more than a century, SOLAS

(December 2014), at 16 to 31, online: Cruise Lines International Association <http://www.cruising.org/docs/default-source/market-research/report-on-operational-incidents-2009-to-2013.pdf?sfvrsn=0>).

[725]The study, conducted for the Cruise Lines International Association (CLIA), examined the number of incidents on cruise ships between 2009 and 2014, as well as the number of fatalities and injuries to passenger and crew that came as a result. The emergencies researched in the study were cruise ship fires, technical breakdowns, strandings/groundings, persons overboard, storm and rogue wave damage, collisions and sinkings. Between 2009 and 2013, there were 102 significant incidents leading to 31 passenger deaths, 19 crew deaths and 215 injuries, the study found. The data included the 32 deaths stemming from the Costa Concordia shipwreck in 2012. An average of 20 minor incidents is reported each year. The report indicates that since 2009, operational incidents — already rare on cruise ships — have declined even further by 13%. During this same time period, cruise ship capacity – defined as the number of lower berths available – increased by 18.6 percent. (*Ibid.* (*Report on Operational Incidents 2009 to 2013 for CLIA Global,*)).

[726]*Op. cit.* 656 (*Safety and Shipping 1912-2012: From Titanic to Costa Concordia: An Insurer's Perspective from Allianz Global Corporate & Specialty*), at 4.

[727]IMO, *What it is*, (October 2013), at 1, online: IMO <http://www.imo.org/About/Documents/What%20it%20is%20Oct%202013_Web.pdf>.

[728]IMO, *Introduction to IMO*, online: IMO <http://www.imo.org/About/Pages/Default.aspx>.

Conventions have served as the pivotal legal instruments to enhance agenda on safety at sea.

The success of the SOLAS Conventions has been predictable for two reasons. First, the Treaty has received universal recognition. To date, all major maritime states are parties to the Convention. Only a few landlocked nations, for obvious reasons, have not signed SOLAS 1974. Second, an effective mechanism for the enforcement of international treaties on safety, Port State Control (PSC), has been put in place and this legal mechanism is more direct and effective than the one under the Chicago Convention for Civil Aviation. The Chicago Treaty does not grant to an airport state an immediate right to halt an aircraft on the ground if it does not comply with international safety provisions. On the contrary, the IMO legal instrument authorizes a port state to detain a ship for noncompliance with international safety regulations until corrective actions are taken.[729]

In the spite of the SOLAS success story, some experts from the cruise industry have raised safety concerns regarding new mega cruise ships. Especially, the alarm has been sounded regarding Royal Caribbean ships such as Oasis of the Seas and Allure of the Seas.[730] These floating cities, with populations of almost 9000 passengers and crewmembers, present many challenges for safe evacuation. Especially disturbing is the fact that the cruise industry is trying to change SOLAS rules to fit their needs.

From the start, Royal Caribbean encountered numerous problems in designing the largest cruise ships in the world, such as lifeboats and evacuation procedures. To begin with, Royal Caribbean had to obtain a waiver to use newly designed mega

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[729]The list of all ships that are currently detained in the Paris MoU region, might be seen at: *Current Detentions*, online: Paris MoU <https://www.parismou.org/detentions-banning/current-detentions>.
[730]More even bigger mega cruise ships are already on order and will be delivered from now till and 2026 . (*Cruise Ship Orderbook*, online: Cruise Industry News <http://www.cruiseindustrynews.com/cruise-news/cruise-ship-orderbook.html>).

lifeboats with capacities more than twice greater than prescribed by SOLAS 1974.[731] Moreover, the 18 mega-lifeboats on board cannot accommodate all passengers; therefore, some passengers would have to be evacuated by means of a "chute and raft system" originally designed only for crewmembers' use.[732] Furthermore, the existing evacuation "chute and raft system" is considered dangerous and unsuitable even for trained crewmembers.[733] Finally, there are many doubts that it is realistic to evacuate almost 9000 people in an orderly and safe manner during the 30-minute timeframe

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[731]Regulation 5 (c) of the SOLAS 1974 on Life Saving Equipment, states: "No lifeboat may be approved (...) which has a carrying capacity (...) more than 150 persons." Royal Caribbean could not build a ship with over 55 lifeboats carrying 150 people each. So in order to cram enough people into lifeboats, the cruise line obtained a waiver to increase the maximum lifeboat capacity up to 370 people. Schat-Harding has developed a 370-person lifeboat and davit system. The Oasis of the Seas and Allure of the Seas cruise ships were the first vessels to be fitted with these new mega lifeboats. (Jim Walker, *Titanic Redux? Can Royal Caribbean Safely Evacuate 8,500 Passengers & Crew from the Oasis of the Seas?*, Cruise Law News, (28 January 2013), online: Cruise Law News <http://www.cruiselawnews.com/2013/01/articles/sinking/titanic-redux-can-royal-caribbean-safely-evacuate-8500-passengers-crew-from-the-oasis-of-the-seas/> & *Mega Lifeboat*, online: The Royal Institution of Naval Architects <http://www.rina.org.uk/mega-lifeboat.html>).

[732]There are only 18 lifeboats on these ships. Each lifeboat has a capacity of 370 people, divided into 354 passengers and 16 crewmembers who are responsible for overseeing the passengers and maneuvering the life boat. With only 18 lifeboats, there is room for only 6,018 passengers; whereas, the *Allure and the Oasis* have a full capacity of 6,296. The passengers who are not permitted into a lifeboat will be forced to use a "chute and raft system" without proper training. (*Ibid.* (*Titanic Redux? Can Royal Caribbean Safely Evacuate 8,500 Passengers & Crew from the Oasis of the Seas?*) & Jim Walker, *Forced to Evacuate the Allure or Oasis of the Seas? Prepare to Become a Navy Seal!,* Cruise Law News, (16 December 2013), online: Cruise Law News <http://www.cruiselawnews.com/2013/12/articles/worst-cruise-line-in-the-world/forced-to-evacuate-the-allure-or-oasis-of-the-seas-prepare-to-become-a-navy-seal/>).

[733]In 2012, during a lifeboat drill aboard the Findlandia cruise ship operated by Eckerö Line in Tallinn, twenty crewmembers received injuries, including broken bones and sprained ankles, as well as friction burns caused by trying to slow their descent during the steep drop into a life raft using "chute and raft system". Further injuries were avoided only when other crewmembers refused to jump. A union representative characterized the evacuation system as "unsuitable and dangerous". In 2002, during a dockside drill in quiet waters in the ferry port of Dover, England, a 52-year-old volunteer died after entering a "chute and raft system" from positional asphyxia, which can occur when abdominal contents are compressed upward against the diaphragm and preventing breathing. More on "chute and raft system" danger see: Jim Walker, *20 Crew Members Injured During Cruise Ship Lifeboat Drill*, Cruise Law News, (22 November 2012), online: Cruise Law News <http://www.cruiselawnews.com/2012/11/articles/rescue-1/20-crew-members-injured-during-cruise-ship-lifeboat-drill/>& *Ibid.* (*Titanic Redux? Can Royal Caribbean Safely Evacuate 8,500 Passengers & Crew from the Oasis of the Seas?*).& Roxanne Gregory, *B.C. Ferries' Evacuation Systems Come under Fire,* Straight, (23 April 2014), online: Straight <http://www.straight.com/news/632216/bc-ferries-evacuation-systems-come-under-fire>.

required by international law,[734] especially during inclement weather.[735] It is also clear that the difficulties would not end even with a successful evacuation. Thousands of people, unfamiliar with ships and the sea, crowded into lifeboats and life rafts, would present a unique search-and-rescue challenge.[736] The IMO has also highlighted that one of the major concerns surrounding the growth of passenger ships is the challenge of successful search and rescue missions if a serious emergency occurs aboard such a vessel in a remote area where infrastructure may be limited, or involving large numbers of passengers of all ages and levels of fitness.[737]

SOLAS 1974 set strict international rules on safety requirements for passenger ships. Today, a disaster similar to the Titanic is virtually impossible for three reasons. First, each cruise ship before setting sail conducts a so-called "muster drill"[738] to prepare passengers for a safe and orderly evacuation in the event of an emergency and to familiarize passengers with escape routes.[739] Second, each cruise ship must have enough lifeboats and life rafts to accommodate every passenger on the ship.[740] Finally, international maritime safety regulations give to port authorities an absolute

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[734]SOLAS 1974, Regulation 29 (i).

[735]David A. Tyler, *On the World's Largest Cruise Ships, Evacuation May Be a Daunting Task*, Professional Mariner, (3 April 2014) online: Professional Mariner <http://www.professionalmariner.com/April-2014/Cruise-ship-evacuation-may-be-daunting-task/> & *Ibid.* (*Titanic Redux? Can Royal Caribbean Safely Evacuate 8,500 Passengers & Crew from the Oasis of the Seas?*).

[736]*Op. cit.* 687 (*Passenger ships*).

[737]*Op. cit.* 656 (*Safety and Shipping 1912-2012: From Titanic to Costa Concordia: An Insurer's Perspective from Allianz Global Corporate & Specialty*), at 49.

[738]In accordance Chapter III, Regulation 26 (b) SOLAS 1974, a passenger muster drill must be conducted by the ship within 24 hours of departure, but many cruise lines, especially after the Costa Concordia disaster, choose to conduct the drill before the ship departs port for the first time. The attendance of the muster drill is strictly enforced by the industry. In general muster drill cannot be avoided. The practice of the safety procedures is mandatory for all passengers and non-compliance may result in disembarkation. (Mike Faust, *Couple Skips Muster Drill, Removed From Cruise*, Cruise Currents, (16 May 2012), online: Cruise Currents <http://www.cruisecurrents.com/archives/4117>).

[739]To alert that the drill is in progress, a general emergency alarm is sounded and, after the signal, the captain explains what the passengers need to do.

[740]Passenger ships engaged on international voyages which are not short international voyages shall carry: lifeboats on each side of such aggregate capacity as will accommodate half the total number of persons on board. (Chapter III, Regulation 27(b) SOLAS 1974).

power to verify that every ship possesses all safety features prescribed by the international law. Simply put, noncompliance with all SOLAS 1974 safety regulations inevitably prevents a ship from leaving a harbour.

Concerning the Costa Concordia incident of January 2012, the human factor caused 32 casualties in this tragedy; similar to the Titanic, this disaster is likely to trigger further improvements in marine safety regulations to prevent possible human errors during the emergency.[741]

As for safety at sea in the future, the latest emerging guiding philosophy for work on passenger ship safety is based on the premise that the regulatory framework should place more emphasis on the prevention of a accident from occurring in the first place and that future passenger ships should be designed for improved survivability so that, in the event of an accident, passengers can stay safely on board as the ship proceeding to port.[742]

.2.3 Conclusive remarks

Consumer safety has been on the radar of the international community for nearly one hundred years. In fact, the oldest international consumer protection instrument on safety, the *Safety of Life at Sea Convention*, was adopted a century ago. International treaties on consumer safety at sea and in the air have been elaborated decades before

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[741] *Op. cit.* 656 at (*Safety and Shipping 1912-2012: From Titanic to Costa Concordia: An Insurer's Perspective from Allianz Global Corporate & Specialty*), 6&54.
[742] *Op. cit.* 687 (*Passenger ships*).

modern concepts of safety for food and non-food consumer products took shape and consumer rights to safety were formally recognized.

Such long delays in developing multilateral treaties on safety for non-food products are due to a few obvious reasons. A half-century time gap between the international conventions on passenger safety and the more recent universal legal instruments on consumer safety derive from dissimilarities amongst the sectors. Maritime and air traveling is transnational by its own nature and from the start safety concerns called for international initiatives. Regarding consumer goods in general, safety had been for long more a national issue than an international one. It became more transnational only recently with the development of cross-border trade. In fact, in the first part of the last century international trade represented no more than 20% of world GDP.[743] Hence, mostly domestic products were circulating on national markets. Any new concerns regarding product safety could be addressed through proper national laws. In the second part of the last century, while market globalization sped up and international trade rapidly soared to more than 50% of world GDP[744], states had to turn to international legal instruments in order to keep actual control on consumer safety issues and related costs and to facilitate interstate trade.

In the area of consumer products, the international community first addressed the safety of food. A standardization program in the area of food safety, known as the *Codex Alimentarius*, was introduced in 1961. Then it took 24 years before the *United Nations Guidelines on Consumer Protection* confirmed consumer safety as a fundamental consumer right and nearly 30 years before the first international treaty on the safety of non-food consumer products was adopted in 1989. International instruments on safety for non-food products such as the Basel, Rotterdam, and

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[743]Esteban Ortiz Ospina & Max Roser, *International Trade: Empirical View*, Our World in Data, online: Our World in Data <http://ourworldindata.org/data/global-interconnections/international-trade/>.
[744]*Ibid.*

Stockholm Conventions were developed only during the past three decades. This time gap is linked to lack or insufficient data regarding the hazardous properties of consumer non-food products.

Safety concerns apropos various dangerous non-food products circulating on the market were not identified as a priority before. For instance, in the U.S., DDT was widely in use domestically till the 1972 ban.[745] Only when scientific data on detrimental health effects of many non-food consumer products became available were appropriate legal instruments introduced.

Over recent years, the international community's efforts in the fields of consumer product and service safety have been predominately focused on chemicals, pharmaceuticals, alternative medicine and international carriage. Under the auspices of the UN, several legal instruments related to safety in these areas have been elaborated and adopted by a majority of countries and new legal frameworks are under development. Notably, little or nothing has been done regarding consumer safety outside of three sectors.

International consumer safety law opted for limited and fragmented regulation targeting only areas of urgent concerns (i.e. chemicals, pharmaceuticals and international carriage). International treaties such as SOLAS, Chicago, Rotterdam, Basel, and Stockholm Conventions, have been implemented virtually by all Member States. Whereas agreements in the form of guidelines, for instance *Good Manufacturing Practices for Pharmaceutical Products* or the *Consolidated List of Products whose Consumption and/or Sale have been Banned, Withdrawn, Severely*

[745] *DDT - A Brief History and Status, United States Environmental Protection Agency*, United States Environmental Protection Agency online: United States Environmental Protection Agency <http://www2.epa.gov/ingredients-used-pesticide-products/ddt-brief-history-and-status>.

Restricted or Not Approved by Governments have been recognized and used by the overwhelming majority of Member States.

Still, regulated areas remain the exception among the wide range of consumer products and even more with consumer services. It is clear that international attention has shifted toward the most potentially deadly products and services. The existing global safety model was built on a selective risk-based approach targeting only specific areas of immediate concerns. Consequently, an abundant amount of dangerous or deadly consumer products and services continue circulating on the market. Millions of people around the world get injured or die because of many dangerous or poor quality consumer products and services that have not been regulated globally. Furthermore, the international safety framework is limited to a few areas and even within those areas it controls only a limited number of unsafe products. For instance, despite thousands of hazardous chemicals presently marketed internationally, only a few dozen have been regulated under the treaties and new harmful substances have been added in a particularly slow pace. As for services, the existing legal framework is limited to the international carriage; no other services have been regulated internationally.

The policy approach has remained dispersed, sector-specific, limited in scope and slow-moving. A more horizontal and comprehensive vision of consumer safety, including a general safety law applicable to all products (and eventually all services) available on consumer markets has emerged only recently in some countries or regions such as the European Union. A global safety net still remains undeveloped in most regions and at the international level.

This lack of global policy derives from the lack of common grounds among countries to assess safety hazards and risks thereof.

Despite that safety is universally proclaimed as a consumer right, the safety properties of a particular product or service may vary from state to state, from region to region, and from one social group to another. Needless to say that such differences in safety standards stem predominately from dissimilarities in socio-economic development among countries. Most of the world's population does not have the financial ability to live in accordance with an elevated "western safety model". A toy with lead paint outlawed for safety concerns in Australia is deemed legally safe in Asia. A car withdrawn from the market in Europe due to unsafe design is classified as a perfectly safe vehicle in most African countries. A hotel without a proper fire escape never officially permitted in Canada is lawfully operated in South America. Hence, depending on socio-economic circumstances every country develops its own suitable legal blueprint for consumer safety. In such circumstances, it is more than challenging to agree on universal safety standards.

To date, only the *Guidelines for Consumer Protection* have remained a pivotal concord on the universal safety. And even though *de jure* the Guidelines are not of a binding nature, the international community has accepted its postulates on safety as imperatives. Most countries worldwide have designed consumer safety policies in accordance to the guiding principles outlined in the United Nations Guidelines on Consumer Protection. Nevertheless, due to their status and limited scope, the Guidelines cannot fill the existing legal vacuum. Despite that the document includes numerous provisions on safety, the devil is in the details, or more precisely, in the lack of them. The idea behind the Guidelines has always been to persuade the Member States to elaborate domestic policies on safety rather than to harmonize the details of such policies. Finally, the Guidelines have not prioritized consumer safety as a central and urgent matter; they treat all consumer issues equally.

As to the impact of the current international initiatives on consumer protection, they also have severe limits. First, all international agreements on safety, except SOLAS,

do not impose compulsory or/and immediate obligations on contracting parties.[746] Many, such as the *Good Manufacturing Practices for Pharmaceutical Products* and *Globally Harmonized System of Classification and Labeling of Chemicals*, come under the form of guidelines. Treaties like the Stockholm Convention gives parties up to 20 years to implement the treaty provisions. Others like the Chicago Convention allow contracting parties to retain a certain degree of flexibility in complying with the norms imposed by the agreement.

Also, while many international treaties on safety include explicit provisions regarding technical and financial aid, such aid provided by UN agencies to assist the state in the compliance process may not be sufficient, especially for countries with limited financial and technical resources. Without proper financing and technical capacities the ability to implement international safety standards is limited or in question. Often developing states struggle to comply with provisions imposed by the international treaties.

Nevertheless, over the course of our study a few remarkable accomplishments by developing states in the field of consumer safety have been observed, especially with respect to legislation. This suggests that even states with limited financial resources are able to achieve the highest degree of compliance with safety rules, as long as there is a clear political willingness to do so.

Flexibility is a natural feature of international tools on safety. It makes consensus possible on at least a minimum set of safety provisions and standards, while allowing signatory countries to adopt or maintain more protective rules. It also allows for an evaluative approach, gradually introducing into the treaties higher levels of protection

[746]The SOLAS has virtually zero legal flexibility and requires absolute and immediate compliance with provisions of the Convention. Nevertheless, this treaty has been around for more than 100 years, giving the contracting parties enough time to adopt adequate national laws and to establish effective national agencies.

or converting the original soft law instrument into a treaty with obligatory nature. And indeed, in some cases successful voluntary consumer protection schemes ultimately were transformed into compulsory treaties on safety. The best example is the Rotterdam Convention, which converted the flawlessly functioning voluntary PIC system introduced in the London Guidelines into an obligation.

Yet, only a handful of binding agreements, which are still quite flexible when it comes to enforcement, have been adopted so far. The majority of international treaties on safety are voluntary. This raises concerns regarding their proper implementation and reporting. Definitely, legal flexibility facilitates the adhesion of parties but cannot guarantee tangible results.

The other noticeable drawback is the absence of an international body exclusively responsible for consumer protection in general, and consumer safety in particular. Despite the fact that the international community has dozens of institutions responsible for all segments or seemingly all aspects of our lives, there is no one institution within the UN network that is directly responsible for consumer protection and consumer safety. So far, the Department of Economic and Social Affairs, which is the UN agency addressing a range of cross-cutting issues from poverty reduction to governance to finance to the environment, conducts most of the coordination work on consumer protection agenda. UN bodies such as World Health Organization, Food and Agriculture Organization, International Maritime Organization, and International Civil Aviation Organization, oversee only sectorial consumer protection and safety, without noticeable effort to harmonize actions amongst themselves. The only visible coordinating work has been done in the area of chemical safety under the synergy taskforce schema amongst Rotterdam, Basel and Stockholm conventions.

This lack of adequate institutional set up at the international level to deal with consumer safety issues is difficult to justify, considering the fact that consumer rights

stated in the UN Guidelines are universally proclaimed and have been given at least some degree of implementation by all countries worldwide.

Finally, the risk of conflicts of interest between free trade rules and national consumer safety measures diminishes the efficiency of mechanisms deemed to protect consumers' life and health. On the one hand, existing free trade rules do not prevent WTO members from adopting or maintaining measures duly justified by the need to protect the safety of consumers. On the other hand, international trade agreements are not consumer protection-oriented as their main goal remains the facilitation of trade. Consumer protection policy is perceived as a by-product of trade policy. Hence, the risk exists that national consumer safety measures be dismantled or at least amended as creating non-legitimate barriers to the free circulation of products and services. Consumer interests are kept hostage to business interests. The Clove Cigarettes saga crystalizes biased practices in the scope of the WTO, when the mechanism designed to protect consumer life and health is used to watch over interests of industry. Such conduct produces a detrimental effect on national consumer safety schemes under WTO rules.

In summary, accomplishments under UN auspices endorse the prominence of global consumer safety. No other fundamental consumer right has received similar credit from the international community. It has been observed that governments have willingly found a common ground when consumer safety is at stake. In some areas international cooperation on consumer safety has soared high. For instance, the current legal frameworks on passenger safety by air and sea have shown extraordinary results with just a few injuries and deaths on record annually.

Finally, a flexible approach is the dominating pattern in international consumer safety law. As part of such an approach, informational tools are most often preferred to regulatory provisions. A clear illustration of this is the prior consent scheme put in

place under the Rotterdam Convention; when the trade of hazardous chemicals is still allowed on the condition that the proper information is transmitted to the importing country and it gives its consent. Rather than completely outlawing the export of certain dangerous chemicals, the international community agreed to communicate a message on their toxic properties and shipments by letting each individual state make decisions on importation and use of harmful substances. Such an informational approach eliminates the necessity to agree on common safety standards, providing every state an opportunity to set a flexible safety model suitable to existing national socio-economic circumstances.

Most international agreements on safety include instruments on information exchange. In fact, in the international realm exchange of information models are being preferred to prohibiting legal patterns.[747]

To conclude, international agreements on consumer safety for non-food products do not completely solve the problems but rather ease them. International law on safety for non-food products is still nascent and only emerging. New and unorthodox approaches should be thought to rectify the global consumer safety crises.

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[747] *Op. cit.* 4 (*Un droit de la consommation est-il encore nécessaire en 2006?*, in *Regards croisés sur les enjeux contemporains du droit de la consommation*) at 18-26.

CHAPTER III

CONSUMER SAFETY ON REGIONAL MARKETS

In recent years, some regional frameworks on consumer protection and safety have shown remarkable results; specifically, significant progress has been achieved in informational exchange on dangerous consumer products. In our quest for global consumer safety, such regional responses may prove to be more complete, accurate and effective than international ones.

Three geographical areas have been selected within the context of this study (3.1). First, we will look at how provisions from the international law instruments on consumer safety, as presented discussed in CHAPTER II, have been implemented at the regional level (3.2). Then, we will scrutinize the existing legal and institutional context of consumer protection and safety in each of the selected regional unions (3.3). Finally, information exchange schemes on dangerous non-food consumer products have been a privilege safety tool on regional level. Hence, a special attention will be given to such schemes which have been made or are going to be made operational (3.4).

3.1 Selection of regional unions

For more than 50 years, regionalism has propagated throughout the globe. Nowadays, regional unions play a crucial role in shaping interstate policies on a broad spectrum of matters, including consumer protection. Nevertheless, there is no universal model suitable for every union. Ultimate goals, level of economic development, strength of political integration, intensity of legal discipline are unique to every region. Each union develops its own blueprint for a legal and institutional framework and molds its policies according to its vital needs. Examining the state of consumer protection and safety in a few selected unions having different levels of political, economic and legal integration will help to draw a picture on how regional policies can affect consumer safety around the globe.

Recent works have shown that regional integration agreements operating in the Americas most commonly do not provide for a comprehensive policy towards consumer safety.[748] For example, while NAFTA[749] has restrictive provisions regarding sanitary and phytosanitary control that can benefit consumer safety to some degree,[750] common, far-reaching consumer safety policy has never been on the NAFTA political agenda. The same can be said about the other regional integration systems in the Americas, such as the Southern Common Market (MERCOSUR), the

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[748] *Op. cit.* 141 (*Le statut de politique de protection du consommateur dans les systèmes régionaux économiquement intégrés. Une première évaluation comparative*).
[749] The *North American Free Trade Agreement* members are the United States, Canada, and Mexico.
[750] NAFTA, (Art 904) *North American Free Trade Agreement*, online: NAFTA Secretariat <https://www.nafta-sec-alena.org/Home/Legal-Texts/North-American-Free-Trade-Agreement>. Detailed analysis on consumer protection and safety in NAFTA see 3.3.2.

Andean Community, and, albeit to a lesser degree, the Caribbean Community (CARICOM). On the American continent, the perception of consumer protection and safety as an issue at regional levels is just emerging and there are no regional sources of consumer protection as of today, though very recent developments toward more recognition of consumer interests in the regionalization process can be observed in MERCOSUR and CARICOM.[751]

The *Cartagena Agreement*, which is the principal treaty of the Andean Community of Nations,[752] has only very limited provisions that may be related to consumer safety. Article 73 provides the right to a member to place import restrictions "to protect the life and health of human beings". The treaty also requires that members harmonize legislation to provide consumers a high level of protection. Apart from the principal treaty, the Andean Community Commission has produced certain directives regarding safety of foods. Moreover, certain decisions of the Community Court of Justice have benefited consumer safety.[753]

MERCOSUR did not mention consumer protection as a common policy in its founding Treaty of Asunción, signed in 1991.[754] The Treaty included only a few proclamations about the improvement of quality of products and services. However, in 1996, the Technical committee of the Union elaborated three resolutions endorsing the need for consumer protection,[755] proclaiming fundamental consumer rights[756] and

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[751]*Op. cit.* 141 (*Le statut de politique de protection du consommateur dans les systèmes régionaux économiquement intégrés. Une première évaluation comparative*) at 26 to 38 & at 15 to 21.
[752]The Community was founded in 1969 and presently counts four members: Bolivia, Colombia, Ecuador, and Peru
[753]For more on consumer protection in the *Andean Community of Nations*, see: *Op. cit.* 141 (*Le statut de politique de protection du consommateur dans les systèmes régionaux économiquement intégrés. Une première évaluation comparative*) at 10 to 14.
[754]The members of MERCOSUR are Brazil, Argentina, Uruguay, Paraguay, and Venezuela.
[755]MERCOSUR, *Defensa do consumidor-Conceitos*, (13 December 1996), MERCOSUR/GMC/RES no.123/96, online: <http://www.cari1.org.ar/spanish/mercosur/resoluciones/res1996/res12396.html>.

giving priority to the "protection of consumers' health and security".[757] Also, the Technical Committee adopted a protocol on consumer protection.[758] However, from the first sign, such progressive development did not bring a desirable outcome. The protocol called for the unification of national legislation and not their harmonization. For Brazil, which has had more progressive consumer protection policy than other members, the ratification of the Protocol would have been a step backwards. As a result of this controversy, Brazil has never ratified it.

In spite of the fact that the MERCOSUR union has not adopted a universal consumer policy, certain important initiatives have been taken. Namely, one of the branches of the Technical Committee has been put in charge exclusively of consumer protection with the objective to contribute to the progressive harmonization of the laws and rules of the member states and to elaborate common standards.[759] At the political level, the *Declaration 2000* proclaimed consumer rights, including safety, as fundamental human rights and listed most of the consumer rights from the UN Guidelines.[760] MERCOSUR has adopted numerous resolutions that directly or indirectly benefit the safety of consumers inside the Union.[761] Finally, several decisions of the Ad Hoc Tribunal and the Permanent Court of the Revision of MERCOSUR have influenced

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[756]MERCOSUR, Defensa do consumidor-Direitos Básicos, (13 December 1996), MERCOSUR/GMC/RES no.124/96, online: <http://www.cari1.org.ar/spanish/mercosur/resoluciones/res1996/res12496.html>.

[757]MERCOSUR, *Defensa do consumidor-Proteção à saúde e segurança do consumidor*, (13 December 1996), MERCOSUR/GMC/RES no.125/96, online: <http://www.cari1.org.ar/spanish/mercosur/resoluciones/res1996/res12596.html>.

[758]*Op. cit.* 141 (*Le statut de politique de protection du consommateur dans les systèmes régionaux économiquement intégrés. Une première évaluation comparative*) at 10 to 14.

[759]For more on the Commission on studies of the consumer law and the Technical Committee see: *Op. cit.* 141 (*Le statut de politique de protection du consommateur dans les systèmes régionaux économiquement intégrés. Une première évaluation comparative*) at 26 to 38.

[760]MERCOSUR, *Declaration presidencial de derechos fundamentales de los consumidores del MERCOSUR*, [2000], ATA 02/2000 MERCOSUR/CCM/CT7 Comite de Defensa del Consumidor.

[761]For a full list of resolutions see: *Op. cit.* 141 (*Le statut de politique de protection du consommateur dans les systèmes régionaux économiquement intégrés. Une première évaluation comparative*), at 30 to 33.

consumer policy on safety.[762]

From its part, CARICOM[763] not only has integrated provisions regarding consumer protection into its founding treaty, as revised, but it also has the most explicit consumer protection policy in the Americas. In accordance with article 67(1), *Standards and Technical Regulations*, the Council for Trade and Economic Development (COTED), in collaboration with competent agencies, is in charge of developing a standardization program on consumer protection. Chapter eight, *Competition Policy and Consumer Protection*, puts consumer protection on a higher level of recognition and establishes a detailed framework for the implementation of community competition policy and the promotion of consumer welfare and protection of consumer interests.[764] The Caribbean Court of Justice, established in 2005, plays a part in consumer protection by interpreting the treaty provisions.[765]

Among consumer matters, consumer safety has been given priority attention. Article 184 (*Promotion of Consumer Interests in the Community*)[766] and Article 185

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[762]For more on the role of the Ad Hoc Tribunal and the Permanent Court of the Revision of MERCOSUR see: *Op. cit.* 141 (*Le statut de politique de protection du consommateur dans les systèmes régionaux économiquement intégrés. Une première évaluation comparative*) at 33 to 38.

[763]Caricom members: Antigua and Barbuda, Belize, Grenada, Montserrat, St. Vincent and the Grenadines, Turks and Caicos Islands, the Bahamas, British Virgin Islands, Guyana, St. Kitts and Nevis, Suriname, Barbados, Dominica, Jamaica, Saint Lucia, Trinidad and Tobago.

[764]Revised Treaty of Chaguaramas establishing the Caribbean Community including the CARICOM Single Market and Economy. CARICOM, *Treaty of Chaguaramas*, 2001, at Chapter 8, online: Caribbean Community Secretariat <http://www.caricomlaw.org>.

[765]For more on the role of the Caribbean Court of Justice see: *Op. cit.* 141 (*Le statut de politique de protection du consommateur dans les systèmes régionaux économiquement intégrés. Une première évaluation comparative*) at 20.

[766]Article 184: The Member States shall promote the interests of consumers in the Community by appropriate measures that: (a) provide for the production and supply of goods and the provision of services to ensure the protection of life, health and safety of consumers; (b) ensure that goods supplied and services provided in the CARICOM single market and economy satisfy regulations, standards, codes and licensing requirements established or approved by competent bodies in the Community; (c) provide, where the regulations, standards, codes and licensing requirements referred to in paragraph (b) do not exist, for their establishment and implementation.

(*Protection of Consumer Interests in the Community*)[767] of the *Revised Treaty of Chaguaramas* established a comprehensive list of measures that Member States must follow in order to advocate consumer safety.[768]

Lastly, the Organization of American States (OAS) has recently made significant steps to create a Pan-American informational framework on consumer safety. In order to strengthen national capacities and regional cooperation with the aim of enabling early detection of unsafe consumer products and the adoption of coordinated actions among the competent agencies, OAS[769] has supported the creation of the Consumer Safety and Health Network (CSHN).[770] The CSHN offers countries a space for technical cooperation to prevent and/or stop, as a region, the circulation of unsafe products in their markets. Among other aspects, the CHSN has promoted and supported the creation and/or the strengthening of consumer product safety national market surveillance systems. A central element of the CSHN, the Inter-American

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[767]Article 185: The Member States shall enact harmonized legislation to provide, inter alia: (....) (d) for the prohibition of production and supply of harmful and defective goods and for the adoption of measures to prevent the supply or sale of such goods including measures requiring the removal of defective goods from the market; (e) that the provision of services is in compliance with the applicable regulations, standards, codes and licensing requirements; (f) that goods supplied to consumers are labeled in accordance with standards and specifications prescribed by the competent authorities; (g) that hazardous or other goods whose distribution and consumption are regulated by law are sold or supplied in accordance with applicable regulations; (...) (i) that producers and suppliers are liable for defects in goods and for violation of product standards and consumer safety standards which occasion loss or damage to consumers; (j) that violations of consumer safety standards by producers or suppliers are appropriately sanctioned and relevant civil or criminal defenses to such violations are available to defendants.

[768]Chapter Eight: *Competition Policy and Consumer Protection*, online: Caribbean Trade Reference Centre <http://ctrc.sice.oas.org/trade/caricom/caric6a.asp>.

[769]The following 21 member states met in Bogotá, Colombia, in 1948 to sign the OAS Charter: Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Haiti, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, United States of America, Uruguay, and Venezuela (Bolivarian Republic of). Subsequently, the following 14 member states joined: Barbados, Trinidad and Tobago (1967); Jamaica (1969); Grenada (1975); Suriname (1977); Dominica (Commonwealth of), Saint Lucia (1979); Antigua and Barbuda, Saint Vincent and the Grenadines (1981); The Bahamas (Commonwealth of) (1982); St. Kitts & Nevis (1984); Canada (1990); Belize and Guyana (1991).

[770]The CHSN is the inter-American interdisciplinary mechanism, specialized in promoting, at a national and hemispheric level, consumer health and safety policies and programs, and the impact they can have on consumers' health and wellbeing.

Rapid Alerts System (SIAR) is the first hemispheric integrated system for the generation, management and rapid and secure exchange of information on consumer safety alerts, based on agreed criteria on principles, general concepts and relevant terminology for regional alerts. Launched December 10th, 2014, SIAR allows national agencies to rapidly generate and exchange information on consumer product safety alerts in a secure and collaborative environment. Available in English, French, Portuguese and Spanish, the system also features detailed information about legislation governing product recalls in different American countries, as well as guidance documents, study reports, analyses of product safety trends, newsletters.[771]

In the Americas, progress in the regionalization of the legal and institutional frameworks for consumer safety has remained slow, dispersed among several institutions and mostly limited to cooperation and exchange of information mechanisms.

Europe is a more useful source of inspiration. Within the European Union integration process, consumer protection policy was recognized as a common policy as early as 1975 and given full status in the Rome treaty establishing the European Community in 1992. Since the inception of the EU, consumer safety has always been a top priority of consumer protection agenda.[772]

Likewise, from the beginning the Commonwealth of Independent States (CIS) has taken some initiatives on developing common policy on consumer protection and safety. In recent years, this process has accelerated; especially, with the inauguration of a new political entity within CIS borders. The recently formed Euro Asian Economic Union (EAEU), with a political and legal structure similar to the EU, has

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[771]More on SIAR see: SIAR, online: OAS <https://www.sites.oas.org/rcss/EN/Pages/about/siar.aspx>.
[772]Detailed analysis on consumer protection and safety in the EU see 3.3.3.

shown great willingness to create a comprehensive policy on consumer protection and safety.[773]

To observe just how well consumer safety policy works at the regional level, it is preferable to choose and compare a few regions with different political and historical backgrounds while having a more or less comparable socio-economical level of development. The EU, CIS/EAEU and NAFTA are seen as an adequate focus group to illustrate and assess the potential developments of regional policies in the area of consumer safety. These economically integrated regions have different political levels of integration but at the same time very similar levels of social and economic development. The approaches to consumer safety in the EU, CIS/EAEU and NAFTA will help in identifying the conditions that must be met at the regional level of governance in order to make consumer safety effective on the regional and national markets.

[773]The CIS comprises 10 former Soviet Republics: Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Ukraine, and Uzbekistan. Turkmenistan discontinued permanent membership as of August 26, 2005, and is now an associate member. Whereas, EAEU members are Kazakhstan, Belarus, Russia, Armenia, and Kyrgyzstan.
Detailed analysis on consumer protection and safety in CIS/EAEU see 3.3.4.

3.2 Implementation of the international law instruments on consumer safety within the selected regional systems

3.2.1 Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

NAFTA[774]

The North American Free Trade Agreement Technical Working Group on Pesticides established under the NAFTA provisions on Sanitary and Phytosanitary Measures is the only agency in North America which works with the chemicals listed in the Rotterdam Convention.[775] Since its creation in 1997, the Technical Working Group has maintained a primary focus on facilitating cost-effective pesticide regulation and trade among the three countries. The Group does this through harmonization and work sharing, while recognizing the environmental, ecological and human health objectives of NAFTA. Therefore, this organization serves solely as a focal point for addressing pesticide issues arising in the context of liberalized trade among the NAFTA countries, and does not have a mandate to implement any provisions of the Rotterdam Convention.[776]

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[774]Our research predominately focuses on Canada and the United States since there is not sufficient data available on the implementation of the international agreements on product (service) safety by Mexico.

[775]Mexico ratified the Convention in May 2005 using the accession as a procedure for ratification.

[776]*The North American Free Trade Agreement Technical Working Group on Pesticides*, online: Health Canada <http://www.hc-sc.gc.ca/cps-spc/pest/part/int/_nafta-alena/index-eng.php>.

Canada

Prior the Rotterdam Convention, Canadian *Export Control List Notification Regulations*[777] served as a legal tool to control international trade of certain dangerous chemicals. To bring national rules in unison with the Convention requirements, *Export of Substances Under the Rotterdam Convention Regulations*[778] had been adopted in 2002.[779] Just recently Canadian regulation has been recast to amalgamate quite similar obligations under two conventions on dangerous substances, Rotterdam and Stockholm. The legal basis for *Export of Substances on the Export Control List Regulations*[780] (the Regulations), as well as two preceding documents are prescribed by subsection 102(1) of the *Canadian Environmental Protection Act, 1999*,[781] which explicitly mandates the Government the right to make regulations in relation to chemicals: a) the use of which is prohibited in Canada; b) subject to an international agreement that requires notification or requires the consent of the country of destination before the substance is exported from Canada; c) the use of which is restricted in Canada. The Regulations explain in details all technical aspects for the export procedure concerning the chemicals under the Rotterdam convention; including conditions of export, permit application, issuance of export permits, labeling etc.[782]

The Chemical Production Division of the Environment Canada[783] and Pest

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[777]*Export Control List Notification Regulations*, SOR/2000-108, online: Canadian Legal Information Institute <https://www.canlii.org/en/ca/laws/regu/sor-2000-108/latest/sor-2000-108.html>.
[778]*Export of Substances Under the Rotterdam Convention Regulations,* SOR/2002-317, online: Canadian Legal Information Institute <https://www.canlii.org/en/ca/laws/regu/sor-2002-317/latest/sor-2002-317.html>.
[779]Canada ratified the Convention in August 2002.
[780]*Export of Substances on the Export Control List Regulations,* SOR/2013-88, online: Canadian Legal Information Institute <https://www.canlii.org/en/ca/laws/regu/sor-2013-88/latest/sor-2013-88.html>.
[781]*Canadian Environmental Protection Act, 1999,* (S.C. 1999, c. 33), online: Canadian Legal Information Institute <https://www.canlii.org/en/ca/laws/stat/sc-1999-c-33/latest/sc-1999-c-33.html>.
[782]Art. 7-22.
[783]*Chemical Production Division*, online: Environment and Climate Change Canada <http://www.ec.gc.ca/toxiques-toxics/Default.asp?lang=En&n=FB6BD2C0-1>.

Management Regulatory Agency of the Health Canada[784] both serve as Designated National Authority (DNA) and Official Contact Point (OCP) of the Convention.

United States

In spite of the fact that the United States are one of the biggest producers of the chemicals listed in the Rotterdam Convention as well as an original creator and signature party (1998) of the Treaty, they have never ratified this international agreement.

The official explanation provided by U.S. Department of State is "lack the authority to implement all [...] provisions" of the Convention.[785] For the United States to be able to ratify international treaties on chemicals safety, the Congress has to amend the U.S. statutes that regulate pesticides and toxic substances: *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA)[786] and *Toxic Substances Control Act* (TSCA).[787] From 2002 to 2006, Congress considered several legislative proposals intended to enable the United States to ratify the Rotterdam and Stockholm conventions. The George W. Bush administration also supported their approval, and chemical industry groups have long echoed calls for congressional action, but the necessary legislative changes to FIFRA and TSCA have proved more difficult than expected given the treaties' broadly nonpartisan reputation. At the same time, larger

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[784]*Pest Management Regulatory Agency*, online: Health Canada <http://www.hc-sc.gc.ca/contact/cps-spc/pmra-arla/infoserv-eng.php>.

[785]*Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade*, [communiqué], online: U.S. Department of State, <http://www.state.gov/e/oes/eqt/chemicalpollution/83010.htm>.

[786]FIFRA is the principal statute that regulates pesticides. Imported pesticides must meet the same requirements as domestically produced pesticides, but exported pesticides are subject to very limited regulation. To comply with the Rotterdam Convention, FIFRA would need to include the PIC provision for exported pesticides.

[787]TSCA is the primary statute that applies to non-pesticidal, non-drug substances. Apart from minimum labeling requirements, TSCA does not require registration for chemicals prior to use or otherwise prohibit or restrict their use for export. To comply with the provisions of the international Conventions on safety of chemicals legislation should require the US Environment Protection Agency to take action to determine the appropriate regulatory action for the chemical.

TSCA reform has been proposed but the fate of those measures, which would give the US Environment Protection Agency authority to regulate toxins and ask manufacturers to prove the safety of new chemicals before bringing them to market, remains uncertain primarily due to industry resistance. Presently, the US administration is renewing the long-running effort to win U.S. ratification of the two international treaties.[788] Meanwhile, the United States participates as an observer in the meetings of the parties of the conventions and in technical working groups.[789]

EU

For the interpretation of the Convention into European law, the European Commission took a few steps. Initially, *Regulation 304/2003 of the European Parliament and of the Council of 28 January 2003 Concerning the Export and Import of Dangerous Chemicals* had implemented the Rotterdam Convention.[790] Consequently, to incorporate number of technical amendments, it was replaced by *Regulation 689/2008 of the European Parliament and of the Council of 17 June 2008 Concerning the Export and Import of Dangerous Chemicals*.[791] Likewise, Regulation 689/2008 was substantially amended several times. In the interest of clarity Regulation 689/2008 was recast into the new *Regulation 649/2012 of the European Parliament and of the Council of 4 July 2012 Concerning the Export and Import of*

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[788]Elana Schor "Obama Admin Steps Up Pressure to Ratify Treaties on Toxics", *The New York Times,* (24 September 2010), online: The New York Times <http://www.nytimes.com/gwire/2010/09/24/24greenwire-obama-admin-steps-up-pressure-to-ratify-treati-73636.html>.

[789]More on drawback with ratification: Mary Jane Angelo, *Everywhere, All the Time: Why the U.S. Should Ratify 3 International Agreements on Persistent Organic Pollutants* (9 March 2016), online: Centre for Progressive Reform <http://www.progressivereform.org/CPRBlog.cfm?fkScholar=6>.

[790]EC, *Regulation 304/2003 of the European Parliament and of the Council of 28 January 2003 Concerning the Export and Import of Dangerous Chemicals*, OJ L 63, 6.3.2003, p. 1.

[791]EC, *Regulation 689/2008 of the European Parliament and of the Council of 17 June 2008 Concerning the Export and Import of Dangerous Chemicals*, OJ L 204, 31.7.2008, p. 1-35, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32008R0689>.

Hazardous Chemicals, which has been applied since 1 March 2014.[792] Primarily all these regulations cover the export of certain hazardous chemicals that are banned or severely restricted within the Union. Nevertheless, the requirements of Regulation (EU) 649/2012 go beyond those of the Rotterdam Convention, because it also provides for import decisions of non-convention-parties having to be respected.

The Member States and the EU Commission jointly carry out tasks with regard to the administrative, technical and scientific aspects of the implementation of the Convention as well as the exchange of information. Every importer/exporter in the EU has to comply with provisions of the Regulation 649/2012.[793]

Every member-state has a DNA contact point which communicates to both: a) the Secretariat of the Convention; b) the Federal Institute for Occupational Safety and Health Federal Office for Chemicals (BAuA) in Germany which is used as the EU Designated National Authority for the implementation of Regulation 649/2012. BAuA is responsible for seeking import/export decisions and for the obligation to report to the European Commission.[794] 5929 export and 441 import notifications were issued in 2013 alone.[795]

Until recently, the European Database of Export and Import of Dangerous Chemicals (EDEXIM) within the scope of responsibility of the Institute for Health and Consumer Protection (IHCP) was the technical tool for managing the entire PIC

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[792]EC, *Regulation 649/2012 of the European Parliament and of the Council of 4 July 2012 Concerning the Export and Import of Hazardous Chemicals* OJ L 201, 27.7.2012, p. 60-106, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:201:0060:0106:en:PDF>.

[793]Penalties for infringement vary for every Member State. In France, for example, import or export of dangerous chemicals without complying with the provisions of regulation is punishable by up to 2 years of detention.

[794]Federal Institute for Occupational Safety and Health Federal Office for Chemicals (BAuA), online: <http://www.baua.de/en/Homepage.html>.

[795]*Annual reporting on PIC Exports and Imports*, online: European Chemicals Agency <https://echa.europa.eu/regulations/prior-informed-consent/annual-reporting-on-pic-exports-and-imports>.

procedure.[796] Since 1 March 2014, the European Chemicals Agency (ECHA) in Helsinki[797] is responsible for the technical implementation of the procedure. In parallel, a new database, e-PIC, has being developed.[798] Until then, all relevant data have to be migrated from EDEXIM to the new database.

Commonwealth of Independent States (CIS)[799]

Only recently did the Russian Federation become a party to the Rotterdam Convention, after *Федеральный Закон Российской Федерации от 8 марта 2011 г. N 30-ФЗ*[800] (the Federal law of the Russian Federation N30- ФЗ) was signed by the President of Russia on March 8, 2011.[801]

For the Russian Federation, participation in the Rotterdam Convention was beneficial. Ratification of the treaty did not impose additional legal or financial obligations, since the Russian Federation had already banned substances regulated by the Convention.[802] Moreover, both the industry and the government are now able to receive timely information on banned, severely restricted chemicals and pesticides from all parties to the Convention, thereby reducing the cost related to expensive research and study regarding the harmful effect of substances on human health.

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[796]*Institute for Health and Consumer Protection*, online: <http://ihcp.jrc.ec.europa.eu>.
[797]*European Chemicals Agency*, online:<http://echa.europa.eu>.
[798]*e-PIC database*, online <http://echa.europa.eu/information-on-chemicals/pic/chemicals>.
[799]Our research predominately focuses on Russia since there is not sufficient data available on the implementation of the international agreements on product (service) safety by other CIS Member States.
[800]*Федеральный закон Российской Федерации от 8 марта 2011 "О Присоединении Российской Федерации к Роттердамской конвенции о Процедуре Предварительного Обоснованного Согласия в Отношении Отдельных Опасных Химических Веществ и Пестицидов в Международной Торговле "* [the Federal law of the Russian Federation N30- ФЗ "On Accession of the Russian Federation to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade"], [translated by author], online: Российская Газета <https://rg.ru/2011/03/11/pesticidy-dok.html>.
[801]Russia did not sign the treaty back in 1998 and used the procedure of accession to join the Convention on April 28, 2011.
[802]To date 89 pesticides banned and 25 are under restrictions, including all listed for PIC producer.

Ultimately, the participation in the selection process of hazardous chemicals and pesticides to be included in the PIC procedure protects Russian economic interests.[803]

The *Directive of the Government of the Russian Federation n. 22 January, 26, 2012 "Regarding Measures to Implement the Obligation under the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade"* clarified the technical aspects of the execution of the provisions of the Convention. For example, the Minister of Health is responsible for annual instalments to the Secretariat of the Convention and the Federal Customs Agency should elaborate the mechanism to control cross border movements of substances under the Convention.[804]

The Environmental Protection Department and the Department of International Cooperation of the Ministry of Natural Resources and Environment[805] serve as OCP; and the Main Department for Agrochemicals and Plant Protection of the Ministry of Agriculture and Food[806] and the Register of Potentially Hazardous Chemical and Biological Substances of the Federal Surveillance Service for Protection of

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[803]*Пояснительная Записка к Проекту Федерального Закона «О Присоединении Российской Федерации к Роттердамской Конвеции о Процедуре Предварительного Обоснованного Согласия в Отношении Отдельных Опасных Химических Веществ и Пестицидов в Международной Торговли от 10 Сентября 1998 Года»* [Explanatory Note on the Federal Law Draft: Regarding the Accession of the Russian Federation to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, September 10, 1998], online: Консультант Плюс <http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=PRJ;n=82457>.

[804]*Постановление от 26 января 2012 Года, О мерах по Обеспечению Выполнения Обязательств Российской Федерации, Вытекающих из Роттердамской Конвенции о Процедуре Предварительного Обоснованного Согласия в Отношении Отдельных Опасных Химических Веществ и Пестицидов в Международной Торговле* [The directive of the Government of Russian Federation n. 22 January, 26, 2012 Regarding Measures to Implement the Obligation under the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade], online: Российская Газета <https://rg.ru/2012/02/07/pesticidy-site-dok.html>.

[805]Ministry of Natural Resources and Environment of the Russian Federation [English], online: <http://www.mnr.gov.ru/english/>.

[806]Ministry of Agriculture of the Russian Federation [Russian], online: <http://www.mcx.ru>.

consumers' rights and welfare of humans, Ministry of Health and Social Policy serve as DNA.[807]

3.2.2 Stockholm Convention on Persistent Organic Pollutants

NAFTA

Canada

Canada played a leadership role in the development and initial implementation of the Stockholm Convention. When negotiations were completed, Canada was the first country to sign and ratify the new treaty in May 2001. As a result of actions taken from the 1970s through the 1990s, there are no stockpiles of POPs pesticides; as well Canada does not produce or use any of the substances listed in the Convention. Hence, the majority of POPs entering Canada's environment now come from foreign sources.

The federal legislation controlling POPs encompasses: the *Canadian Environmental Protection Act, 1999*,[808] and the *Pest Control Products Act.*[809] Additionally, Canadian Toxic Substances Management Policy[810] guides the assessment of existing and new chemical substances and provide for their assessment against criteria of persistence,

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[807]To date more than 10,000 dangerous substances are recorded, including all chemicals subject to the Rotterdam Convention. ФБУЗ "Российский Регистр Потенциально Опасных Химических и Биологических Веществ" Роспотребнадзора — Национальный Корреспондент Подпрограммы ЮНЕП по Химическим Веществам. [Register of Potentially Hazardous Chemical and Biological Substances] ФБУЗ online: <http://rpohv.ru>.

[808]*Op. cit.* 781 (*Canadian Environmental Protection Act, 1999*).

[809]*Pest Control Products Act* (S.C. 2002, c. 28) online: Justice Laws Website <http://laws-lois.justice.gc.ca/eng/acts/P-9.01/>.

[810]*Toxic Substances Management Policy*, online: Environment and Climate Change Canada <https://www.ec.gc.ca/toxiques-toxics/default.asp?lang=En&n=2A55771E-1>.

bioaccumulation and toxicity. The recent domestic initiative categorizing 23,000 chemicals in commerce will give the information base needed to identify candidate POPs and to support and/or review each pollutant's nomination to the Convention.

Finally, the Government of Canada created the CAD$20 million Canadian POPs Fund in March 2000. A significant portion of these funds has been used for education and awareness projects among developing countries and countries with economies in transition and for inventory building, thus assisting national governments with their decisions to sign and ratify the Convention.[811]

United States

In the spite of the fact that more than 15 years ago, in April 2001, George W. Bush endorsed the treaty and later that year submitted the Stockholm Convention to the U.S. Senate for its advice and consent to ratification, like the Rotterdam Convention the international agreement on POPs has never been ratified by the US.[812]

Since the first meeting of the Stockholm Convention in May 2005, where the United States was relegated to observer status, pressure has been rising for U.S. ratification. In July 2005 Secretary of State Rice and Environment Protection Agency Administrator Johnson sent a joint letter to the House and Senate leadership warning of "negative repercussions for U.S. leadership" in international chemicals discussions if Congress does not act quickly to adopt necessary implementing legislation.[813] Nonetheless, the Congress has never heard endless government calls for action and no real steps have yet been done toward the ratification.

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[811] *Canada's National Implementation Plan under the Stockholm Convention on Persistent Organic Pollutants,* online: Stockholm Convention <http://chm.pops.int/Implementation/NIPs/NIPSubmissions/tabid/253/>.

[812] *President Bush Sends the Stockholm Convention on Persistent Organic Pollutants to Senate for Ratification*, U.S. Environmental Protection Agency (11 April 2002), online: U.S. Department of State <http://2001-2009.state.gov/g/oes/rls/prsrl/press/jan/9748.htm>.

[813] *Letter to Senator Frist* (22 July 2005), online: Centre for International Environmental Law <http://www.ciel.org/Publications/POPs_Frist_22Jul05.pdf>.

Meanwhile, the United States has taken strong domestic action to reduce emissions of POPs. For example, none of the original POPs pesticides listed in the Stockholm Convention is registered for sale and distribution in the United States today and in 1978 Congress prohibited the manufacture of new industrial and consumer equipment with POPs components and severely restricted the use of remaining stocks. In addition, since 1987, the federal government and the states have effectively reduced environmental releases of POPs to land, air, and water from U.S. sources.[814] The only obstacle preventing the ratification is an antagonistic position of U.S. lawmakers regarding the "adding mechanism" of the treaty.

Even during the final debate over what steps could be taken in the future to add other POPs to the Convention, the US and its allies argued that no formal steps under the auspices of the Convention should be taken on this key issue until ratification by at least 50 nations is achieved. The final version of the treaty was a blueprint of the US's proposal (which was fronted by 77 nations after strong US lobbying behind the scenes) which focuses exclusively on old chemicals that lack, to a large degree, any strong economic constituency because for the most part the targeted chemicals are already banned or heavily regulated in the developed world.[815]

Since the original dirty dozen POPs represent only a few of these life-threatening chemicals, the Stockholm Convention contains a crucial "adding mechanism" for identifying other POPs and incorporating them into the international agreement. As U.S. negotiators hammered out the treaty's terms, they insisted on a rigorous, scientific review process for evaluating potential POP proposed by parties, before it could be listed with unanimous consensus. Yet the treaty contains an explicit "opt

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[814] *Persistent Organic Pollutants: A Global Issue, A Global Response*, online: U.S. Environmental Protection Agency <http://www2.epa.gov/international-cooperation/persistent-organic-pollutants-global-issue-global-response>.

[815] *UN Conference Approves POPs Convention in Stockholm*, online: Our Stolen Future <http://www.ourstolenfuture.org/policy/pops/2001-0522popsconvention.htm>.

in" provision for new POPs listings, a problem for the United States as it does not want to be forced to regulate a new POP against its will.[816]

EU

The Stockholm Convention was explicitly made open for signature and ratification to Regional Economic Integration Organizations (REIO) with legal personality. The European Community is regarded as such an organization.[817]

In contrast to the United States, the European Union, throughout the entire negotiations on the provisions of the Convention, proved far more progressive and precautionary in its positions. In the final moments of debate, to save key elements of the treaty that defined the general process of including new chemicals, and also understanding that even in expurgated form the treaty would be still immensely valuable, especially because of the economic assistance it would bring to developing countries attempting to manage hazardous chemicals, the EU agreed to the US proposal.[818]

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[816]*U.S. Ratification of the Stockholm Convention: Analysis of Pending POPs Legislation,* (13 March 2006), online: Center for International Environmental Law <http://www.ciel.org/Publications/POPs_Bills_28Feb2006.pdf>.

[817]The Stockholm Convention defines parties and Regional Economic Integration Organizations (REIOs) in its Article 2. A REIO means an organization constituted by sovereign states of a given region to which its Member States have transferred competence in respect of matters governed by the Stockholm Convention and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to the Stockholm Convention. Article 23 lays down a specific voting rule for REIOs: A REIO, on matters within its competence, shall exercise its right to vote with a number of votes equal to the number of its Member States that are parties to the Stockholm Convention. Such an organization shall not exercise its right to vote if any of its Member States exercises its right to vote, and vice versa.

[818]*Op. cit.* 815 (*UN Conference Approves POPs Convention in Stockholm*).

Submitted in 2007, *Community Implementation Plan for the Stockholm Convention on Persistent Organic Pollutants* (EU Plan)[819] in detail depicts legal and technical aspects of implementation. The overall purpose of the EU Plan is not only to fulfill the EU's legal obligations but also to take stock of actions taken and lay down a strategy and action plan for further Community measures related to POPs included in the Stockholm Convention. The EU Plan aims to: a) identify the existing Community level measures related to POPs; b) assess their efficiency and sufficiency in meeting the obligations of the Stockholm Convention; c) identify needs for further Community level measures; d) establish a plan for implementing the further measures; e) identify and strengthen links and potential synergies between POP management and other environmental policies and other policy fields; and f) increase awareness on POPs and their control measures.[820]

At the time of ratification, the EU had a total of 100,000 tonnes of POPs stocks and approximately 800,000 tonnes[821] of POPs present in environment.[822] As for unintentionally released POPs, it has been estimated that approximately 10,000 tonnes has been released in the environment every year. The major sources responsible for releases are power generation, road transport, steel industry and industrial/consumer waste.[823]

The main legal instrument for implementing the Stockholm Convention in the EU is Regulation (EC) No 850/2004.[824] Entered into force on 20 May 2004, it is directly

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[819]EC, *Community Implementation Plan for the Stockholm Convention on Persistent Organic Pollutants,* SEC (2007) 341, online: European Commission <http://ec.europa.eu/environment/chemicals/international_conventions/pdf/sec_2007_341.pdf>.
[820]*Ibid.* at 9-10
[821]The total amount that has been spilled to the environment of all the EU states.
[822]*Op. cit.* 819 (*Community Implementation Plan for the Stockholm Convention on Persistent Organic Pollutants*), at 12-21.
[823]*Ibid.* at 18-20
[824]EC, *Regulation 850/2004 of the European Parliament and of the Council of 29 April 2004 on Persistent Organic Pollutants and Amending Directive 79/117/EEC*, OJ L 158, 30.4.2004, p. 7–49,

applicable in all Member States, including those which are not yet parties to the Stockholm Convention.[825] The Regulation bans production, placing on the market and use of all intentionally produced POP substances listed in the Stockholm Convention. It also obliges Member States to draw up and maintain comprehensive release inventories and to communicate to the Commission and to the other Member States their national action plans on measures to minimize total releases of these substances.

Finally, the European Union provides significant amount of funding to environmental projects and programs[826] within the EU, in neighbouring countries and in developing countries.[827]

CIS

Signed by Russia back in May 2002, the Convention was ratified 9 years later in August 2011. The Russian Government also declared that in accordance with paragraph 4 of article 25 of the Convention any amendment to POPs listing would enter into force for the Russian Federation only upon the deposit of its instrument of ratification, acceptance, approval or accession with respect thereto.[828] Hereby, Russian obtained "an insurance policy" to avoid in the future any detrimental obligations regarding newly added POPs.

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online: <EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32004R0850>.

[825]Italy and Malta signed the treaty back to 2001 but have never ratified.

[826]For example, during 2007-2013 period a budget of 1,854 million € was allocated.

[827]More on Financial instruments see; *Op. cit.* 819 (*Community Implementation Plan for the Stockholm Convention on Persistent Organic Pollutants*), at 29 & 30.

[828]*Status of Ratifications*, online: Stockholm Convention <http://chm.pops.int/Countries/StatusofRatifications/PartiesandSignatories/tabid/252/Default.aspx#a-decl-RU>.

The POP's problem in Russia is unique and somehow similar to one in developing countries, due to uncontrolled use of old stocks of pesticides by consumers. Many families who grow a variety of crops for personal consumption or to sell on the market use POP pesticides. Harmful to consumer health formulations are coming from old vast Soviet stockpiles at home or through illegal trade from POP's depositories. Similar problem exists in many CIS Member States.[829]

Regrettably, Russia has still not submitted the National Implementation Plan, despite the dead line of August 2013. After long delay, Russia has slowly moved in the right direction to meet its obligations under the Convention protecting the environment and Russian consumers from toxic POPs.

Just recently, the Premier Minister of Russia adopted a directive *Regarding the Measure to Implement Russian Federation's Obligations under the Stockholm Convention on Persistent Organic Pollutants at 22 May 2001.*[830] The document incorporates a few important endorsements to speed up the elaboration of the National Implementation Plan. The Ministry of Natural Resources and Environment of the Russian Federation (NRER) is named to be the government body in charge of

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[829]The problem of obsolete pesticide stocks in the Russia and most ex-Soviet states is related to the legacy of the political agenda in the former Soviet Union, aiming at the use of chemicals in all spheres of economic activity. CIS Member States inherited tens of thousands tons of hazardous pesticides, which are currently "time-bombs", presenting a serious threat to the environment and health of the population. Studies conducted by the World Bank in 2008-2010, revealed a number of problems related to stocks of obsolete pesticides: a) poor technical condition of warehouses and container used to store hazardous chemicals; b) local population embezzles old stockpiles from poorly protected depositories to use at households; c) conducting preventive measures on chemical safety are ineffective; d) public is not properly informed about the harmful effects of pesticides on human health and the environment. (*Obsolete Pesticides Technical Study in the Kyrgyz Republic, the Republic of Tajikistan, and the Republic of Uzbekistan,* online: Obsolete Pesticides <https://obsoletepesticides.net/site/central-asian-technical-study-on-obsolete-pesticides/>).

[830]*Постановление от 30 Июля 2014 Года №720, О Мерах по Обеспечению Выполнения Российской Федерацией Обязательств, Предусмотренных Стокгольмской Конвенцией о Стойких Органических Загрязнителях от 22 Мая 2001 г.* [Directive №720, 30 July, 2014, Regarding the measure to implement Russian Federation's obligations under the Stockholm Convention on persistent organic pollutants at 22 May, 2001], online: Government of Russia <http://government.ru/docs/14081/>.

all aspects relating to the Convention implementation.[831] The NRER is responsible for work coordination between numerous government institutions[832] as well serving as the National Contact Point. The Prime Minister gave the government a six months timeframe to submit the National Implementation Plan to the Secretariat of the Convention. Nevertheless, to date no plan has been transferred.

3.2.3 The Basel Convention on the control of transboundary movements of hazardous wastes and their disposal

NAFTA

There are no specific provisions on hazardous waste trade in NAFTA. Meanwhile, over 90% of hazardous waste trade done by NAFTA countries is between NAFTA parties[833] and Mexico is the biggest importer of hazardous North American waste (by volume).[834] As a party to the Basel Convention, Mexico should not consent to any hazardous waste shipment for which it cannot guarantee the environmentally sound management. However, if Mexico does consent to receive dangerous waste, no one can prevent shipping (or force re-importation) even if the exporting companies or

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[831] *Ministry of Natural Resources and Environment of the Russian Federation*, online: <http://www.mnr.gov.ru/english/>.

[832] Document lists 17 government bodies responsible for implementation of the Convention, including the *Russian Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing (Rospotrebnadzor)*, online: <http://www.rospotrebnadzor.ru/en/>.

[833] Shipment between the US and Canada is regulated by bilateral agreement requiring the environmentally sound management of hazardous waste.

[834] Rebecca Slocum, *Rethinking Hazardous Waste under NAFTA*, Americas Program, Center for International Policy, (August 2009), online: Basel Action Network <http://ban.org/library/Features/090810_rethinking_hazardous_waste_under_nafta.html>.

authorities in US or Canada know the shipment will be illegally discarded. The result is that 50-80% of hazardous waste is dumped illegally.[835]

The relation between NAFTA and the Basel Convention is quite unique. In general, in the event of any inconsistency between NAFTA and other international agreements, NAFTA rules prevail.[836] Nonetheless, according Art.104, obligations under a limited number of international environment agreements including the Basel Convention, expressly predominate over NAFTA principles in the event of discrepancy.[837] Surprisingly, Basel convention provisions overrule the free trade regimes. Hence, the international treaty may serve as indispensable tool to prevent the flow to the south of both hazardous waste and unsafe second-hand consumer items. In theory, this dynamic ought to benefit consumer safety across North America - providing politicians have the genuine willpower to do so. Mexico, where used consumer goods from the US and Canada,[838] such as second-hand cars,[839] have

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[835]*Ibid.*

[836]NAFTA Article 103 (2).

[837]Article 104: Relation to Environmental and Conservation Agreements: In the event of any inconsistency between this Agreement and the specific trade obligations set out in: a) the *Convention on International Trade in Endangered Species of Wild Fauna and Flora*, done at Washington, March 3, 1973, as amended June 22, 1979, b) the *Montreal Protocol on Substances that Deplete the Ozone Layer*, done at Montreal, September 16, 1987, as amended June 29, 1990, c) the *Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal*, done at Basel, March 22, 1989, on its entry into force for Canada, Mexico and the United States, or d) the agreements set out in Annex 104.1. (Annex 104.1: Bilateral and Other Environmental and Conservation Agreements: a) *The Agreement Between the Government of Canada and the Government of the United States of America Concerning the Transboundary Movement of Hazardous Waste*, signed at Ottawa, October 28, 1986; b) *The Agreement Between the United States of America and the United Mexican States on Cooperation for the Protection and Improvement of the Environment in the Border Area*, signed at La Paz, Baja California Sur, August 14, 1983.), online: Organization of American States <http://www.sice.oas.org/trade/nafta/chap-01.asp#An104.1>.

[838]Transboundary waste movements between Mexico and Canada are subject to Basel Convention, because both are Basel Parties and do not have a separate bilateral agreement regarding hazardous waste shipments, similar to US-Mexico one.

[839]In accordance with the conditions of NAFTA, in August 2005 Mexico issued a decree allowing 10-15 year-old vehicles to be imported from the United States and Canada. This represented a dramatic break from the previous policy that prohibited entry for all used vehicles except for certain vehicles used in agriculture. Virtually overnight a vigorous trade flow emerged and just between 2005 and 2008 over 2.5 million used vehicles were exported from the United States to Mexico. (Lucas W. Davis & Matthew E. Kahn, *International Trade in Used Vehicles: The Environmental Consequences of NAFTA*,

flooded the market, would benefit the most. Regrettably, the reality is grim, since Mexico continues letting dangerous waste pour through the border.

Canada

Canada participated in the development of the Convention, was one of the original signatories in 1989 and ratified the treaty on August 28, 1992. In 1992, Canada complied with its international obligations by bringing the former *Export and Import of Hazardous Waste Regulations* (EIHWR) into force. The *Export and Import of Hazardous Waste and Hazardous Recyclable Material Regulations* (EIHWHRMR)[840] revoked and replaced the EIHWR in November 2005.[841] These Regulations work toward ensuring that hazardous wastes and hazardous recyclable materials are managed safely and in a manner that protects the environment and human health. In addition to the environmental benefits that Canada's commitment to the Basel Convention provides, it harmonizes the Canadian framework with nations in the European Union and the Organization for Economic Co-operation and Development (OECD) with respect to transboundary movements of hazardous wastes and hazardous recyclable materials. It is with OECD member countries that most Canadian hazardous waste transactions destined for recovery/recycling take place.[842]

(January 2010) at 3, online: University of California (Hass School of Business) <http://faculty.haas.berkeley.edu/ldavis/Davis%20and%20Kahn%20AEJ%202010.pdf >).

[840]*Export and Import of Hazardous Waste and Hazardous Recyclable Material Regulations*, SOR/2005-149, online: Government of Canada, Justice Laws Website <http://laws-lois.justice.gc.ca/eng/regulations/SOR-2005-149/>.

[841]The EIHWR required modification because a number of changes had occurred both domestically and internationally since 1992. Among these was the entry into force of the *Canada Environment Protection Act 1999* (CEPA), which included new authorities with respect to hazardous wastes and hazardous recyclable materials that did not exist under the former CEPA. By implementing these new authorities and modernizing the former control regime, the EIHWHRMR help Canada adapt to its evolving international obligations, and contribute to the protection of the environment and human health.

[842]*Canada and Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal*, online: Environment and Climate Change Canada <http://www.ec.gc.ca/gdd-mw/default.asp?lang=en&n=1C6F3B4C-1>.

Today, Canada continues to be a strong participant in Basel Convention activities. Environment Canada's Waste Reduction and Management Division develops and represents the Canadian position on issues such as: a) development of technical guidelines related to Environmentally Sound Management (ESM) practices; b) clarification of the scope of the Basel Convention (waste lists); c) harmonization of the OECD and Basel Convention control systems; d) consideration of work on hazard classes; e) drafting technical guidelines related to recycling operations; and f) ESM guidelines for various hazardous recyclable materials.[843]

Finally, Canada and the United States have entered into a comprehensive agreement[844] on the transboundary movement of hazardous waste.[845] Each year, approximately 900,000 metric tonnes of hazardous waste cross the Canada-U.S. border, on its way to an environmentally sound recycling, treatment or disposal site. This agreement sets out specific administrative conditions for the export, import, and transportation of hazardous waste between the two countries.[846]

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[843]*Ibid.*

[844]*The Agreement Between the Government of Canada and the Government of the United States of America Concerning the Transboundary Movement of Hazardous Waste* was signed on October 28, 1986. The Agreement ensures that the transboundary movement of hazardous waste is handled safely and that such waste is shipped to facilities that are authorized by the importing jurisdiction. (*Agreement Between the Government of Canada and the Government of the United States of America Concerning the Transboundary Movement of Hazardous Waste 1986*, online: Environment and Climate Change Canada <http://www.ec.gc.ca/gdd-mw/default.asp?lang=en&n=C59BCC26-1>).

[845]Article 11 of the United Nations Basel Convention allows countries to enter into bilateral/multilateral agreements or arrangements, as long as these agreements or arrangements do not detract from environmentally sound management of wastes. The Canada-U.S. Agreement, together with its supporting regulatory framework, is compatible with the control procedures under the Basel Convention.

[846]*Canada-US Agreement Concerning the Transboundary Movement of Hazardous Waste*, online: Environment and Climate Change Canada <http://www.ec.gc.ca/gdd-mw/default.asp?lang=En&n=EB0B92CE-1>.

United States

The United States signed the Basel Convention in 1990. The U.S. Senate provided its advice and consent to ratification in 1992. However, before the United States can ratify the Convention, there is a need for additional legislation to provide the necessary statutory authority to implement its requirements.[847] Specifically, the Congress must enact legislation restricting the import and export of hazardous waste as set forth by the Basel Convention, through amendments to the *Resource Conservation and Recovery Act of 1976* (RCRA). These amendments would require waste shippers to obtain assurances of environmentally sound disposal and would grant authority to re-import hazardous wastes that are found to be illegally transported.[848] Until that time, as a non-party to the Convention, the U.S. participates in the meetings of the Convention Parties, but is not allowed to vote.

Meanwhile, being a non-Party to the Convention, the U.S. has still defended its own position on currently debated issues on the scope of application of the Convention, include classification of, and control systems for, used and scrap electronics and materials for repair, refurbishment, and remanufacturing. First, finding that the current Basel system for controlling international shipments of hazardous waste makes trade in many of these materials difficult, and in some cases impossible, the U.S. supports consideration of alternative systems of control for "e-waste" under the

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[847]Political opposition is the primary reason why the US has refused to ratify the Basel Convention. Opposition comes from environmental groups who claim the treaty is too weak as well as industry who claims it would be a burden on the manufacturing industry. (Kevin Kallmyer, *Basel Convention on the Control of Transboundary Movements of Hazardous Wastes*, University of Mary Washington, online: Cedadebate <http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCAQFjAA&url=http%3A%2F%2Fwww.cedadebate.org%2Fforum%2Findex.php%3Faction%3Ddlattach%3Btopic%3D749.0%3Battach%3D141&ei=Ho5nVLT8GoyigwSPvoPoCQ&usg=AFQjCNHSO9t2Rx5Zsszn_P7a9dGoPVhDOw&sig2=y2eJp5bL8oK8OmNB0xodbw&bvm=bv.79142246,d.eXY>).

[848]Noah M Sachs, *Out of Sight, Out of Mind: Ratifying the Basel Convention on Transboundary Waste*, (1 May 2012), online: Centre for Progressive Reforms <http://www.progressivereform.org/CPRBlog.cfm?idBlog=08A5B515-BA05-B72A-9AE04583A239DE21>.

Convention. Second, in view of the fact that Basel parties are beginning to argue that the Convention applies, in its current form, to the international movement of used products for repair, refurbishment, or remanufacture, the U.S. insists that the international movement of equipment for repair, refurbishment, or remanufacturing does not constitute movement of waste, and thus is not impacted by the Convention or its procedures.[849]

EU

The EU has fulfilled its obligations on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal. Approved by the EU in February 1993, the Council Decision on Basel Convention came into force on 7 February 1994.[850] Beforehand, *Council Directive 91/689/EEC of 12 December 1991 on Hazardous Waste*[851] introduces a precise and uniform definition of hazardous waste and aims to ensure ecologically sound management of the waste flow. In addition, Articles 17 to 20 of Directive 2008/98/EC[852] regulate hazardous waste labeling, record keeping, monitoring and control obligations from the waste producer to the final disposal or recovery. Mixing of hazardous waste with other categories of waste, substances or materials is banned in order to prevent risks for the environment, human health. This provision makes illegal the practice whereby consumer waste (second-hands good) and hazardous wastes are mixed or shipped together. Finally, the legal regime under

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[849]*US and Basel Convention*, online: US Department of State <http://2001-2009.state.gov/g/oes/env/c18124.htm>.

[850]EC, *Council Decision of 1 February 1993 on the Conclusion, on Behalf of the Community, of the Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (Basel Convention)*, OJ L. 39, 16.2.1993, p. 1–2, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31993D0098>.

[851]EC, *Council Directive 91/689/EEC of 12 December 1991 on Hazardous Waste*, OJ L 377, 31.12.1991 p.20-27, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31991L0689:EN:HTML>.

[852]EC, *Directive 2008/98/EC of the European Parliament and the Council of 19 November 2008 on Waste and Repealing Certain Directives*, OJ L 312/3, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:312:0003:0030:en:PDF>.

the Directive permits exemptions that may be granted to installations dealing with hazardous wastes with more restrictions than for installations dealing with other wastes.

In spite of that, the legislation on hazardous waste management was developed in all European states the frameworks often were not in compliance with the Basel Convention charters. To assist in the implementation of the Basel Convention and relevant obligations into national legislations, the project on Legal Assistance for the Elaboration and Adaptation of National Legislation for the Effective Implementation of the Basel Convention was realized in new and non-EU Member States.[853]

CIS

Considering the fact that the USSR had signed the Basel Convention in 1990, the states of the post-Soviet space also actively joined the process of accession to the treaty and formation of national legislation in the field of waste management.[854] Numerous actions targeting the transboundary movement of hazardous and other waste were taken over the years. In 1992 the Inter-Parliament Assembly of CIS states adopted the basic document *On Principles of Ecological Safety in the States of the Commonwealth.*[855] In December 1993 the *Agreement on Interstate Movement of Hazardous and Categorized Cargoes*[856] was signed by all CIS states. In 1996 the

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[853]States received assistance under the project: Bulgaria, Macedonia, Republic of Serbia, and Montenegro. The project was funded by Austria and Belgium with the professional support from the Secretariat of the Basel Convention. (*Projects in Central and Eastern Europe*, online: Basel Convention <http://www.basel.int/Default.aspx?tabid=2345>).

[854]Tajikistan did not sign the Basel Convention; nevertheless, the national law on the waste management is homogeneous to the CIS prototype.

[855]*О Принципах Экологической Безопасности в Государствах Содружества*, 1992 [On Principles of Ecological Safety in the States of the Commonwealth, 1992], online: Priroda <http://www.priroda.ru/law/detail.php?ID=6382>.

[856]*Соглашение о Межгосударственных Перевозках Опасных и Разрядных Грузов*, 1993 [Agreement on Interstate Movement of Hazardous and Categorized Cargoes, 1993], online: Kazakhstan News-City <http://kazakhstan.news-city.info/docs/sistemso/dok_perefz.htm>.

Agreement of the CIS States on Control of Transboundary Movement of Hazardous and Other Waste[857] in the framework of the Customs Union was adopted. In June of 2000, the Subregional Meeting on Hazardous Waste Management and Their Transboundary Movement Control reconfirmed the necessity of establishment and improvement of national systems of hazardous waste management with regard to: a) reduction of waste discharged during production; b) elaboration of environmentally sound methods of waste destruction/utilization; and c) transboundary waste movement. Finally, the CIS Ministerial Meeting in 2003 on Information Exchange Regarding Transboundary Waste Movement urged to continuing further harmonization of the interstate normative-legal base.[858]

In a majority of CIS countries the legislation related to Basel Convention is based on the regional model law: *On Production and Consumption Waste*,[859] adopted by the CIS Inter-Parliament Assembly back in 1998.[860] Hence, the formation of legislation in CIS countries had gone according to similar scenarios.[861] As a result, basic legal principles and technical tools used are alike.[862] Finally, the Basel Convention

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[857]*Соглашение Стран СНГ о Контроле за Трансграничной Перевозкой Опасных и Других Отходов*, 1996 [Agreement of the CIS States on Control of Transboundary Movement of Hazardous and Other Waste, 1996], online: Pravo Levonevsky <http://pravo.levonevsky.org/bazaby09/sbor79/text79354.htm>.

[858]*Executive Summary of the Review of the Existing National and International Legislation in the Field of Monitoring and Control of Transboundary Movement of Hazardous Wastes and their Environmentally Sound Management,* Centre for International Projects, Moscow, 2005, at 6, online: Basel Convention <http://www.basel.int/Default.aspx?tabid=2345>.

[859]*О Модельном Законе "Об Отходах Производства и Потребления"* [Model Law "On Production and Consumption Waste"], online: Pravo Levonevsky <http://pravo.levonevsky.org/bazaby/org327/basic/text0170.htm>. Republic of Kazakhstan and Turkmenistan did not adopt any specific law on waste.

[860]Decision of Inter-Parliament Assembly of the Member States of the Commonwealth of Independent States on 15 June 1998 №11-9.

[861]In those countries, which did not adopt any specific law on waste (Republic of Kazakhstan and Turkmenistan), regulation of the relationship in the field of hazardous waste management is carried out on the basis of the provisions of individual norms of different legislative and other normative legal acts of environmental legislation, such as law on the environment protection, decisions of the governments on order and rules of hazardous waste transportation, on fees for the environment pollution, on waste placement.

[862]In CIS countries legislation related to Basel Convention is based on the main law - Law on Wastes/Law on Production and Consumption. Also, many Member States adopted additional acts and

Regional Center in the Russian Federation for CIS States has served as a platform to coordinate joint actions amongst Member States.[863]

3.2.4 Globally Harmonized System of Classification and Labeling of Chemicals

NAFTA

In spite of the fact that the GHS facilitates free trade and all three North American states are strongly committed to harmonize safety standards on chemicals, there are no coordinated activities on the implementation of the GHS in the scope of NAFTA. Only bilateral actions contributing to the GHS realization have been taken place.

On February 4, 2011, the Prime Minister of Canada and the President of the United States established the Canada-U.S. Regulatory Cooperation Council (RCC). The RCC is designed to align Canadian and American regulatory approaches in various sectors.[864] One of the key objectives of the RCC is the facilitation of trade between the two countries. In December 2011, one of 29 initiatives announced as part of the RCC Joint Action Plan was the coordinated implementation of the GHS. Specifically,

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resolutions to implement such law. Russia has 66 laws and directives on the matter. In contrast, Uzbekistan has only one main legislation: *Law of the Republic of Uzbekistan of 5 April 2002 №362- II "On Wastes"*. For complete list of laws and regulations see: *Op. cit.* 858 (*Executive Summary of the Review of the Existing National and International Legislation in the Field of Monitoring and Control of Transboundary Movement of Hazardous Wastes and their Environmentally Sound* Management), at 11 to 24.

[863] *Op. cit.* 858 (*Executive Summary of the Review of the Existing National and International Legislation in the Field of Monitoring and Control of Transboundary Movement of Hazardous Wastes and their Environmentally Sound Management*).

[864] "Hazardous Products Regulations: Regulatory Impact Analysis Statement", *Canada Gazette*, Vol. 148, No. 32, (9 August 2014), online: Canada Gazette <http://gazette.gc.ca/rp-pr/p1/2014/2014-08-09/html/reg1-eng.php>.

Canada and the United States agreed to align and synchronize the implementation of common classification and labeling requirements for workplace hazardous chemicals. This includes developing a mechanism to maintain alignment as the system is updated and modernized or new requirements or standards are put in place. To date, the effort has been successful. As a result, both countries adopted common label and safety data sheet information for hazardous chemicals.[865] The system was in place by both countries in 2015.[866]

Canada

In October 2003, the Canadian government organized a workshop to identify issues and options/solutions associated with the implementation of GHS in Canada. Since 2004, Canada has been conducting technical consultations around multi-stakeholder sectoral working groups.[867] Canada's principal objective has been a harmonization to the greatest extent possible with other countries. To date, the GHS has been implemented in the four main sectors: Transport, Industrial/Workplace, Consumer Products and Agriculture/Pesticides.[868] Meanwhile, Canada has raised concerns that: a) trade barriers may result if countries adopt different hazard classes/categories for the classification of untested mixtures for health hazards, and b) different countries

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[865]Some minor differences between the Canada *Hazardous Products Regulations* (HPR) and the United States (U.S.) *Hazard Communication Standard* (2012) do however exist. For more information see: *WHMIS 2015 — Variances Between the HPR and the United States Hazard Communication Standard*, 2012, online: Heath Canada <http://www.hc-sc.gc.ca/ewh-semt/occup-travail/whmis-simdut/ghs-sgh/classification/hazardous-products-produits-dangereux/variances-ecarts-eng.php>.

[866]*Canada-United States Regulatory Cooperation Council Joint Forward Plan August 2014*, online: Health Canada <http://www.hc-sc.gc.ca/ahc-asc/legislation/acts-reg-lois/rcc-ccmr/index-eng.php>.

[867]In February 2006, the Government produced the document "*Comparison of Sector Interim Recommendations or Preferred Options*," a summary of the results of the deliberations by the sectors affected by the implementation of the GHS.

[868]*Report on Preparation of GHS Implementation by the OECD Countries*, (ENV/JM/MONO(2007)8), Paris: OECD, 2007, at 15, online: OECD <http://www.oecd.org/chemicalsafety/testing/38735710.pdf>.

may implement different versions of the GHS document, e.g., 2003 version vs. 2005 version, which could result in a lack of international harmonization.[869]

The implementation of the Globally Harmonized System of Classification and Labeling of Chemicals requires both legislative and regulatory amendments at the federal, provincial and territorial levels. In 2013, Health Canada conducted public consultations on draft regulations to implement the GHS. In June, 2014, legislative amendments to the *Hazardous Products Act* (HPA), as well as consequential and coordinating amendments to some other federal Acts, including the *Hazardous Materials Information Review Act,* received Royal Assent.[870] In order to implement the GHS Canadian Government also repealed and replaced the *Controlled Products Regulations* (CPR) with proposed new regulations the *Hazardous Products Regulations* (HPR).[871] These changes then resulted in changes to federal, provincial and territorial occupational health and safety legislation and regulations.[872]

Health Canada adopted HPR in February 2015. A transition period began when the regulations come into force on June 1, 2015. The transition to the GHS will take place in phases to give key partners and stakeholders sufficient time to make the necessary regulatory and system adjustments. Specific attention will also be given to ensuring consistency across Canada through coordination and alignment between

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[869]*Ibid.* at 29.

[870]In addition, consequential amendments are being proposed to the following regulations: *Food and Drug Regulations; Consumer Chemicals and Containers Regulations, 2001; Safety of Human Cells, and Tissues and Organs for Transplantation Regulations*. Amendments are also being proposed to the following two regulations made under the *Canadian Environmental Protection Act, 1999:* (i) *New Substances Notification Regulations (Chemicals and Polymers)* and (ii) *Export of Substances on the Export Control List Regulations. (Request for Comments - Proposal to Implement the GHS in Canada*, online: Health Canada <http://www.hc-sc.gc.ca/ewh-semt/consult/_2013/ghs-sgh/index-eng.php>.)

[871]*Hazardous Products Regulations* (SOR/2015-17), online: Justice Laws <http://laws-lois.justice.gc.ca/eng/regulations/SOR-2015-17/>.

[872]*Technical Guidance on the Requirements of the Hazardous Products Act (HPA) and the Hazardous Products Regulations (HPR) - WHMIS 2015 Supplier Requirements - Phase 1*,online: Health Canada <http://www.hc-sc.gc.ca/ewh-semt/occup-travail/whmis-simdut/ghs-sgh/classification/hazardous-products-produits-dangereux/index-eng.php>.

federal, provincial, and territorial jurisdictions. Finally, after the adoption of the GHS, annual savings (due to productivity and health and safety benefits) for the industry are estimated at $82.1 million commencing in year 2017. [873]

United States

Within the United States, key federal agencies with responsibility for regulatory and international affairs formed an interagency committee coordinated by the Department of State to address implementation of GHS. Participating agencies include the Consumer Product Safety Commission (CPSC), Department of Commerce, Department of Transportation (DOT), Food and Drug Administration (FDA), Environmental Protection Agency (EPA), Occupational Safety and Health Administration (OSHA), Office of the U.S. Trade Representative, Department of Agriculture, and National Institute of Environmental Health Sciences.

The CPSC adhere to the mandates for decision making of the *Consumer Product Safety Act*, *Federal Hazardous Substances Act*, *Flammable Fabrics Act*, and *Poison Prevention Packaging Act.*[874]

In 2007, CPSC compared selected portions of the *Federal Hazardous Substances Act* (FHSA)[875] regulatory requirements to the GHS for classification and labeling. This comparison identified some of the technical differences between the FHSA and GHS. A preliminary legal feasibility assessment was also conducted to assess what, if any, changes would be needed to the FHSA should certain provisions of the GHS be adopted and implemented. The staff work indicated that a more complete technical

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[873] *Op. cit.* 864 (Hazardous Products Regulations: Regulatory Impact Analysis Statement).
[874] *Policy of the U.S. Consumer Product Safety Commission on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS)*, online: CPSC <https://www.cpsc.gov/About-CPSC/Policies-Statements-and-Directives />.
[875] *Federal Hazardous Substances Act*, (15 U.S.C. 1261-1278, 122 Stat. 3016), online: CPSC <https://www.cpsc.gov/s3fs-public/fhsa.pdf>.

comparison was needed.

In 2008, CPSC initiated a contract to complete a side-by side comparison of the FHSA and the GHS. This review will determine which sections of the GHS might be considered for implementation, as well as whether statutory or regulatory changes would be necessary for eventual implementation.[876] No farther information has been provided. In any event, the US pledged to fully implement GHS by 2017.[877]

Meanwhile, the U.S. Department of Labor's Occupational Safety and Health Administration has already revised its Hazard Communication Standard, aligning it with the United Nations' global chemical labeling system. Once implemented, the revised standard will improve the quality and consistency of hazard information in the workplace, making it safer for workers by providing easily understandable information on appropriate handling and safe use of hazardous chemicals. This update will also help reduce trade barriers while providing cost savings for businesses that periodically update safety data sheets and labels for chemicals covered under the *Hazard Communication Standard.*[878] After the GHS implementation, annual productivity benefits are estimated at $698.6 million.[879]

Mexico

In June 2011, Mexico published a national standard based on GHS, becoming the first NAFTA member to do so. The standard establishes the criteria for the

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[876]*GHS Implementation*, online: UNECE <http://www.unece.org/trans/danger/publi/ghs/implementation_e.html#c25877>.

[877]*US Department of Labor's OSHA Revises Hazard Communication Standard Regulation Protects Workers from Dangerous Chemicals, Helps American Businesses Compete Worldwide*, (20 March 2012), online: United States Department of Labor <https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=22038>.

[878]The Final Rule was published on March 26, 2012 and became effective May 25, 2012. (*The Hazard Communication,* online: United States Department of Labor <https://www.osha.gov/dsg/hazcom/index.html>).

[879]*Op. cit.* 864 (Hazardous Products Regulations: Regulatory Impact Analysis Statement).

classification and labelling of chemicals and the preparation of Safety Data Sheets according to the GHS. The standard is not mandatory, meaning GHS can be used on a voluntary basis and is not enforced.[880] Although the standard is not mandatory, it is authorized for use as an alternate means to comply with the provisions of the mandatory standard NOM-018-STPS-2000,[881] addressing the identification of chemical hazards and its related hazard communication at the workplace.[882]

EU.

Prior to the adoption of the GHS the EU had already put in place a system to classify, label and package hazardous chemicals. The *Dangerous Substances Directive*[883] and *Dangerous Preparations Directive*[884] were the core tools of the former scheme for over 40 years.

The White Paper formulated in 2001 by the European Commission proposed that the EU should simplify the existing EU classification and labeling system and improve comprehensibility through application of the Globally Harmonized System.[885] At

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[880]*Norma Mexicana (NMX-R-019-SCFI-201) Sistema Armonizado de Clasificacion y Comunicacion de Peligros de los Productos Quimicos*, [Spanish] online: Diario Oficial de la Federation <http://dof.gob.mx/nota_detalle.php?codigo=5166277&fecha=04/11/2010>.

[881]*Norma Oficial Mexicana (NOM-018-STPS-2000), Sistema Para la Identificación y Comunicación de Peligros y Riesgos por Sustancias Químicas Peligrosas en los Centros de Trabajo*, [Spanish] online: Secretaria del Trabajo y Previsión Social <http://www.stps.gob.mx/bp/secciones/dgsst/normatividad/normas/Nom-018.pdf>.

[882]*Op. cit.* 876 (*GHS Implementation*).

[883]EC, *Directive 67/548/EEC of 27 June 1967 on the Approximation of Laws, Regulations and Administrative Provisions Relating to the Classification, Packaging and Labeling of Dangerous Substances OJ 196, 16.8.1967, p. 1–98,* online: European Commission <http://ec.europa.eu/environment/archives/dansub/pdfs/67_548_en.pdf>.

[884]EC, *Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 Concerning the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Relating to the Classification, Packaging and Labeling of Dangerous Preparations*, OJ L 200, 30.7.1999, p. 1–68, online, EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31999L0045>.

[885]*The White Paper: Strategy for a future Chemicals Policy*, COM(2001) 88 (final), at 24, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2001:0088:FIN:EN:PDF>.

that moment, work was still underway to develop a global system for managing chemicals.[886]

Two main factors are seen as driving forces for the EU to implement GHS. First, the REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) regulation, adopted by the EU on 18 December 2006,[887] requires that classification and labeling results of hazardous substances and mixtures that are placed on the EU market by importers and manufacturers, irrespective of tonnage, be brought to the official notice of the European Chemicals Agency (ECHA).[888] The GHS criteria definitely eases the notification process in the EU because the classification criteria that are used for substances and mixtures imported from outside the EU are same as those used in the EU, hence EU importers can easily transmit the classification and labeling results to ECHA. Second, in terms of the cost and benefit analysis of the GHS implementation in the EU, the result of comprehensive study had showed that the EU's delayed adoption of the GHS would result in losses of roughly € 224 million in exports and € 184 million in imports.[889] The outcomes from this evaluation are

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[886]*Ibid.* at 28.

[887]EC, *Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 Concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Establishing a European Chemicals Agency, Amending Directive 1999/45/EC and Repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC*, OJ L 396, 30.12.2006, p. 1–850, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32006R1907>.

[888]a) Importers and manufacturers must notify hazardous substances if they are placing them on the market, on their own or in mixtures and irrespective of the tonnage; b) Importers and manufacturers must notify substances subject to registration under the REACH Regulation if they are placing them on the market; c) Existing registrations of substances placed on the market may need to be updated with the CLP classification and labeling; d) Notification should be made within one month of placing a substance on the market; e) Notification is free of charge. (*Practical guide 7: How to Notify Substances to the Classification and Labelling Inventory, European Chemicals Agency*, 2012, online: European Chemicals Agency <http://echa.europa.eu/documents/10162/13643/pg_7_clp_notif_en.pdf>).

[889]EC, *Impact Assessment of Implementing the GHS: Work Package 1, Final Report for the DG of Enterprise and Industry*, London: Risk & Policy Analysts Limited (2006), online: European Commission, <http://ec.europa.eu/growth/sectors/chemicals>.

believed to have triggered some concerns within the EU, particularly among chemical industries.[890]

In 2007 the European Commission submitted a proposal for the classification, labelling and packaging of substances and mixtures that is based on the GHS scheme.[891] In the following year, the *Regulation 1272/2008 of the European Parliament and of the Council* (CLP Regulation) was adopted.[892] The CLP Regulation is based on the 2nd revised edition of the GHS. For substances, it replaced Directive 67/548/EEC in December 2010 and for mixtures, it replaced EU Directive 1999/45/EC in June 2015.[893] To adjust CLP Regulation to technical and scientific progress and align with latest edition of the GHS, the Commission has regularly published Adaptation to Technical Progress (ATP) to the CLP Regulation. So far, six ATPs have been adopted. Operators had an eight-month transition period to adapt the labeling and packaging of substances and mixtures to these new classifications.[894] To date, no specific problems with implementation of the CLP regulation have been reported.

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[890]Goh Choo TA *et al*, *A Comparison of Mandatory and Voluntary Approaches to the Implementation of Globally Harmonized System of Classification and Labeling of Chemicals (GHS) in the Management of Hazardous Chemicals,* Industrial Health, (20 October 2011), at 767, online: Academia <https://www.academia.edu/3013741/A_Comparison_of_Mandatory_and_Voluntary_Approaches_to_the_Implementation_of_Globally_Harmonized_System_of_Classification_and_Labelling_of_Chemicals_GHS_in_the_Management_of_Hazardous_Chemicals>.

[891]EC, *The Proposal for a Regulation of the European Parliament and of the Council on Classification, Labelling and Packaging of Substances and Mixtures, and Amending Directive 67/548/EEC and Regulation (EC) No 1907/2006 - Legislative Text as Adopted on 27 June 2007 by the European Commission* (COM (2007) 355 final), online: Eur-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52007PC0355>.

[892]EC, *Regulation 1272/2008 of the European Parliament and of the Council of 16 December 2008 on Classification, Labeling and Packaging of Substances and Mixtures, Amending and Repealing Directives 67/548/EEC and 1999/45/EC, and Amending Regulation 1907/2006*, 31.12.2008, L 353/1, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF>.

[893]*Ibid.* Article 57.

[894]Adaptations to Technical Progress were adopted in 2009, 2011, 2012, 2013 (twice), and 2014. (*Adaptations to Technical Progress to the CLP Regulation*, online: REACH <http://www.reach.lu/mmp/online/website/menu_hori/news/93/900_EN.html>).

CIS

In most CIS countries there are no systems of classification and labeling of chemicals, nor registers of potentially hazardous chemical and biologically active substances.[895] Russia meanwhile, has attempted to implement the GHS: at the legislative level through the technical regulations *On Safety of Chemical Products*; at the regulatory and technical level by means of state standards (GOSTs). The technical regulations should be put in place in 2017.[896]

On a positive note, a few GOSTs implementing the GHS were recently adopted by CIS states. A mandatory CIS standard, GOST 31340-2013,[897] prepared by Russia under the auspices of the Interstate Council for Standardization, Metrology and

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[895] *Выполнение СПМРХВ в Регионе ВЕКЦА*, [SAICM implementation in East Europe, Caucasus and Central Asia (EECCA) region] (Russian), online: MOGNOVSE <http://mognovse.ru/jrk-vipolnenie-spmrhv-v-regione-vekca.html>.

[896] Work on the technical regulations "On safety of chemical products" has been ongoing for a decade without a visible end. The Document several times radically changed its content, concept and even the name. The first version attempted to create a "Russian REACH", introducing pre-market chemicals registration. However, this approach had several drawbacks including the lack of clear criteria to evaluate chemical hazards. In addition, various ministries could not agree on who would be responsible to run the system. As a result, in early 2009, this approach was abandoned. The subsequent versions permitting registration only chemical with specific hazards were dismantled as well. The latest draft proposes to assess hazardous properties of chemicals through a rather complicated procedure of product registration. Finally, due to recent "dynamic" geo-political developments across of the CIS including the creation of a new political and economic interstate unions (Eurasian Economic Community (EAEC), Customs Union) inside the existing one, no final legal status of the document has yet been defined. A few options are on the table: a) the law will be adopted as a Russian Federal Technical Regulation; b) the law will be adopted as a Russian Federal Law On the Safety of Chemicals; c) the law will be adopted as the Customs Union Technical Regulations "On Safety of Chemical Products; d) the law will be adopted as of EurAsEC Technical Regulations On Safety of Chemical Products. [The Final draft was adopted in October 2013. As expected, the law to be in force in 2017] (More on CIS geo-political multi-levels structure, including Eurasian Economic Commission (EEC), and the Customs Union see 3.3.4.). (*СГС в Техническом Регламенте* [GHS in Technical Regulation] (Russian), online: REACH (Website Supporting Russian Exporters) <http://www.reach.ru/reglament-reach/pyblikachii/407-russian-face-of-reach> & *On Safety of Chemical Products*, online: EEC <http://www.eurasiancommission.org/en/act/texnreg/deptexreg/tr/Pages/bezopChemProd.aspx>).

[897] *ГОСТ 31340-2013 Предупредительная Маркировка Химической Продукции. Общие Требования* [GOST 31340-2013 Labelling of chemicals. General requirements], online: Электронный Фонд <http://docs.cntd.ru/document/1200107846>.

Certification of the Commonwealth of Independence States,[898] was aligned with the fourth revision of GHS.[899] The standard became effective on August 1, 2014 in six CIS states.[900] Transition dates and compliance deadlines still remain to be announced.

In addition, the Eurasian Economic Union,[901] which includes Russia, Kazakhstan and Belarus, Armenia and Kyrgyzstan, adopted a technical regulation on the safety of chemicals[902] that would become legally binding in July 2017, if the five countries agree on the implementation details. The regulation includes an obligation to classify and label chemicals according to GHS.[903]

Finally, the following seven GHS standards have already been approved to support the technical regulations *On Safety of Chemical Products*: (GOST 30333-2007) Chemical Production Safety Passport: General requirements; (GOST 31340-2007) Labelling of Chemicals: General Requirements; (GOST R 53856-2010) Classification of Chemical Hazards: General Requirements; (GOST R 53855-2010) Classification of Chemicals Hazardous Due their Physical and Chemical Properties: Test Methods for Explosives; (GOST 53854-2010) Classification of Chemical Mixtures for Health Hazards; (GOST 53857-2010) Classification of Chemicals for Environmental Hazards: General Requirements; (GOST 53858-2010) Classification of Chemical Mixtures for Environmental Hazards. These standards will become mandatory only after the entry into force of EAEU technical regulation *On Safety of Chemical*

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[898]*The Interstate Council for Standardization, Metrology and Certification of the Commonwealth of Independence States (CIS)*, online: Euroasian Interstate Council<http://www.easc.org.by/english/mgs_org_en.php>.
[899]*Op. cit.* 897 (*ГОСТ 31340-2013 Предупредительная Маркировка Химической Продукции. Общие Требования* [GOST 31340-2013 Labelling of chemicals. General requirements]), at art.1& 4.
[900]Six states are: Russia, Belorussia, Uzbekistan, Kirgizstan, Tajikistan, and Armenia.
[901]Eurasian Economic Commission, online: EEC <http://www.eurasiancommission.org/en/Pages/default.aspx>.
[902]*О Безопасности Химической Продукции* [On Safety of Chemical Products], online: Eurasian Commission <http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/tr/Documents/TRHimiyaVGS.pdf>.
[903]*GHS Implementation*, online: UNECE <http://www.unece.org/trans/danger/publi/ghs/implementation_e.html#c25881>.

Products. The Technical Regulation will define a transitional period for the classification and labeling of chemicals according to the new standards. It is expected that all GHS hazard classes and categories will be implemented. Additional standards (in accordance with OECD guidelines) on testing of hazardous chemicals due to their physical and chemical properties and of chemicals dangerous for the environment are currently being developed.[904]

3.2.5 Strategic Approach to International Chemicals Management (SAICM)

NAFTA

Canada

The Chemicals Management Plan (CMP) is a Government of Canada initiative with a $300 million budget aimed at reducing the risks posed by chemicals to Canadians and their environment. The Government of Canada launched the first phase of the CMP in 2006 and launched the second phase of the CMP in 2011. CMP includes realistic and enforceable measures that will protect the health and safety of Canadians by means of product labeling improvement programs and vigorous control of the import of dangerous chemicals.

Since the launch of the CMP in 2006, Canada has addressed approximately 1,700 existing substances in commerce and 3,000 notifications for new substances that were proposed for introduction into the domestic market. During the second phase of the

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[904] *Ibid.*

CMP, launched in 2011, approximately 600 substances have been addressed. Canada completed the objectives of the second phase of the program in 2016. Key deliverables of this second phase include: a) risk assessments and risk management; b) over 450 pre-market evaluations on new substances per year; c) environmental and health monitoring, surveillance and research programs; and d) international engagement and cooperation.[905] To provide the public with the latest information about hazardous chemicals, a new Web portal was also launched.[906]

United States

The U.S. has taken the lead in supporting a regional approach for SAICM implementation, and has developed a strategy with Canada and Mexico for regional implementation of SAICM in North America. The Council of Ministers of the North American Commission for Environmental Cooperation (CEC)[907] in June 2008 approved a renewed North American agenda for chemicals management, involving the following: a) establish a foundation for chemicals management in North America to increase comparability of chemical management approaches across North America,

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[905]*Chemicals Management Plan Progress Report*, online: Environment and Climate Change Canada <http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=FEB6CAEE-1#s6>. More information on Canada's approach to the Management of Chemicals see: UN, *Canada National Reporting to CSD-18/19: Thematic Profile on Chemicals*, online: UN <http://www.un.org/esa/dsd/dsd_aofw_ni/ni_pdfs/NationalReports/canada/Chemicals.pdf>.

[906]The website contains a lot of useful information on dangerous substances; nevertheless, the information provided is intended more for professional than consumer use. (*Chemical Substances*, online: Chemical Substances <http://www.chemicalsubstanceschimiques.gc.ca/index-eng.php?utm_source=VanityURL&utm_medium=URL&utm_campaign=chemicalsubstances.gc.ca>).

[907]The Council is the CEC's governing body and is composed of the highest-level environmental authorities (cabinet level or equivalent) from Canada, Mexico, and the United States. Meeting at least once a year to set the CEC's overall direction, including its budget and activities, the Council oversees the implementation of the North American Agreement on Environmental Cooperation and serves as a forum for the discussion of environmental matters within the scope of the Agreement. (*North American Commission for Environmental Cooperation*, online, CEC <http://www.cec.org/Page.asp?PageID=1226&SiteNodeID=207&BL_ExpandID=566>).

with special emphasis on assisting Mexico;[908] b) develop and implement a sustainable regional approach for environmental and human biomonitoring and assessment to enhance North American monitoring capacity supporting Mexico in the initial stages of implementation; c) reduce or eliminate the risk from chemicals of mutual concern in North America;[909] and d) improve environmental performance of sectors to reduce the risks from toxic chemicals in North America by working strategically with key industrial sectors. The United States has had a number of programs and activities underway that contribute to meeting the objectives of SAICM.[910] Equally, on the regional level, many projects were accomplished and many more have been started.[911]

EU

Since the adoption of SAICM, significant steps have been undertaken by the European Community in order to implement this important tool for global chemicals management. In particular, the new EU Chemicals Legislation REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) which entered into force on 1 June 2007, has been beneficial by delivering on a number of objectives and elements of SAICM such as improving the availability of data for chemicals, improving risk assessment and risk management of chemicals, encouraging the use of suitable alternatives to unsafe substances, promoting industry participation, etc. REACH implementation is coordinated with relative stakeholders on regional and international levels.

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[908]An early initiative in this area is to involve supporting Mexico's efforts to develop an inventory of industrial chemicals.

[909]This includes continuation of efforts to reduce the risk from mercury; dioxins and furans, and hexachlorobenzene; and lindane and other isomers of hexachlorocyclohexane.

[910]More than 50 effective or completed activities have been done so far. For detail list of projects and activities see: *Compilation of Responses to the Temporary Questionnaire for Reporting on SAICM Implementation: United States*, online: SAICM <http://www.saicm.org/index.php?option=com_content&view=article&id=390:responses-second-session-of-the-international-conference-on-chemicals-management-iccm2&catid=89:iccm-2>.

[911]For detail list of NAFTA project and activates see: *Commission for Environmental Cooperation: Pollutants*, online: CEC <http://www.cec.org/our-work/pollutants>.

The European Chemical Agency (ECHA) website[912] is available in all EU languages and contains a large amount of information helping the participants (including from outside of the EU) to comply with REACH. A part of the information is accessible to the public, contributing to knowledge on how to use chemicals safely. In addition to REACH, the Commission has been very active in implementation various projects and activates on chemical safety.[913]

CIS

Between 2006 and 2009, the implementation of SAICM by CIS states was rather fragmented. Only individual projects were carried out due to limited availability of funds. In most countries, there was no understanding of the need for a more structured and integrated approach to achieve the sound management of chemicals. However, after 2009 the second session of the International Conference on Chemicals Management, the situation gradually began to change for the better.

CIS countries have started to develop national legislation aimed at long-term strategic planning in the field of chemical safety, starting with a comprehensive review of existing national legal, organizational, administrative, and technical frameworks related to the sound management of chemicals. Starting from 2009, CIS states have implemented 16 projects, including: a) identification of hot spots of pollution by persistent organic pollutants and heavy metals; b) chemicals in products; c) mercury

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[912] *European Chemicals Agency*, online: ECHA <http://echa.europa.eu>.

[913] On full list of the EU project and activities see: *Compilation of Responses to the Temporary Questionnaire for Reporting on SAICM Implementation: European Union*, online: SAICM <http://www.saicm.org/index.php?option=com_content&view=article&id=390:responses-second-session-of-the-international-conference-on-chemicals-management-iccm2&catid=89:iccm-2>.

pollution and mercury-contaminated food; and d) encouraging public participation in decision-making in the field of chemical safety.[914]

Despite some progress in the work in the field of chemical safety in the CIS region, there are specific issues that require urgent solutions, such as obsolete pesticide stocks, out-of-date technological equipment in chemical facilities,[915] weak state control over the import of dangerous chemicals, management of municipal solid waste and electronics, and quality control of imported food, toys and consumer products. Although CIS countries have initiated a large number of programs and projects at the state level, the results in the field of chemical safety in the region remain unsatisfactory due to weak interstate coordination of implementation of the relevant projects and programs.[916]

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[914]For more details see: *Выполнение СПМРХВ в Регионе ВЕКЦА*, [SAICM Implementation in East Europe, Caucasus and Central Asia (EECCA) Region] (Russian), online: MOGNOVSE <http://mognovse.ru/jrk-vipolnenie-spmrhv-v-regione-vekca.html>.

[915]For instance, in the Russian Federation, currently operates more than 10 000 potentially hazardous chemical enterprises. The vast majority of these facilities were built 40 - 50 years ago. Today, technological equipment on this facilities is obsolete and physically worn out. (*Постановление от 27 Октября 2008 года О Федеральной Целевой Программе "Национальная Система Химической и Биологической Безопасности Российской Федерации (2009- 2013 годы)"*, Directive of the Government of the Russian Federation October 27, 2008 N 791, Regarding the Federal Program the National System of Chemical and Biological Security of Russian Federation 2009 – 2013] (Russian), online: EMERCOM of Russia <http://www.mchs.gov.ru/document/3591324>).

[916]*Ibid.*

3.2.6 WHO Guidelines for Medicine Donations

NAFTA

Canada

From the start, the Government of Canada has considered the Guidelines useful and appropriate but has not endorsed or approved them. The International Affairs Directorate of Health Canada has brought the Guidelines to the attention of Canadian organizations that are involved with drug donations.[917]

To support developing countries' efforts in meeting the health needs of their population, the 2007 federal budget announced a new tax incentive for corporations that donate medicines to Canadian eligible charities for use outside of Canada.[918] The incentive allows for donations of medicines to be made to Canadian charities found eligible by the Department of Foreign Affairs, Trade and Development (DFATD). The eligibility to registered charities will be granted if donors can demonstrate that they respect and adhere to international guidelines, policies, and principles with regard to international development and humanitarian assistance, particularly in the context of the delivery of medicines to the developing world. In particular, DFATD will assess whether the Canadian charities seeking eligibility: a) act in a manner consistent with the principles and objectives of the interagency Guidelines; b) demonstrate appropriate expertise in delivering medical donations to the developing world; and c) have implemented appropriate policies and practices with respect to the

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[917]Radha Asher, Robin Gray, & Hans Hogerzeil, *First-Year Experiences with the Interagency Guidelines for Drug Donations*, WHO: Department of Essential Drugs and Medicines Policy, Geneva, 2000, at 14, online: WHO <http://whqlibdoc.who.int/hq/2000/WHO_EDM_PAR_2000.1.pdf>.

[918]The Donations of Medicines Eligibility Program began accepting applications from registered charities for the first time on 1st July 2008.The regulations related to this program received Royal Assent on 12th March 2009.

delivery of international development and humanitarian assistance. The aim of this program is to ensure that donations of medicines to developing countries are appropriate, safe, effective, and useful.[919]

United States

The US has always taken a proactive position regarding overseas drug donations. Even before the Guidelines were formally issued, US government agencies had adopted guidelines that all drugs shipped to locations abroad must have a minimum 12-month shelf life before expiry. After the international recommendations were adapted, the *WHO Guidelines for Drug Donations* were presented during several national meetings to over 100 stakeholders from the United States pharmaceutical industry, private voluntary organizations and representatives from developing countries.[920] The United States Pharmacopoeia Convention, the leading US institution for drug safety standards, has also adopted the Guidelines.[921] Moreover, an informal alliance of private voluntary agencies and pharmaceutical and medical device companies was formed in 1996 and formally incorporated in 1999 as the Partnership for Quality Medical Donations (PQMD). Its members share a common commitment to addressing concerns and advancing effective and appropriate medical donations. PQMD was first U.S. organization to endorse the 2010 Guidelines revision. PQMD members enhance medical donation standards, promote effective donation practices, and inform policy makers and the general public on the donation process.[922] In 2014

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[919]*Canada Acting to Improve the Regime for Donations of Medicines to the Developing World*, (16 May 2008) online: Department of Finance Canada <https://www.fin.gc.ca/n08/08-038-eng.asp >.
[920]*Op. cit.* 917 (Radha Asher, Robin Gray, & Hans Hogerzeil), at 12.
[921]The U.S. Pharmacopeial Convention (USP) is a scientific non-profit organization that sets standards for the quality and purity of medicines manufactured, distributed and consumed worldwide. USP attempts to improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines. USP's drug standards are enforceable in the United States by the Food and Drug Administration, and these standards are used in more than 140 countries. More on USP, online: *U.S. Pharmacopeial Convention* <http://www.usp.org>.
[922]More on PQMD see online: *Partnership for Quality Medical Donations* <http://www.pqmd.org>.

the PQMD Guidelines for Quality Medical Product Donations (PQMD Guidelines)[923] were adopted. Aligning with general WHO donation standards, this very detailed document embraces all issues relating to drug donations. In April 2016 the PQMD Guidelines were updated.

From its side, the federal regulator, the Food and Drug Administration (FDA), requires that donated overseas medical products must meet specific standards for safety, effectiveness, and labeling in order to ensure that health care providers and patients have information necessary to understand a drug product's risk as well as its safe and effective uses. Additionally, firms are required to demonstrate that their manufacturing processes meets Good Manufacturing Practices standards,[924] as well as demonstrate that these products are properly transported and stored. Finally, FDA rules that donated drugs have at least one year before their expiration.[925]

EU

The Guidelines have never received a formal endorsement from the EC. Perhaps the nonexistence of the common policy on international humanitarian aid might be a basic explanation for why the document has never been translated into EU regulations. Nevertheless, the Guidelines received an eager reception from the pharmaceutical industry and especially from organizations engaged in medicine donating projects; such as DIFÄM (Germany), ReMed (France), Wemos Foundation (Netherlands), Prosalus (Spain), and Parmacisti Senza Frontiere (Italy).

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[923] *PQMD Guidelines for Quality Medical Product Donations*, (April 2016), online: Partnership for Quality Medical Donations <http://www.pqmd.org/pillars/donation-guidelines/>.
[924] More on Good Manufacturing Practices see 2.2.2.2.
[925] *Questions and Answers for the Public Questions and Answers for the Public: Donating Drugs to International Humanitarian Relief Efforts*, online: Food and Drugs Administration <http://www.fda.gov/downloads/NewsEvents/PublicHealthFocus/UCM249617.pdf>.

German Institution for Medical Mission (DIFÄM)[926] translated the Guidelines into German for use in Germany, Austria and Switzerland, and distributed 6,200 copies. Additionally, it published information about the Guidelines in 30 German newsletters, and organized meetings and seminars on the subject. Action Medeor, a non-profit drug supply organization, distributed the Guidelines in German. It also developed a poster presentation for conferences and teaching.[927] In Italy, the Mario Negri Institute for Pharmacological Research[928] and the Ministry of Health[929] translated the Guidelines into Italian and disseminated them widely within the country.[930] The Wemos Foundation,[931] with support from the Dutch Government, coordinated a Working Group on Donations with 18 organizations subscribing to the Guidelines, including Nefarma,[932] the Dutch pharmaceutical manufacturers' association.[933] Not-for-profit organizations from Germany, Italy and the UK, under the umbrella of EURMED, coordinate medicine donations from all 28 EU Member States. All donations submitted to EURMED are subject to rigorous assessment to ensure that they are safe and adhere to the WHO Guidelines for Drug Donations.[934]

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[926]German Institution for Medical Mission, in English, online: <http://difaem.de/en/home/>.
[927]*Op. cit.* 917 (Radha Asher, Robin Gray, & Hans Hogerzeil), 14&15.
[928]*Mario Negri Institute for Pharmacological Research*, [English], online <http://www.marionegri.it/mn/en/>.
[929]*Ministero della Salute*, [Italian]: online <http://www.salute.gov.it>.
[930]*Op. cit.* 917 (Radha Asher, Robin Gray, & Hans Hogerzeil), at 15.
[931]*The Wemos Foundation*, [English], online: <http://www.wemos.nl/Eng/>.
[932]NEFARMA, [English], online: <http://www.nefarma.nl/website/engels/nefarma-english>.
[933]*Op. cit.* 917 (Radha Asher, Robin Gray, & Hans Hogerzeil), at 16.
[934]EURMED was founded in 2014 by three leading European medical NGOs (Action Medeor, Banco Farmaceutico and International Health Partners), with the shared objective of ensuring the efficient and effective use of product donations from the European healthcare industry to address the needs of underserved communities around the world. EURMED Online (an online donation tool) oversees a system for the needs-based allocation of donated product to NGOs serving people in need, in a secure, effective and transparent manner. EURMED ensures that all donated medical product is safely and professionally handled and reaches those in need quickly. *EURMED*, online: EURMED <http://www.eurmed.eu>.

CIS

Only recently has Russia increased international aid commitments. Even so, as a state with a transitional economy, it still remains far below the levels achieved by most "traditional" donors and some "new" donors.[935] Russian humanitarian aid is primarily directed towards the former Soviet republics, highlighting Russia's traditional regional focus in terms of aid giving.[936] Another notable characteristic is that humanitarian aid, including medicine, is distributed predominantly through the government agency EMERCOM.[937] In general, the Russian Government has refrained from cooperation with Russian or International NGOs. For example, only in 2012 did Russia started limited collaboration with the key humanitarian agencies, the International Red Cross and Red Crescent Movement, to resolve the humanitarian crises in Syria. Recent legislation has placed new restrictions on NGOs, preventing them from operation domestically and internationally.[938]

EMERCOM is Russia's principal humanitarian/emergency response operator. According to the ministry's official website, it is engaged in four major strands of work in the area of humanitarian response: the development of a legislative framework for international co-operation; co-operation with the UN to respond to humanitarian crises worldwide; co-operation with other countries with advanced emergency management systems; and exchanges of experience in the area of

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[935]So-called "new"/"emerging" (or "re-emerging") /"non-traditional" donors, such as the BRICS countries (Brazil, Russia, India, China and South Africa), Turkey and the Gulf states. (*Op. cit.* 432 (Anna Brezhneva & Daria Ukhova), at 2).

[936]*Op. cit.* 432 (Anna Brezhneva & Daria Ukhova), at 2.

[937]This ministry has been providing a range of humanitarian assistance to foreign countries for nearly two decades and more recently has begun to collaborate with other governments, international organizations, and agencies. (*Op. cit.* 432 (Anna Brezhneva & Daria Ukhova), at 6).

[938]*Russia: Government against Rights Groups,* Human Rights Watch, (24 October 2016), online: Human Rights Watch <http://www.hrw.org/news/2015/01/18/russia-government-against-rights-groups>.

emergency/humanitarian response. [939] EMERCOM does not provide any information if the agency has adhered to the Guidelines in its operations. Presumably, it has been done since this semi-military Government structure is operating "in accordance with Russian and International laws" and no problems with safety for international medicine donation has been reported.

Other CIS state-members do not presently have sufficient financial recourses or developed pharmaceutical industry to be important donors of medicine.

3.2.7 Good Manufacturing Practices for Pharmaceutical Products and Certification Scheme

In general, GMPs have been issued as guides to the achievement of consistent product quality, with interpretation and individual variations being accepted. This model is considered by the majority of states and the industry to be the best approach. On the contrary, the GMPs for pharmaceuticals developed by the FDA exclusively employ the concept of "how to", where absolute compliance with FDA regulation is required.[940]

NAFTA

Canada

As it was mentioned above, Canada was fist state which had introduced a GMPs

[939]EMERCOM, online: <http://en.mchs.ru/>.
[940]More on different approaches to the GMPs see: *Op. cit.* 472 (Joseph D. Nally) at 335 to 349.

scheme back in 1957, long before it was achieved on the international level. The most recent edition of the Canadian Good Manufacturing Practices Guidelines (Canadian Guidelines) was released in 2009.[941] The introduction of this document clarifies a few points about the nature of the Canadian Guidelines. First, this code is an administrative document that is intended to facilitate compliance by the regulated party with the *Canadian Food and Drugs Act*, its associated regulations, and the applicable administrative policies. Second, the Canadian Guidelines are not intended to provide legal advice regarding the interpretation of the act or regulations. In the event of any inconsistency or conflict between that act or regulations and the Canadian Guidelines, the act or the regulations take precedence. Third, the content of this document should not be regarded as the only interpretation of the GMP Codes, nor does it intend to cover every conceivable case. Finally, alternative means of complying with these Canadian Guidelines can be considered with the appropriate scientific justification. Different approaches may be called for as new technologies emerge.

The Canadian Guidelines incorporate all postulates from the WHO version, including provisions on labeling and product recall. In some respect, the Canadian adaptation is more logical and practical. The regulations are highlighted and then followed by the rational for the regulation and an interpretation with more detail of how compliance might be assured.[942]

The application of GMPs in Canada is handled through licensing. In order to conduct activities relating to the fabrication, packaging/labeling, testing, importation, distribution or wholesaling of drugs, a manufacturer/distributor must comply with the requirements of the *Food and Drug Regulations*, which covers GMPs. The Drug

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[941] *Good Manufacturing Practices (GMP) Guidelines*: *Health Products and Food Branch Inspectorate*, (GUI-0001), Health Canada, (2009), online: <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/compli-conform/gmp-bpf/docs/gui-0001-eng.pdf>.

[942] *Op. cit.* 472 (Joseph D. Nally) at 334.

GMP Compliance program (part of the Health Products and Food Branch Inspectorate) is responsible for conducting inspections of establishments that are involved in activities covered by the Establishment Licensing framework. These inspections are conducted to verify the compliance with GMPs which is a requirement for the issuance of an Establishment License. After an initial on-site inspection, a regular inspection is conducted within 12 months. The dates of the next inspection are different: Fabricators, Packagers/Labelers and Testing Labs are inspected on a two year cycle; Importers, Wholesalers and Distributors are inspected on a three year cycle.[943] The report indicates that most Canadian industry is highly compliant with GMPs. For instance, in the 2010-2011 fiscal year, 415 inspections were conducted resulting in less than 6 % (25 establishments) being found to be non-compliant.[944]

United States

Since its foundation in 1906, the federal government regulatory agency Food and Drugs Administration (FDA) has taken steps to make the consumer drug market a safer place. Even before the GMP regulation was introduced, the FDA acted to make it illegal to sell "adulterated" or "misbranded" drugs.[945] Under the 1938 *Food, Drug, and Cosmetic Act* (FDCA) manufacturers have been required to prove the safety of medicine before marketing them to consumers.[946] As a response to the Thalidomide

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[943]*Summary Report of the Drug Good Manufacturing Practices (GMP): Inspection Program (April 1, 2006 to March 31)*, (21 December 2011) at 3, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/compli-conform/gmp-bpf/summary-report-sommaire-eng.pdf>.
[944]*Ibid.* at 5&6.
[945]"That it shall be unlawful for any person to manufacture within any Territory or the District of Columbia any article of food or drug which is adulterated or misbranded, within the meaning of this Act". Violation could lead to one year's imprisonment at Sec 1. (*Federal Food and Drugs Act of 1906*, Pub. L. No. 59-384 34 Stat. 768 (1906), online: FDA <http://www.fda.gov/regulatoryinformation/legislation/ucm148690.htm>).
[946]*FDA History: The 1938 Food, Drug, and Cosmetic Act*, online: FDA <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054826.htm>.

disaster,[947] in 1963 the Kefauver-Harris Amendments introduced new features to the FDCA. The new federal regulations mandated efficacy as well as safety before a drug could be marketed, established good manufacturing practices by the drug industry, and granted the FDA greater powers to access company production and control records to verify those practices.[948] However, after the 1972 incident with contaminated intravenous fluids,[949] the FDA realized that the 1963 GMPs were not of sufficient rigor to prevent quality mishaps occurring in pharmaceutical product manufacture and testing. As a result, vigorous GMP regulations were adopted in 1976,[950] which have not changed much since.[951]

The United States is one of the three states where the GMPs have been enshrined in law as legal regulations.[952] Non-compliance with the GMPs during manufacturing and testing is taken by the courts as evidence that the drug is adulterated,[953] and hence such medicine cannot be marketed.[954] The FDA vigilantly monitors drug

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[947]A famous example of a drug exerting harmful effects on a large group of people is thalidomide, which was introduced in 1957 as a sedative with the special feature that it was extremely safe even in over dosage. It was therefore even recommended specifically for use in pregnancy. After its introduction, reports of increased incidence of fetal malformation ('seal limbs') came in simultaneously from Hamburg and Sydney, and the connection with thalidomide was made in early 1961. The drug was withdrawn from the market in late 1961, by which time an estimated 10,000 malformed babies had been born. For more on the Thalidomide disaster see: H. Sjöström, *Thalidomide and the Power of the Drug Companies* (Manchester: Penguin, 1972)..

[948]*FDA History: Drugs and Foods Under the 1938 Act and Its Amendments*, online: FDA <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm055118.htm>.

[949]In 1972, two large multi-national manufacturers (Abbott and McGaw Laboratories) sold a large volume of contaminated intravenous fluids.

[950]*Drug Applications and Current Good Manufacturing Practice (CGMP) Regulations*, online: FDA <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm090016.htm>.

[951]Michael H. Anisfeld, *International GMP, The Advent of GMPs*, online: Globepharm <http://www.globepharm.org/what-is-gmp/international-GMPs/advent-of-gmps.html>.

[952] The other two states are Japan and South Korea.

[953]Non-compliance with the GMPs during manufacturing and testing does not mean automatically that drugs are unsafe. However, marketing such medicine is illegal. (*Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs: General*, (Title 21, Volume 4) at Sec 210.1(b) online: FDA <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=210&showFR=1>).

[954]*Op. cit.* 951 (Michael H. Anisfeld)

manufacturers' compliance with GMP regulations. The approval process for new drug and generic drug marketing applications includes a review of the manufacturer's compliance with the GMP. FDA inspectors determine whether the pharmaceutical company has the necessary facilities, equipment, and skills to manufacture the new drug. Decisions regarding compliance with GMP regulations are based upon inspection of the facilities, sample analyses, and compliance history of the company. Failure to comply can also lead to a decision by FDA not to approve an application to market a drug.[955] During the 2014 financial year 645 Inspectional Observation Summaries on drugs were issued.[956] The most common non-compliance with GMPs noticed during this period was the absence of proper written records on production operation.[957]

At the interstate level, the Joint Action Plan for the Canada-United States Regulatory Cooperation Council calls for enhancing collaboration on enforcement and compliance with GMP by increasing mutual reliance on each other's routine surveillance inspection reports of manufacturing facilities for drugs, rather than having to conduct unnecessarily duplicative inspections in the other country. It should reduce unnecessary duplicative costs for manufacturers of pharmaceutical and minimize the delays in introducing medicine to the marketplace without compromising the safety, efficacy and quality of products.[958]

During 2013 initial observational GMP inspections occurred at two sites in Canada and two more in the U.S. A jointly-planned Common Electronic Submission Gateway project between the U.S. Food and Drug Administration (FDA) and Health Canada

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[955]*Op. cit.* 950 (*Drug Applications and Current Good Manufacturing Practice (CGMP) Regulations*).
[956]*FY 2014 Inspectional Observation Summaries*, online: FDA <http://www.fda.gov/ICECI/Inspections/ucm424098.htm#Drugs>.
[957]More on FDA Inspections see: *Inspections, Compliance, Enforcement, and Criminal Investigations*, online: FDA <http://www.fda.gov/ICECI/default.htm>.
[958]U.S.-Canada Regulatory Cooperation Council, online: <http://trade.gov/rcc/>.

began in August 2013 with participation from a range of firms. This framework enables the industry to submit drug applications for market authorization electronically to both the U.S. FDA and Health Canada.[959]

EU

2015 marked the 50th anniversary of pharmaceutical legislation in the EU.[960] Today the EU legal framework for medicinal products for human use guarantees high standards of quality and safety of medicinal products through a system of marketing authorizations.[961] Marketing authorizations are required by all pharmaceutical manufacturers in the European Union whether the products are sold within or outside of the Union. EU-GMP guide is a key element of this system.

The manufacturing or importation of medicinal products, including investigational medicinal products, is subject to a manufacturing or import authorization. The holder of such an authorization is obliged to comply with the principles and guidelines of Good Manufacturing Practice for medicinal products and to use as starting materials only active substances (active pharmaceutical ingredients), which have been manufactured in accordance with GMP.[962]

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[959]*Common Electronic Submission Gateway*, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/cesg-pcde/index-eng.php>.

[960]The first community document regarding pharmaceuticals was *Council Directive 65/65/EEC of 26 January 1965 on the Approximation of Provisions Laid Down by Law, Regulation or Administrative Action Relating to Proprietary Medicinal Products*, O.J 02, 09.02.1965, p. 369–373, online: Eur-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31965L0065:EN:HTML>.

[961]The European system for the authorization of medicinal products for human and animal use was introduced in January 1995 with the objective of ensuring that safe, effective and high quality medicines could quickly be made available to citizens across the European Union. (More on the European system for the authorization of medicinal products see: *Procedures for Evaluating Medicinal Products and Granting Marketing Authorization,* online: European Commission <http://ec.europa.eu/health/authorisation-procedures_en.htm>).

[962]*Quality of Medicines and Good Manufacturing Practices (GMP),* online: European Commission <http://ec.europa.eu/health/human-use/quality/index_en.htm>.

The first edition of the EU GMP guide was published 1989.[963] Today, the Directive 2003/94/EC laying down principles and guidelines of Good Manufacturing Practice (EU-GMP) for medicinal products for human use stipulates detailed guidelines which are used in assessing applications for manufacturing authorizations and as a basis for inspection of manufacturers of medicinal products.[964] EU-GMP covers all aspects of the WHO GMP Guidelines. The Guide is presented in three parts and supplemented by a series of annexes. Part I covers GMP principles for the manufacture of medicinal products. Part II covers GMP for active substances used as starting materials. Part III contains GMP related documents, which clarify regulatory expectations.

As for imported active substances, *Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 Amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, as Regards the Prevention of the Entry into the Legal Supply Chain of Falsified Medicinal Products* introduces EU-wide rules for the importation of active substances. According to Article 46b(2), active substances can only be imported if the active substances are accompanied by a written confirmation from the competent authority of the exporting third country which confirms that the standards of Good Manufacturing Practice and control of the plant are equivalent to those in the European Union.[965] Whenever an active substance-manufacturing site is found not to comply with EU GMP following an inspection by an EU Member State, a Statement of Non-Compliance is issued and

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[963]EC, *The Rules Governing Medicinal Products in the European Union EU: Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use*, (SANCO/C8), (2010), EC: Health and Consumer Directorate-General at Introduction, online: European Commission <http://ec.europa.eu/health/files/eudralex/vol-4/2011_intro_en.pdf>.

[964]EC, *Commission Directive 2003/94/EC of 8 October 2003 Laying Down the Principles and Guidelines of Good Manufacturing Practice in Respect of Medicinal Products for Human Use and Investigational Medicinal Products for Human Use*, OJ L 262, 14.10.2003, p. 22–26, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32003L0094>.

[965]EC, *Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 Amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, as Regards the Prevention of the Entry into the Legal Supply Chain of Falsified Medicinal Products,* OJ L 174, 1.7.2011, p. 74–87, online: Eur-Lex <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011L0062>.

entered in EudraGMDP.[966] EudraGMDP is the EU database contains the following information on: a) manufacturing and import authorizations; b) Good Manufacturing Practice certificates; c) statements of non-compliance with GMP; and d) GMP inspection planning in third countries.[967]

Established in 1995, the European Medicines Agency (EMA)[968] is responsible for the scientific evaluation of applications for EU marketing authorizations for human medicines in the centralized procedure.[969] The Agency also is responsible for coordinating GMP inspections in connection with the assessment of marketing-authorization applications. Furthermore, the Commission revises on a regular basis the GMP guidelines in collaboration with the EMA. However, the Agency only provides scientific opinions and it is not responsible for issuing decisions on whether to grant, suspend or revoke a marketing authorization for any medicine. The legal decisions on marketing authorization are the exclusive prerogative of the European Commission.[970]

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[966]*Op. cit.* 962 (*Quality of medicines and Good Manufacturing Practices*).

[967]Additionally the EudraGMDP database contains information on: wholesale distribution authorizations; Good Distribution Certificates (GDP); Statements of non-compliance with GDP; and Registration of manufacturers, importers and distributors of active substances for human use located in the European Economic Area. The European Economic Area (EEA) comprises all Member States of the EU as well as Iceland, Liechtenstein and Norway. More on EudraGMDP see: online: *EudraGMDP* <http://eudragmdp.ema.europa.eu/inspections/displayWelcome.do>.

[968]The European Medicines Agency is a decentralized agency of the European Union, located in London. It has similar functions to the FDA. More on EMA see: online, *European Medicines Agency* <http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/Home_Page.jsp&mid=>.

[969]Under the centralized procedure, pharmaceutical companies submit a single marketing-authorization application to the EMA. Once granted by the European Commission, a centralized marketing authorization is valid in all European Union Member States, as well as in the European Economic Area. Under EU law, a company can only start to market a medicine once it has received a marketing authorization.

[970]*Marketing authorizations*, European Medicines Agency, online: European Medicines Agency <http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000091.jsp&mid=WC0b01ac0580028a42>.

CIS

The first GMP standards in the CIS states were introduced in 1991. At that moment, CIS states were still part of the USSR. Just a few months later, the USSR became history. Nevertheless, some manufacturers, especially those who exported their products, commenced using GMP guidelines.[971]

In 1998, a joint decree of the Ministry of Economics and Ministry of Health of the Russian Federation inaugurated the first Russian version of GMP standards for industry (OST 42-510-98). This document established rules for pharmaceutical product manufacturing and quality control inspection. However, such standards were applicable only for new or fully renovated productions facilities.[972] Hence, they had little or no impact on existing pharmaceutical industry facilities. Just a few years later, in 2004, the State Committee of the Russian Federation for Standardization and Metrology published State Standard GOST R 52249-2004.[973] This time Russian bureaucrats chose the easiest way to develop a new document and simply translated EU-GMP 2003 guidelines into Russian. Hereby, not only time and resources were saved but also total legal harmonization was instantly reached with the European Union GMP' rules.

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[971]Марианна Мирзоян, *GMP: Теперь в России* (Marianna Mirzoiyn, "GMP is Now in Russia"), [translated by author]), 6 November 2013, online: Медпортал, <http://medportal.ru/mednovosti/main/2013/11/06/243gmp/>.

[972]*О Введении в Действие Стандарта Отрасли ОСТ 42-510-98 "Правила Организации Производства и Контроля Качества Лекарственных Средств (GMP)"* (On Introduction of the Industry Standard OST 42-510-98 "Rules of Production and Quality Control of Medicines (GMP)" [translated by author]) at Art 3, online: CNTD <http://docs.cntd.ru/document/901755081>.

[973]ГОСТ Р 52249-2004, Правила Производства и Контроля Качества Лекарственных Средств (GOST R 52249-2004 Rules of Production and Quality Control of Medicines [translated by author]), online: VSEGOST <http://vsegost.com/Catalog/54/5420.shtml>.

To maintain GMP State Standards updated and identical to the EU-GMP, new GOST R 52249-2009 was entered into force on 1 January 2010.[974] This Standard is a translation into Russian of the EU-GMP regulations of January 31, 2009.[975] The new GOST applies to all types of drugs and establishes the general requirements for their production and quality control, as well as specific requirements for the manufacture of active pharmaceutical ingredients and certain types of drugs.

In spite of the fact that since 2004 Russia has had comprehensive GMP Standards, the Federal law did not prescribe specific obligations regarding GMP use and there are no statistics on how many pharmaceutical firms followed GMPs. Many Russian manufacturers used GMPs on a voluntary base to make it easier to market their products to foreign companies who require conformity with GMP.[976] This situation has been changed over the last few years.

Federal Law 61 *"On the Circulation of Pharmaceuticals"*, introduced in April 2010, was the first significant step to improve legislation regulating the pharmaceutical market at all stages from drug development to production and distribution. The law set state control for safety, quality and efficacy of medicines[977] and established a deadline, January 1, 2014, for the transition to the new rules for the manufacture and quality control of pharmaceuticals in accordance with State Standard GOST R 52249-2009 for GMP.[978] The Directive of the Ministry of Industry and Trade of the Russian Federation on June 14, 2013 № 916 restated all postulates of the GOST R 52249-

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[974]ГОСТ Р 52249-2009, Правила Производства и Контроля Качества Лекарственных Средств (GOST R 52249-2009 Rules of Production and Quality Control of Medicines [translated by author]), online: VSEGOST <http://vsegost.com/Catalog/48/48198.shtml>.
[975]*Ibid.* at art. 4.
[976]*Op. cit.* 971 (Marianna Mirzoiyn).
[977]*Федеральный Закон Российской Федерации от 12 Апреля 2010 г. N 61-ФЗ Об Обращении Лекарственных Средств* (Federal Law of Russian Federation on April 12, 2010, N 61, On the Circulation of Pharmaceuticals [translated by author]), at Article 1 & 45, online: Российская Газета <http://www.rg.ru/2010/04/14/lekarstva-dok.html>.
[978]*Ibid.* at art. 71.5

2009, assuring the law implementation.[979] Unfortunately, not all manufacturers could meet GMP requirements after the transition period.

In 2014, the Ministry of Industry and Trade inspected more than 70 pharmaceutical companies. More than half of producers did not meet GMP requirements. Only 28 enterprises received GMP certification.[980] On the positive side, the majority of problems with GMP implementation, noticed during inspections, was not connected to production or logistic cycles. The two most common violations reported are related to GMP administration: personnel in charge of GMP *modus operandi* did not have appropriate qualifications and the production process was not adequately documented. Both violations do not pose direct risks to drugs safety and might be fixed without significant investments.[981] Nevertheless, it is expected that up to 30% of pharmaceutical factories functioning now in Russia will not be able to pass GMP inspections and might be closed for good.[982]

The Treaty of the Eurasian Economic Union, signed by the heads of state of Belarus, Kazakhstan and Russia in May 2014, establishes uniform rules for the US $40 billion common pharmaceuticals and medical products market.[983] Article 30 of the Treaty sets a legal framework to comply with good pharmaceutical practices, based on the following principles: a) harmonization and unification of legislation of Member

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[979]*Приказ Министерства Промышленности и Торговли РФ от 14 июня 2013 г. № 916* (The Directive of the Ministry of Industry and Trade of the Russian Federation on June 14, 2013 № 916 [translated by author]), online: Качество РФ <http://качество.рф/documents/order>.

[980]Екатерина Чернышова, "Страна двух таблеток" (Ekaterina Chernishova, The Country of Two Pills [translated by author]) *Kommersant*, (9 December 2014), online: Kommersant <http://www.kommersant.ru/doc/2625142>.

[981]*Op. cit.* 971 (Marianna Mirzoiyn).

[982]Today approximately 600 pharmaceutical production facilities are operating in Russia. 180 possess out of date equipment and require costly transformation to meet GMP standards. (*Op. cit.* 980 (Ekaterina Chernishova)).

[983]*Договор о Евразийском Экономическом Союзе* (EAEU Treaty [translated by author]), online: EAEU <https://docs.eaeunion.org/Pages/DisplayDocument.aspx?s=bef9c798-3978-42f3-9ef2-d0fb3d53b75f&w=632c7868-4ee2-4b21-bc64-1995328e6ef3&l=540294ae-c3c9-4511-9bf8-aaf5d6e0d169&EntityID=3610>.

States in the field of medicines; b) ensuring the unity of the mandatory requirements for the quality, effectiveness and safety of medicines circulating in the Union; c) adoption of common rules in the field of drugs; d) development and application of similar or comparable methods of research and monitoring of quality, effectiveness and safety of medicines; e) the harmonization of legislation of Member States in the field of control and supervision; f) common policy in licensing and institutional line of work. The single market has operated since January 1, 2016. During 2015, 25 new regional agreements defining principles and rules of harmonized requirements for drugs testing, registration, and guidelines of Good Manufacturing Practice were elaborated and signed.[984]

The latest draft version for the GMP-EAEU was published at the end of February 2015.[985] According to this document, the newly inaugurated EAEU licensing system ensures that only approved and safe medicine is marketed in the Union.[986] Manufacturers must obtain appropriate licenses, be regularly inspected by the competent authorities, and use risk management principles for quality. Compliance with Good Manufacturing Practice is mandatory to obtain licenses for production. In general, GMP-EAEU is analogous to the European counterpart.

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[984]*Гармонизация Обращения Лекарственных Средств и Медицинских Изделий в Рамках Евразийского Экономического Союза* (Harmonization of Drug and Medical Products Circulation within the Eurasian Economic Union [translated by author]), (17 December 2014), online: Esculap-Med <http://www.esculap-med.ru/news/details/garmonizaciya_obrashheniya_lekarstvennykh_sredstv_i_medicinskikh_izdelijj_v_ramkakh_evrazijjskogo_ehkonomicheskogo_soyuza>; *ЕАЭС Намерен Создать Общий Рынок Лекарственных Изделий и Медпрепаратов на Территории Стран-Участниц Союза* , (EAEC Intends to Create a Common Market of Pharmaceuticals and Medicinal Products [translated by author]), ХИМРАР, (17 December.2014), online: ХИМРАР <http://www.chemrar.ru/i-news/index.php?ELEMENT_ID=19174>.

[985]*Правила Надлежащей Производственной Практики (GMP) ЕАЭС*, Версия 4.0 от 20.02.2015 (Rules for Good Manufacturing Practices (GMP) EAEU, Draft 4.0, (20 February 2015) [translated by author]), online: Eurasian Commission <http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/konsultComitet/Documents/Проект%20Правил%20GMP%20редакция%20от%202015%2002%2020%20на%20сайт.pdf>.

[986]Licenses for production are mandatory for all manufacturers of medicine in the Member States, regardless of whether the products are sold on the territory of the Union or intended for export.

To conclude, the European Commission Directives have established mandatory GMPs application in all member-states for decades. Pan-European institutions have provided vigorous control on GMPs implementation. On the opposite side of the Atlantic Government agencies have taken initial steps toward legal and instrumental GMPs harmonization. The FDA and Health Canada are jointly working on mutual inspection model. As for CIS, Member States, leading by Russia are willing to recognize GMPs as a fundamental instrument to guaranty consumer safety. The new entity EAEU, with legal discipline similar to the EU, has been working around the clock to make GMPs mandatory in all Member States. The final version of EAEU-GMPs has not been released; nevertheless, an overview of the published drafts suggests that virtual conformity with EU-GMPs will be reached.

3.2.8 Medical Products and the Internet: a Guide to find reliable information

NAFTA

Canada

The 2012 Health Canada guide *Buying Drugs over the Internet* stipulates the following focal points: a) the risks associated with buying drugs online; b) the status of Internet pharmacy in Canada; c) minimizing your risk; and d) Health Canada's role. The guide provides basic information on how consumer should buy quality drugs over the Internet. Notably, the provinces regulate the practice of pharmacies in Canada, and any licensed pharmacy that offers Internet services must meet the standards of practice within its own province. All drugs approved for sale in Canada

have an eight-digit Drug Identification Number (DIN). The DIN assures you that Health Canada has assessed a drug and considers it safe and effective when used as directed on the label. The DIN also provides a way to track adverse drug reactions.[987]

Health Canada also issues alerts on suspicion or illegal e-pharmacies and works with the Canada Border Services Agency to stop the importation into Canada of any shipments of such website products.[988]

The National Association of Pharmacy Regulatory Authorities (NAPRA) also takes a proactive position. NAPRA provides consumer information regarding virtual drugs shopping in Q&A formula.[989]

United States

The FDA released two consumer guides on the matter: *Buying Prescription Medicine*

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[987]A Drug Identification Number (DIN) is a computer-generated eight-digit number assigned by Health Canada to a drug product prior to being marketed in Canada. The DIN is unique and serves as a tool to help in the follow-up of products on the market, recall of products, inspections, and quality monitoring. It uniquely identifies all drug products sold in a dosage form in Canada and is located on the label of prescription and over-the-counter drug products that have been evaluated and authorized for sale in Canada. A DIN uniquely identifies the following product characteristics: manufacturer; product name; active ingredient(s); strength(s) of active ingredient(s); pharmaceutical form; route of administration. Once a drug has been authorized, Health Canada issues a DIN which permits the manufacturer to market the drug in Canada. For drugs where there is minimal market history in Canada, there is a more stringent review and the drug is required to have a DIN in order to be marketed in Canada. A DIN lets the user know that the product has undergone and passed a review of its formulation, labeling and instructions for use. A drug product sold in Canada without a DIN is not in compliance with Canadian law. (*Drug Identification Number (DIN)*, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/fs-fi/dinfs_fd-eng.php> & *Buying Drugs over the Internet*, online: Health Canada, <http://healthycanadians.gc.ca/drugs-products-medicaments-produits/drugs-medicaments/internet-eng.php>).

[988]*Health Canada Warns Canadians about Buying Prescription Drugs Online from the Global Pharmacy Canada Website*, Health Canada, (27 July 2010), online: Health Canada <http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2010/13414a-eng.php>.

[989]*Questions and Answers for Consumers*, online: National Association of Pharmacy Regulatory Authorities <http://napra.ca/pages/Practice_Resources/QuestionsandAnswersConsumers.aspx?id=3177#Answer14>.

Online: A Consumer Safety Guide[990] and the *Possible Dangers of Buying Medicines over the Internet.*[991] Both guides provide quite similar information on safety tips to consumer for shopping on line for drugs. In general delivered information resembles on Health Canada model.

Another useful FDA resource is the *Buying Medicines Over the Internet: Quick Tips for Buying Online* portal where all information on online drug shopping has been pulled together.[992]

Finally, the FDA takes actions against bogus e-pharmacies. Just recently, in partnership with international regulatory and law enforcement agencies, the FDA took action against more than 9,600 websites that illegally sell potentially dangerous, unapproved prescription medicines to consumers. These actions included the issuance of regulatory warnings, the shutting down of offending websites and seizure of US $41,104,386 worth of illegal medicines worldwide.[993]

EU

The EU has not endorsed the WHO guidelines nor translated them into the official languages of the EU members. And indeed, the guidelines have been delegated

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[990] *Buying Prescription Medicine Online: A Consumer Safety Guide*, online: FDA <http://www.fda.gov/Drugs/ResourcesForYou/ucm080588.htm>.

[991] *The Possible Dangers of Buying Medicines over the Internet*, online: FDA <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048396.htm>.

[992] *Buying Medicines Over the Internet: Quick Tips for Buying Online*, FDA, online: FDA <http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/buyingmedicinesovertheinternet/default.htm>.

[993] Many of these websites appeared to be operating as a part of an organized criminal network that falsely purported its websites to be "Canadian Pharmacies." These websites displayed fake licenses and certifications to convince U.S. consumers to purchase drugs they advertised as "brand name" and "FDA approved." The drugs received as part of operation were not from Canada, and were neither brand name nor FDA approved. These websites also used certain major U.S. pharmacy retailer names to trick U.S. consumers into believing an affiliation existed with these retailers. (*FDA Takes Action to Protect Consumers from Dangerous Medicines Sold by Illegal Online Pharmacies*, FDA, (27 June 2013), online: FDA <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm358794.htm>).

mostly to the national authorities, not to the regional entities. Nevertheless, the European Commission has introduced an interesting concept to fight bogus e-pharmacies practices and to help consumer when he/she shops online for drugs.

The EU has a strong legal framework for the licensing, manufacturing and distribution of medicines. At the end of the distribution chain, only licensed pharmacies and approved retailers are allowed to offer medicines for sale, including the legitimate sale via the Internet.[994]

The Directive, which came into force on 21 July 2011[995], aims to prevent falsified medicines from entering the legal supply chain and reaching patients.[996] It introduces harmonized safety and control measures for Internet sales. The Directive has also introduced an obligatory logo that will appear on the websites of legally operating online pharmacies and approved retailers in the EU.[997] The logo will allow consumers to identify authorized online pharmacies and approved retailers providing authentic, authorized medicines. Clicking on the logo will link to the national regulatory authority websites, where all legally operating online pharmacies and approved

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[994]*Falsified Medicines*, European Medicines Agency, online: EMA <http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000186.jsp&mid=WC0b01ac058002d4e8 >.

[995]Member States had to start applying its measures in January 2013.

[996]EC, *Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 Amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, as Regards the Prevention of the Entry into the Legal Supply Chain of Falsified Medicinal Products*, OJ L 174, 1.7.2011, p. 74–87, online: Eur-Lex <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011L0062>.

[997]The national flag and the text are an integral part of the logo. The flag in the middle left side of the logo corresponds to the Member State where the pharmacy or retailer is registered or authorized. Only national flags of the EU Member States as well as those of Norway, Iceland and Lichtenstein are allowed. Therefore, a logo displaying the EU flag, for example, will not be authentic. The logo links to the website of the national competent authority listing all legally operating online pharmacies/retailers. By simply clicking on the logo a purchaser of the medicines online will be sent to the entry of the pharmacy on that national list, thus completing the verification process. The logo can be trusted only if a purchaser, after clicking, is redirected to the entry of that pharmacy on the list of legally operating online pharmacies and retailers registered in that Member State on the national authority web-page (*Directive 2011/62/EU* at Article 85c & 85d)

retailers in their respective countries will be listed. PR campaigns to raise awareness of the logo and the dangers of falsified medicines were run across the Europe. [998] The system has been operational since July 1, 2015.

CIS

The Russian government has not ever endorsed *Medical Products and the Internet: a Guide to find reliable information* guide. The valid reason is that the conventional model of an online pharmacy in Russia is illegal. The *Decree of the Government of the Russian Federation 81 of 2002*[999] amending the *Federal law № 55 of 1998*[1000] bans the delivery of drugs to the consumer from a retailer who does not have a "stationary point of selling". As a result, an online pharmacy in Russian today can only be a real pharmacy shop with a website (or call center) and delivery service. Hence, to some degree, virtual e-pharmacies do exist in Russian. Consumer still can make an order with delivery to home, work or any desirable address; however, the pharmacy business must be genuine and play in accordance with the rules for a regular pharmacy.

Observations

Today, when online drug marketing is booming, it remains as important as ever to

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[998]EC, *Commission Implementation Regulation (EU) No 699/2014 of 24 June 2014 on the Design of the Common Logo to Identify Persons Offering Medicinal Products for Sale at a Distance to the Public and the Technical, Electronic and Cryptographic Requirements for Verification of its Authenticity*, OJ L 184, 25.6.2014, p. 5–7, online <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2014_184_R_0004&qid=1403861374882&from=EN>.

[999]*Постановление Правительства РФ от 06.02.2002 N 81·О Внесении Изменений и Дополнений в Правила Продажи Отдельных Видов Товаров* (Government Decree of 06.02.2002 N 81 On Amendments and Additions to the Rules of the Sale of Certain Goods [translated by author]), online: Консультант <http://www.consultant.ru/document/cons_doc_LAW_136273/>.

[1000]*Постановление Правительства РФ от 19 января 1998 г. N 55, Об Утверждении Правил Продажи Отдельных Видов Товаров* (The Government of Russian Federation Resolution January 19, 1998 N 55 On the Rules of the Sale for Certain Goods [translated by author]), online: Гарант <http://base.garant.ru/12108380/>.

arm the consumer with truly vital and universal information on how to buy medical products over the Internet.

The postulates of the WHO Guidelines provide crucial information to the consumer who uses e-pharmacies. The problem is that many consumers are unfamiliar with such information. National guidelines on this issue may contain only partial information. For example, Health Canada's *Buying Drugs over the Internet* includes only a few provisions of the WHO Guidelines.[1001] At the same time, not every consumer would look over the eight pages of the WHO Guidelines. The Guidelines should be revised to make them more clear-cut and less time-consuming to read.

Moreover, it would be more useful if the businesses selling medical products online were obliged to provide to consumers information on the WHO Guidelines on their Web sites before the consumer makes a final decision.

With the blossoming of e-pharmacies, national authorities have less and less time to pass on the warnings of the WHO Guidelines to the consumer. In this respect, the EU model of on-line drug marketing looks very attractive. The idea of an authenticity logo with redirection to a national registry function is simple and inexpensive. Every state can make it available to consumer to verify the legitimacy of an e-pharmacy in no time.

The Russian model, where only a physical pharmacy business may sell drugs online is also interesting and should be studied. So far no problems with the Russian pattern of drug distribution on-line have been reported.

[1001] *Op. cit.* 987 (*Buying Drugs over the Internet*).

3.2.9 WHO Guidelines for Appropriate Use of Herbal Medicines

NAFTA

Canada

In 2010, 73% of Canadians regularly took Natural Health Products (NHPs).[1002] In Canada, herbal medicines are sold in pharmacies as over the counter medicines, in special outlets, by licensed and unlicensed practitioners, and in multilevel marketing. Regulation of herbal medicines was introduced in Canada in 2004[1003] in separate laws within the *Food and Drugs Act*.[1004] Regulations apply to the sale; manufacture; packaging; labeling; importation; distribution; storage and recall of natural health products.

The law permits making claims about the medical and health properties attributed to herbal medicines. To market an herbal product, the manufacturer and importer must have both a site license and a product license. Special GMP rules for the manufacturing of herbal medicines are enforced by submitting to inspection before a license is granted. In addition, to obtain a license, the manufacturer and importer must demonstrate that the traditional use of the herbal product is safe and does not produce harmful effects on consumer health. Requirements for safety assessment include reference to documented scientific research on similar products and satisfactory evidence of compliance with the safety requirements laid down in the regulations.[1005]

[1002]*Natural Health Product Tracking Survey: Final Report 2010,* Ipsos Reid, (13 January 2010), at 6, online: National Library of Canada Electronic Collection <http://epe.lac-bac.gc.ca/100/200/301/pwgsc-tpsgc/por-ef/health/2011/135-09/report.pdf >.
[1003]*Natural Health Products Regulations*, (SOR/2003-196), online: Justice Laws <http://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/page-1.html#docCont>.
[1004]*Food and Drugs Act,* (R.S.C., 1985, c. F-27), online: Justice Law <http://laws-lois.justice.gc.ca/eng/acts/F%2D27/>.
[1005]There are two documents: the *Pathway for Licensing Natural Health Products Making Modern*

Finally, regulations prescribe that product license holders must monitor and report to Health Canada all adverse reactions related to their product.

Natural and Non-prescription Health Products Directorate (part of the Health Products and Food Branch of Health Canada) (NNHPD) is the regulating authority for natural health products for sale in Canada. Its mandate is to ensure that Canadians have access to natural health products that are safe, effective and of high quality while respecting freedom of choice and philosophical and cultural diversity.[1006] The NNHPD will employ a risk-based approach that focuses on those elements of an application that most directly relate to safety and efficacy and may request additional documentation as necessary.[1007] A post marketing surveillance system that includes monitoring of adverse effects of herbal medicines was established in 1965 and is the same as for conventional pharmaceuticals.[1008]

New Approach to Natural Health Products

In 2012, as part of NNHPD's ongoing commitment to continuous improvement, the *New Approach to Natural Health Product* regulatory framework was introduced. The

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Health Claims and the *Pathway for Licensing Natural Health Products Used as Traditional Medicines use Risk-Based Approach for Determining Safety and Efficacy Evidence for Natural Health Products. Risks* related to safety and efficacy includes potential risks due to: a) an ingredient's physical or chemical form; b) the seriousness of the health claim and the conditions of use implied; and c) the health impact from lower than expected performance of the product. (For more information see: the *Pathway for Licensing Natural Health Products Making Modern Health Claims*, Health Canada: Natural and Non-prescription Health Products Directorate, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodnatur/legislation/docs/modern-eng.pdf>).

[1006] *Natural Health Products*, online: Health Canada: Natural and Non-prescription Health Products Directorate <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>.

[1007] *Quality of Natural Health Products Guide*, Health Canada: Natural and Non-prescription Health Products Directorate, (1 May 2015), at 1, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodnatur/legislation/docs/eq-paq-eng.pdf>.

[1008] *Op. cit.* 518 (*National Policy on Traditional Medicine and Regulation of Herbal Medicines Report of a WHO Global Survey*) at 77&78.

document outlined a more efficient, flexible regulatory approach, protecting health and safety while enabling consumer access and industry innovation and growth.[1009]

NNHPD proposed to implement a Three Class System to determine the amount of time required to review a product license application based on the level of certainty (i.e. how much is known about the product – pre cleared information). By streamlining the product license application process the NNHPD proposes to drastically reduce product review times. The aim is to review 99% of products in 30 days or less.

New Natural Health Products Regulations set out the requirements governing the sale, manufacture, packaging, labeling, importation, distribution and storage of NHPs. The objective of the NNHPR is to provide reasonable assurance that products offered for sale in Canada are safe, efficacious and of high quality.[1010]

In December 2012, NHPD published the *Pathway for Licensing NHPs Making Modern Health Claims*[1011] and *Pathway for Licensing NHPs Making Traditional Health Claims.*[1012] This guidance document provides information to help product license applicants determine the evidence (type and amount of data) to provide as part of a product license application to support the safety (risk) and efficacy (benefit) of natural health products (NHPs) that make modern health claims.

[1009]*The Approach to Natural Health Products*, Health Canada: Natural and Non-prescription Health Products Directorate, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/nhp-new-nouvelle-psn-eng.php>.
[1010]*Pathway for Licencing NHPs Making Modern Health Claims*, Health Canada: Natural and Non-prescription Health Products Directorate, at 5, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodnatur/legislation/docs/modern-eng.pdf>.
[1011]*Ibid.*
[1012]*Pathway for Licencing NHPs Making Traditional Health Claims*, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodnatur/legislation/docs/tradit-eng.pdf>.

Additionally, the NNHPD published an updated *Quality of Natural Health Products Guide*.[1013] It outlines the requirements for ensuring high quality NHPs, while allowing for flexibility in how these requirements are met.

Lastly, significant efforts have been made to increase the amount of monographs available for applicants. NNHPD has published over 250 monographs representing hundreds of herbal ingredients. Under the current system of herbal registration, over 70,000 herbal medicines have been registered and over 2,000 site licenses have been issued.[1014]

United States

Today, the US is one of the biggest markets for herbal medicine reaching a total estimated figure of seven billion dollars in 2015.[1015] The regulatory framework for herbal medicine has been established by means of the *Dietary Supplement Health and Education Act* (DSHEA) since 1994.[1016] DSHEA covers vitamins; minerals; herbs or other botanicals; amino acids; other dietary substances to supplement the diet by increasing dietary intake; and any concentrate, metabolite, constituent, extract, or combination of any such ingredients. Although many such products (particularly herbs) are marketed for their alleged preventive or therapeutic effects, the law has made it difficult or impossible for the FDA to regulate them as drugs. Under DSHEA,

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[1013]*Quality of Natural Health Products Guide*, Health Canada: Natural and Non-prescription Health Products Directorate, (1 May 2015), online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodnatur/legislation/docs/eq-paq-eng.pdf>.
[1014]*Op. cit.* 1009 (*The Approach to Natural Health Products*).
[1015]*Op. cit.* 523 (*Herbal Dietary Supplement Sales in US Increased by 7.5% in 2015*).
[1016]*Dietary Supplement Health And Education Act of 1994*, (Public Law 103-417), FDA, (1994), online: FDA <https://ods.od.nih.gov/About/DSHEA_Wording.aspx>.

even hormones, such as DHEA and melatonin, can be marketed as supplements, as long as any drug-like properties of the product are not advertised.[1017]

DSHEA defines and classifies dietary products, outlines safety obligations, and sets standards for testing and requirements for label information. Article 9 gives the FDA the authority to establish GMP for the herbal medicine production. As for safety, the marketer is responsible for determining that the product is safe, and that no false or misleading claims are stated regarding properties of herbal medicine. With the exception of a new active ingredient, the FDA does not require a pre-market safety product review. Because manufacturers are not required to submit safety information before marketing supplements, the FDA must rely on adverse event reports, product sampling, information in the scientific literature, and other sources of evidence of danger. Hence, potentially unsafe products may be marketed to consumer.[1018] For this reason, the DSHEA has been often criticized for being an industry-driving bill causing more harm to consumers than good.[1019]

On the positive side, the *Dietary Supplement and Non-Prescription Drug Consumer Protection Act* was introduced in 2006.[1020] It requires manufacturers of dietary supplements and non-prescription drugs to notify the FDA about serious adverse events related to their products; manufacturers must report deaths; life-threatening experiences; inpatient hospitalizations; persistent or significant disability or

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[1017] Stephen Barrett, "Why Consumers Need More Protection Against Claims for Dietary Supplements and Herbs", *International Journal of Toxicology,* September/October, 2003, 22:5, online: International Journal of Toxicology <http://ijt.sagepub.com/content/22/5/391.abstract >.

[1018] Stephen Barrett, *How the Dietary Supplement Health and Education Act of 1994 Weakened the FDA*, online: Quackwatch <http://www.quackwatch.com/02ConsumerProtection/dshea.html>.

[1019] *"Big Supplement" Lashes out, and John McCain Caves in*, Science Blogs, (March 2010), online: Science Blogs <http://scienceblogs.com/insolence/2010/03/08/big-supplement-lashes-out-and-john-mccai/>; Steven Novella, "Herbs Are Drugs: Science of Medicine", Skeptical Inquirer, 37:2, (March/April 2013), online: Skeptical Inquirer <http://www.csicop.org/si/show/herbs_are_drugs>.

[1020] *Dietary Supplement and Non-Prescription Drug Consumer Protection Act*, 2006, Public Law 109–462 (S. 3546), online: FDA <http://www.fda.gov/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAct/ucm148035.htm >.

incapacity; birth defects; or the need for medical intervention to prevent any such problems.

Established in 1998, the National Center for Complementary and Integrative Hea*lth* (NCCIH) is the Federal Government's lead agency for scientific research on complementary health approaches. NCCIH is a part of the National Institutes of Health within the U.S. Department of Health and Human Services. The mission of NCCIH is to define, through rigorous scientific investigation, the usefulness and safety of complementary and integrative health interventions and their roles in improving health and health care. Gathered scientific evidence provide crucial information on the safety and efficacy of herbal medicines for all stakeholders: consumers, health professionals, and lawmakers.[1021]

EU

Before 2004 the EU did not have a coordinated regulatory approach to herbal medicines. Nevertheless, Member States had quite similar governing patterns.[1022] For instance, Belgium introduced regulation of herbal medicines back in 1969. It is similar to the one on the conventional pharmaceuticals, including safety requirements and the GMP rules. There is no registration scheme. The national post-marketing surveillance system established in 1990 includes adverse effect monitoring of herbal medicines.[1023]

[1021]National Center for Complementary and Integrative Health, online: NCCIH <https://nccih.nih.gov>.
[1022]*Op. cit.* 518 (*National Policy on Traditional Medicine and Regulation of Herbal Medicines Report of a WHO Global Survey*) at 95 to118.
[1023]*Op. cit.* 518 (*National Policy on Traditional Medicine and Regulation of Herbal Medicines Report of a WHO Global Survey*) at 98.

Similarly, French Regulation, 1985 and German Regulation, 1976 on herbal medicines use the same laws and regulations as for conventional pharmaceuticals, with similar requirements for safety, GMPs, and post-marketing surveillance. However, in contrast to Belgium, both states introduced registration schemes; 787 herbal medicines are registered in France and more than 3500 in Germany.[1024]

In general, EU legislation on pharmaceutical products for human use has also been applied to traditional herbal medicines. However, existing differences and uncertainties about the status of traditional herbal medicinal products in the Member States were not clarified until 2004. In order to overcome those difficulties and uncertainties encountered by Member States in applying pharmaceutical legislation to traditional herbal medicinal products in a uniform manner, a simplified registration procedure was introduced in 2004 by the *Directive 2004/24/EC on Traditional Herbal Medicinal Products*.[1025] This procedure aims to safeguard public health and facilitate the free movement of such products by introducing harmonized rules in this area.[1026]

Directive 2004/24/EC, defies herbal medicinal products as any medicinal product exclusively containing as active ingredients one or more herbal substances, or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.[1027] Under this regulation, all herbal medicinal products are required to obtain an authorization to market within the EU. To obtain an

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[1024] *Op. cit.* 518 (National Policy on Traditional Medicine and Regulation of Herbal Medicines Report of a WHO Global Survey) at 101 & 102.

[1025] EC, *Amended by Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 Amending, as Regards Traditional Herbal Medicinal Products, Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use*, OJ L 136, 30.4.2004, p. 85-90., online: European Commission <http://ec.europa.eu/health/files/eudralex/vol-1/dir_2004_24/dir_2004_24_en.pdf>.

[1026] EC, *Herbal Medicinal Products*, online: European Commission <http://ec.europa.eu/health/human-use/herbal-medicines/index_en.htm#geninf>.

[1027] Art.1.

authorization, a marketer needs to demonstrate that the herbal medicine has been in use within the EU for at least 30 years or 15 years within the EU and 30 years outside the EU.[1028] The simplified procedure allows the registration of herbal medicinal products without requiring particulars and documents on tests and trials on safety and efficacy. All herbal medicines must be manufactured according to Good Manufacturing Practice.

A Committee on Herbal Medicinal Products (HMPC) has been established at the European Medicines Agency.[1029] A major task for the HMPC is to establish Community monographs for traditional herbal medicinal products, and, with the objective of further facilitating registration and harmonization in the field of traditional herbal medicinal products, prepare a draft list of herbal substances which have been in medicinal use for a sufficiently long time, and hence are considered not to be harmful under normal conditions of use.

To further facilitating the registration of certain traditional herbal medicinal products in the EU, a *List of Herbal Substances, Preparations and Combinations thereof for Use in Traditional Herbal Medicinal Products* has been established on the basis of the scientific opinion of the HMPC.[1030] As regards the safety and efficacy of a traditional herbal medicinal product, applicants can refer to the list. Nevertheless, they would still need to demonstrate the quality of the medicinal products they seek

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[1028] Art.16.

[1029] *Committee on Herbal Medicinal Products*, online: European Medicines Agency <http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000264.jsp>

[1030] EC, *Commission Decision 2008/911/EC of 21 November 2008 Establishing of a List of Herbal Substances, Preparations and Combinations thereof for Use in Traditional Herbal Medicinal Products*, OJ L 328, 6.12.2008, p. 42–48, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:328:0042:0048:en:PDF>.

to register. The List has been continuously revised, with the latest update in February 2015.[1031]

CIS

The use of herbal medicine in Russia not only has a long history, but also has accumulated diverse knowledge from a rich ethnic background. There are hundreds of ethnic groups in Russia, each with a long tradition of herbal medicine use. Slavic, Tibetan, and Chinese traditional herbal medicines have been commonly used in Russian for centuries.[1032]

Russian law on herbal medicines is the same as for conventional pharmaceuticals. The *Federal Law of 12.04.2010 N 61-FZ On Circulation of Medicines*[1033] is the key regulation on the matter. According to the law, herbal medicine is medicine produced or manufactured from one or more species of medicinal plants and packaged for consumer use.[1034]

The requirements for the herbal medicines safety assessment are identical to conventional pharmaceuticals; hence, products with herbal content must undergo clinical trials on safety equal to conventional pharmaceuticals before being approved for consumer use. The implementation of manufacturing requirements is ensured through licensing of the manufacturing process, compliance with established regulations and certification of products. Article 45 establishes universal mandatory manufacturing regulatory requirements for both herbal and conventional medicines.

[1031] *Op. cit.* 1026 (*Herbal Medicinal Products*).
[1032] *Op. cit.* 516 (C.K. Ong *et al.*) at 135.
[1033] *Федеральный закон от 12.04.2010 N 61-ФЗ "Об Обращении Лекарственных Средств"* (The Federal Law of 12.04.2010 N 61-FZ "On Circulation of Medicines" [translated by author]) online: Consultant <http://www.consultant.ru/document/cons_doc_LAW_176361/>.
[1034] Art. 4.

As for interstate level, the final version of the Euro Asian Economical Union (EAEU) regulation *On Circulation of Medicines* has not been published yet. Nevertheless, the draft of the *EAEU Rules for Good Manufacturing Practices* treats herbal and conventional medicine alike.[1035] Thus, it might be projected that EAEU regulation on pharmaceuticals will be similar to Russian, with universal safety and quality rules for herbal and conventional medicines.

3.2.10 WHO Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine

NAFTA

Canada

Over the past several years, more and more Canadians have been turning to complementary and alternative health care to treat illness and promote health.[1036] Nevertheless, the Federal Government has only marginal involvement in CAM regulation.

CAM practices are regulated at the provincial level. Regulatory frameworks in different provinces are moving forward at different speeds. Also, the regulatory

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[1035] *Op. cit.* 985 (*Rules for Good Manufacturing Practices (GMP) EAEU*, Draft 4.0).
[1036] *Complementary and Alternative Health Care: The Other Mainstream?*, Health Policy Research, Issue 7, (November 2003), online: Health Canada <http://www.hc-sc.gc.ca/sr-sr/pubs/hpr-rpms/bull/2003-7-complement/index-eng.phpf>.

environment varies from one practice to another. While some practitioners, like chiropractors, are regulated consistently across the country, others, like naturopaths, are regulated differently in each province. Although the Federal Government is not responsible for CAM regulation, it constantly engages in consulting with practitioners and provincial governments as they address issues related to scope of practice, training and accreditation.[1037]

United States

The US approach to CAM is similar to the Canadian one. Regulatory controls surrounding complementary/alternative medicine involve six related areas of law: licensing, scope of practice, malpractice, professional discipline, third-party reimbursement, and access to treatments.[1038] State laws dominate the first five areas. Federal laws control the sixth; some CAM treatments are covered in full by Federal health programs Medicaid and Medicare.[1039] There has been done very little in respect of CAM on the Federal level. Nevertheless, a set of very comprehensive consumer safety information on different types of CAM therapies has been provided in an easy-to-use form by the National Center for Complementary and Integrative Health (NCCIH). NCCIH information helps consumers to understand a therapy's potential benefits, risks, and scientific evidence to health and safety.[1040]

[1037]*Ibid.*

[1038]In each of these areas, legal state rules aim to safeguard consumers against fraud and to ensure patient protection against dangerous practices and practitioners.

[1039]WHO, *Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review*, 2001, at 66, online: WHO <http://apps.who.int/medicinedocs/pdf/h2943e/h2943e.pdf>.

[1040]*National Center for Complementary and Integrative Health*, online: NCCIH <https://nccih.nih.gov>.

EU

Surveys conducted in several European countries have shown a high demand for CAM. The European Commission estimates that spending on CAM by consumers now tops EUR 100 million. There are currently more than 150,000 registered medical doctors with additional CAM certification, plus there are more than 180,000 registered and certified non-medical CAM practitioners.[1041]

The European Parliament (*Resolution A4-0075/97*)[1042] and The Parliamentary Assembly of the Council of Europe (*Resolution 1206 (1999)*)[1043] both passed resolutions recommending a stronger harmonization of non-conventional medicine in Europe.

Nevertheless, the EU has continually confirmed that it is up to each Member State to organize and regulate their health care system. The EU Treaties have repeatedly established that health policy is a national responsibility for the Member States. This is thoroughly confirmed in the Lisbon Treaty in TITLE XIV Public Health Article 168 number 7(4): "Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them..." Obviously, this fundamental provision also applies to

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[1041]*Complementary Medicine Popular Across Europe*, online: European Commission <http://ec.europa.eu/research/infocentre/article_en.cfm?artid=28813>.
[1042]European Parliament, *Resolution on the Status of Non-Conventional Medicine* (A4-0075/97), (6 March 1997), online: Euro-CAM <http://www.cam-europe.eu/dms/files/Parliament_documents/EuropeanParliamentResolution1997.pdf>.
[1043]Parliamentary Assembly, *Resolution 1206 (1999), A European Approach to Non-conventional Medicines*, (4 November 1999), online: Parliamentary Assembly <http://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-en.asp?fileid=16727&lang=en>.

CAM. Hence, is very unlikely to see the EU regulation on CAM in the foreseeable future.[1044]

The Cross-Border Healthcare Directive 2011/24/EU[1045] together with the Professional Qualifications Directive 2005/36/EC[1046] only indirectly encourage some degree of harmonization CAM practices, treatments and safety standards.[1047]

To date, 19 of 39 state-members have a general CAM legislation, 11 of these have a specific CAM law and six countries have included provisions on CAM in the national regulatory framework on healthcare. In addition to the general CAM legislation, some countries have regulations on specific CAM treatments. For instance, acupuncture is regulated in 26 countries.[1048]

Meanwhile, Brussels does not have any agenda to develop pan-European guidelines on CAM, despite the fact that current EU regulation and education chaos for CAM

[1044]Solveig Wiesener *et al. Legal Status and Regulation of CAM in Europe: Part I- CAM Regulations in the European countries*, CAMbrella, 2012, at 10, online: Wien University <https://phaidra.univie.ac.at/detail_object/o:291583>.

[1045]The Directive 2005/36/EC describes the patients' rights with regard to access safe and good quality treatment. Patients should experience equal treatment with the citizens of the country in which they are treated and the treatment shall be based on quality and safety standards of healthcare. (EC, *Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the Application of Patients' Rights in Cross-border Healthcare*, OJ L 88, 4.4.2011, p. 45–65, online: Eur-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0024>). This Directive can bear influence on CAM practices and CAM patients whether the specific treatment/practitioner is registered as conventional or non-conventional in the country of interest. However resent survey did not found that CAM treatment has been an important subject of interest in the cross-border healthcare legislation in the Member States. (*Op.* cit 1044 (Solveig Wiesener *et al.*) at 14).

[1046]The Directive 2005/36/EC on the recognition of professional qualifications is the legal basis for free movement of professionals in Europe. A profession is considered regulated when access to it and the exercise of it are subject to the acquisition of a specific professional qualification: "it should be laid down that any host Member State in which a profession is regulated must take account of the qualifications obtained in another Member State and assess whether they correspond to those which it requires". (EC, *Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the Recognition of Professional Qualifications*, OJ L 255, 30.9.2005, p. 22–142, online: Eur-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32005L0036>).

[1047]*Op.* cit 1044 (Solveig Wiesener *et al.*) at 9 &13.

[1048]*Op.* cit 1044 (Solveig Wiesener *et al.*) at 10.

makes it impossible to provide consistently safe services to patients. A centralized and coordinated European approach for research to obtain reliable information on CAM cost, safety and effectiveness has been seen as a first step in in right direction to improve today status quo.[1049]

CIS

Russia does not have an official policy on CAM. However, CAM has been regulated since 1993. Provisions of the *Federal law 323* established rules for CAM licensing.[1050] The Law defines Traditional Medicine as healing methods rooted in folk experience which are based on the use of knowledge and practical skills in the assessment and restoration of health. Citizens of the Russian Federation who receive a license issued by regional Health Authorities have the right to practice CAM only in that designated region. CAM is not a part of the universal state health care. Illegal practice of CAM is an administrative and criminal offence.[1051]

Regrettably, the new Law of 2011 does not clarify the aspects of licensing nor provide an explanation regarding the minimum education to be qualified for CAM, as it was previously.[1052] Regional authorities have received a carte blanche to regulate CAM; hence, the matter of CAM safety and quality has been delegated to regional governments. Obviously, the absence of federal harmonized requirements on CAM licensing leads to different safety standards from region to region.

[1049]*Op. cit.* 1041 (*Complementary Medicine Popular Across Europe*).
[1050]Since 1993 till recently, the Federal Law on Health Care :*"Основы Законодательства Российской Федерации об Охране Здоровья Граждан" (утв. ВС РФ 22.07.1993 N 5487-1)* (Fundamentals of the Legislation on Health Care 1993 [translated by author]) regulated aspects related to CAM. Adopted in 2011 the Federal Law on Health Protection, in general, restated the postulates from 1993. (*Федеральный Закон от 21.11.2011 N 323-ФЗ "Об Основах Охраны Здоровья Граждан в Российской Федерации"* (On the Fundamentals of Health Protection in the Russian Federation [translated by author]) online: Российская Газета <http://www.rg.ru/2011/11/23/zdorovie-dok.html>).
[1051]Art. 50.
[1052]The 1993 Law required basic medical education to practise CAM.

Official consumer safety information on CAM is not available from the Federal sources.

As for the CIS, explicit policies on CAM exist in Azerbaijan, Kazakhstan, Kyrgyzstan, and Tajikistan. These policies deal primarily with the training and licensing of folk healers, who are permitted to practice without formal medical education in all of the above counties except Kyrgyzstan.[1053]

Observations

To conclude, the regulatory approach to Traditional, Complementary and Alternative Medicine remains uneven. While national and regional policies on safety of CAM products (Herbal Medicine) have been well defined and implemented, the safety of CAM medical services has never received similar attention from federal and regional governments.

In most cases, the safety of Herbal Medicines has been treated identically or similar to the safety of conventional medicine. National and regional policies have been developed in accordance with principles outlined in the Guidelines AUNM, Guidelines on CAM and GMPs. To oversee the quality and safety of Herbal Medicines, specialized agencies have been instituted on federal and regional levels. Under existing schemas adverse reactions from herbal remedies have to reported and analyzed.

On the contrary, federal and regional policies on other forms of CAM have been absent or appeared sporadically. As a rule, consumer safety of CAM services has

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[1053] *Op. cit* 516 (WHO Global Atlas of Traditional, Complementary and Alternative Medicine) at 111.

been delegated to local authorities. Federal or regional governments have shown little interest to regulate or at least harmonize the legal landscape on safety of CAM medical services. Even the European Commission with its predilection to legal uniformity has repeatedly refused to consider EU regulation on the matter.

There is no tangible explanation for such *status quo*. Hypothetically, this unusual situation might exist due to the nature of the CAM. Herbal Medical products are marketed internationally and call for international response. In contrast, CAM medical services can be consumed only locally, directly from CAM provider to consumer. Hence, safety issues, if any, might be solved through local regulation. Nevertheless, the absence of regional or national polices on CAM services is difficult to justify; especially when CAM popularity is growing exponentially. At a minimum, federal and regional governments should provide information to consumers on the safety of CAM services in accordance with the WHO Guidelines on CAM.

3.2.11 Convention on International Civil Aviation (Chicago Convention 1944)

There are more than 10,000 International Standards and Recommended Practices (SARPs) in 19 Annexes to the treaty. It would not be possible to review the implementation of even the most important SARPs for every state in question. On the positive side, under the Universal Safety Oversight Audit Program (USOAP), ICAO has routinely reviewed every state on Effective Implementation (EI) of the safety-related SARPs contained in the Annexes to the Convention and related ICAO documents.

Here below, we will use only existing ICAO data on safety implementation for every

essential area audited by the USOAP.[1054] Obviously, the percent representation presents only the general state of compliance without specifying the drawbacks with the SARPs execution. Nevertheless, it will give a clear picture of the level of collaboration by the Member States in achieving the highest practicable degree of uniformity in regulations, standards, procedures and organization in relation to aircraft, personnel, airways and auxiliary services in all matters in which such uniformity will facilitate and improve safety of air navigation.

[1054]ICAO, *Safety Audit Information*, online: ICAO <http://www.icao.int/safety/Pages/USOAP-Results.aspx>.

	Legislation	Organization	Licensing	Operations	Airworthiness	Accident Investigation	Air Navigation Services	Aerodromes	Average
Global Average[1055]	67%	65 %	72%	67%	74%	55%	57%	59%	64%
NAFTA									
Canada[1056] (2005)	91%	94%	98%	90%	97%	92%	96%	99%	94%
The US (2007)	82%	100%	94%	95%	97%	82%	84%	96%	91%
Mexico (2007)	86%	79%	97%	97%	95%	81%	72%	79%	85%
The EU									
Germany [1057]	61% (!)[1058]	88%	99%	88%	97%	95%	85%	86%	87%

[1055]The EI of each Audit Area is rated from 0% to 100%, with 0% being "Not Implemented" and 100% being "Fully Implemented". The EI score represents the percentage of satisfactory USOAP protocol questions applicable for a given state

[1056]All NAFTA Member States are presented in this table.

[1057]For the EU, four Member States with highest passenger traffic and four Member States with lowest passenger traffic are selected. (EC, *Overview of EU-28 Air Passenger Transport by Member States in 2013 Passengers Carried (in 1000)*, online: EC <http://ec.europa.eu/eurostat/statistics-explained/index.php/File:Overview_of_EU-28_air_passenger_transport_by_Member_States_in_2013_passengers_carried_(in_1000)_.png>).

[1058](!) –state implementation level is lower as global average.

France (2008)	100%	100%	100%	98%	98%	97%	86%	92%	96%
The UK (2009)	90%	86%	95%	87%	97%	84%	96%	99%	92%
Spain (2010)	77%	81%	91%	89%	90%	75%	91%	74%	84%
Slovenia (2010)	43% (!)	50% (!)	84%	70%	70% (!)	33% (!)	85%	36% (!)	58%(!)
Slovakia (2009)	91%	64% (!)	86%	62% (!)	75%	43%	85%	89%	74%
Estonia (2010)	76%	73%	82%	60% (!)	77%	34% (!)	74%	48% (!)	66%
Luxemburg (2006)	62% (!)	86%	93%	86%	91%	44% (!)	57% (!)	55%	68%
The EAEU Russia[1059] (2008)	65% (!)	75%	95%	81%	90%	91%	57% (!)	99%	81%

[1059]For CIS, all EAEU Member States are selected.

Kazakhstan	67% (!)	45% (!)	74%	72% (!!)[1060]	65% (!)	48% (!)	72%	54% (!)	62%(!)
Belarus (2009)	67% (!)	42% (!)	58% (!)	63% (!)	54% (!)	60%	44% (!)	50% (!)	55%(!)
Armenia (2008)	100%	83%	94%	91%	99%	91%	99%	99%	95%

The Safety Audit data from NAFTA, EU and EAEU have revealed a few interesting facts. In general, most states have implemented SARPs and have met minimum requirements on safety. Only in Kazakhstan has ICAO identified a Significant Safety Concern with respect to the ability to properly oversee national air operators.

NAFTA has showed the greatest achievements in SARPs execution, especially Mexico with indicators as high as 97% in Operations[1061] and 95% in Airworthiness.[1062] On the opposite side of the Atlantic, the data reveals a great disparity in accomplishments between "old" and "new" Member States. The UK, Germany, Spain, Luxemburg, and especially France have showed remarkable results, whereas Estonia, Slovakia, and Slovenia still have to improve their performance. Surprisingly, Germany and Luxemburg have scored only 61% and 62% respectively for Legislation accomplishment, [1063] while Slovakia has achieved 91% in the same field. As for EAEU, most states have kept up performance in harmony with global average. In contract, Armenia not only has received the best result in EAEU, but also has scored the highest results overall among all selected states. In fact, in areas of Air

[1060]In May 2009, ICAO has identified a significant safety concern with respect of ability of this state to properly oversee its airlines (air operators) under its jurisdiction.
[1061]Canada has only 90% and the U.S. has 95%.
[1062]Canada and the U.S. have both received 97%.
[1063]Global Average is 67%.

Navigation Services, Aerodromes, Airworthiness, and Legislation Armenia has fully implemented all ICAO safety standards.

Finally, a few interesting points should be underlined. First, even if all states are quite advanced in implementing safety standards, successes have not been consistent and vary from one state to another. Second, in areas of Licensing, Operations and Airworthiness all states have shown the biggest progress in implementation, whereas in the area of Accident Investigation, all states have accomplished little. Third, the accomplishments seen in developing states such as Armenia and Mexico have been much greater than in developed states; this is especially true in the area of Legislations.[1064] Hence, even states with limited financial resources are able to achieve the highest degree of compliance with ICAO safety rules, as long as there is political will.

3.2.12 International Conventions for the Safety of Life at Sea (SOLAS)

NAFTA

Canada

Canada implemented SOLAS 1974 postulates on passenger safety through three key instruments: *Canada Shipping Act, Canadian Supplement to the SOLAS Convention,*

[1064]In 2016, GDPs per capita based on purchasing power parity (PPP): in Armenia (~US$ 8,000) and Mexico (~US$ 17,000) were extremely low in comparison to Canada (US$ 44,000) and Germany (~US$ 47,000). (World Bank, *GDP Per Capita, PPP: (Current International $),* online: World Bank <http://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>).

and Ship Safety, Passenger Ship Operations and Damaged Stability Standards (Convention Ships).

On July 1, 2007, the *Canada Shipping Act, 2001* (CSA 2001)[1065] replaced the previous *Canada Shipping Act* (CSA)[1066] as the principal legislation governing safety in marine transportation. It applies to Canadian vessels operating in all waters and to all vessels operating in Canadian waters (including cruise ships). The key objective of the CSA 2001 is to promote the sustainable growth of the marine shipping industry without compromising safety. CSA has established legal framework for: safety inspections; safety documentation; safety requirements for ship constriction, crew, and passengers; navigation; search and rescue operations.

The *Canadian Supplement to the SOLAS Convention* (Supplement to the SOLAS) is on the construction, equipment and inspection requirements of SOLAS 1974. Constantly reviewed, the Supplement to the SOLAS outlines a set of mandatory Canadian-specific requirements related to SOLAS and associated Codes, Recommendations, Guidelines and Interpretations published in IMO Circulars and Resolutions referenced in this document and the policy. The document is intended for use by vessel owners and operators, shipyards, and ship designers.[1067]

Finally, the Canadian Coast Guard has adopted Standards for the design and operation of Canadian registered passenger ships. *Ship Safety, Passenger Ship Operations and Damaged Stability Standards (Convention Ships)* is based upon

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[1065]*Canada Shipping Act, 2001*, (S.C. 2001, c 26), online: Justice Laws Website <http://laws-lois.justice.gc.ca/PDF/C-10.15.pdf>.

[1066]The CSA was one of Canada's oldest pieces of legislation, and was based on the *British Merchant Shipping Act* of 1894. It had been amended many times over the years and had become difficult to use and in need of reform. (*Canada Shipping Act*, 2001, online: Transport Canada <https://www.tc.gc.ca/eng/marinesafety/rsqa-csa2001-menu-1395.htm>).

[1067]*The Canadian Supplement to the SOLAS Convention*, online: Transport Canada <https://www.tc.gc.ca/eng/marinesafety/tp-menu-515-4289.htm>.

amendments to SOLAS 1974 and intended to enhance the safety of passenger ships by defining standards of residual damage stability and by ensuring that a stability assessment of a vessel's condition prior to sailing can be readily performed by ship personnel.[1068]

The Transportation Safety Board of Canada (TSB) is the government agency in charge of the advancement of transportation safety in the maritime sector. The TSB conducts independent safety surveys and communicates identified safety risks to appropriate parties to take remedial action.[1069] Being a party to the Paris MoU, Canada has implemented a Port State Control scheme (PSC).

United States

U.S. maritime safety law consists of federal statutes and regulations written to implement the international legal framework on safety at sea. The U.S. ratified SOLAS 1974. Nevertheless, over the years, the U.S. has demonstrated a mixed dynamic in the implementation of SOLAS Conventions. On the one hand, SOLAS 1929 was ratified only in 1936 in the aftermath of the 1934 fire on the passenger ship Morro Castle off of the coast of New Jersey and the ensuing public outcry.[1070] On the other hand, the U.S. has exercised its influence in advancement of SOLAS Conventions. A number of national law provisions adopted at different stages

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[1068]*Ship Safety: Passenger Ship Operations and Damaged Stability Standards: Convention Ships*, (TP 10405 E), online: Transport Canada <https://www.tc.gc.ca/eng/marinesafety/tp-tp10405-menu-1045.htm>.

[1069]*Transportation Safety Board of Canada*, online: Transportation Safety Board of Canada <http://www.bst-tsb.gc.ca/eng/>.

[1070]Keith B. Schumacher, *Marine Disasters and Merchant Ship Design*, online: USCG <http://www.uscg.mil/history/ops/marinesafety/docs/1958_Schumacher_MarineDisasters&MerchantShipDesign.pdf>.

frequently have been incorporated at the international level.[1071] Nowadays, Title 33[1072] and Title 46[1073] of the U.S. Code and a multitude of Coast Guard regulations[1074] make applicable SOLAS 1974 provisions in the U.S. legal order.[1075]

The responsibility for maritime passenger safety falls mainly to the U.S. Coast Guard. This Agency improves safety at sea through complementary programs of mishap prevention, search and rescue, and accident investigation. Prevention activities include the development of standards and regulations, various types of plan review and compliance inspections, and a variety of programs designed to enhance safety at sea. The Coast Guard also develops and enforces vessel construction standards as well as domestic shipping and navigation regulations.[1076]

To ensure compliance, the Coast Guard reviews and approves plans for ship construction, repair, and alteration and it inspects vessels for safety.[1077] Finally, through its own Port State Control Program[1078] the Agency aims to eliminate

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[1071]For instance, in 1968, the U.S. unilaterally required all passenger ships operating from U.S. ports to meet the *1966 Fire Safety Amendments* or *U.S Passenger Vessel Requirements*. Subsequently, those Amendments and Requirements were incorporated into SOLAS 1974.

[1072]*U.S. Code: Title 33 Navigation and Navigable Waters*, online: Law Cornell <https://www.law.cornell.edu/uscode/text/33>.

[1073]*U.S. Code: Title 46 Shipping*, online: Law Cornell <https://www.law.cornell.edu/uscode/text/46>.

[1074]The US Coast Guard has constantly updated its regulatory framework in accordance to the SOLAS requirements. Through Circulars information regarding the recent amendments to SOLAS 1974 is disseminated to industry and Coast Guard personnel. (*Navigation and Vessel Inspection Circular N 2-84: Amendments to the 1974 Safety of Life at Sea (SOLAS) Treaty*, Department of Transportation: US Coast Guard, online: US Coast Guard <https://www.uscg.mil/hq/cg5/nvic/pdf/1984/n2-84.pdf>).

[1075]Iliana Christodoulou-Varotsi, *Maritime Safety Law and Policies of the European Union and the United States of America: Antagonism or Synergy?,* Springer Science & Business Media, (2008), at 50 &51.

[1076] *Missions*: *Maritime Safety*, online: U.S. Coast Guard <http://www.uscg.mil/top/missions/MaritimeSafety.asp>.

[1077]*Ibid.*

[1078]The U.S. is not a member of any Port State Control MoU.

substandard passenger ship from U.S. ports.[1079] Under this program, both U.S. and foreign vessels operating in U.S. ports are routinely inspected to enforce safe operations in U.S. waters. In 2014, US Coast Guard Safety Report indicated 329 safety deficiencies on cruise ships.[1080]

EU

EU administration officials have taken maritime safety very seriously. With the adoption of the new *Third Maritime Safety Package* (TMSP) in March 2009, the EU has continued to deliver a strong message that substandard shipping will no longer be tolerated. TMSP was adopted with the main objective of restoring the competitiveness of the sector while benefiting only those operators who respect the applicable safety standards, in particular by increasing the pressure on owners of sub-standard ships. TMSP endorses international regulations on safety including SOLAS 1974 and Athens Convention. The package includes two Regulations and six Directives adopted between November 2010 and January 2012.[1081]

[1079] *Foreign & Offshore Compliance Division*, online: U.S. Coast Guard <http://www.uscg.mil/hq/cgcvc/cvc2/?BV_SessionID=@@@@0627973807.1432756504@@@@&BV_EngineID=cccdadggfkgmkmicfngcfkmdfhfdfgl.0>.

[1080] The most common deficiencies observed on cruises ships in US ports were: Fire Screen Doors not Operating Properly (31 occurrences); Impeding Means of Escape (26 occurrences); Drills and Crew Training Issues (25 occurrences); Problems with Lifeboats and Rescue Boats (21 occurrences); Improper Utilization of Categorized Spaces (17 occurrences); Problems with Fire Detection Systems/Smoke Detection (13 occurrences); Fire Suppression Systems (12 occurrences); Emergency Lighting Issues (7 occurrences); Fuel and Oil Leaks (7 occurrences). Some deficiencies were corrected prior to the ship's departure and other deficiencies were corrected by giving the crew additional time. (*United States Coast Guard Top Cruise Ship Deficiencies of 2014*, online: United States Coast Guard <http://www.uscg.mil/hq/cg5/csncoe/docs/Top%20Defs/Top%20Cruise%20Ship%20%20Deficiencies%20of%20%202014.pdf>).

[1081] 1) EC, *Directive 2009/21/EC of the European Parliament and of the Council of 23 April 2009 on Compliance with Flag State Requirements,* OJ L 131, 28.5.2009, p. 132–135, online: Eur-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32009L0021>. This Directive was adopted to ensure the flags of all EU countries have good standing – in particular, none should be blacklisted or on the grey list of Paris memorandum of understanding (Paris MoU) on Port State Control. 2) EC, *Regulation No. 391/2009 of the European Parliament and of the Council on Common Rules and Standards for Ship Inspection and Survey Organisations*, O.J. L 131, 28 May 2009, pp. 11-

Analogous to the Titanic tragedy, the Estonia disaster in the Baltic Sea in 1994 became a catalyst, raising particular concerns in the EU about the safety of passenger vessels.[1082] The Community has since adopted numerous measures addressing this problem.

Just four years after the Estonia tragedy, *Council Directive 98/18/EC of 17 March*

23, online: Eur-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:131:0011:0023:EN:PDF>. This Regulation sets out measures to be followed by organizations entrusted with the inspection, survey and certification of ships for compliance with the international conventions on safety at sea SOLAS 1974. The Annex specifies the requirements to be met by the organizations above-mentioned in order to enjoy or continue to enjoy European Community recognition; 3) EC, *Directive 2009/15/EC of the European Parliament and of the Council of 23 April 2009 on Common Rules and Standards for Ship Inspection and Survey Organisations and for the Relevant Activities of Maritime Administrations*, OJ L 131, 28.5.2009, p. 47–56 online: Eur-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:131:0047:0056:EN:PDF>. Directive makes the inspection procedures of classification societies more rigorous and empower the Commission to carry out audits and impose penalties; 4) EC, *Directive 2009/16/EC of the European Parliament and of the Council of 23 April 2009 on Port State Control*, OJ L 131, 28.5.2009, p. 57–100, online: Eur-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:131:0057:0100:EN:PDF>. The Directive increases pressure on at-risk ships, by extensively reforming the control mechanisms in port states to make them more efficient; 5) EC, *Directive 2009/17/EC of the European Parliament and of the Council of 23 April 2009 Amending Directive 2002/59/EC Establishing a Community Vessel Traffic Monitoring and Information System*, OJ L 131, 28.5.2009, p. 101–113, online: Eur-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:131:0101:0113:EN:PDF>. The Directive improves knowledge of maritime traffic by improving the collection of information and setting up a network for sharing information between EU countries; 6) EC, *Directive 2009/18/EC of the European Parliament and of the Council of 23 April 2009 Establishing the Fundamental Principles Governing the Investigation of Accidents in the Maritime Transport Sector and Amending Council Directive 1999/35/EC and Directive 2002/59/EC of the European Parliament and of the Council*, OJ L 131, 28.5.2009, p. 114–127, online: Eur-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:131:0114:0127:EN:PDF>. The Directive was adopted to improve maritime safety by providing clear EU guidelines for technical investigations and lessons learnt after accidents at sea; 7) EC, *Regulation No 392/2009 of the European Parliament and of the Council of 23 April 2009 on the Liability of Carriers of Passengers by Sea in the Event of Accidents*, OJ L 131, 28.5.2009, p. 24–46, online: Eur-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:131:0024:0046:EN:PDF>. The Directive introduces a modern and uniform set of rules on compensating passengers victims of accidents aboard cruise ships and ferries; 8) EC, *Directive 2009/20/EC of the European Parliament and of the Council of 23 April 2009 on the Insurance of Shipowners for Maritime Claims*, OJ L 131, 28.5.2009, p. 128–131, online: Eur-lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:131:0128:0131:EN:PDF>. The Directive requires all shipowners to be insured against damage to third parties caused by their ships.

[1082] It was the deadliest shipwreck in the Baltic Sea in peacetime, costing 852 lives. More on this the Estonia disaster please see: *Estonia Ferry Disaster*, online: Estonia Ferry Disaster <http://www.estoniaferrydisaster.net/estonia/index.html>.

1998 on Safety Rules and Standards for Passenger Ships[1083] was adopted to introduce a uniform level of safety for new and existing passenger ships by harmonizing safety standards. It incorporated the provisions of IMO's SOLAS convention for the Safety of Life at Sea by establishing detailed technical requirements which focus on passenger ship construction, stability, fire protection and life-saving equipment. It has been modified several times to reflect developments in the SOLAS Convention and to include specific access and public information requirements for persons with reduced mobility or disabilities. The original Directive and its modifications were consolidated and codified in Directive 2009/45/EC,[1084] which has since been updated by Commission Directive 2010/36/EU.[1085]

The Commission is currently undertaking a passenger ship safety legislative review, which comprises an ex-post evaluation of the current legislation; a review of the current rules; stability rules to damaged vessels; as well as operational issues such as water tight doors, safe return to port, evacuation procedures etc. This is with a view to preparing legislative proposals in the near future.[1086]

The European Maritime Safety Agency (EMSA) was established in 2002 with headquarters in Lisbon.[1087] The Agency provides technical assistance and support to the European Commission and Member States in the development and

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[1083]EC, *Council Directive 98/18/EC of 17 March 1998 on safety rules and standards for passenger ships*, OJ L 144, 15.5.1998, p. 1–115, online: Eur-Lex <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31998L0018>.
[1084]EC, *Directive 2009/45/EC of the European Parliament and of the Council of 6 May 2009 on safety rules and standards for passenger ships*, OJ L 163, 25.6.2009, p. 1–140, online: Eur-Lex <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009L0045>.
[1085]EC, Commission Directive 2010/36/EU of 1 June 2010 amending Directive 2009/45/EC of the European Parliament and of the Council on safety rules and standards for passenger ships, OJ L 162, 29.6.2010, p. 1–135, online: Eur-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1432920816969&uri=CELEX:32010L0036>.
[1086]More on passenger safety in EU see: EC, *Safety of Passenger Ships*, online: EC <http://ec.europa.eu/transport/modes/maritime/safety-and-environment/safety-passenger-ships_en>.
[1087]EC, *Regulation 1406/2002 of the European Parliament and of the Council of 27 June 2002 establishing a European Maritime Safety Agency*, OJ L 208, 5.8.2002, p. 1–9, online: Eur-Lex <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32002R1406>.

implementation of EU legislation on maritime safety. Its assistance is particularly relevant in the continuous process of updating and developing new legislation, monitoring its implementation and evaluating the effectiveness of the measures in place.

In order to monitor the implementation of the Community *Acquis*, the Agency carries out inspections in Member States and, in specific areas, in third countries. Such inspections started in 2004 and intensified over the last years. The Agency also has the task of assisting Member States with the practical implementation of EU legislation, organizing appropriate training activities and promoting a dissemination of best practices in the EU.

In October 2010, the European Commission proposed to update the EMSA Regulation to adapt its tasks following the entry into force of the Third Maritime Safety Package and to reinforce cooperation with neighbouring countries.[1088]

CIS

Five CIS members - Armenia, Belarus, Kyrgyzstan, Tajikistan, and Uzbekistan – are among the few states that have never been a part of the SOLAS Convention due to their landlocked geographic location. As a result, nothing has been done on the interstate level regarding the implementation of the SOLAS 1974 provisions.

On the other hand, Russia has been a party to the SOLAS 1974 since 1979.[1089] The

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[1088] More on the European Maritime Safety Agency see: EC, *European Maritime Safety Agency*, online: EC <http://ec.europa.eu/transport/modes/maritime/safety/emsa_en.htm> & EMSA, online: EMSA <http://www.emsa.europa.eu>.

[1089] USSR ratifided SOLAS 1974 in 1979. (*Постановление Совета Министров СССР от 2 ноября 1979 г. N 975 "О принятии СССР Международной конвенции по охране человеческой жизни на море, 1974 года"*, [Resolution of the Council of Ministers of the USSR, November 2, 1979, Regarding Ratification International Convention SOLAS 1974], online: Consultant

provisions of the Treaty have been executed through numerous Resolutions, Directives and Codes.[1090] In the spite of the fact that Russia has fully implemented SOLAS 1974, no distinct regulation on maritime passenger safety has been adopted. The present legal framework on SOLAS 1974 appears puzzling and chaotic.[1091]

The Federal Agency of Sea and River Transport is responsible for law enforcement functions in the field of maritime transport.[1092] Russia also has implemented Port State Control scheme as a party of Paris MoU.

<http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=ESU;n=21174>). In international law, the Russian Federation was recognized as the successor state to the Soviet Union. Unless denounced, a treaty ratified by the Soviet Union remains in force for Russia.

[1090]For instance, to implement SOLAS 1974 postulates on the Global Maritime Distress and Safety System (GMDSS) the following Directives were adopted. (*Постановление Правительства РФ от 03.07.97 N 813 "О Создании и Функционировании Глобальной Морской Системы Связи при Бедствии и для Обеспечения Безопасности"*, [RF Government Directive N 813, 03.07.97 "Regarding the Establishment and Operation the Global Maritime Distress and Safety System "], online: Законодательная База Российской Федерации, <http://zakonbase.ru/content/nav/22355>). Merchant Shipping Code of the Russian Federation replicates many SOLAS 1974 provisions. (*Кодекс Торгового Мореплавания Российской Федерации от 30.04.1999 N 81-ФЗ*, [Merchant Shipping Code of the Russian Federation, 30.04.1999, Federal Law 8,] online: Consultant <http://www.consultant.ru/document/cons_doc_LAW_177298/>). The most resent Government Directive on SOLAS 1974 fully executes newly added provisions of the Chapter XI-2 on maritime security. (*Постановление Правительства Российской Федерации от 3 ноября 2007 г. N 746 О Реализации Положений Главы XI-2 Международной Конвенции по Охране Человеческой Жизни на Море 1974 года и Международного Кодекса по Охране Судов и Портовых Средств* [Resolution of the Government of the Russian Federation, November 3, 2007 N 746 "On the Implementation of the Provisions of Chapter XI-2 of the International Convention for the Safety of Life at Sea, 1974 and the International Code for the Security of Ships and Port Facilities], online: Morflot <http://www.morflot.ru/transportnaya_bezopasnost/solas_74.html>).

[1091]Most technical specifications on ship safety features defined in SOLAS 1974 have been restated by *Постановление Правительства РФ от 12 августа 2010 г. No 620 "Об Утверждении Технического Пегламента о Безопасности Объектов Морского Транспорта"* [Government Directive of August 12, 2010 No 620 "On Approval of Technical Regulations on Safety of Maritime Transport", online: ГОСТ <http://www.gost.ru/wps/wcm/connect/85e03a00455e487cb079b5e4dfffd2ca/Post_Prav_09.08.2010_№+620.pdf?MOD=AJPERES>. Also, the Article 49 of the Project of the law on maritime passenger carriage (not yet in force) postulates safety procedures for passenger evacuation during the emergency; the same document restate provisions of the Athens Convention. (*Об Утверждении Правил Морской Перевозки Пассажиров* [Regarding the Rules on Maritime Carriage of Passengers], online: Министерство Экономического Развития Российской Федерации <http://economy.gov.ru/minec/about/structure/depregulatinginfluence/doc20120216_03>).

[1092]*Federal Agency of Sea and River Transport*, (in Russian) online: Morflot <http://www.morflot.ru/ob_agentstve.html>.

3.3 Assessing the *Acquis* in the selected regional systems in the area of consumer safety

3.3.1. Evaluation parameters

Consumer safety is directly linked to consumer protection. Hence, to reveal the measures taken, if any, at the regional level in the area of consumer safety requires scrutinizing both the general state of common consumer protection policies and specific consumer safety-related measures in place in each region.

In assessing the success and potential of the strategies of the EU, CIS/EAEU and NAFTA regarding consumer policy and the actual achievements made in terms of consumer legislation on safety, the following four parameters will be considered.[1093]

(i) The legitimacy of regional consumer safety-related initiatives: Are consumer protection and consumer safety among the explicitgoals of the integrated regional system? Does the treaty governing the regional union include provisions relating to consumer protection and/or consumer safety? Do all fundamental consumer rights receive credit in regional political agenda or only consumer safety?

(ii) The autonomy of the regional policy towards consumers: Are consumer protection and/or consumer safety admitted as legitimate exemptions from the application of the treaty free trade rules? If yes, under which conditions?

[1093] *Op. cit.* 141 (*Le statut de politique de protection du consommateur dans les systèmes régionaux économiquement intégrés. Une première évaluation comparative*) at 1 to 4 & *Op. cit.* 140 (Thierry Bourgoignie & David Trubek), at 1 to14.

Is such autonomy, if any, also confirmed with regard to the institutional framework for consumer protection and/or consumer safety put in place at the regional level? Are consumer protection and/or consumer safety the subject of a separate common policy or are they perceived as the by-product of other policies, such as competition or trade?

(iii) The form of legal approximation chosen at the regional level in the area of consumer protection and consumer safety: What is the actual impact of the regional legal integration process in the area of consumer protection and consumer safety on the national policies of the Member States? Do regional policies and initiatives actually help in or force reshaping the national legal landscape in the field of consumer protection and consumer safety? Are harmonization tools introduced or cooperation mechanisms only? Does harmonization, if any, go beyond negative harmonization and imply positive harmonization actions?

(iv) The scope of the regional *Acquis* in the areas of consumer protection and consumer safety: How far and complete are the achievements made at the regional level in the area of consumer protection and consumer safety?

3.3.2 NAFTA and Consumer safety

Little has been done regarding regional consumer protection on this side of the Atlantic. NAFTA, a North American formation with exclusively economic goals, does not include any provisions dealing directly with consumer protection. The objectives of NAFTA are primarily to facilitate trade among the Member States, and not necessarily to harmonize consumer protection laws in the Member States, or to create a common consumer policy; there are just a few postulates in the North American agreement that may be attributed to the matter.[1094]

As a trade agreement, NAFTA sets the rules of trade and investment between Canada, the United States, and Mexico. Since the agreement entered into force on January 1, 1994, NAFTA has systematically eliminated most tariff and non-tariff barriers to free trade and investment between the Member States. Although the desire to maintain a balance between free market and consumer protection was explicitly stated in the Agreement Preamble -"create an expanded and secure market for the goods and services produced in their territories"- this never materialized into substantial legal instruments directed at making the market secure and safe. While covering the highly consumerized North American continent with more than 400 million people, the Agreement does not include any provisions directly regarding consumers. Yet NAFTA does incorporate a mechanism to allow Member States to adopt "standards-related measures" relating to the protection of consumers, as long as they are non-discriminatory and necessary for pursuing legitimate objectives.

In accordance with Article 904.1 of the Agreement, "each party may adopt, maintain or apply any standards-related measure, including any such measure relating to safety,

[1094] *Op. cit.* 159 (James P. Nehf) at 113.

the protection of human, animal or plant life or health, the environment or consumers, and any measure to ensure its enforcement or implementation. Such measures include those to prohibit the importation of a good of another party or the provision of a service by a service provider of another party that fails to comply with the applicable requirements of those measures or to complete the party's approval procedures (...) In pursuing its legitimate objectives of safety or the protection of human, animal or plant life or health, the environment or consumers, each party may establish the level of protection that it considers appropriate".[1095]

Each state is allowed to decide about the level of protection actually granted to consumers, using relevant international standards from international institutions [1096] (art. 905.1). Such national protective measures are held as legitimate obstacles to the free interstate circulation of products and services provided that the following three conditions are met:

(i) the adopted measure is applied to the extent necessary to achieve the appropriate level of protection (art. 712.5 & 904.4);
(ii) it must not create a disguised restriction on trade between the parties (art. 712.6 & 907.2); and
(iii) according to the circumstances, taken measures should be based on scientific principles and adequate risk assessment (art. 712.3 & 907.1).

Needless to say, these provisions primarily address the validity of national consumer laws and do not call for an affirmative consumer protection policy at the regional

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[1095]NAFTA at 904.1. Equally, art. 712.1 dedicated to *Sanitary and Phytosanitary Measures,* incorporates identical provisions.
[1096]Art.915 lists international standardization bodies: the *International Organization for Standardization (ISO)*, the *International Electrotechnical Commission (IEC), Codex Alimentarius Commission*, the *World Health Organization (WHO)*, the *Food and Agriculture Organization (FAO)*, the *International Telecommunication Union (ITU)*, and etc.

level.[1097]

The Agreement does not require the parties to harmonize their protective measures, nor does it establish any regional authority in charge of such approximation. It solely calls for technical cooperation aiming at minimal harmonization and mutual recognition agreements at the regional level to remove non-tariff barriers, which can potentially include consumer protection laws.[1098] Parties are encouraged to "work jointly to enhance the level of safety and of protection of [...] consumers". (art.906.1) and, "without reducing the level of safety or of protection of [...] consumers, to make compatible respective standards-related measures, so as to facilitate trade in a good or service" (art. 906.2). Furthermore, on request of another member state, member states are required to seek, "through appropriate measures, to promote the compatibility of a specific standard or conformity assessment procedure that is maintained in its territory with the standards or conformity assessment procedures maintained in the territory of the other member state" (art. 906.3).

On the one hand, the treaty does not require member States to reduce the existing national level of consumer protection. Standards approximation is conducted without reducing the level of safety or protection of consumers. Hence, member states may maintain or introduce more protective legislation. On the other hand, the member states are strongly encouraged to use international standards as the benchmark, and they have the burden of establishing that the national provisions are justified by necessary and legitimate objectives. Thus, to the extent that international standards for consumer protection are less protective of consumer interests than the standards of a NAFTA member state, there can be a tendency toward "downward harmonization".

[1097] *Op. cit.* 159 (James P. Nehf) at 115.

[1098] Thierry Bourgoignie & Julie St-Pierre, "Le statut de politique de protection du consommateur dans les systèmes régionaux économiquement intégrés. Une première évaluation comparative" (2007) 20:1 *Quebec Journal of International Law*, at 8, online: Revue québécoise de droit international <http://www.sqdi.org/wp-content/uploads/20.1_bourgoignie.pdf> & *Op. cit.* 159 (James P. Nehf) at 116.

It has been observed that such "downward harmonization" is occurring.[1099]

The treaty has not established any institution responsible for consumer protection in North America. In fact, the institutional framework established by the Treaty is fragmental, and without a centralized body to which legislative or executive powers would be transferred. It is limited to dispute resolution forums and administrative agencies with little authority to adopt binding measures.

The treaty does, however, establish a Committee on Standards-Related Measures with the purpose to move the member states toward mutual standards recognition. Hence, national consumer protection measures that represent barriers to trade might be harmonized under the patronage of this Committee. In addition, less formal institutional work on standards-related measures has been executed through working groups and other subsidiary bodies.[1100]

Finally, the U.S. preference for unilateralism combined with the Canadian and Mexican preferences for dealing bilaterally with the United States has neutralized efforts to create a North American Community, similar to the European one. Many decisions, such as mutual recognition or equivalency agreements, are negotiated bilaterally between national trade offices using NAFTA norms as a guide.[1101]

In the safety area, more initiatives have been taken towards greater coordination and *information exchange* on the North American continent. Such cooperation has been introduced out of the scope of NAFTA, through bi- or trilateral agreements.

[1099] *Op. cit.* 159 (James P. Nehf) at 122.
[1100] More on NAFTA institutional framework see: *Op. cit.* 159 (James P. Nehf).
[1101] *Ibid.* (James P. Nehf).

The first step was made in 2004 when the US, Canada and Mexico signed the *Trilateral Cooperation Charter*[1102]. With the purpose of protecting and promoting human health, the Charter calls for increased communication, collaboration, and exchange of information among the three countries in the areas of drugs, biologics, medical devices, food safety, and nutrition. It requests to identify appropriate lines of communication to ensure a continual exchange of information on compliance and enforcement activities among the three countries. Even if the Charter did not list all consumer products and concentrates exclusively on foods and drugs, it demonstrated a political willingness to cooperate in exchanging information for the sake of consumer safety in North America.

The next key move was made under the *Security and Prosperity Partnership of North America* (SPP) project. This was a region-level dialogue which took place from March 2005 to August 2009. It addressed diverse issues, such as border facilitation, the environment, and food and product safety; and included measures to improve overall North American competitiveness. Under the SPP, commitments were made to strengthen existing mechanisms in the region, including information sharing on import safety issues and best practices to ensure the safety of food and products before they enter North America.[1103]

The major breakthrough happened in June 2005, when the *Memorandum of Understanding between the Healthy Environments and Consumer Safety Branch of the Department of Health of Canada and the Consumer Product Safety Commission*

[1102]*Trilateral Cooperation Charter Between The Health Products and Food Branch, Health Canada, Canada, The Food and Drug Administration, Department of Health and Human Services, the United States of America, and the Federal Commission for the Protection from Sanitary Risks, Secretaria de Salud Mexico*, online: Wayback <http://web.archive.org/web/20061020024258/http://www.fda.gov/oia/charter.html>.

[1103]For more information on the SPP project see: *Security and Prosperity Partnership of North America,*, online: SPP <www.spp-psp.gc.ca/eic/site/spp-psp.nsf/eng/home>.

of the United States of America regarding Cooperation related to the Safety of Consumer Products (MoU)[1104] was signed, as a part of the SPP commitments.

The Memorandum recognizes the importance of timely and effective communication and collaboration between U.S. and Canadian governmental authorities, especially on matters relating to the safety of consumer products. Under the MoU, the US and Canada intend to establish mechanisms by which the sharing and exchange of documents and information between their employees relating to the risk management, enforcement, compliance, laboratory testing, product recall, regulatory development, and post-marketing surveillance of consumer products would be facilitated. In addition, the Parties agree to make compatible some of their respective safety standards. To insure smooth standard unification procedure, the US and Canada decide to notify each other and discuss the degree of approximation, prior to any action or publication of information regarding measure taking. Hereby, the Memorandum not only enhances collaboration on dangerous consumer products information exchange, but, more importantly, it encourages standards approximation to harmonize product recall procedures on both sides of the border.

The MoU covers the entire spectrum of consumer products. The document also comprises postulates regarding informational exchange between Member States on existing consumer protection measures. These include a broad range of data such as existing national regulations on consumer protection measures, guidance documents, policies, procedures, inspection reports, product sample test results, and scientific and technical documents related to consumer products. Nevertheless, this exchange is conducted only for the information purpose and does not constitute any obligation to approximate laws or regulations. The agreement also specifies that all relevant

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[1104] *Memorandum of Understanding between the Healthy Environments and Consumer Safety Branch of the Department of Health of Canada and the Consumer Product Safety Commission of the United States of America regarding Cooperation related to the Safety of Consumer Products*, online: CPSC <https://www.cpsc.gov/PageFiles/64600/05212.pdf>.

information regarding a product which is to be shipped across the US-Canada border while being prohibited or non-compliant with the law applicable in the exporting country must be communicated.

The document encompasses specific provisions regarding the exchange of information on product recalls. Notably, the Memorandum requires sharing information about regulatory actions including market withdrawals and product recalls. Additionally, the MoU obliges to transfer the information on product recalls of consumer products.

To fulfill their obligations, both sides commit themselves to provide appropriate funds, personnel, and other resources. Designated points of contact are, for the US, the Director of the Office of International Programs and Intergovernmental Affairs, Federal Consumer Product Safety Commission and, for Canada, the Director of the Consumer Product Safety Bureau, Product Safety Program, Department of Health of Canada.

The MoU supplements existing mechanisms and institutions leaving the door open for separate arrangements to handle cooperation more efficiently and expeditiously. While the Memorandum does not create any legal obligations under international law, for the first time a North American intergovernmental agreement sets up a legal basis for the cross-border exchange of information on dangerous consumer products. Noticeably, the signing parties agreed to establish a mechanism for regular bilateral meetings and to modify the Memorandum by mutual consent. Hereby, green light is given for further dialog with the potential to establish a comprehensive and structured system for the rapid exchange of information on dangerous products.

The most recent related development on the North American continent happened in October 2009, when the US, Canada and Mexico signed the new *Trilateral*

Cooperation Charter.[1105] In many ways this Treaty emphasizes the same postulates as the Charter of 2004. Nevertheless, it includes innovative provisions which all contribute to the building up of a rapid information exchange network on the entire North American continent.

Recognizing the importance of work done under the previous agreement and the mutual benefits of collaborating on product safety within North America, the Charter intents to improve product safety from a product life-cycle approach, as well as to protect and promote public health on the North American continent through the exchange of information on issues of mutual interest related to product safety, such as product recalls.

The Charter covers all categories of consumer products including, but not being limited to the following: drugs, biologics, cosmetics, medical devices, dietary supplements/natural health products, and food.

Under the Charter of 2009, the Participants may invite other organizations or agencies to participate in the discussions regarding product recall and information exchange.[1106]

Finally, the *North America Cooperative Engagement Framework on Consumer Product* has been developed to guide the overarching trilateral activities between Health Canada, the U.S. CPSC, Mexican Office of the Federal Prosecutor for the Consumer (Profeco) in the following areas: a) increase awareness and understanding of the flow of consumer products within North America in the context of the global

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[1105]*Trilateral Cooperation Charter between the Secretariat of Health of the Mexican United States, through the Federal Commission for the Protection from Sanitary Risks; the Health Products and Food Branch of the Department of Health of Canada; and the Food and Drugs Administration within the Department of Health and Human Services of the United States of America*, (14 October 2009).

[1106]Regrettably, publicly available information on work done under the Charters is fragmental and scarce. Hence, no accurate evaluation of the actual state of consumer protection and safety under the Charter in the scope of North America cooperation can be presented.

market; b) facilitate and provide opportunities for regulators in North America to enhance knowledge and expertise on consumer product safety; c) cooperation on training to promote consumer awareness on the safe use of consumer products; d) enhance and maintain on-going communication, cooperation and information exchange between North American regulators, including consultation on proposed regulations and voluntary standards.[1107]

North America Consumer Product Safety Summits, as a part of North America Cooperative Engagement Framework on Consumer Product Safety, have taken place on a regular basis: first in September 2011, then in September 2013, and most recently in November 2015.

The aim of the 2015 Summit was to take note of the progress made, to develop a path forward for additional collaboration, and to encourage stakeholders in the region to work together toward a stronger culture of consumer product safety. The Summit focused on customs cooperation, legal frameworks for product recalls, international collaboration by nongovernment stakeholders, industry-adopted best practices, the role of voluntary product safety standards, and effective approaches to managing risk.

The parties also acknowledged that since the last Summit in 2013 the three government organizations in charge of product safety have made significant progress in their cooperative engagement, particularly in the following three areas:[1108] a)

[1107]*North America Consumer Product Safety Summit 2013 - Joint Statement*, online: Health Canada <http://www.hc-sc.gc.ca/cps-spc/advisories-avis/info-ind/najs-nadc-eng.php>.

[1108]For more information on North America Cooperative Engagement Framework on Consumer Product and North America Consumer Product Safety Summits see: *Consumer Product Safety Commission*, online: CPSC <http://www.cpsc.gov/en/> & Health Canada, online: Health Canada <http://www.hc-sc.gc.ca/index-eng.php>.

trilateral recalls;[1109] b) Early Consultation Initiative;[1110] c) information sharing activities.[1111]

These summits provide an opportunity for leaders in Mexico, Canada, and the United States to present their shared visions for enhanced consumer product safety cooperation among NAFTA countries. They also provide the opportunity to discuss trilateral initiatives and develop an agenda for future engagement that reflects the three jurisdictions' shared priorities in the area of product safety.[1112]

The results of work under MoUs and the *Trilateral Cooperation Charter* have been fruitful. Successes have been achieved in respect to information exchanges and joint product recalls. The first official US/Canada joint recall occurred in February 2009. By the end of that year, already 19 joint product recalls were initiated. Since then, numerous products have been jointly recalled on both sides of the border, such as toys, household products, electronics, and sport equipment. Since 2013, trilateral recalls have taken place regularly.[1113]

To conclude, it is crystal clear that the primary objective of the NAFTA agreement is to promote free trade among member countries. For this purpose, trade barriers such

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[1109]Since 2013, the three countries have conducted seven trilateral recalls, three of which were announced simultaneously in all three markets, including the first-ever trilateral recall, which involved approximately 5 million unsafe strollers that posed amputation and laceration hazards.

[1110]In 2015, concrete steps were taken to enhance consultations and alignment among North American regulators on product hazards before regulatory and standards development activities.

[1111]Consistent with each jurisdiction's legal requirements, the three North American regulators have increased the flow of information shared with one another on consumer product safety issues and approaches, particularly in the area of import surveillance. (*The Third America Consumer Product Safety Summit Joint Statement*, (19 November 2015), online: CPSC <http://www.cpsc.gov/en/Business--Manufacturing/International/International-Activities/The-Third-America-Consumer-Product-Safety-Summit-Joint-Statement/>).

[1112]*First North America Consumer Product Safety Summit*, (26 September 2011), online: CPSC <http://www.cpsc.gov/es/Business--Manufacturing/International/International-Activities/FIRST-NORTH-AMERICA-CONSUMER-PRODUCT-SAFETY-SUMMIT/>.

[1113]For more information on the joint recalls see: *U.S. Consumer Product Safety Commission* online: SPSC <www.cpsc.gov>, or *Health Canada*, online: Health Canada <www.hc-sc.gc.ca>.

as national consumer protection measures should as a rule be eliminated and consumer protection should not be encouraged by national policy-makers. Consumer protection is not stated as a specific objective of NAFTA. Only consumer safety receives attention in the Agreement. Consumer information, education, protection of economic interests, redress, and financial protection have never been on the NAFTA agenda.

Consumer safety is admitted as a legitimate exemption from the application of the treaty free trade rules. Member States are therefore encouraged to harmonize their national protective measures where these constitute a barrier to trade. Measures creating barrier to trade will only be permitted if they prove to be necessary, proportionate, scientifically based, and consistent with international provisions.

The existing *Acquis* on consumer safety is very limited in scope, encompassing a few provisions in the principal treaty. No uniform laws or regional codification on consumer protection and safety have been adopted under the NAFTA umbrella.

Recently certain notable initiatives have been taken in parallel to NAFTA in North America in the fields of exchange of information about dangerous consumer products and services and product recalls. Bi/Trilateral Cooperation Charters and Memoranda of Understanding recommend a road map for actions to build up a common framework for consumer safety in North America. The documents, however, have not delivered technical and legal details for the future safety network. Those parameters still should be defined. Moreover, as was mentioned above, Charters and MoUs are "soft law" agreements and do not impose any obligations on Member States. None of the documents establishes a timeframe for the Member States to approximate legal and instrumental bases in the area of consumer safety. Yet, recent examples of successful teamwork, with real results in product recall schemas and informational exchanges on dangerous products show how much even voluntary obligations are

able to produce positive results for the safety of consumers if there is a political willingness.

As a regional organization without a centralized legislative or executive power, NAFTA's essential work is carried out via committees and subcommittees concentrating predominately on removing tariff and non-tariff barriers. No specific committee responsible for consumer protection and safety has been established. Analogously, no permanent body has been established as a part of regional policies under Bi-and Trilateral Charters or MoUs.

Existing NAFTA institutions lack authority to adopt a legal framework that directly affects national consumer protective measures in Member States. In fact, national laws and regulations remain outside the scope of NAFTA as long as they do not constitute barriers to trade. Harmonization initiatives and mutual recognition agreements have been taken only to extend the reduction of trade barriers and not to form national or regional policies on consumer protection and safety. Hence, the actual effect of regional initiatives on national decision-making processes is quite limited and dictated purely by necessity of free trade, not consumer protection.

Hence, NAFTA is a good illustration of Negative Harmonization.

3.3.3 Consumer safety policy in the European Union

Nowadays, the European Community consumer protection policy combines all necessary elements and mechanisms to guarantee adequate and efficient protection for consumers in all 28 Member States.[1114] Nevertheless, consumer protection was not a priority topic for the European policy-makers when the European Economic Community was formed in 1957. It took 35 years before consumer protection in Europe was formally confirmed as a separate common policy.

The main goal of the *Rome Treaty Establishing the European Economic Community*[1115] signed by six European countries in 1957 was economic integration between Member States through the creation and good functioning of a common market. Special emphasis was put on the elimination of barriers and obstacles likely to prevent the free movement of goods, people, services, and capital.[1116] The 1957 Treaty did not recognize the need for consumer protection policy.

Paris Summit 1972

The first steps toward the recognition of a European consumer policy were taken at the Paris Summit of 1972, when the Heads of State or government of the Member

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[1114]For a general presentation and assessment of consumer protection policy at the EC level see: Thierry Bourgoignie, *Droit et politique communautaires de la consommation: une évaluation des acquis* in *Melanges Claude Masse*, ed. by Pierre-Claude Lafond (Cowansville: Yvon Blais, 2003); & Gilles Paisant, *Défense et illustration du droit de la consummation*, (Paris: LexisNexis, 2016) at 29 and ff.; & Iain Ramsay, *Consumer Law and Policy: Text and Materials on Regulating Consumer Markets*, (Oxford and Portland, Oregon : Bloomsbury Publishing, 2012); & Stephen Weatherill, *EU Consumer Law and Policy,* (Northampton: Edward Elgar, 2013); & Norbert Reich, *et al.*, *European Consumer Law*, (Cambridge: Interscientia, 2014).

[1115]EC, *Treaty Establishing the European Economic Community, EEC Treaty - original text (non-consolidated version)* Rome, (25 March 1957), online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3Axy0023>.

[1116]*Ibid.* at art. 3.

States decided that economic integration should bring about positive changes in the everyday life of Community citizens. As a result, the first Plan of action in favor of consumers was adopted three years later[1117]. This first consumer program was structured along five fundamental consumer rights: health and physical integrity, economic interests, effective redress, education, and representation in the decision-making process – and enumerates a list of initiatives to be taken at the European level in order to give actual implementation to each of the proclaimed consumer rights.

Nevertheless, this explicit recognition did not quickly bring about all expected results, as the legal basis for initiatives in the area of consumer protection could not be found in the Treaty provisions. Moreover, it was difficult to obtain the required unanimity of Member States for matters not directly related to the main goal of the treaty, i.e., economic integration. As a result, consumer policy was restricted to informational goals as it was assumed that a better-informed consumer could better contribute to the good functioning of the common market and be protected against potential market failures. During the period between 1975 and 1990, the vast majority of consumer-related directives adopted at the European Community level shared a similar concern for increasing consumer information or protecting the quality of consumer consent and choice so that he/she could play an active role in the marketplace.[1118]

[1117]EC, *Council Resolution of 14 April 1975 on a preliminary programme of the European Economic Community for a consumer protection and information policy*, OJ C 92, 25.4.1975, p. 1–1, online: <Eur-Lex<http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31975Y0425(01)>.

[1118]*Op. cit.* 1114 (Thierry Bourgoignie) at 271.

Cassis de Dijon

One major development that sped up the evolution of consumer protection policy in the European Community was the *Cassis de Dijon* case of February 20, 1979.[1119] In this landmark case, the European Court of Justice (ECJ) confirmed that national consumer protection measures do constitute clear obstacles to free trade and hence must be dismantled by national governments, but at the same time that consumer protection could be admitted, under certain conditions, as a legitimate exemption from the application of the free trade rules of the treaty[1120]

Effective free trade requires the application of the country of origin rules and mutual recognition of norms among the Member States, but national consumer protection measures may be maintained or introduced if the Member State can prove that consumer protection is the actual goal of the concerned measure (causation test) and that the measure remains proportionate to the goal to be completed (proportionality test).[1121] This formula provides a standard against which the compatibility of national consumer protection provisions with the free movement of goods is measured.[1122]

When these conditions are met, the Member States remain sovereign to decide for their consumers. As a result, more approximation of the national laws regarding consumer protection will have to be sought for in order to avoid distortions of

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[1119]*Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein Case, Reference for a Preliminary Ruling: (Hessisches Finanzgericht - Germany), Measures Heaving an Effect Equivalent to Quantitative Restrictions*, (20 February1979), No.120/78, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:61978J0120:EN:HTML>.

[1120]For detail analysis on *Cassis de Dijon* case and its repercussions on consumer protections and safety in the EU see: Reiner Schulze, Hans Schulte-Nolke, Jackie Jones, *A Casebook on European Consumer Law*, (Oxford/Portland: Hart Publishing, 2002) at 31 to 47; & Katalin Judit Cseres, *Competition Law and Consumer Protection*, (Kluwer Law International, 2005); & Rogier W. De Very, *Towards a European Unfair Competition Law: A Clash Between Legal Families: a Comparative Study of English, German and Dutch Law in Light of Existing European and International Legal Instruments*, (Leiden/Boston: Martinus Nijhoff, 2006) at 30 to 33.

[1121]*Op. cit.* 140 (Thierry Bourgoignie & David Trubek) at 166.

[1122]Ibid. at 36.

competition and further trade barriers caused by different legislative, regulatory or administrative provisions of the Member States.[1123] "Negative harmonization" implemented by ECJ calls for "positive harmonization" intervention by Community legislation to remove obstacles to trade proved admissible pursuant to the Cassis de Dijon formula.

The importance of the *Cassis de Dijon* case for consumer protection in the EU cannot be overstated. The formula developed by the ECJ in this case has formed a lasting basis for determination of whether the consumer protection laws of Member States are accepted under the fundamental freedoms laid down by the EC Treaty. Consumer protection has been included in the catalog of requirements that may be used to justify an obstacle to trade. In so doing the ECJ has raised the policy of consumer protection to the objective of Community law.[1124]

Before the judgment in *Cassis de Dijon,* the EC Treaty made only cursory mention of the consumer. By granting consumer protection prominent status, the ECJ gave effect to the Preliminary Programme of the European Economic Community for a Consumer Protection and Information Policy in 1975 which formulated all fundamental consumer rights and laid down a foundation for the present concept of a European consumer protection agenda, long before consumer protection found its way into the EC Treaty as an independent policy.[1125]

The EU Treaties of 1993 and 1999

The decisive step in the development of European consumer policy came with the

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[1123] *Op. cit.* 1114 (Thierry Bourgoignie), at 280 to 281.
[1124] *Op. cit.* 1120 (Reiner Schulze, Hans Schulte-Nolke, Jackie Jones) at 36.
[1125] *Ibid.* at 36 to 38.

Maastricht Treaty amending the EC treaty.[1126] Signed in 1993, the Maastricht Treaty clearly identified consumer protection as an autonomous policy. A new Article 129A entitled "Consumer Protection" was introduced which explicitly mandates the European authorities to adopt and implement measures aimed at providing European consumers a high level of protection. Article 129A stated that "the Community shall contribute to the attainment of a high level of consumer protection through measures in the context of the completion of the internal market and specific action which supports and supplements the policy pursued by the Member States to protect the health, safety and economic interests of consumers and to provide adequate information to consumers".[1127] There was an explicit requirement that the level of protection to be ensured to consumers at the level of the Community must be high, thus preventing the approximation process from being conducted along the lowest common denominator among the countries.

Later, in 1999, the Amsterdam Treaty added to the text two consumer rights which had not been referred to in 1993, i.e., consumer education and the right of consumers to organize themselves in order to represent and defend their interests.[1128]

Moreover, both treaties introduced a few important related features. First, decision-making under Article 129A would now follow the qualified majority voting pattern introduced in the Treaty and escape the requirement of a highly unlikely unanimous vote. Second, the same article makes it clear that the intent is not to limit the development of national consumer protection measures. EC directives in the consumer field do not prevent any Member State from maintaining or introducing more stringent protective measures. Third, consumer protection policy was given a

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[1126]EC, *Maastricht Treaty* (1993), online: Europe <https://europa.eu/european-union/sites/europaeu/files/docs/body/treaty_on_european_union_en.pdf >.
[1127]*Ibid.* at art. 129A.
[1128]EC, *Amsterdam Treaty*, (*OJ C 325, 24.12.2002, p. 33–184*), at art.129A, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A12002E%2FTXT>.

broad understanding, as consumer protection requirements must be taken into account in defining and implementing all other Community policies and activities.[1129]

The latest Treaty signed in Lisbon in 2007 gave consumer protection in the EU new prominence by reconfirming the postulates from previous Treaties and enhancing prerequisites that consumer protection has to be an area of shared competence between the Union and the Member States.[1130]

The *Charter of Fundamental Rights of the European Union* introduced by the Treaty of Nice of 2001 recognizes consumer protection as one of the basic right of every citizen in the EU.[1131] Article 38, entitled *Consumer protection*, states that the Union policies shall ensure a high level of consumer protection.

The recognition of consumer protection as an imperative and autonomous policy by the fundamental treaties has given fruitful results in lawmaking.

During the past decades the European Union adopted several directives, regulations, decisions and recommendations on a large variety of consumer issues. All main consumer concerns have been given consideration: consumer safety (horizontal and vertical legislation on product safety, strict liability imposed upon the producer for defective products, etc.), consumer information (product labeling, product-related claims, indication of prices, precontractual disclosure requirements, etc.), protection

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[1129]*Ibid.* at art.129A. New separate Article 12 was introduced in Lisbon Treaty to signify the importance of taking into account Consumer protection in defining and implementing other Union policies and activities.

[1130]*Consolidated Version of the Treaty on the Functioning of the European Union*, (art. 4(f)), [2012] O.J. L 326/01, online: EUR-Lex <http://eur-lex.europa.eu/JOHtml.do?uri=OJ:C:2012:326:SOM:EN:HTML>.

[1131]*Charter of Fundamental Rights of the European Union*, OJ C 303, 14.12.2007.p.1. (This text repeats and adapts the Charter proclaimed on 7 December 2000, and replaces it with effect from 1 December 2009, the date of entry into force of the Treaty of Lisbon. By virtue of the first subparagraph of Article 6(1) of the Treaty on European Union, the Charter proclaimed in 2007 has the same legal value as the Treaties.).

of consumers' economic interests (elimination of unfair contract terms, prohibition of unfair or aggressive commercial practices, prohibition of misleading advertising, regulation of consumer credit, protection against over indebtedness, etc.), access to justice and handling of consumer disputes, and representation of consumers' collective interests.[1132] The requirement for integrating consumer protection considerations into other Community policies has become more of a reality, in particular in the fields of agricultural policy and food safety,[1133] e-commerce,[1134] general interest services,[1135] and financial services.[1136]

Consumer Safety *Acquis*

The *Acquis* with regard to consumer safety is also quite abundant.[1137] To date the EU has developed a broad spectrum of legal instruments which have a direct impact on consumer safety.[1138] Regional initiatives include the Directives of 1992 and 2001 on General Product Safety[1139], and the *Directive of 1985 on Liability for Defective Products*,[1140] the establishment and operation of a Rapid Alert System for dangerous products (RAPEX),[1141] Scientific Committees for consumer safety,[1142] the common

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[1132]*Op. cit.* 1114 (Stephen Weatherill) at 10 to 28.
[1133]*Op. cit.* 1123 (Thierry Bourgoignie) at 301 to 302.
[1134]*Ibid.* at 302 & 303.
[1135]*Ibid.* at 303 & 304.
[1136]*Ibid.* at 304 & 305.
[1137]More on Consumer Acquis see: *Ibid.*
[1138]The *EU Consumer Law Acquis Database, online: EC Consumer Law Compendium* <http://www.eu-consumer-law.org/ >.
[1139]EC, *Commission Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety (Text with EEA relevance)*, [2001] O.J. L 011/4, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0095:EN:HTML>.
[1140]EC, *Commission Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999 Amending Council Directive 85/374/EEC on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products*, [1999] O.J. L 141/20, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31999L0034>.
[1141]RAPEX is established as the EU rapid alert system that facilitates the rapid exchange of information between Member States and the Commission on measures taken to prevent or restrict the

framework for the marketing of products, conformity assessment procedures, EC marking,[1143] and market surveillance,[1144] as well as a great number of sector-by-sector[1145] directives applicable to particular categories of consumer products, such as food,[1146] toys, electrical appliances, medical devices, drugs, cosmetics and chemicals[1147] and the safety of particular services.[1148]

The *Directive on General Product Safety* (Directive on GPS), adopted in 1992 and replaced in 2001, occupies a privileged place in the EU legal framework for consumer safety. Before the 90s, consumer safety law in the EU was dispersed and fragmented, consisting of vertical detailed prescriptive technical specifications applicable only to certain categories of products.

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marketing or use of products posing a serious risk to the health and safety of consumers with the exception of food, pharmaceutical and medical devices, which are covered by other mechanisms. (Detailed analysis of RAPEX is presented in 3.4.1). EC, *Rapid Alert System for Non-Food Dangerous Products,* (RAPEX), online: EC <http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/index_en.htm>.

[1142]EC, *Commission Decision 2008/721/EC of 5 August 2008 Setting up an Advisory Structure of Scientific Committees and Experts in the Field of Consumer Safety, Public Health and the Environment and Repealing Decision 2004/210/EC* [2008] O.J.L 241, online: EUR-Lex <http://europa.eu/legislation_summaries/consumers/consumer_safety/l28153_en.htm>.

[1143]EC, *Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a Common Framework for the Marketing of Products, and Repealing Council Decision 93/465/EEC*, [2008] O.J.L 218, online: EUR-Lex <http://europa.eu/legislation_summaries/consumers/consumer_safety/l10141_en.htm>.

[1144]EC, *Regulation No 765/2008 of the European Parliament and of the Council of 9 July 2008 Setting out the Requirements for Accreditation and Market Surveillance Relating to the Marketing of Products and Repealing Regulation (EEC) No 339/93 (Text with EEA Relevance),* [2008] O.J.L 218, online: EUR-Lex <http://europa.eu/legislation_summaries/consumers/consumer_safety/l33248_en.htm>.

[1145]The safety of toys, dangerous products resembling foodstuffs, protection of video game users, medical devices, hot-water boiler, and etc.

[1146]EC, *Regulation No 178/2002 of the European Parliament and of the Council of 28 January 2002 Laying Down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority and Laying Down Procedures in Matters of Food Safety* [2002] O.J.L 031,online: EUR-Lex <http://europa.eu/legislation_summaries/consumers/consumer_safety/f80501_en.htm>; EC, *Regulation No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed* [2003] O.J.L 268, online: EUR-Lex <http://europa.eu/legislation_summaries/consumers/consumer_safety/l21154_en.htm>.

[1147]Full list of the EC Directives on safety of Services and sector-by-sector Directives see: *EUR-Lex: Consumer Safery*, online: EUR-Lex <http://eur-lex.europa.eu/summary/chapter/consumers/0903.html?root=0903>.

[1148]Fire safety in existing hotels, safety rules and standards for passenger ships, railway safety, and etc.

Contrary to this sectoral approach, the Directive on GPS introduces general safety obligations and requirements applicable to all products intended to be used or likely to be used by consumers. It acts as umbrella legislation. If there is no vertical Community act applicable, the directive does apply. The Directive on GPS applies only to the aspects or risks not covered by specific safety requirements imposed by vertical Community acts (e.g., directives on toys safety).

The Directive on GPS introduces a set of far-reaching safety obligations imposed on producers and other economic operators. Additionally, it requires the Member State authorities to set up an adequate and coordinated market surveillance system including specifically designated competent institutions, efficient and proactive market controls, common conformity assessment procedures, certification and accreditation schemes, efficient administrative corrective measures and criminal sanctions. Exceptionally, the European Commission itself is granted the authority to take action against safety hazards detected in more than one Member State.

Under the provisions of the Directive, producers are obliged to place only safe products on the market.[1149] A safe product is defined as any "product which, under normal or reasonably foreseeable conditions of use including duration (...) does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons (...)".[1150]

In addition, producers are obliged: a) to provide consumers with the relevant information to enable them to assess the risks inherent in a product and b) to take appropriate action including, if necessary to avoid these risks, withdrawal from the market, adequately and effectively warning consumers or recall from consumers.[1151]

[1149]Article 3.1.
[1150]Article 2(b).
[1151]Article 5.1.

From its side, the Member State is required to ensure that producers and distributors comply with their obligations under the Directive in such a way that products placed on the market are safe. For this purpose, Member States have to establish competent authorities with necessary powers to monitor the compliance of products with the general safety requirements as prescribed under the Directive.[1152] Additionally, Member States have to lay down the remedies and sanctions applicable to infringements of the national provisions on product safety and to ensure that they are implemented.[1153] Also, the Directive on GPS imposes on the Member States an obligation to constantly survey the market place, to update its scientific and technical knowledge concerning the safety of products, and to periodically review and evaluate the functioning of the control activities and their effectiveness.[1154] Finally, the Directive on GPS specifies actions that must to be taken in case of a dangerous product posing a serious risk to the consumer, including consumer warnings and product ban and/or recall procedures.[1155] Member States are also required to actively participate, along common conditions and procedural rules, in the regional system for the rapid exchange of information on dangerous products (so-called RAPEX).[1156]

The EU legal order ensures that community directives on consumer protection are timely and correctly implemented by all Member States. If a Member State fails to implement a consumer protection Directive, the Commission can institute proceedings under Article 258 of the *Treaty on the Functioning of the European Union* (TFEU), which may lead to a fine imposed by the European Court of Justice under Article 260 of TFEU.[1157]

[1152]Article 6.
[1153]Article 7.
[1154]Article 9.
[1155]Article 8.
[1156]Articles 11-13.
[1157]EC, *Consolidated Version of the Treaty on the Functioning of the European Union*, OJ C 326, 26.10.2012, p. 47–390, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:12012E/TXT>.

All such achievements are not only impressive in terms of the number of Community acts actually adopted in the area of consumer protection in general and consumer safety in particular, but even more importantly in terms of substance. Initiatives taken go far beyond the objective of increasing consumer information in the marketplace and have a more interventionist tone. Mandatory product labels and safety-related disclosures are imposed, information for consumers about safety matters is promoted and increased, unfair terms, such as disclaimers of liability, are prohibited from consumer contracts, as are unfair marketing practices; unsafe consumer goods are prohibited on the market place; strict pre-and post-market obligations are imposed upon producers and distributors; no-fault liability rules are set in case of defective product; comprehensive market surveillance schemes are put in place; remedial action, as implemented by all Member States, include actions for injunction, product recalls and product withdrawals, administrative financial penalties and criminal sanctions.

The two most recent policy programmes adopted by the European Union in the area of consumer protection give much emphasis to the issue of consumer safety. One of the priorities of the Consumer Policy Strategy for the years 2007 to 2013[1158] was to enhance EU consumers' welfare in terms of price, choice, quality, diversity, affordability and safety and to protect consumers effectively from the serious risks and threats that they cannot tackle as individuals. The most recently adopted Consumer Program for the Years 2014-2020 focuses on four key areas, among which product safety.[1159] With € 24,657,000 budget, the 2015 Annual Work Program sets

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[1158]The Consumer policy strategy 2007-2013 was subject to evaluation, which concluded that the strategy and program have been successful. (EC, *EU Consumer Policy Strategy 2007-2013, Empowering Consumers, Enhancing their Welfare, Effectively Protecting them,* Brussels, 13.3.2007, COM(2007) 99 final, online: European Commission <http://ec.europa.eu/consumers/overview/cons_policy/doc/EN_99.pdf>).

[1159]EC, *Regulation No 254/2014 of the European Parliament and of the Council of 26 February 2014 on a Multiannual Consumer Programme for the Years 2014-20 and Repealing Decision No 1926/2006/EC*, JO L84/42 20.3.2014, p. 44 online: Eur-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2014:084:0042:0056:EN:PDF>.

out the necessary elements for the implementation of the objectives and actions of the Consumer Program for the Years 2014-2020 in a consistent manner.[1160]

Lastly, the draft legislation or so-called New Package has been proposed to boost product safety rules. Two new legal acts are being proposed with the aims to make it easier to restrict or remove unsafe products from European markets, to boost Europe's track-and-trace capabilities in the world of global supply chains, and to strengthen common market surveillance systems and practices throughout the European Union[1161]. It also provides for simplified and accelerated information processes within the RAPEX system. [1162]

EC Institutions

The European Commission, the European Parliament and the European Court of Justice have all played an important role in the development of an active consumer

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[1160]EC, *Commission Implementing Decision of 11.12.2014 Concerning the Adoption of the Work Program for 2015 and the Financing for the Implementation of the Multiannual Consumer Program for the Years 2014-2020*, C (2014) 9323 final, online: <http://ec.europa.eu/consumers/eu_consumer_policy/financial-programme/docs/c_2014_9323_f1_commission_implementing_decision_v2_p1_791655_en.pdf>; EC, *Annex to the Commission Implementing Decision Concerning the Adoption of the Work Programme for 2015 and the Financing for the Implementation of the Multiannual Consumer Programme for the Years 2014-2020*, C(2014) 9323 final, 11.12.2014, online: EC <http://ec.europa.eu/consumers/eu_consumer_policy/financial-programme/docs/c_2014_9323_f1_annex_v2_p1_791657_en.pdf>.

[1161]EC, *Product Safety and Market Surveillance Package, Proposal for a Regulation of the European Parliament and of the Council on Consumer Product Safety and Repealing Council Directive 87/357/EEC and Directive 2001/95/EC*, 2013/0049 (COD), online: Council of the EU <http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%205892%202013%20INIT>& EC, *Product Safety and Market Surveillance Package Proposal for a Regulation of the European Parliament and of the Council on Market Surveillance of Products and Amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC,2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EU) No 305/2011, Regulation (EC) No 764/2008 and Regulation (EC) No765/2008 of the European Parliament and of the Council*, online: Council of the EU <http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%205890%202013%20INIT>.

[1162]For more information on the New Package see: European Council, *Reinforcing Product Safety and Market Surveillance*, online: European Council <http://www.consilium.europa.eu/en/policies/product-safety-market-surveillance/>.

protection policy at the EU level.[1163]

Since 1975, consumer protection plans of actions or strategies have been prepared by the European Commission and then adopted by the Council of Ministers. Such programs state the objectives and priorities of the common initiatives to be taken in favor of consumers in the Community and also set up a detailed calendar for action by the European institutions.

Within the European Commission, one administrative structure in charge of consumer protection – either as a separate directorate general or associated to a related policy field such as internal market, environment, competition, health or justice - has been established since the early 70s. The Commission also takes action to support European consumer organizations and research in consumer related fields.

The European Parliament, as the only directly elected body of the European Union, has always played an active role in promoting legislation with an impact on the daily lives of citizens. The same pioneering role can be observed regarding the Court of Justice of the European Union (ECJ).[1164] Namely, by making consumer protection a legitimate exception from the treaty rules relating to free movement of goods and services, the Court has become the first institution to explicitly refer to the need for consumer protection in the common market and for filling the gap in the treaty with regard to this policy field. Experience shows that when having to decide about the compatibility of some national consumer protection measures with the Treaty's free trade and internal market policy requirements, the Court of Justice of the European

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[1163]Thierry Bourgoignie, *Eléments pour une théorie du droit de la consommation: au regard des développements du droit belge et du droit de la Communauté économique européenne,* Bruxelles: Story-Scientia, (1988) at 77 to 85.

[1164]Verica Trstenjak, *The Court of Justice of the EU and its Influence on Consumer Law,* Presentation to the summer programme in consumer law and policy organized at UQAM by GREDICC, 4th to 9th July 2016.

Union plays a well-balanced arbitration role. Furthermore, a recent series of ECJ cases on unfair contract terms demonstrates how the ECJ is gradually developing a genuine European law on the control of unfair contract terms and at the same time how it is laying down the foundations of a genuine European consumer procedural law.[1165]

To sum up, the European Union has an outstanding record when it comes to consumer protection and safety. A first explicit recognition of consumer protection as a key Union policy came in 1972 during the Paris summit. Since then consumer protection has become one of the pivotal social policies of the Union and has been reconfirmed in all fundamental Treaties. All basic consumer rights, including the right to safety, have received full recognition in the EU.

Since 1979 the Court of Justice of the European Union has confirmed that consumer protection may under certain conditions be admitted as a legitimate exemption from the application of the free trade rules of the Treaty. In addition, since 1993 consumer protection has been identified as an autonomous policy with the goal to provide European consumers with a high level of protection.

The scope of the European *Acquis* in the area of consumer protection is ample and consists of numerous directives covering all consumer protection matters. The *Acquis* with regard to consumer safety is also sufficient, constantly updated and comprises a set of legal instruments and policies to protect adequately the consumer health and

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[1165]Jorge Pegado Liz, *Compatibility of National Consumer Protection Measures with Free Trade Rules in the EU 2007* (Montreal: UQAM, GREDICC, 2007) at 1 to 8 & Hans W. Micklitz, *Mohamed Aziz–Sympathetic and Activist, but Did the Court Get it Wrong?*, European Constitutional Law Network (ECLN) Conference: When The ECJ Gets It Wrong, Florence (2013), online: European Constitutional Law Network <http://www.ecln.net/tl_files/ECLN/Florence%202013/Micklitz%20-%20The%20ECJ%20gets%20it%20wrong%20Aziz-30-11-14.pdf>.

life. The *General Product Safety Directive* and the Rapid Alert System for Dangerous Products are the pivotal instruments of the European consumer safety framework.

All three branches of power have taken a part in in the development of an active consumer protection policy at the EU level. The executive branch, the European Commission, is in charge of developing and implementing consumer protection plans of actions or strategies, as well as proposing drafts of EU legislation. The legislative branch, the European Parliament together with the Council, has endorsed legislation on a broad range of consumer issues. As to the European Court of Justice, its role in the consumer protection area has always been constructive, as shown by the *Cassis-de-Dijon* case.

The EU maintains a sound legal discipline when it comes to the implementation of the Treaty provisions or Directives. All Member States must develop, adopt, and retain common consumer protective measures pursuing policies and technical standards developed by European institutions. In fact, to become a member of the EU, a candidate state must accept and implement the European *Acquis* with regard to consumer protection and safety. Hence, regional initiatives on consumer protection and safety have direct effects on national decision-making processes.

Lastly, the EU is a classic case of Positive Harmonization, since the EU, while promoting free trade, also admits that consumer protection is a valid exemption from the strict application of the Treaty free trade rules and calls for active harmonization efforts. Until today, there has been no political move to use negative harmonization for dismantling national consumer safety measures.

3.3.4 Consumer safety in post-Soviet Union region

Regional integration within the boundaries of the former Soviet space has always been a painful and apathetic process.[1166] Every effort to integrate the ex-Soviet republics under a supranational umbrella has been seen as an attempt to reanimate the Soviet Union. To safeguard their sovereignty, former Soviet states have resisted any real political or economic integration. The Commonwealth of Independent States (CIS), a quasi-regional structure that materialized shortly after the collapse of the Soviet Union, has always served as a suitable political platform to discuss common issues and to coordinate actions without seeking integration. Despite the fact that the CIS has been mostly a political forum without any legal discipline, over the years this interstate institute has solved a set of problems including consumer protection matters.

As well, the formation of the Eurasian Economic Union (EAEU) was carried out based on existing agreements within the framework of CIS.[1167] The recently inaugurated EAEU, a regional structure with fewer Member States and an EU archetype, does not replace CIS but is rather created as a parallel regional body.

Today, two regional organizations with different political and legal structures are thus in place - CIS (3.4.1) and EAEU (3.4.2). Both organizations have in their agendas the topics of consumer protection and consumer safety.

[1166]More on regionalism within ex-Soviet realm see: Mikhail A Molchanov, *Eurasian Regionalisms and Russian Foreign Policy*, (Surrey: Ashgate Publishing, 2015), at 23 to112 & Eurasian Commission, *Eurasian Economic Integration: Facts and Figures*, at 6 to 11, online: Eurasian Commission <http://www.eurasiancommission.org/en/Documents/broshura26_ENGL_2014.pdf>.

[1167]*CIS vs. EaEU?*, (30 May 2014), online: Vestnik Kavkaza <http://vestnikkavkaza.net/articles/politics/55865.html>.

3.3.4.1 Commonwealth of Independent States

There is a lot of speculation and myth surrounding the creation of the Commonwealth of Independent States. The creation of the CIS in 1991 was dictated mainly by political goals and was not aimed at bringing about economic or social integration. The social-economic agenda that appeared in some early CIS documents was used only as camouflage to calm political opponents and the population. The republics of the USSR had the highest possible social-economic integration on all levels. The CIS was used only as a mechanism of disintegration of the USSR. Thus, the political elite of the former Soviet republics used the CIS as a highly suitable political model for transition from socialism to a new form of semi-capitalism. During the first years of the CIS, the well-worked economic and social ties among the republics were interrupted under the pretext that it might jeopardize independence. Thus, originally, the CIS was not designed for the economic prosperity of the population and served only the geo-political ambitions of some members. Nevertheless, economic agreements adopted in the following years have shifted the CIS agenda toward a political union with some degree of economic integration.

The initial CIS Treaty signed by Russia, Belarus, and Ukraine on December 8, 1991 does not include any provisions regarding consumer protection and it merely states that each member should protect the economic and social rights of its citizens.[1168] The *Charter of the Commonwealth of Independent States* signed just two weeks later changed little by adding only a few stipulations on interstate joint activity in the

[1168]CIS, *Соглашение о Создании Содружества Независимых Государств,* (The Agreement on Creation of the Commonwealth of Independent States [translated by author]), online: CIS Executive Committee <http://cis.minsk.by/page.php?id=176 >.

spheres of health and environmental protection.[1169] As a result, each member has developed its own blueprint on how to approach consumer protection.

During the first years, all ten CIS states[1170] actually gave attention to the issue of consumer protection. However, the urgency with which measures have been taken and the scope of their approach varied greatly from state to state. One of the reasons why there are major differences between the approaches followed by each state towards the development and implementation of consumer protection policy was the absence of agreements or guidelines that could compel or invite members to follow common standards or rules in the areas of consumer protection or product safety. Only four years after its formation, the CIS made some first moves toward developing common consumer protection policy.

The first initiative came in 1995 with the adoption of the *Recommendation on Common Principles Regulating Consumer Protection in Assembly Member States*.[1171] The idea behind this document was to guide newly born Member States toward the adoption of similar rules for consumer protection. The proclaimed goals were to harmonize the legal and administrative basis for consumer protection in the CIS, to create equal conditions for all consumers in the community, and to establish uniform effective working mechanisms to protect consumers.

[1169]CIS, *The Charter of the Commonwealth of Independent States,* at Art. 4, online: Dipublico, <http://www.dipublico.org/100617/charter-establishing-the-commonwealth-of-independent-states-cis/>.

[1170]The CIS comprises 10 former Soviet Republics: Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Ukraine, and Uzbekistan. Turkmenistan discontinued permanent membership as of August 26, 2005, and is now an associate member. Ukraine has never ratified the CIS Treaty and de-jure is not a member. Nevertheless, de-facto Ukraine has participated in CIS since the inception. Georgia was a Member State from 1993 to 2009.

[1171]CIS, *О Рекомендательном Законодательном Акте "Об Общих Принципах Регулирования Защиты Прав Потребителей в Государствах - Участниках Межпарламентской Ассамблеи* (The Recommendation on Common Principles Regulating Consumer Protection in Member States [translated by author]), online: CIS Executive Committee, <http://www.lawbelarus.com/world/sub02/texa3945.htm>.

The Recommendation contains a blueprint of a prototypical consumer protection law to be adopted by every Member State. In fact, closer look reveals that most of the provisions from the agreement have migrated to the national consumer protection regulations. As a result, national consumer protection laws in the CIS look as if they were written with carbon paper.[1172] Furthermore, in view of the fact that the Recommendation restates all the international norms highlighted in the *UN Guidelines for Consumer Protection 1985*, every Member State incorporated those basic rights into national law.[1173]

The document advises Member States on which provisions should be part of national consumer protection laws. Among such provisions one can find safety of goods (works, services), defined as "the absence of unacceptable risks associated with the likelihood of harm to the life, health or property of the consumer, under normal condition of use, storage, transportation, goods disposal (result of work, services) or in the process of performance (provision of services)".[1174]

The Recommendation also deals with cross-border trade and consumer disputes. In accordance with Article 4 consumers are free to choose applicable law when seeking redress: the law of the Member State where the service was provided or the purchase was made; the law of the Member State where the product or service originates; or the law of the Member State where the consumer resides. This provision gives unprecedented legal flexibility to consumer seeking redress.

As for consumer safety, the document calls for the adoption of a comprehensive common policy on the matter by every Member State. To be specific, products and

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[1172]Close examination confirms that the national consumer protection laws developed by CIS Member States have similar patterns and follow proposals prescribed in the Recommendations.
[1173]Article 2 lists all fundamental consumer rights.
[1174]Article 8.

services have to be safe for the life and health of the consumer.[1175] Producers/service providers are liable in the case of an unsafe product or service causing harm to consumer life and health. The damage caused to consumer life and health due to product/services design flaws or defects must be fully compensated.[1176]

Five years later, on December 25, 2000, the members of the CIS agreed on two key documents regarding common consumer protection policy and made it a priority.

The first document was a treaty on *Implementation of Coordination Regarding Common Practices in Competition*,[1177] whereby the members of the CIS admit that such coordination is crucial both for fair competition within the CIS free market and for the protection of consumer rights. CIS members established legal and administrative frameworks for fair competition within the CIS and for promoting consumer protection in direct and indirect ways. For example, it forbids the provision of any false information to consumers about the nature, ways, place of production, quality, or consumer characteristics of a product. The treaty prohibits the maintenance of unreasonably high prices through the use of a market monopoly or by limiting production, and it makes it illegal for producers to conclude agreements that restrict competition.[1178]

The same treaty set up the Interstate Antitrust Committee with the authority to develop antitrust rules, regulations, and mechanisms of application, as well as criteria for and methods of evaluating antitrust activities.[1179] Moreover, members of the CIS

[1175]Article 2.
[1176]Article 9.
[1177]CIS, *Договор о Проведении Согласованной Антимонопольной Политики* (Implementation of Coordination Regarding Common Practices in Competition [translated by author]), online: CIS Executive Committee, <http://cis.minsk.by/page.php?id=1938>.
[1178]Article 3
[1179]Article 4.

agreed to exchange information regarding consumer markets and companies found guilty of antitrust infractions.

The second document raised consumer protection within the Community to a completely new level. Indeed, the *Accord Regarding the Basic Directions of Cooperation Among Members of the CIS within the Sphere of Consumer Protection* (Accord)[1180] paves the way for a common consumer protection policy scheme and makes consumer protection a key element of "economic integration." The preamble to the agreement lists the goals of the CIS through the treaty: a) activation of trade cooperation among members of the union; b) creation of a true free trade zone within the CIS; c) protection of consumers against defective products and services; d) implementation of common consumer policy within the CIS; and e) increasing well-being of population within the union. It is also interesting to note that the preamble specifies that the parties acknowledge and follow the international norms highlighted in the *UN Guidelines for Consumer Protection 1985* in developing this Accord.

The Accord specifies the main goals of the parties to the agreement: "...to create a judicial and administrative basis for the implementation of common consumer protection policy against bad practices and create equal conditions of protection for citizens of each Member State."[1181] In other words, the agreement is designed to push the members of the CIS toward harmonization of consumer protection strategy that would benefit every consumer by virtue of truly universal protection within the CIS.

[1180]CIS, *Соглашение об Основных Направлениях Сотрудничества Государств Участников Содружества Независимых Государств в Области защиты Прав Потребителей* (The Accord Regarding the Basic Directions of Cooperation Among Members of the CIS within the Sphere of Consumer Protection [translated by author]), online: CIS Executive Committee <http://e-cis.info/page.php?id=21315 >.

[1181]Article 2.

The parties also agreed to cooperate in a broad range of consumer protection policies. Basically, the agreement embraces all major points of the *UN Guidelines for Consumer Protection 1985* and reconfirms the rights of consumers in accordance with international law, including consumer safety, education, redress, etc.[1182] Regrettably, the Accord remains silent on the crucial issue of reconciliation of national consumer protection measures with free trade rules, and no interstate body in charge of arbitrating such conflicts is set up.

Under the Accord, each Member State commits itself to implementing consumer protection policy through a designated national authority. The Interstate Antitrust Committee is designated as the body in charge of the implementation of the provisions of the agreement at the CIS level.[1183] After the meeting held on October 13, 2004, under the auspices of the Interstate Antitrust Committee, the Member States decided to create a subcommittee as part of the Interstate Antitrust Committee to be responsible solely for consumer protection policy.

Another CIS institute that takes part in the approximation of consumer protection policy is the Interparliamentary Assembly. Founded in 1992 as a consultative body among parliaments of the Member States, this organization does a significant amount of work in harmonizing national legislation regarding consumer protection. The most significant input with the aim of promoting a mutual approach in developing a legal basis for consumer protection by Member States is the adoption in 1995 of the above-mentioned *Recommendation on Common Principles Regulating Consumer Protection in Assembly Member States.*

In October 2009 during the conference "Consumer Protection in CIS during the Crises, Actual Questions" CIS Member States admitted that coordinated actions

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[1182]Article 5.
[1183]Article 6.

under the *Accord Regarding the Basic Directions of Cooperation among Members of the CIS within the Sphere of Consumer Protection* could not solve the problem of unsafe products and services on the Community market. The participants called for urgent measure to be taken in the sphere of consumer protection and consumer safety at the interstate level. As an outcome, in May 2011 the CIS Consultative Advisory Committee on Consumer Protection (Committee) was established.[1184] With the mandate to design more effective consumer protection policy in the CIS, the Committee coordinates work of national consumer protection institutions and public consumer organizations "in accordance with international norms and standards".[1185]

In November 2011, the Committee held its first meeting at which the president and the secretariat were elected. The participants exchanged information regarding the status of consumer protection in the CIS. A newly created workgroup was asked to prepare "conceptual agenda for future actions to guarantee effective consumer protection at the interstate level." The second meeting of the Committee with the motto "Actual Aspects of Consumer Protection and Perspectives of Development for National Consumer Protection Networks" was held in April 2012. Participants from the EU Commission and Consumers International attended the conference. Two key safety-related issues were discussed during the meeting: CIS plan to strengthen the level of safety for products and services on the common market and actions to be taken to prevent the import and circulation of unsafe products.

[1184]The legal status of the committee is specified in amended Article 6 of the Accord 2000.

[1185]CIS, *Протокол о Внесении Изменений в Соглашение об Основных Направлениях Сотрудничества Государств – Участников Содружества Независимых Государств в Области Защиты Прав Потребителей от 25 января 2000 года* (Protocol Amending *the Accord Regarding the Basic Directions of Cooperation among Members of the CIS within the Sphere of Consumer Protection*, January 25, 2000 [translated by author]), online: CIS Executive Committee <http://www.e-cis.info/page.php?id=20676>.

In the final resolution of the meeting, the parties underlined a few positive developments over recent years: consumer protection has become a key state policy in all Member States; the harmonization of consumer protection laws of the Member States went successfully in accordance with guidelines set out in the *Recommendation on Common Principles Regulating Consumer Protection in Member States 1995*; the adopted national legal instruments fully recognize international basic consumer rights; and institutions responsible for consumer protection have been put in place on national and inter-state levels.

Nevertheless, the parties did admit that there were clear obstacles in developing consumer protection at the inter-state level. Existing national and inter-state policies did not provide sufficient safety for consumers. Besides, the presence on the Community marketplace of unsafe and counterfeit products is seen as the result of a lack of competition and the absence of adequate legal tools at the regional level.

Under the auspices of the Interstate Advisory Committee, Member States were urged to take a few crucial steps: developing an inter-state legal framework which better protects consumers in a free market driven by globalization processes; further harmonization of national consumer protection legal instruments; reviewing existing national regulations to better reflect the international standards and practices; creation of an inter-state system for the rapid exchange of information on dangerous products on the market; and designing conceptual information networks to educate consumers and promote their rights.[1186] Numerous follow-up meetings have taken place, where Member States discussed various consumer protection issues including consumer safety. Nevertheless, no uniform and specific agenda on consumer safety has been adopted. Such platform has been predominantly used to

[1186]CIS, *Актуальные Вопросы Защиты Прав Потребителей от Государствах - Участниках СНГ (Информационно-Аналитический Обзор),* (Actual Questions Regarding Consumer protection in the CIS *Member-States* (Informative- Analytical Review [translated by author]), online: CIS Executive Committee <http://www.e-cis.info/page.php?id=23359>.

communicate knowledge and to share experience on consumer protection and safety amongst Member States.[1187]

3.3.4.2 The Eurasian Economic Union (EAEU)

Today, the Eurasian Economic Union represents an integrated single market of 183 million people and a gross domestic product of over 4 trillion U.S. dollars (PPP). However, the road toward the EAEU was not easy. Although the idea to unite ex-Soviet states under the umbrella of a regional superstructure similar to the EU was first proposed back in 1994, it took more than 20 years before the new union was born. The attempt to clone the success of the EU amongst the CIS members took a graduate approach through a few stages and was parallel to CIS processes but with fewer participant states.[1188]

Many steps taken during the 1990s emulated the EU integration blueprint. For instance, a 1995 *Customs Union Treaty* had the purpose to create an open borders area without passport controls between Member States similar to the Schengen zone. However, before 2000 the process was slow and, essentially, signed treaties had only a declarative nature.

The first fundamental step toward the EAEU was done in 2000 when Russia, Belarus, Kazakhstan, Kyrgyzstan and Tajikistan established the Eurasian Economic

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[1187]More on the CIS Advisory Committee on consumer protection see: CIS, *CIS Advisory Commettee on Consumer Protection* (in Russian), online: Rospotrebnadzor <http://rospotrebnadzor.ru/deyatelnost/zpp/sng/>.

[1188]*Op. cit.* 1166 (Mikhail A Molchanov) at 23 to112; & Eurasian Economic Commission, *Eurasian Economic Integration: Facts and Figures*, at 6 to 11, online: Eurasian Commission <http://www.eurasiancommission.org/en/Documents/broshura26_ENGL_2014.pdf>.

Community (EAEC) creating a common market for its Member States.[1189] Just three years later, the Treaty on the *Single Economic Space* by Belarus, Kazakhstan, and Russia further continued the integration process towards the creation of a broader, integrated single market.

The next phase of integration was the creation of the Eurasian Customs Union of Belarus, Kazakhstan, and Russia in January 1, 2010. The Customs Union was a predecessor of the EAEU with a purely economic integration agenda similar to NAFTA: the elimination of intra-bloc tariffs, establishing a common external tariff policy, and the elimination of non-tariff barriers.

Shortly after, on 1 January 2012, the three states established the Eurasian Economic Space which ensures the effective functioning of a single market for goods, services, capital, and labour and aims to establish coherent industrial, transport, energy and agricultural policies. The architecture of the European Commission was used as a prototype for the Eurasian Economic Commission, a newly inaugurated regulatory agency for the Eurasian Economic Space.

On 29 May 2014, the presidents of Kazakhstan, Belarus and Russia signed the *Treaty on the Eurasian Economic Union* (Treaty), which came into effect on 1 January 2015[1190]. Armenia and Kyrgyzstan joined the EAEU on 2 January and 6 August 2015, respectively. In addition to the Eurasian Economic Commission (Commission/EEC),[1191] the union comprises two additional supranational institutions:

[1189]Uzbekistan joined EAEC in 2006.

[1190]EAEU, *Treaty on the Eurasian Economic Union*, online: EAEU <https://docs.eaeunion.org/en-us/Pages/DisplayDocument.aspx?s=bef9c798-3978-42f3-9ef2-d0fb3d53b75f&w=632c7868-4ee2-4b21-bc64-1995328e6ef3&l=540294ae-c3c9-4511-9bf8-aaf5d6e0d169&EntityID=3610>.

[1191]Eurasian Economic Commission (EEC) is a permanent regulatory body of the Eurasian Economic Union with the main objectives to ensure the functioning and development of the EAEU and to prepare proposals for its further integration. The Eurasian Commission takes decisions on broad array of policies: customs, macro-economy, competition regulations, energy and etc. More on EEC see: Eurasian Commission [in English], online: EEC <http://eurasiancommission.org/en/Pages/default.aspx>.

the Court of the EAEU[1192] and the Eurasian Development Bank.[1193]

It is important to underline that the EAEU is not a political bloc with an economic agenda as is nowadays the EU *per se*. The primarily goal of the Union is economic integration; in some respects it resembles NAFTA.

In contrast to the original EU 1957 Treaty, where consumer protection did not exist as one autonomous regional strategy, the EAEU 2014 Treaty refers explicitly to consumer protection as one of the Union key policies. Section XII, which is exclusively dedicated to Consumer Protection consists of two articles: Article 60 "Consumer Protection Safeguards", and Article 61 "Consumer Protection Policy". In accordance with the provisions of Section XII, everyone in the Union must benefit from consumer protection under the legislation of the Member States or under the Treaty. The Member States have to conduct agreed policy in the sphere of consumer protection aimed at creating equal conditions for the citizens of the Member States in order to protect their interests against dishonest activities of economic entities, as defined in Annex 13 to the Treaty.

Annex 13 to the Treaty "Protocol on Agreed Policy in the Sphere of Consumer Protection" consists of the following parts. Part I. "General Provisions" defines terms; for example: consumer,[1194] seller,[1195] *mala fide* economic entities[1196]. Part II.

[1192]The Court of the EAEU is in charge of dispute resolution and interpretation of the legal order within the EAEU.

[1193]The Eurasian Development Bank (EDB) is an international financial organization established to promote economic growth in its Member States, extend trade and economic ties between them, and support integration in Eurasia. Any country or international organization that shares EDB's goals is eligible to join it. More on EDB see: EDB [in English], online: EDB <http://www.eabr.org/e/>.

[1194]"Consumer" means a natural person intending to order (buy) or ordering (acquiring, using) goods (works, services) exclusively for personal (domestic) use, not related to any business activities.

[1195]"Seller" means an organization, irrespective of the form (type) of ownership, as well as a natural person registered as an individual entrepreneur, selling goods to consumers under purchase and sale agreements.

[1196]"*Mala fide* economic entities" means sellers, manufacturers and contractors conducting their activities with violations of the consumer protection legislation of the Member States and customary

"Implementation of Main Directions of Consumer Protection Policy" sets agreed political agenda in the sphere of consumer protection. Namely, in order to form for the EAEU citizens equal conditions Member States must implement a coordinated policy in the field of consumer protection in accordance with norms of national and international laws. The Treaty calls for establishing a mechanism for the timely and reliable exchange of information regarding goods/services and manufacturers/sellers/contractors to consumers, state authorities, and consumer public associations. Additionally, the document requires elaborating measures to prevent the activities of *mala fide* economic entities and sales of low-quality goods (services) on the territories of Union. Part III. "Interaction with Public Consumer Associations" covers aspects of common policy between Member States and consumer organizations; specifically, establishing a system of information exchange in the sphere of consumer protection between the Member States. Part IV. "Interaction between Authorized Authorities in the Sphere of Consumer Protection" calls for the interstate information exchange and cooperation on various subjects of the consumer protection, including consumer rights violations and measures taken to ensure compliance with the consumer protection legislation. Part V. "Powers of the Commission" sets a consumer agenda for the supra-national authority. Namely, the Commission issues recommendations to the Member States on the application of measures aimed at improving the efficiency of interaction between authorized officials in the sphere of consumer protection, and the procedure for implementing the provisions referred to the Treaty. Finally, the Commission is entitled to create advisory bodies for the protection of consumer rights in the Member States.

In addition to Section XII, consumer protection policies are outlined in Article 70, "Objectives and Principles of Regulation of Financial Markets" (the Member States have to conduct agreed regulation of financial markets within the Union to ensure

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business practices, when these violations may cause or have caused material or non-material damage to consumers and/or the environment.

guaranteed and effective protection of the rights and legitimate interests of consumers of financial services) and Article 76 "General Rules of Competition" (any actions (omission) of dominant economic entities should be prohibited if misleading as to the nature, method and place of manufacture, consumer properties, quality and quantity of goods or their manufacturers).

As for consumer safety, the Treaty includes numerous provisions directly related to the matter. Namely, Annex 9 to the Treaty "Protocol on Technical Regulation within the Eurasian Economic Union" defines the notion of safety as "the absence of unacceptable risk related to any potential of causing harm and/or injury". Article 53 "Circulation of Products and Validity of Technical Regulations of the Union" states that all products released into circulation on the territory of the Union must be safe. The product safety agenda in the Union is enforced through harmonized technical regulations and interstate agreements that have direct effect on the territory of the Union. In order to meet the requirements of the interstate technical regulations and assess their conformity, international and regional (interstate) standards may be applied on a voluntary basis during this transitional period.[1197]

The Treaty also sets a legal basis for establishing a common mechanism for the exchange of information on dangerous products, equivalent to the EU RAPEX. If a Member State becomes aware of any actions that may harm the health or safety of people on the territory of that Member State or on the territories of other Member States, it shall inform all other Member States and the EAEU Commission as soon as possible through the newly inaugurated information systems of the Union[1198]

Additionally, some Treaty stipulations target safety matters in specific sectors. Article

[1197]It is not clear what time frame will be set for the transition period. The Treaty elaborates that the procedure for entering into force of the technical regulations of the EAEU and transitional provisions are to be determined under the technical regulations of the EAEU and (or) an act of the Commission. (Article 52 "Technical Regulations and Standards of the Union")
[1198]Article 68.

30 "Establishing a Common Market of Medicines" calls for ensuring the uniformity of mandatory requirements for the quality, effectiveness, and safety of circulation of medicines on the territory of the Union. Article 86 "Coordinated (Agreed) Transport Policy" calls for the establishment of policy on safe operation of transport in the Union.

Finally, the Treaty admits consumer safety as a legitimate exemption from the application of free trade rules. Article 52 "Circulation of Products and Technical Regulations of the EAEU" and Article 56 "General Principles of the Application of Sanitary, Veterinary and Sanitary and Phytosanitary Quarantine Measures" clearly specifies that sanitary, veterinary, and phytosanitary quarantine measures might be applied on the basis of principles having a scientific justification and only to the extent necessary to protect human, life and health. Measures taken should be based on international and regional standards, guidelines and/or recommendations.

Since the adoption of the Treaty, important steps have been taken to establish a supranational body exclusively responsible for consumer protection. On May 25, 2015, the Eurasian Economic Commission (EEC) took the decision to establish a Consumer Rights Protection Consultative Committee (CRP Committee), and approved the regulation on CRP Committee. The CRP Committee was formed the following September.[1199]

The CRP Committee is an advisory body of the Commission charged with pursuing agreed consumer protection policy in the Union. This policy is aimed at creating

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[1199]EAEU, *Распоряжение Коллегии ЕЭК от 28.09.2015 № 101 "О Составе Консультативного Комитета по Вопросам Защиты Прав Потребителей Государств - Членов Евразийского Экономического Союза"*(EA Commission Regulation of 28.09.2015 № 101 "On the Composition of the Eurasian Economic Union Advisory Committee on Consumer Protection" [translated by the author]), online: Eurasian Commission <http://www.eurasiancommission.org/ru/act/texnreg/depsanmer/kk/Documents/Распоряжение%20Коллегии%20№%20101%20от%2028%20сентября%202015%20г.pdf>.

conditions for the protection of consumers against unfair activity of economic entities in the Union and preparing recommendations for the EEC to improve cooperation between Member States in this fields of consumer protection.

The major duties of the CRP Committee are:

(i) to develop effective mechanisms and principles for coordinated policy in the field of consumer protection amongst Member States;
(ii) to coordinate cooperation between Member States in the field of consumer protection;
(iii) to harmonize legislation of Member States in the field of consumer protection;
(iv) to enhance cooperation in the field of consumer protection between the EEC and international organizations, including public associations of consumers;
(v) to adopt measures limiting dishonest businesses practices;
(vi) to prevent the flow of low-quality goods (services) on the territory of the Member States;
(vii) to prepare proposals on draft recommendations of the Commission for the Member States in the field of consumer rights protection; and
(viii) to consider other issues concerning consumer rights protection through consultations.[1200]

[1200]EAEU, Положение *от 25.05.15 № 59 "О Консультативном Комитете по Вопросам Защиты Прав Потребителей Государств – Членов Евразийского Экономического Союза"* (Decision of 25.05.15 № 59 on the Advisory Committee on Consumer Protection in Member States of the Eurasian Economic Union [translated by author]), online: Eurasian Commission <http://www.eurasiancommission.org/ru/act/texnreg/depsanmer/kk/Documents/Решение%20Коллегии%20№%2059%20от%2025%20мая%202015%20г.pdf>.

3.3.4.3 Additional comments on CIS and EAEU achievements

In conclusion, when it comes to consumer protection and safety, CIS and EAEU have demonstrated dissimilar dynamics. Consumer fundamental rights have never been a part of the CIS Treaty 1991. In fact, during the first years of its existence, CIS did not have any consumer protection agenda. Nevertheless, the adoption four years later of the *Common Principles of Consumer Protection Regulation in Member States 1995* and *Accord Regarding the Basic Directions of Cooperation among Members of the CIS within the Sphere of Consumer Protection* set an autonomous consumer protection policy. In the scope of this policy, all fundamental consumer rights received recognition.

The two Agreements also brought into line principal national laws on consumer protection and established an institutional framework. In the following years, the harmonization of primary consumer protection laws of the CIS Member States has been successfully implemented. Since 2004 a specialized subcommittee of the CIS Interstate Antitrust Committee has been responsible for consumer protection policy. However, the Agreements did not establish a mechanism to resolve conflicts between national consumer protection measures and free trade rules.

Although numerous documents related in a certain degree to consumer protection and safety have been adopted in the scope of CIS, the *Acquis* in this area seems fragmental and insufficient. Successful harmonization of the basic national consumer protection laws has not brought similar legal approximation in other areas. For instance, no technical harmonization on safety requirements for consumer products has been achieved. Moreover, due to the CIS's legal status, all agreements have only an advice-giving nature. At most, the Community

declares consumer protection as an integral part of the CIS free trade zone policies and calls to harmonize national legal and technical bases on the matter. Legal discipline, similar to that of the EU, does not exist. The CIS's institutions, with only advisory and consulting status, have little power to review how Member States approach national consumer protection regulation. In view of such circumstances, harmonization attempts remain limited and "soft".

CIS is a case of positive harmonization. Similar to the EU, the Union has moved toward common consumer protection policies making consumer protection and safety a key element of economic integration. Unlike the EU, the CIS does not possess attributes of negative harmonization. Signed in 2011, the *Free Trade Zone Treaty* is silent regarding consumer protection measures and mainly opts for the prevention of unfair competition practices amongst Member States.[1201]

On the contrary, a consumer protection agenda was part of the EAEU founding Treaty of 2014. Article 60 "Consumer Protection Safeguards", Article 61 "Consumer Protection Policy", and Annex 13 to the Treaty "Protocol on Agreed Policy in the Sphere of Consumer Protection" explicitly define consumer protection as one of the Union key autonomies policies. Regrettably, the Treaty does not list all internationally recognizable fundamental consumer rights. It only stipulates that the Member States implement coordinated policy in the field of protection of rights of consumers under the norms of international law.

So far no specific regional agreements on consumer protection and safety have been adopted in the scope of the Union. The regional *Acquis* in the area of consumer protection and consumer safety is still under development. At this stage, numerous technical regulations on consumer products safety are undergoing regulatory impact

[1201]CIS, *Договор о Зоне Свободной Торговли*, [Free Trade Zone Treaty], (in Russian), online: CIS <http://cis.minsk.by/reestr/ru/index.html#reestr/view/text?doc=3183>.

assessment.[1202] No general product safety regulation, similar to the EU Directive on GPS, has been developed at the moment. Hence, the actual effect of regional initiatives on national decision-making processes cannot yet be measured. Nevertheless, taking into the account that regional laws are directly applicable in the territory of the EAEU, it might be projected that national laws and regulations on consumer protection and safety will be harmonized.

Consumer Rights Protection Consultative Committee in the Eurasian Economic Union was put in place just recently. Up to now, no results of its work have yet been observed.

The EAEU is based on the notion of positive harmonization. Yet, when it comes to consumer safety, the EAEU Treaty includes a negative harmonization concept. Sanitary, veterinary-sanitary and phytosanitary quarantine measures are applied based on scientifically justified principles and only to the extent required to protect life and health of humans.[1203]

Lastly, the consumer protection and safety agenda in the newly established EAEU is impressive and includes a comprehensive set of guiding rules for success. In many respects, the EAEU fundamental treaty reproduced the existing postulates of the EU one. Such a remarkable start provides an optimistic outlook for the future of consumer protection and safety in the Union. Evidently, the ultimo success of consumer safety in the EAEU depends on how the new regional entity will proceed and how far the politicians are ready to go to protect consumer life and health.

[1202]For full list of technical regulation are under development see EAEU Commission Law Portal, online: EAEU Commission <https://docs.eaeunion.org/en-us/>.

[1203]Article 56 "General Application Principles for Sanitary, Veterinary-Sanitary and Phytosanitary Quarantine Measures" & Annex 12 "Protocol on Application of Sanitary, Veterinary-Sanitary and Phytosanitary Quarantine Measures".

To summarize, after a "quiet" decade, consumer protection and especially consumer safety have become a strategic area in the post-Soviet realm. Nevertheless, the newly elaborated agenda in the CIS still remains at a declaratory level. To date, nothing substantial has been done to implement recently announced plans. One can only speculate on the potential outcome of the future legal changes. On the other hand, taking into account the success of positive harmonization under Agreement 1995, it might be predicted that upcoming changes will considerably reshape the legal landscape in the region and bring consumer safety in the CIS to an elevated level.

On the other hand, the future of consumer safety in the newly formed EAEU looks quite bright. From the very beginning, Member States have shown political willingness to shape a vigorous consumer safety agenda in the Union. As mentioned above, the matter of safety is well defined in the founding treaty. However, the most dramatic difference between the EAEU and CIS is that the new regional entity introduced legal discipline resembling the EU pattern. The major weakness of the consumer protection framework in the CIS has always been its declarative nature. The CIS has never established any genuine mechanisms to implement numerous agreements on consumer protection and safety. Whereas the EAEU, from the start, has possessed a robust legal and institutional framework to realize fully consumer protection and safety polices. The only existing drawback is limited membership, with only four states currently in the Union. However, Vietnam has already signed agreements on a free trade zone with the EAEU[1204] and a few CIS and non-

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[1204] *Agreement on Free Trade Zone between the EAEU and Socialist Republic of Vietnam Signed According to the Results of the Second Session of the Eurasian Intergovernmental Council*, (29 May 2015), Eurasian Commission, online: Eurasian Commission <http://www.eurasiancommission.org/en/nae/news/Pages/29-05-2015-5.aspx> & *Vietnam - Eurasian Economic Union FTA*, [text], online: WTO Centre Vietnam <http://wtocenter.vn/other-agreement/vietnam-eurasian-economic-union-fta-full-content>.

CIS states are engaged in negations to join the Union free trade zone in the near future.[1205]

3.4 Regional schemes for the exchange of information on dangerous consumer products

As seen, consumer safety has received a certain degree of attention in every regional union and every union has developed its own pattern for the legal and institutional set up to deal with the matter. In spite of dissimilarities, all three selected regional systems have opted for information exchange on dangerous consumer products as a preferred tool to deal with urgent consumer threats. However, the scope and operation of the exchange procedures actually designed vary from one regional system to the other. The exchange of information system put in place in the EU is presented first, as this is by far the most advanced (3.4.1). Initiatives going in the same direction developing among NAFTA countries (3.4.2) and in the post-Soviet regional space (3.4.3) are then described.

[1205]Currently, Tajikistan is negotiating the agreement with the EAEU and Egypt, Israel, and Iran are entreating the idea to join the Union. *(Tajikistan Paves the Way to Eurasian Union Cental Asia-Caucasus Analyst,* (7 January 2015), online: Cental Asia-Caucasus Analyst <http://www.cacianalyst.org/publications/field-reports/item/13113-tajikistan-paves-the-way-to-eurasian-union.html> & "Egypt to Join Russia-led Eurasian Free Trade Zone", (10 February 2015), Russia Today online: Russia Today <https://www.rt.com/business/230987-egypt-russia-free-trade/> & EAEU, *The 26th Session of the Eurasian Economic Council Board: On Creation of Joint Research Group to study the Desirability of Conclusion of the Agreement on the Free Trade Area between the Customs Union and the Common Economic Space Member States and the State of Israel*, online: Eurasian Commission <http://www.eurasiancommission.org/en/nae/events/Pages/03-09-2013-1.aspx> & "EEU, Iran Mull over Free Trade Agreement", Belarus News, (16 April 2015), online: Belarus News <http://eng.belta.by/economics/view/eeu-iran-mull-over-free-trade-zone-agreement-11708-2015>).

3.4.1 The European Union Rapid Exchange Information System on Dangerous Goods (RAPEX)

Legal basis

The Rapid exchange of information on dangers stemming from the use of consumer products or RAPEX, was instituted by the European Commission in 1984[1206] as a proactive response to an alarming number of accidents resulting from consumer products freely circulating on the EU common market and as a necessary addendum to the vertical approach existing in the EU under which only specific and limited groups of consumer product were covered.[1207] The aim was to permit the rapid exchange of information between the Member States and the European Commission on measures and actions taken in relation to products posing a serious risk to the health and safety of consumers and to inform Member States and the Commission of the conclusions of follow-up action taken by national authorities with regard to information exchanged through RAPEX.

Already by the end of 1979, the Commission presented the Council of Ministers with a proposal for a decision setting up a Community system for information on the dangers stemming from the use of consumer products.[1208]

[1206]EC, *Council Decision 84/133/EEC of 2 March 1984 Introducing a Community System for the Rapid Exchange of Information on Dangers Arising from the Use of Consumer Products*, [1984] *J.O. L 70/16, online:* EUR-Lex <*http://europa.eu/legislation_summaries/other/l32039_en.htm*>.

[1207]Françoise Maniet, " Le système d'échange rapide d'informations sur les produits dangereux (ou RAPEX) mis en place dans l'Union Européenne " (2010) 75 *Revista de Direito do Consumidor,* at 298-333; & Françoise Maniet, *Nanotechnologies et produits de consommation Quels risques ? Quels encadrements ?,* (Cowansville (Québec):Yvon Blais), (2012), at 171 &172.

[1208]EC, *Proposal for a Council Decision Introducing a Community System for the Rapid Exchange of Information on Dangers Arising from the Use of Consumer Products*, J.O. L 79/C 321/04, online: Eur-Lex <http://eur-lex.europa.eu/JOHtml.do?uri=OJ:C:1979:321:SOM:en:HTML>.

The desire of the Commission to set up such an information system in 1979 was based upon the following observations:[1209]

(i) unofficial and informal exchanges of information between the Member States' authorities do not offer the guarantee that all dangers and risks in the market place will be actually detected and the occurrence of accidents actually prevented;
(ii) dangerous situations are becoming more and more frequent and serious, whether they relate to foodstuffs (fatal intoxication) or household equipment (electrical goods, motor cars, etc.);
(iii) experience shows that the information which is actually disseminated and exchanged is not always relevant or adequate to allow for appropriate measures to be rapidly taken at the common market level.

Furthermore, the Commission was attempting, in its proposal, to achieve recognition of its own ability to adopt, where necessary, appropriate measures valid for the whole common market. "The setting up of the rapid information exchange system therefore, originally, intended to go further than the simple transmission of data, aspiring in addition to achieve the launching of appropriate measures in the Member States".[1210] Note that this particular wish of the European Commission was not met until the adoption of the Directive 92/59/EEC of 29 June 1992 on General Product Safety, which grants the Commission some, although very limited, powers to intervene directly on the market place.[1211]

[1209]R. Milas, "La signification juridique de l'institution d'un système communautaire d'échange rapide d'informations sur les dangers découlant de l'utilisation de produits de consommation", *Revue du Marché Commun*, (1984) 274, at 77.
[1210]*Op. cit.* 1207 (Le système d'échange rapide d'informations sur les produits dangereux (ou RAPEX) mis en place dans l'Union Européenne).
[1211]*Ibid.*

The proposal of 1979, as adopted in 1984, put in place for a four-year period a system which was consequently extended for a further two years until it was finally integrated into Article 8 of Directive 92/59/EEC of 29 June 1992 on General Product Safety.[1212] This Directive for the first time introduced into European law general product safety and market surveillance obligations.[1213] To facilitate RAPEX application by the Commission and national authorities, the Directive of 1992 was replaced by *Directive 2001/95/EC of 3 December 2001 on General Product Safety* (GPSD).[1214] GPSD further details the provisions of the previous Community act and provides national authorities with simple and clear operating criteria. Concerns for increased efficiency and uniform implementation of the system led to the *Commission Decision 2004/418/EC of 29 April 2004*[1215] laying down guidelines for the management of the Community Rapid Information System (RAPEX).[1216] In December 2009, in order to ensure more efficient and effective notification procedures in line with best practice" and "establish a methodology for risk assessment" the 2004 Guidelines were replaced by the Guidelines for the management of the Community Rapid Information System 'RAPEX' established

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[1212]EC, Council Directive 92/59/EEC of 29 June 1992 on General Product Safety [1992], OJ L 228, 11.8.1992, p. 24–32, online: EUR-Lex, <http://eur-lex.europa.eu/Result.do?T1=V3&T2=1992&T3=59&RechType=RECH_naturel&Submit=Search>.

[1213]*Op. cit.* 1207 (Le système d'échange rapide d'informations sur les produits dangereux (ou RAPEX) mis en place dans l'Union Européenne).

[1214]EC, *Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety*, [2002], OJ L 11, 15.1.2002, p. 4–17, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32001L0095>.

[1215]EC, *Commission Decision 2004/418/EC of 29 April 2004 Laying Down Guidelines for the Management of the Community Rapid Information System (RAPEX) and for Notifications Presented in Accordance with Article 11 of Directive 2001/95/EC*, [2004], OJ L 151, 30.4.2004, p. 83–117, *online: EUR-Lex* <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0418:EN:NOT>.

[1216]Decision 2004/418/EC also provides guidelines for notifications presented in accordance with Article 11of GPSD, which establishes a notification procedure for the exchange of information between Member States and the Commission on measures taken in relation to consumer products which do not meet RAPEX criteria; for example, a product posing a non-serious risk to the health and safety of consumers. The Article 11 notification mechanism is treated as an independent procedure that is separate from the notification procedure established under RAPEX.

under Article 12 and of the notification procedure established under Article 11 of *Directive 2001/95/EC* (the General Product Safety Directive).[1217]

Role of RAPEX

Nowadays, RAPEX plays an important role in the area of product safety; it complements other actions taken both at national and at European levels to ensure a high level of consumer safety in the EU. RAPEX data help to: a) prevent and restrict the supply to consumers of dangerous products; b) monitor the effectiveness and consistency of market surveillance and enforcement activities carried out by Member State authorities; c) identify needs and provide a basis for action at EU level; and d) make for consistent enforcement of the EU product safety requirements and thus the smooth functioning of the internal market.[1218]

Products covered by RAPEX

The RAPEX covers all non-food[1219] "products intended for consumers" – products that are designed and manufactured for and made available to consumers, as well as so-called "migrating products" – products that are designed and manufactured for

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[1217]EC, *Commission Decision 2010/15/ of 16 December 2009 Laying Down Guidelines for the Management of the Community Rapid Information System RAPEX Established under Article 12 and of the Notification Procedure Established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive)*, [2010], OJ L 22, 26.1.2010, p. 1–64, online: Eur-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010D0015:EN:NOT>.

[1218]*Ibid.* at 1.1.

[1219]Food and Feed are covered by EC, *Regulation No 178/2002 of the European Parliament and of the Council of 28 January 2002 Laying Down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority and Laying Down Procedures in Matters of Food Safety*, OJ L 31, 1.2.2002, p. 1–24, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32002R0178>. The European Rapid Alert System for Food and Feed (RASFF) was put in place more than 30 years ago. It covers all consumer food and feed, and operates analogously to the RAPEX. More on RASFF see: EC, *Rapid Alert System for Food and Feed of the European Union*, 2009, online: European Commission, <http://ec.europa.eu/food/safety/rasff_en >.

professionals, but are likely to be used by consumers, e.g. a power drill or a table saw. Such products may have been purchased, hired or received at no cost by the consumer or they may be part of a service provided to the consumer.[1220] All such situations are covered by RAPEX.

The RAPEX does not cover services, second-hand products supplied as antiques, products reserved for professional use, and products subject to equivalent notification procedures imposed by other Community legislation, such as medicinal products for human use[1221], medical devices[1222], in vitro diagnostic medical devices[1223] and active implantable medical devices[1224]. Consumer products such as toys, cosmetics, electrical appliances, personal protective equipment, machinery, construction materials, and motor vehicles remain covered by the RAPEX requirements in the GPSD even though they are subject to sector-specific Directives, since these Directives do not provide a similar rapid information exchange system.[1225]

[1220] For example: cars and lawn-mowing machines rented or leased in rental offices and tattoo inks and implants (that are not classified as medical devices) implanted beneath the skin of a consumer by a service provider; products used on the premises of a service provider, provided that consumers themselves actively operate a product (e.g. start or stop the machine). Sun-beds used in tanning salons are examples of such products.

[1221] EC, *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001, on the Community Code Relating to Medicinal Products for Human Use* [2010], O.J. L 311 and EC, *Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Veterinary Medicinal Products* [2001], O.J. L 311.

[1222] EC, *Directive 93/42/EEC of 14 June 1993 Concerning Medical Devices* [1993] O.J. L 169.

[1223] EC, *Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in Vitro Diagnostic Medical Devices*, [1998] O.J. L 331.

[1224] EC, *Directive 90/385/EEC of 20 June 1990 on the Approximation of the Laws of the Member States Relating to Active Implantable Medical Devices*, [1990] O.J. L 189.

[1225] In cases where RAPEX notifications are made for products falling under sector directives, a separate notification must be sent (to the service responsible for the sector directive) in addition to the RAPEX notification, since two different notification procedures serve different purposes. Sector notifications are used solely to inform that the product does not comply with the requirements laid down in sectoral directives. For information on the relationship between the notification procedures and their purposes see: EC, *Guidance Document on the Relationship between the GPSD and Certain Sector Directives*, online: European Commission <http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/guidance_gpsd_en.pdf>.

RAPEX consists of several complementary components. On the regional level elements are: the legal framework, which regulates how the system operates (i.e. the GPSD and the Guidelines); the on-line RAPEX application, which allows Member States and the Commission to exchange information rapidly via a web-based platform; the RAPEX Contact Points networks, which consists of the single RAPEX Contact Points responsible for operating RAPEX in all the Member States; the Commission RAPEX Team in the department responsible for the GPSD, which examines and validates documents submitted through RAPEX and maintains and ensures correct operation of the RAPEX system; the RAPEX Contact Points network, which consists of the single RAPEX Contact Points responsible for operating RAPEX in all the Member States; the RAPEX website,[1226] which provides summaries of RAPEX notifications and RAPEX publications, such as RAPEX statistics, RAPEX annual reports and other promotional materials. The national RAPEX network includes: single national RAPEX Contact Point and all the state authorities involved in ensuring consumer product safety.[1227]

RAPEX design and procedure

The overall management and supervision of RAPEX are ensured by the Commission RAPEX Team in the Commission unit responsible for general product safety. The RAPEX website provides summaries of RAPEX notifications and RAPEX publications, such as RAPEX statistics, RAPEX annual reports and other promotional materials.

Information is collected at RAPEX contact points located in each EU Member State. National authorities are required to designate one single RAPEX contact point and

[1226]EC, *RAPEX*, online: EC <http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/reports/index_en.htm >.
[1227]*Op. cit.* 1217 (Decision 2010/15) at 1.2 and 5.1.

ensure that this contact point transmits, through a national exchange of information systems, all relevant information that is to be notified to the European Commission.

Common procedural and operational rules will ensure uniform interpretation and implementation of the system throughout the network of RAPEX national contact points.

The RAPEX procedure comprises four phases:

(i) First, when measures are being taken regarding dangerous goods on a national market, the concerned national market surveillance authority promptly informs the national Contact Point, who then notifies the European Commission;

(ii) Second, the European Commission verifies the conformity of the application with the provisions of the directive and RAPEX operational rules, and disseminates the information to the Contact Points in all other Member States;

(iii) National Contact Points then forward the information to the relevant market surveillance authorities in their respective countries;

(iv) In each Member State, the competent market surveillance authority verifies if the notified product is present on the market and if preventive or corrective measures are necessary; information about measures taken must then be transmitted to the national contact point, who then informs the Commission, which itself communicates the information to the contact points in the other member countries.

RAPEX notification criteria

RAPEX applies to measures which prevent, restrict or impose specific conditions on the marketing and use of consumer products posing a serious risk to the health and safety of consumers.

Under the GPSD, Member States have a legal obligation to notify the Commission when the following four notification criteria are met:

(i) The product is a consumer product covered by RAPEX;

(ii) The product is subject to measures that prevent, restrict or impose specific conditions on its possible marketing or use.

> Both measures taken in relation to dangerous products either on the initiative of a producer/distributor ("voluntary measures") or as ordered by an authority of a Member State ("obligatory measures") must be notified through RAPEX. Article 8(1)(b) to (f) of the GPSD provides a list of the different categories of measures that are reportable under RAPEX, including the following: marking a product with appropriate warnings on the risks it may present; making the marketing of a product subject to prior conditions; warning consumers of the risks that could be posed by a product for certain persons; temporary ban on the supply, offer to supply and display of a product; ban on the marketing of a product and any accompanying measures; withdrawal of a product from the market; recall of a product from consumers; destruction of a withdrawn or recalled product.;

(iii) The product poses a serious risk to the health and safety of consumers.

> Before an authority of a Member State decides to submit a RAPEX notification, it always performs the appropriate risk assessment in order to assess whether a product to be notified poses a serious risk to the health and safety of consumers.[1228]According to Article 2 d) of the GPSD, a serious risk means "any risk which requires rapid intervention by the public authorities, including risks of which the effects are not immediate".[1229] To harmonize the notification conditions and to help national authorities to identify serious risks, the European Commission has put forward new risk assessment guidelines; Appendix 5 presents in detail the risk assessment methodology as a common reference within the RAPEX system;

(iv) The detected serious risk has a cross-border effect.

> A Member State is required to submit a RAPEX notification only if it considers that the effects of the risks posed by a dangerous product go or can go beyond its territory. In the light of the free movement of products in the internal market, and the fact that products are imported into the European Union through different distribution channels and the consumers buy products during stays abroad and via the internet, national authorities are encouraged to interpret the cross-border effects criterion in a fairly broad sense.[1230]

[1228]*Op. cit.* 1217 (Decision 2010/15) at 2.3.1.
[1229]As RAPEX is not intended for the exchange of information on products posing non-serious risks, notifications on measures taken with regard to such products cannot be sent through RAPEX.
[1230]*Op. cit.* 1217 (Decision 2010/15) at 2.4.

RAPEX types of notifications

Under RAPEX Guidelines, there are two types of notifications regarding dangerous consumer products, namely "Article 12 notification" and "Article 12 notification requiring emergency action". As soon as all notification criteria are met, an "Article 12 notification" must be prepared and submitted to the Commission by the Member State. Subsequently, if a product poses a life-threatening risk and/or there have been fatal accidents and in other cases where a RAPEX notification requires emergency action by all Member States, the notifying Member State prepares and submits to the Commission a RAPEX notification classified in the RAPEX application as "Article 12 notification requiring emergency action".[1231] In some cases, when information about product or safety aspects is not complete, questionable, or subject to discussion at the EU level, or when preventive and restrictive measures have not yet been taken by the producer or distributor, or measures are being taking in relation to a consumer product posing a serious risk which however circulates only on the national market, the Member State may disseminate through the RAPEX application a "Notification for information" [1232]clearly indicating the reasons for so doing.

Content of notifications

The Member State has to do everything possible to confirm that all fields of the notification form are completed with the required data. In case when the required information is not available, the national competent authority has to clearly indicate and explain reasons. Once the missing information becomes available, the notifying Member State has to update its notification. [1233]

[1231]*Ibid.* at 3.1.1.
[1232]*Ibid,* at 3.1.2.
[1233]To avoid any unnecessary duplication, the Contact Point checks that the product concerned has not already been notified through the application by another Member State. If the product has already been notified, the Contact Point submits a reaction to the existing notification and provides any additional

To ensure that the information provided is correct and complete, RAPEX Contact Points provide all national authorities that participate in the RAPEX network with instructions on the scope of data required to complete the standard notification form. Even if part of the information required by the Guidelines is not yet available, Member States have to observe the established deadlines and not delay a RAPEX notification on a product posing a very serious or life-threatening risk to the health and safety of consumers.[1234]

To avoid any confusion with similar products of the same category or type that are available on the EU market and to help promptly identify the notified product and take appropriate actions,[1235] notifications sent by the notifying Members State to the Commission include the following types of complete, detail and accurate data:[1236]

(i) Information enabling the notified product to be identified, i.e. product category, product name, brand, model and/or type number, barcode, customs code, description of the product accompanied by pictures, its packaging and labels, etc.;

(ii) Information on the safety requirements applicable to the notified product;

(iii) A risk description of the notified product, including test reports and a complete risk assessment with conclusions and information on known accidents or incidents.

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information, such as additional vehicle identification numbers, a detailed list of importers and distributors, additional test reports, etc.

[1234] *Op. cit.* 1217 (Decision 2010/15) at 3.2.1.

[1235] *Ibid.* at 3.2.1.

[1236] *Ibid.* at 3.2.2.

(iv) Information on the supply chains, importers, and distributors of the notified product;

(v) Information on obligatory or voluntary measures taken such as category, duration, and scope;

(vi) Eventually, requests for confidentiality.[1237]

The notifying Member State as soon as possible and not later than by the deadline, informs the Commission of any changes to the status of the notified measures, to the risk assessment, and to new decisions regarding confidentiality.[1238] In spite of the fact that the Commission examines, validates and disseminates notifications among Member States through the RAPEX application, responsibility for the information provided lies solely with the notifying Member State.[1239]

The confidentiality issue

Before 2000, despite pressures and requests continuously made by consumer organisations, the public, and third-party countries, the information distributed through the RAPEX system was confidential.[1240] With the adoption of the GPSD, as a general rule information regarding dangerous consumer products posing a risk to health and safety has to be in free circulation and accessible to the public.[1241] Overviews of both types of notifications, "Article 12 notifications" and "Article 12 notifications requiring emergency action", are posted on the Commission RAPEX

[1237] *Ibid,* at 3.2.2.
[1238] *Ibid.* at 3.2.3.
[1239] Point 10 of Annex II to the GPSD: *Responsibility for the information provided lies with the notifying Member State.*
[1240] *Op. cit.* 1207 (Le système d'échange rapide d'informations sur les produits dangereux (ou RAPEX) mis en place dans l'Union Européenne)
[1241] Article 16(1) of the GPSD.

website; similarly Member States make this information public in the national language.[1242]

Nevertheless, the information made available to the public is no more than a summary of RAPEX notifications and includes only product identification and information about the risks and measures taken to prevent or restrict those risks. The Commission and the Member States do not disclose entire notifications to the public, as some of this information, due to its nature, is confidential (professional secrets) and needs to be protected;[1243] thus, information relating to the safety properties of products may be disseminated only if circumstances so require to protect the health and safety of consumers.[1244]

Furthermore, a notifying Member State may intentionally request confidentiality in a notification; however, such specific request has to be accompanied by a justification clearly stating the reasons. All requests for confidentiality are subject to examination by the Commission.[1245] The RAPEX Guidelines provide details on technical aspects regarding handling of notifications covered by confidentiality.[1246]

Role of the Commission

There are a few important aspects where the role of the Commission is crucial. The Commission checks all notifications received through the RAPEX application:

[1242] *Op. cit.* 1217 (Decision 2010/15) at 3.3.1.
[1243] The Commission and the Member States should not "disclose information [...] which, by its nature, is covered by professional secrecy in duly justified cases, except for information relating to the safety properties of products which must be made public if circumstances so require, in order to protect the health and safety of consumers". (Article 16 (2) of the GPSD).
[1244] *Op. cit.* 1217 (Decision 2010/15) at 3.3.2.
[1245] Article 16 (1) and (2) of the GPSD.
[1246] *Op. cit.* 1217 (Decision 2010/15) at 3.3.3 and 3.3.5.

(i) Regarding correctness of notifications, the Commission confirms that the relevant requirements set out in the GPSD and in the Guidelines are met; the notified product has not already been the subject of a notification (to avoid any unnecessary duplication); a notification is made in accordance with the criteria set out in Guidelines; the information provided is in line with the applicable product safety legislation and the relevant standards; and the correct notification procedure has been used;[1247]

(ii) Regarding completeness of notifications, the Commission checks that it is complete, giving special attention to product identification, risk description, measures, traceability and distribution channels.[1248]

If there are serious doubts as to the risks posed by the product notified via the RAPEX application, the Commission may carry out an investigation to assess the safety of the product; in particular, it may: ask any Member State to provide information or clarification; ask for an independent risk assessment and independent testing (laboratory or visual) of the product under investigation; consult other entities specializing in the safety of consumer products; etc. During investigation, the Commission may suspend validation of a notification or temporarily remove the overview already published on the RAPEX website. After an investigation, depending on the outcome, the Commission may validate and distribute through the RAPEX the notification previously suspended, change the status of the notification, or permanently withdraw the notification from the RAPEX.[1249] While notifications distributed through the RAPEX are kept in the system for an unlimited period of time, the Commission may permanently or temporarily withdraw a notification from the RAPEX if there is proof that the notification criteria are not met, or there is proof

[1247] *Ibid.* at 3.4.1.
[1248] *Ibid.* at 3.4.2.
[1249] *Ibid.* at 3.4.4 and 3.5.

that products covered by a notification are no longer marketed and that all items have already been withdrawn and recalled in all Member States, or Member States agree that it is not useful to exchange information on certain safety aspects that have been notified through the RAPEX application. The Commission may re-publish a RAPEX notification on the RAPEX website, if the status of application has been changed.[1250]

Furthermore, in accordance with Point 9 of Annex II to the GPSD, the Commission may inform the national contact points regarding products posing serious risks imported into or exported from the Community and the European Economic Area. In other words, the Commission may transmit information to the Member States about dangerous non-food consumer products of EU and non-EU origin that, according to the information available, are likely to be on the EU market. This mainly concerns information that the Commission receives from third countries, international organizations, businesses, or rapid alert systems operating abroad.[1251]

Follow-up by the Member States

Member States ensure appropriate follow-up to RAPEX notifications and to information on dangerous products sent by the Commission.[1252] Upon receipt of a notification, a Member State, in cooperation with business associations in non-binding voluntary compliance, examines the information provided in the notification and takes appropriate action in order to:

(i) Establish whether the product is being marketed on its territory;

(ii) Assess what preventive or restrictive measures should be taken with regard to

[1250] *Ibid.* at 3.8 and 3.9.
[1251] *Ibid.* at 3.6.
[1252] Even though notifications for information do not require any specific follow-up, Member States are encouraged to ensure follow-up to such notifications.

the notified product found on its market;

(iii) Perform additional risk assessment and testing of the notified product; and

(iv) Collect any additional relevant information.

Member States communicate to the Commission any follow-up regarding RAPEX notifications and transmit detailed, complete and updated information in the form of reactions to notifications, regarding: the presence on the market of the notified product, including full details of the product in question; measures taken (type, category, scope, duration); risk assessment made, including the results of tests; and relevant additional information.[1253]

Deadlines

The Guidelines establish strict timeframes for the Commission and Member States regarding deadlines to submit notifications, follow-ups and other procedures. Namely, notifications under "Article 12 notification" have to be submitted in 10 days; under "Article 12 notification requiring emergency action" in 3 days. For follow-ups, the deadlines are 45 and 20 days accordingly.[1254]

Risk assessment methodology

The Guidelines include a risk assessment methodology (Risk Assessment Guidelines for Consumer Products) developed by a working group of Member State experts and

[1253] *Op. cit.* 1217 (Decision 2010/15) at 3.7 and 4.
[1254] *Ibid.* at Appendix 3.

recommended to all EU national authorities to assess the level of risks posed by consumer products and to decide whether a RAPEX notification is necessary.[1255]

Before a RAPEX notification is sent to the Commission, the risk assessment is always performed by an authority of a Member State that either carried out the investigation and took appropriate measures or monitored voluntary action taken with regard to a dangerous product by a producer or a distributor.[1256] Any unclear issues should be resolved by the Contact Point and responsible authority before a notification is transmitted through RAPEX.[1257]

The Risk Assessment Guidelines for Consumer Products are based on a quantitative characterization of risks assessment method adapted to the specific requirements of non-food consumer products.[1258] Guidelines divide risk assessment technique into three phases: Phase 1: determines how severe the consumer's injury may be through anticipating an injury scenario in which the intrinsic product hazard harms the consumer; Phase 2: determines the probability of the consumer being injured in practice by the intrinsic product hazard; and Phase 3: combines the hazard (in terms of severity of the injury) with the probability (in terms of a fraction) to obtain the risk.[1259]

[1255]*Ibid.* at 2.3.2.

[1256]Risk assessments on dangerous consumer products submitted by producers and distributors to the competent authorities of Member States should include a detailed description of the risk. National authorities receiving such assessments examine their content and analyze the risk. Since risk assessments carried out by producers and distributors are not binding on Member State authorities, it is therefore possible for an authority of a Member State to come to a different conclusion regarding the risk assessment from a conclusion drawn in a business notification. (Article 5(3) of the GPSD).

[1257]*Op. cit.* 1217 (Decision 2010/15) at 2.3.3.

[1258]The base of RAPEX assessment methodology was elaborated in Kinney GF, Wiruth AD *Practical Risk Analysis for Safety Management,* China Lake, CA: NWC Technical Publication 5865, Naval Weapons Center, California, 1976.

[1259]*Op. cit.* 1217 (Decision 2010/15) at 2.2 and Annex 5 *Risk Assessment Guidelines for Consumer Products*.

A few steps have to be taken to assess the risk of the product. First, the product should be identified unambiguously, including name, brand, model name, type number, etc.[1260] Second, keeping in mind that the same product might have not one but many hazards, product hazard/hazards have to be determined, e.g. electrical hazard, choking hazard, heat or fire hazard, etc.[1261] Third, since, the abilities and behaviour of the consumer using the product may greatly influence the level of risk, it is crucial to have a clear idea of the type of consumer pictured in the injury scenario; injury scenarios with different types of consumers have to be considered. Fourth, possible injury scenarios have to be elaborated on the base of the schema: product defect →dangerous situation → accident → injury. Fifth, different degrees of severity of the injury caused to the consumer under probable scenarios have to be established. Sixth, the probability that an injury scenario may indeed materialize during the expected lifetime of the product has to be calculated. Finally, once the severity of the injury and the probability have been determined, the risk level can be assessed by combining both. Once the risk assessment is complete it can be used to decide whether action needs to be taken to reduce the risk and thus prevent harm to a consumer's health.[1262]

Enlargement of the RAPEX

Article 12 (4) of the General Product Safety Directive reserves the possibility of participation by others entities in the RAPEX. Applicant countries to the European Union, countries outside the EU, and international organisations are not allowed to participate except under special arrangements concluded and agreed upon by the

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[1260] When the hazard may be limited to a distinct part of the product which can be separated from it and also separately available to consumers, e.g. rechargeable batteries of notebook computers, it is sufficient only to assess the distinct part of the product.
[1261] Table 2 of the Guidelines groups hazards linked to the size, shape and surface of a product, to potential, kinetic or electric energy, to extreme temperatures, and others.
[1262] *Op. cit.* 1217 (Decision 2010/15) at 3.1 to 3.7 and Annex 5.

European Union. Such partnership agreements are based on reciprocity and include provisions on confidentiality corresponding to those applicable in the Union.

During the 1990s and early 2000s when Europe was going through the unification process, the European Commission denied immediate access to candidate member states to the RAPEX. Instead, the European Commission provided technical assistance to set up a system similar to the RAPEX system, the so-called TRAPEX or Transitional RAPEX[1263]. Nine countries in Central and Eastern Europe took part in TRAPEX: Bulgaria, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia and Slovenia; a Secretariat based in the consumer market surveillance authority of Hungary provided administration and coordination. Full access to RAPEX was granted only after the candidate countries formally joined the EU.

Nowadays, the RAPEX network comprises the European Economic Area (EEA) which consists of the 28 Member States of the European Union (EU) and the three European Free Trade Association (EFTA) States: Iceland, Liechtenstein, and Norway.[1264] The EFTA Surveillance Authority, which is based in Brussels, plays the same role as the European Commission in the RAPEX network. The RAPEX notifications are transmitted to the EFTA Surveillance Authority, which disseminates

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[1263]F.Maniet & B.Dunaj, eds., *The implementation process of E.U. directives on product safety, product liability and unfair contract terms: The European Directive on general product safety and its implementation in the E.U Member states*. (Louvain: Centre de Droit de la Consommation, Université Catholique de Louvain, 1994) at 59-79.

[1264]28 Member States of the European Union are Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Ireland, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Spain, Slovakia, Slovenia, Sweden and the United Kingdom.
It was established by the EEA Agreement, an international agreement which enables EFTA states to participate fully in the European internal market. For the sake of clarity, the EFTA Surveillance Authority issues corresponding guidelines applicable in the EFTA States; this guide simplifies the work of economic operators and the competent authorities in the EFTA States by defining the particular conditions, especially isolated circumstances or products, for which notification is not appropriate. For more, see: *RAPEX Notifications* online: EFTA Authority <http://www.eftasurv.int/internal-market-affairs/notifications/rapex-notifications/>.

them to the participating countries. Equally, any measures or actions taking by the EFTA countries are communicated to the Surveillance Authority which verifies the completeness of the information and, depending on the type of the notification, assesses the compliance of the national measures with the EEA rules and forwards the information to the European Commission.

International Cooperation

RAPEX-CHINA

In recent years China has become one of the biggest exporters of consumer products to the EU. For instance, around 85% of all toys on the European market come from China.[1265] No wonder that products of Chinese origin represent a large percentage of the dangerous products notified under the RAPEX system. The Chinese authorities are concerned about this situation and are taking measures to ensure that the safety requirements are adhered to.[1266] The Memorandum of Understanding (MoU) signed in January 2006 between the European Commission's Directorate General for Health and Consumer Policy (DG SANCO) and the General Administration of Quality Supervision, Inspection and Quarantine of China (AQSIQ) inaugurated the "RAPEX-CHINA" system. Under this agreement, China receives partial and indirect access to RAPEX. The "RAPEX-CHINA" on-line application provides regular and rapid transmission of data between the EU and China product safety administration. DG SANCO communicates to the Chinese authorities the information on consumer products originating from China which have been notified as dangerous by the authorities of the Member States via RAPEX. AQSIQ conducts investigation regarding all the notifications and, when necessary, adopts measures to prevent or

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[1265]EC, *Bilateral Cooperation*, online: European Commission <http://ec.europa.eu/consumers/consumers_safety/international_cooperation/bilateral_cooperation/index_en.htm>.

[1266]EC, *RAPEX-CHINA Application*, online: European Commission *<ec.europa.eu/consumers/cons_safe/news/rapex_china_en.pdf>*.

restrict further export of the notified dangerous consumer products to the EU. Furthermore, AQSIQ sends the Commission a detailed report on the results of the investigations and measures adopted with regard to notified products. These reports are submitted quarterly.[1267] Therefore, RAPEX-CHINA allows the Chinese authorities to follow up directly on notifications regarding unsafe products coming from their territory and identify areas where safety standards are weak.

In November 2008 the MoU was upgraded and strengthened in view of the significant progress made over the first three years of cooperation with China. The updated MoU includes: a) clearer reference to the RAPEX-China system and the roles in this respect of both sides; b) more opportunities to cooperate, for example by undertaking joint enforcement actions; c) establishment of working groups between the EU and AQSIQ; d) clarification on the confidentiality understanding regarding the exchange of information; and e) giving a role to the Member States and stakeholders in the cooperation framework.[1268]

Another upgrade took place in October 2010. Both partners decided that the existing Working Groups on Medical Devices and Cosmetics under the DG ENTR-AQSIQ Consultation Mechanism on Industrial Products will be continued under the Memorandum of Understanding on Administrative Co-operation Arrangements between DG SANCO and AQSIQ.[1269]

[1267]EC, *RAPEX-CHINA System*, online: European Commission <http://eeas.europa.eu/delegations/china/eu_china/food_safety_and_consumer_protection/rapex_china_system/index_en.htm>.

[1268]EC, *Memorandum of Understanding on Administrative Cooperation Arrangements Between DG SANCO and AQSIG*, online: European Commission <http://ec.europa.eu/consumers/archive/safety/int_coop/docs/memorandum_china_annexes.pdf>.

[1269]EC, *Joint Statement of Extension of Memorandum of Understanding on Administrative Cooperation Arrangements Between DG SANCO and AQSIG*, online: European Commission <http://ec.europa.eu/consumers/archive/safety/int_coop/docs/joint_statement_of_extention_of_mou_on_adm_coop_arrangements_between_sanco__aqsiq_en.pdf>.

RAPEX-US

In February 2005, under the Transatlantic Economic Partnership, DG SANCO and the US Consumer Product Safety Commission agreed a set of Guidelines to strengthen transatlantic cooperation in product safety. These guidelines encompass the regular exchange of (non-confidential) information and establish a series of joint initiatives to help safeguard consumers' health and safety.

The areas of cooperation under these Guidelines include: a) exchange of scientific, technical, and regulatory information to help ensure the safety of consumer products; b) exchange of information on emerging issues of significant health and safety relevance within their scope of authority (information regarding products and manufacturers may be exchanged if necessary and permitted under the laws applicable in the EU and U.S.); c) exchange of information on standardization activities and cooperation in comparatively assessing specific product safety standards and in initiating standardization activities according to their respective rules and procedures; d) exchange of general information on market surveillance and enforcement activities; d) exchange of information on risks identified and measures taken with respect to products originating from each of their respective territories; e) exchange of information in case of major withdrawal/recall operations of mutual interest; and f) exchange of information on risk assessment and product testing.[1270]

RAPEX-Japan

In April 2008, Europe and Japan agreed to strengthen their cooperation at international and bilateral levels in the area of product safety. In a *Joint Statement*

[1270]EC, *Guidelines for Information Exchange and on Administrative Cooperation between the U.S. Consumer Product Safety Commission and the Directorate- General Health and Consumer Protection of the European Commission*, online: European Commission <http://ec.europa.eu/consumers/archive/cons_safe/prod_safe/coop_USA_guidelines.pdf>.

both sides agreed to enhance the exchange of information on non-food product safety policies. In particular, it was agreed to share publicly available information on non-food product safety policies as well as on information on recent major recalls and withdrawals from the market of dangerous non-food products, including those imported from third countries, triggered by accidents or by market surveillance and monitoring activities in Japan and the EU.[1271]

Evaluation of the RAPEX

Number of notifications

The 2015 annual report released by the Commission shows a continuous positive dynamic regarding the number of notifications sent through the RAPEX system in recent years. The number of notifications has been increasing dramatically, from 4 in 1984 to 2323 in 2015. Nevertheless, during the 80s and 90 less than 100 notifications were sent each year. With the adoption of the General Product Safety Directive in 2001, the number of measures notified in which a serious risk was involved has grown exponentially from 67 in 2003 to 2072 in 2015.[1272]

More notifications result from: increased awareness and attention given to product safety by authorities and companies; the greater number of market surveillance actions carried out jointly by several national authorities; the training and seminars provided by the European Commission for different stakeholders; and the

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[1271] *17th Japan-EU Summit Tokyo: 23 April 2008 Joint Press Statement*, online: EU-Asia <http://www.eu-asiacentre.eu/links.php?cat_id=25&level=0&tree=25&code=4 >.

[1272] EC, *2015 Annual Report on the Operation of the Rapid Alert System for Non-Food Dangerous Products RAPEX*, 2016, online: the Directorate-General for Health and Consumers of the European Commission <http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/reports/docs/rapex_annual_report_2015_en.pdf >.

enlargement of the European Union to 27 members states between 2004 and 2007.[1273]

In 2015, the European Commission distributed through the RAPEX system 2123 notifications on consumer products posing serious risks to health and safety:

(i) 2072 of these notifications were distributed to Member States as notifications under Article 12 of the GPSD (preventive or restrictive measures on products presenting a serious risk to the health and safety of consumers either taken by national authorities or carried out voluntarily by economic operators, e.g. stopping or banning of sales, withdrawals from the market, recalls from consumers);

(ii) 320 notifications were distributed to Member States under Article 11 of the GPSD (measures taken by national authorities with regard to products posing risks classified as less than serious);

(iii) 51 notifications were distributed to Member States for information purposes, as they did not qualify for distribution under either Article 12 or Article 11 (professional products and to products causing other risks, such as environmental risks).

Product category of the notified product

The product categories most frequently notified through the RAPEX system in 2015 were:

[1273]EC, *Keeping European Consumers Safe 2011 Annual Report on the Operation of the Rapid Alert System for Non-Food Dangerous Products RAPEX*, 2011, online: the Directorate-General for Health and Consumers of the European Commission <http://ec.europa.eu/consumers/safety/rapex/docs/2011_rapex_report_en.pdf>.

(i) Toys (555 notifications, 27%);
(ii) Clothing, textiles and fashion items (346 notifications, 17%);
(iii) Motor vehicles (214 notifications, 10%);
(iv) Electrical appliances (199 notifications, 9%);
(v) Jewellery (117 notifications, 6%).

Country of origin of the notified product

China (including Hong Kong) is identified as the country of origin in 62% of cases in 2015. The high number of RAPEX notifications concerning Chinese products results from the significant market penetration of Chinese manufactured consumer products in European markets. Fifteen percent of all notifications sent through RAPEX concerned products originating from the 28 EU Member States and 3 EFTA/EEA countries. Ten percent of all notifications sent through RAPEX contained no information about the country of origin of the notified product; it remains a very low level, given that in 2004, for instance, the number of cases with an unidentified country of origin was as high as 23%.

Notifications by type of risk

Some RAPEX notifications concern products presenting more than just one risk (a toy can pose a choking risk due to small parts and, simultaneously, a chemical risk due to excessive levels of a restricted substance). The total number of notified risks is accordingly higher than the total number of notifications. The five most frequently notified risk categories:

(i) Chemical 572 notifications (25%);
(ii) Injuries 524 notifications (22%);
(iii) Choking 395 notifications (17%);

(iv) Electric shock 281 notifications (12%);

(v) Strangulation 177 notifications (8%).

Notifying country

In 2015, 28 EU Member States, plus 2 EFTA states, sent notifications through the RAPEX system.[1274] The following are the five most frequently notifying countries: Spain (239 notifications, 11%); Hungary (228 notifications, 10%); Germany (208 notifications, 9%); Bulgaria (151 notifications, 7%); France (135 notifications, 6%).

Type of notified measure

The share of cases in which compulsory preventive and restrictive measures have been ordered by national authorities is 60% (1289 notified cases). In 750 notified cases (35%), economic operators took preventive and restrictive measures on a "voluntary" basis (without the formal intervention of a national authority). In 33 cases (1.4%), "voluntary" actions were complemented by compulsory measures taken by the national authority.

Reactions

In 2015, all the EU Member States, plus Norway and Iceland, sent 2744 reactions to RAPEX notifications. Only Liechtenstein did not report a reaction to any RAPEX notifications. The following five countries accounted for 42% of all reactions: Spain (319 reactions, 12%); Denmark (209 reactions, 8%); Norway (186 reactions, 8%); Netherlands (203 reactions, 7%); Sweden (181 reactions, 7%). Ninety percent of all reactions concerned RAPEX notifications related to the following six product categories: motor vehicles (1943 reactions, 72%); toys (226 reactions, 8%); clothing,

[1274]Liechtenstein did not send RAPEX notifications.

textiles and fashion items (97 reactions, 4%); electrical appliances (60 reactions, 2%); jewellery (55 reactions, 2%); childcare articles (82 reactions, 3%).

RAPEX- China

Between 2006 and 2013, AQSIQ submitted 16 quarterly reports on enforcement action taken with regard to RAPEX notifications.[1275] Chinese authorities have investigated and adopted measures in relation to 2549 RAPEX notifications. 1459 investigations (57%) were concluded by preventive and restrictive measures either adopted by AQSIQ or taken voluntarily by a Chinese manufacturer/exporter. Export bans which prevent the further export of dangerous consumer products to the EU and thus complement measures taken by the European authorities, remain the most frequently taken measure. A strengthened supervision over Chinese companies involved in the manufacturing and/or export of dangerous goods, the second most frequent measure, takes place when production has already stopped and thus no export ban can be imposed.

In 1090 cases (43%) no measures have been taken, mainly because a responsible Chinese manufacturer could not be found, often due to lack of accurate and complete information regarding producer, lack of proof of their involvement in the manufacturing of dangerous products, or company bankruptcy (liquidation).

[1275] "Rapid Alert System on Dangerous Products - RAPEX 2013", *EU Business,* (25 March 2014), online: EU Business <http://www.eubusiness.com/topics/consumer/rapex-2013/>.

3.4.2 NAFTA and information exchanges on dangerous consumer products

The success of RAPEX in the EU has never been cloned in North America. Only recently have a few steps been made towards duplicating the European accomplishment. However, the newly adopted Canadian consumer product safety law strengthens the legal and institutional frameworks for a RAPEX-like system to be developed.

Canada Consumer Product Safety Act 2010

Until recently, Canada did not have proper defense mechanisms against dangerous consumer products. Many crucial elements such as product recalls and information exchanges did not have a clear legal basis.[1276] Lately, new Canadian regulations fulfilled the legal vacuum and introduced new rules of the game for the economic operators on consumer markets.

Before the adoption of the *Canada Consumer Product Safety Act 2010* (CCPSA),[1277] consumer product recalls and information exchanges in Canada were primarily voluntary actions. The *Hazardous Products Act* of 1985[1278] (HPA) provided inadequate instruments for government intervention and limited abilities to initiate consumer product recalls. For example, the HPA did not grant government with the authority to issue product recall orders. Rather, the HPA remained largely dependent on industry taking a voluntary approach to product recalls and related matters out of

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[1276] N. Vézina, F. Maniet, "La sécurité du consommateur au Québec... deux solitudes : mesures préventives et sanctions civiles des atteintes à la sécurité" *Les Cahiers de droit*, 49:1, (2008) at 57-95.
[1277] *Canada Consumer Product Safety Act 2011*, (S.C. 2010, c. 21), online: Justice Laws <http://laws-lois.justice.gc.ca/eng/acts/C-1.68/index.html>.
[1278] *Hazardous Products Act 1985*, (R.S.C., 1985, c. H-3), online: Justice Laws <http://laws-lois.justice.gc.ca/eng/acts/H-3/>.

concern for potential liability and reputation consequences.[1279] Product recall itself was only a logistic action and did not involve the obligation to inform consumers.[1280] Furthermore, according to HPA guidelines, if an incident with a consumer product circulating on the Canadian market happened abroad, the distributor/importer or producer/exporter did not have the obligation to take any action, or to inform consumers or the competent authorities about a potential danger. Likewise, if an unsafe product was recalled from the national market, the HPA did not require the dissemination of notifications regarding the recall to foreign entities.

The regulatory regime introduced by the CCPSA reshapes dramatically the government approach to the matter of consumer product safety in the new global environment. Namely, the Act states mandatory incident reporting criteria and authorizes the government to order and supervise all steps of the product recall. The Act fosters cooperation with foreign governments and international organizations, in particular by sharing information, in order to effectively address dangers posed by consumer products.[1281]

The purpose of the CCPSA is to protect the public by addressing or preventing dangers to human health or safety that are posed by consumer products in Canada, including those that circulate within Canada and those that are imported.

In general, the Act, as any comparable piece of legislation on consumer safety, sets the rules of the game for consumer market operators. For instance, it prohibits the manufacture, import, advertisement, or sale to a consumer of a product that is a

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[1279]Paul Michael Blyschak *et al.* "The Canada Consumer Product Safety Act Now in Force", (21 June 2011), online: McCarthy Tétrault <http://www.mccarthy.ca/article_detail.aspx?id=5456>.
[1280]"A consumer product recall is the removal from distribution, sale, or consumer use of a product that does not comply with legislation in Canada, or poses an unacceptable risk to the health and safety of consumers or users of the product." (*Recalling Consumer Products - A Guide For Industry*, online: Health Canada <www.hc-sc.gc.ca/cps-spc/pubs/indust/recalling-guide-2005-04-rappel-eng.php>).
[1281]*Op. cit.* 1277 (*Canada Consumer Product Safety Act* 2011), at art. 3.

danger to human health or safety, the subject of a recall order, or does not meet the requirements set out in the regulations.[1282]

Analogously to the RAPEX, the definition of "consumer product" means a product, including its components, parts or accessories, that may reasonably be expected to be obtained by an individual to be used for non-commercial purposes, including for domestic, recreational and sports purposes, and includes its packaging.[1283] Nevertheless, a broad array of products such as food, drugs, cosmetics, vehicles and etc. fall outside the legal sphere of the Act and are covered only by the sector-specific legislation.[1284] In contrast, such products in the EU remain covered by the RAPEX even when subject to sector-specific Directives, as long as these Directives do not provide a similar rapid information exchange system.[1285]

The Act defines "danger to human health or safety" as any unreasonable hazard - existing or potential - that is posed by a consumer product during or as a result of its normal or foreseeable use and that may reasonably be expected to cause the death of an individual exposed to it or have an adverse effect on that individual's health - including an injury - whether or not the death or adverse effect occurs immediately after the exposure to the hazard, and includes any exposure to a consumer product that may reasonably be expected to have a chronic adverse effect on human health. Such broad definitions of "consumer products" and "danger to human health or safety" combine to create a wide general prohibition, the reach of which will

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[1282] *Ibid.* at art. 5 to 8.
[1283] *Ibid.* at art. 2.
[1284] The Schedule 1 of the Act lists consumer products covered by specific legislation: *Food and Drugs Act* embraces food, drugs and cosmetics (*Food and Drugs Act 1985*, R.S.C., 1985, c. F-27), online: Justice Laws <http://laws-lois.justice.gc.ca/eng/acts/F-27/>), *Motor Vehicle Safety Act* deals with vehicles (*Motor Vehicle Safety Act 1993*, (S.C. 1993, c. 16), online: Justice Laws < http://laws-lois.justice.gc.ca/eng/acts/M-10.01/ >) and etc.
[1285] For example, the sector- specific Canadian *Motor Vehicle Safety Act* prescribes defects reporting procedure and how to evaluate safety risks arising from such defects.

ultimately be left to determination by Health Canada.[1286]

If there are reasonable grounds to believe that a consumer product is a danger to human health or safety under the Act, Health Canada may issue a written order to recall or a written order to take measures in order to stop the manufacturing, importation, packaging, storing, advertising, selling, labeling, testing or transportation of the dangerous consumer product. If no actions are taken within the time specified, Health Canada, on its own initiative and at the expense of the manufacturer/importer, will carry out the recall or measure required.

Certainly, the Act does not institute a rapid alert network. Nevertheless, many features of the Act could help in designing a rapid alert system for information exchanges on dangerous goods.

Similarly to the RAPEX, the Act sets up mandatory incident reporting requirements. For its part, Article 14 provides criteria under which incident reports must be submitted. "Incident" means, with respect to a consumer product:

(i) an occurrence in Canada or elsewhere that resulted or may reasonably have been expected to result in an individual's death or in serious adverse effects on their health, including a serious injury;

(ii) a defect or characteristic that may reasonably be expected to result in an individual's death or in serious adverse effects on their health, including a serious injury;

[1286] *Op. cit.* 1277 (*Canada Consumer Product Safety Act 2011*) at art. 2.

(iii) incorrect or insufficient information on a label or in instructions - or the lack of a label or instructions - that may reasonably be expected to result in an individual's death or in serious adverse effects on their health, including a serious injury; or

(iv) a recall or measure that is initiated for human health or safety reasons by:

a foreign entity;

a provincial government.

The Act specifics that a recall or measure that is initiated by a foreign entity must be qualified as an incident. General definition "foreign entity" prescribes to collect information from a broad range of sources such as foreign governments or foreign public bodies; this would include existing alert networks such as the RAPEX. Information from such sources will have to be collected and analyzed and relevant actions taken accordingly; meanwhile the Act sets out the framework only for a passive alert network, as it does not call to share information regarding incidents in Canada with foreign entities.[1287]

Equally to the RAPEX, the Act establishes time frames for reporting. After economic operators become aware of the incident, the Act gives them two days to provide the authorities and, if applicable, the person from whom they received the consumer product, with all the information in their control regarding any incident related to the product. Furthermore, a written report containing information about the incident, the specific product involved in the incident, as well as products, which may be involved in a similar incident, and any measures proposed to be taken has to be submitted within 10 days after the day on which the market operator becomes aware of the

[1287] *Op. cit.* 1277 (*Canada Consumer Product Safety Act* 2011), at art. 14.1.

incident.[1288]

The provisions of the Act concerning government disclosure of confidential business and product information echo the RAPEX approach to the matter.[1289] Confidential business information in relation to a consumer product may be disclosed to a government body that carries out functions relating to the protection of human health without the consent of the business operator and without prior notice provided that the business operator will be notified not later than the next business day.[1290] When the consumer product raises a serious and imminent danger to human health and when the disclosure of the information is essential to address the danger, confidential business information may be disclosed to anyone without consent, prior to or following notifications.[1291] Accordingly, information about a danger to human health or safety that a consumer product poses may be disclosed to the public.[1292]

Shortly after the adoption of the Act, Health Canada elaborated templates of *Consumer Product Incident Report Forms for Industry and Consumers*.[1293] The forms require the consumer or market operator to submit detailed information about the product involved in the incident (type, label or package data, place and means of obtaining), information about who is reporting (involved person, business operator, third party), information about the incident (date of the incident, number of people affected and their age and sex, incident and injury type, body parts affected and treatment revived), as well as supporting documents and pictures. Foreign Recall notifications are listed as triggering documents for reporting an incident.

[1288]*Ibid.* (*Canada Consumer Product Safety Act* 2011), at art. 14.2 and 14.3.
[1289]Disclosure of confidential information should not affect the provisions of the *Privacy Act*. (*Privacy Act 1985*, (R.S.C., 1985, c. P-21), online: Justice Laws <http://laws-lois.justice.gc.ca/eng/acts/P-21/index.html>)
[1290]*Op. cit.* 1277 (*Canada Consumer Product Safety Act* 2011), at art. 16.
[1291]*Ibid.* (*Canada Consumer Product Safety Act* 2011), at art. 17.
[1292]*Ibid.* (*Canada Consumer Product Safety Act* 2011), at art.18.
[1293]*Report an Incident Involving a Consumer Product*, online: Health Canada <http://www.hc-sc.gc.ca/cps-spc/advisories-avis/incident/index-eng.php>.

Nevertheless, the document does not provide specific guidelines for action to be taken after a notification from foreign body is received.

No Guidelines on how information regarding incidents should be assessed, collected and used have been elaborated and no uniform risk assessment methodology proposed. Nevertheless, the Act constitutes a first step forward as it forces economic operators to monitor and gather incident data from global sources. However, as already pointed out, the system remains a passive one, as it does not order the sharing with foreign entities of data on recalls originated in Canada.

Towards a North American RAPEX?

Taking into consideration the high priority of consumer safety on market places and cross-border trade within the NAFTA region, one still remains surprised by the fact that a system similar to the RAPEX does not exist on the North American continent. Are there circumstances which create obstacles for the US, Canada, and Mexico to institute a functional and effective network for information exchange on dangerous consumer products?

First, it should be remembered that North America and Europe have completely different geo-political structures. On one side of the Atlantic, most European countries have been amalgamated under the umbrella of the super-government of the EU, with straightforward goals to promote the interests of consumers and to ensure a high level of consumer protection, as well as to contribute to protecting the health, safety and economic interests of consumers.[1294] On the other side, the US, Canada and Mexico are without any mutual political structure and without any consumer

[1294]EC, *Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, signed at Lisbon, 13 December 2007*, [2007] J.O. L C 306/01, at Art. 169, online: EUR-Lex <http://eur-lex.europa.eu/JOHtml.do?uri=OJ:C:2007:306:SOM:en:HTML>.)

safety provisions ever being referred to in the NAFTA. Economic agreements on this side of the Atlantic promote trade and business cooperation, with consumer protection not being explicitly held as a priority.[1295] Such a discrepancy might be seen as a major reason why North America lacks a political determination to have a sound, vigorous and compulsory policy on consumer safety. The dominant ideology is that interventions in consumer markets must remain voluntary, even when safety is at stake.

However, Canada, as reflected by the adoption of the new CCPSA, now comes closer to the EU government-driven, regulatory approach as opposed to the passive American CPSC voluntary system mainly driven by consumer complaints.[1296]

Second, the jurisdiction of the new CCPSA differs from the jurisdiction of the U.S. *Consumer Product Safety Act* due to discrepancies in the definitions of a consumer product. Under the U.S. CPSA, a consumer product is any article, or component part thereof, produced or distributed for sale to a consumer for personal use, consumption or enjoyment and does not include "any article which is not customarily produced or distributed for sale to, or use or consumption by, or enjoyment of, a consumer."[1297] The CCPSA's definition of a consumer product embraces a much broader range of goods. Under the Act, a consumer product is a product, including its components, parts or accessories, that may reasonably be expected to be obtained by an individual to be used for non-commercial purposes, including for domestic, recreational and sports purposes, and includes its packaging. While the US law stipulates that only products to be sold or marketed to consumers are consumer products, Canadian law

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[1295]Patti Goldman, *NAFTA and Consumer Rights: How NAFTA Jeopardizes Health, Safety and Environmental Standards*, (October 1993), online: Multinational Monitor <http://www.multinationalmonitor.org/hyper/issues/1993/10/mm1093_04.html>.
[1296]*Canada Poised to Launch, Enforce New Consumer Product Safety Act, Database*, (20 June 2011), online: PRWeb <http://www.prweb.com/releases/2011/6/prweb8579747.htm>.
[1297]*Consumer Product Safety Act*, 1972, (PL 92-573; 86 Stat.1207) at art. 3.5 and art. 3.5.A.

virtually includes any product if there is reason to believe that consumers are likely to obtain such product. For example, industrial machinery operated for personal use will be subject to the Canadian law, while not to the US Act.

There are also significant differences in the reporting obligations. Under the Canadian law national and foreign businesses or/and authorities require to report when incorrect/insufficient information about the product or a defect/characteristic of the product may reasonably be expected to result in an individual's death or in serious adverse effects on their health, including a serious injury. Under the U.S. Act, a manufacturer or distributor has to report only when he obtains information which reasonably supports the conclusion that the product: is banned; fails to comply with applicable safety rules, regulations, or voluntary standards; contains a defect which could create a substantial product hazard; or creates an unreasonable risk of serious injury or death.[1298] Hence, under the CPSC incorrect/insufficient information about dangerous product does not trigger obligations to report.

Furthermore, under the Canadian act, the level of potential harm that requires a report is arguably much broader and includes not only immediate effect after injury, but also a chronic adverse effect on human health, for example from long lasting exposure to chemical components of a consumer product.

Time frames for reporting are different as well. The U.S. CPSA requires reporting immediately upon learning of information from which one could reasonable conclude that the product may contain a defect that presents a substantial product hazard or presents a risk of serious injury or death. In accordance with U.S. CPSC's guidelines,

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[1298] *Ibid.* (*Consumer Product Safety Act*, 1972), at art. 15b.

immediately is a twenty-four hour period.[1299] In contrast, under the CCPSA reporting must take place within two days after becoming aware of the incident.

Such differences between the relevant US and Canadian laws are indeed problematic for the creation of a sound and effective network for the mutual exchange of information on consumer products held to be dangerous on either side of the border.

Despite such obstacles, the progress made in the field of information exchange on dangerous consumer products provides a cautious optimism regarding a possible RAPEX-like system in North American. The new *Canadian Consumer Product Safety Act*, recent North American agreements, and joint product recalls all together may be seen as paving the way for increased cooperation on the matter. Cooperation will be promoted and facilitated, but it would be premature to conclude that these initiatives will lead to the setting-up of a joint network for the exchange of information on dangerous consumer goods between the US, Canada and Mexico.

Indeed, it would be naïve to believe that the geo-political situation in North America will change in the near future. Most probably, the U.S. and Canadian governments will continue to promote interstate trade and business. Consumer protection will stay an important but not high priority issue. Under such circumstances, only currently existing instruments and bodies of consumer protection have to be used or urgently modified to institute the North American equivalent of RAPEX.

The following scenarios could be considered.

[1299] *Recall Handbook, A Guide for Manufacturers, Importers, Distributors and Retailers on Reporting Under Sections 15 and 37 of the Consumer Product Safety Act and Section 102 of the Child Safety Protection Act and Preparing for, Initiating Including CPSC Fast Track Product Recall Program and Use of Social Media*, online: CPSC <https://www.cpsc.gov/s3fs-public/8002.pdf>.

The first and most realistic one is that already existing legal instruments for information exchange on dangerous consumer products will be used without major changes. U.S. and Canadian joint recalls will be the key outcome of such teamwork. Differences in law and lack of important RAPEX features such as common risk assessment methodology or joint interstate body will limit the effects of such cooperation.

A second possible development would be progressive legal unification on both sides of the border and the addition of missing legal elements. The introduction of a permanent joint body exclusively responsible for information exchange on dangerous consumer products would be an ideal culmination of such collaboration. From the technical and financial sides, it would be an easy task in view of the fact that government bodies with functions similar to RAPEX already exist. The biggest challenge will be on the legal dimension of the matter. Binding legal consensus is a rare practice on this side of the Atlantic. Rather, a non-binding legal arrangement looks like a more pragmatic solution under the circumstances. Taking into account the slow progress over recent decades in interstate negotiations on consumer protection matters, even this scenario looks not quite realistic in the foreseeable future. It seems that only mass-scale disasters and resulting pressure from an outraged public to make the consumer market a safer place might force politicians to act promptly and make necessary changes.

However, as already pointed out, Article 14 of CCPSA requires reporting when incidents occur worldwide;[1300] and recalls are initiated by a foreign entity,[1301] regardless of discrepancies in regulations triggering a recall or incident reporting. The manufacturer/importer has to verify if the product or its components have ever been

[1300]An occurrence (of incident) in Canada or elsewhere that resulted or may reasonably have been expected to result in an individual's death or in serious adverse effects on their health, including a serious injury.

[1301]A recall or measure that is initiated for human health or safety reasons by a foreign entity.

marketed in Canada. If this is the case, all information required by the CCPSA has to be submitted to Health Canada within 24 hours, even if the national law of the country where the manufacturer is established or from where the product is imported provides for different reporting and deadline obligations. As a result, the new Canadian law does constitute a serious challenge for multinational companies with operating departments in multiple geographic locations, especially when distribution channels are not controlled by the producer, for example online sales. Hereby, the Canadian Act propagates an obligation to report far beyond its border and drives harmonization of reporting techniques worldwide, hence imposing a new legal context upon US companies.

For years, Canada has been a desirable market place for American companies because of its close geographical location and the high spending power of the Canadian consumer. Nowadays, US manufacturers, especially those with international distribution networks, have to be constantly on alert since there is a significant chance that their product, once recalled somewhere, will make its way to the Canadian market place. Besides, for Ottawa it is easier to go after the US producer and collect heavy fines than engage in a court battle with businesses located overseas. As a result, US manufacturers should comply with all obligations made under the new Canadian Act and this forces *de facto* US companies to put into practice recall and notification techniques as prescribed by the CCPSA. In many ways such techniques already mimic RAPEX procedures. This also suggests that in the future, laws and practices on both sides of the US-Canadian border will be closer and render possible the management of a common RAPEX-like system.

Finally, since the adoption of the CCPSA, millions of hazardous consumer products have been withdrawn from national markets on both sides of the border. Canada-US joint recalls have increased exponentially and become routine procedures. Only 28

joint recalls were made in 2011, compared to 81 in 2014 and 79 in 2015.[1302] When a joint recall has effect, a special bulletin published simultaneously by the US and Canada authorities is accessible for everyone on government websites. It includes quite similar data as a RAPEX notification: name of product, quantity of units sold, name of importer or producer, description of hazard, number of incidents/injuries reported, detail product description (alphanumeric code and serial number), name of retail/distributor, dates when product was sold, remedies or guidelines for further actions, contact information, and image of the product.

Furthermore, cooperation in joint recalls and information exchange already has spread across the entire North American continent. Under the North America Cooperative Engagement Framework on Consumer Product Safety,[1303] the Consumer Product Safety Commission of the United States of America (U.S. CPSC), the Federal Consumer Protection Agency of the United States of Mexico (Profeco), and Health Canada have agreed to enhance and maintain on-going cooperation and information exchange between North American regulators, including consultation on potential joint recalls or corrective actions. In November 2014, US, Mexico and Canada jointly issued the first tri-national joint product recall - of Graco strollers.[1304] Since then, numerous hazardous consumer products have been eliminated from the North American market through coordinated actions. And even if there are not accurate statistics on how many joint recalls have been triggered by the Canadian Act, the new legislation has definitely helped to pave the road toward RAPEX-like application in the North American.

[1302]For more information on Canada-US joint recalls please consult Health Canada, online: <http://healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php>.
[1303]More on *North America Cooperative Engagement Framework on Consumer Product Safety* see: *Product Safety Summit*, online: Product Safety Summit <http://productsafetysummit.com/en/home/>.
[1304]*Alert: Graco Children's Products Inc. Recalls Strollers & Travel Systems*, (20 November 2014), online: Health Canada <http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2014/42149r-eng.php?_ga=1.186515818.216261415.1445610077>.

3.4.3 CIS and EAEU

In spite of the fact that CIS has existed already for 15 years, very little or nothing has been done in the field of information exchange on dangerous products. On the other hand, discussions on this issue have been around for a while. The need for an interstate database on dangerous consumer products, similar to the European one, has been sounded frequently. Nevertheless, a RAPEX-like system has not yet been inaugurated in the scope of CIS.

Recently, talks regarding the necessity for a system on hazardous products information exchange have intensified. In 2013, CIS members agreed on common interstate standards in various fields, including consumer products. Under the adopted plan of actions, more than 3300 technical requirements will be revised and harmonized. As a part of this reform, a RAPEX-like information system on dangerous consumer products will be introduced.[1305] To date, no detailed information on a legal status and operational features of the system has been provided, nor has a specific date been announced for when the system will start to operate.

Quite an opposite, the EAEU approach to the information exchange on dangerous consumer products has been proactive from the beginning. Since the foundation of the Union, a system of technical regulation has been created within the EAEU which in many ways resembles the European model. It is based on technical regulations which specify general safety requirements to any product before it goes to the common market. To accompany this process, a framework of EAEU information

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[1305]Гульназ Данилова "В СНГ Создадут Единый Координирующий Орган в Сфере Технической Политики", (Gulnaz Danilova, CIS creates a Single Coordinating Body in the Field of Technical Policies [translated by author]), (18 June 2013), *Russian Business Newspaper*, 901(23) online: Russian Business Newspaper <http://www.rg.ru/2013/06/18/tovari.html>.

exchange system on dangerous consumer products, analog of the EU RAPEX, has been endorsed.

During the meeting on October 7, 2015 a draft of an *International Treaty on the Rules and Procedures to Ensure the Safety and Handling of Products, the Requirements for which are not Established by the Technical Regulations of the Eurasian Economic Union* was presented by a working group comprising of representatives of the Eurasian Economic Commission and experts of Member States. This treaty is seen as a key document that would bring balance between the freedom of circulation of products and consumer safety in the market of the Union

The motto of the document is: "all consumer goods that are in circulation in the market of the Union should be safe during their use, storage, transportation and sale". In the draft the best international and European practices are taken into account, including the provisions of the EU General Product Safety Directive (GPS Directive).[1306] Similar to the GPS Directive, the document highlights the need for adequate market surveillance systems at national levels and for the exchange of information between EAEU states regarding dangerous products made available on the market.

In accordance with Article 5, the Member States have to monitor consumer products safety. Information on potentially dangerous products circulating on the national markets has to be collected, analyzed and transmitted to the newly inaugurated Integral Union Information System. Once risks associated with consumer health and life are confirmed, products are listed as dangerous and the Member States take joint corrective actions, including product ban and recall. The Eurasian Commission is

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[1306]EAEU, *The EEC is Preparing a Treaty on Ensuring the Common Safety of Products*, online: Eurasian Commission <http://www.eurasiancommission.org/en/nae/news/Pages/08-10-2015-1.aspx>.

designated as the authority responsible for the management and technical supervision of the EAEU System.[1307]

To date, no specific information on the Integral Union Information System has been released. It can be expected that the future EAEU exchange of information system on dangerous products will be the equivalent of the EU RAPEX system, taking into account the fact that the Eurasian Union is a copycat of the European success story.

3.4.4 Observations

It is crystal clear that RAPEX has become a triumphant European project in the field of consumer safety. It skyrocketed from just 4 notifications in 1984 to 2123 in 2015. What dry data does not show is how many human lives have been saved and how many injuries have been prevented due to simple information exchange. Today 90 % of national authorities and 60% of consumer organizations in Europe find RAPEX a useful application to enhance consumer safety in the EU.[1308]

[1307] *Договора о Правилах и Порядке Обеспечения Безопасности и Обращения Продукции, Требования к Которой не Установлены Техническими Регламентами Евразийского Экономического Союза (Проект)*, (International Treaty on the Rules and Procedures to Ensure the Safety and Handling of Products, the Requirements for which are not Established by the Technical Regulations of the Eurasian Economic Union (draft)), online: Комитет РСПП по техническому регулированию, стандартизации и оценке соответствия <http://docs.cntd.ru/document/420295691>.

[1308] EC, *Commission Staff Working Paper: Impact Assessment: Accompanying the document: Proposal for a Regulation of the European Parliament and of the Council on a Consumer Programme 2014-2020*, COM.2011.1320 (final), at 18, online: European Parliament <http://www.europarl.europa.eu/meetdocs/2009_2014/documents/imco/dv/com_sec(2011)1320__consp_/com_sec(2011)1320__consp_en.pdf>.

Finally, this pivotal mechanism of consumer safety goes beyond the EU borders. Cooperation between RAPEX and China has already produced fruitful results. Meanwhile, teamwork between RAPEX and the U.S. authorities initiated under the Transatlantic Economic Partnership suggests that information exchange on dangerous consumer products is moving to the global realm. This trend has also been spreading on a regional level in both NAFTA in CIS.

The North American prototype for hazardous products information exchange and joint recalls is not by any means an equivalent of the European model. It does not possess many essential technical features, such as common risk assessment methodology for instance. The legal status is also dissimilar to the European counterpart. It is a voluntary scheme. In fact, the North American arrangements are very limited and cannot be put in the same category as RAPEX, *per se*. On the positive side, the North American and European models retain similar goals: to keep markets safe from hazardous consumer products. This yet imperfect information exchange and joint recalls scheme constitutes a big step in the right direction to ensure consumer safety in scope of NAFTA. It should not be forgotten that in the early days only a few notifications were sent through the European Rapid Exchange Information System.[1309] With millions of dangerous products already recalled to date, the future of North American quasi RAPEX looks quite optimistic.

The future of the information exchange on dangerous consumer products in the post-Soviet realm looks quite bright as well. From the start the EAEU has taken consumer safety very seriously. The legal basis for general consumer safety and information exchange was drawn just a few months after the Union was formally formed. Needless to say that it took more than 25 years before RAPEX was set up under an umbrella of the United Europe.

[1309]Only 4 notifications were sent in 1984 through the RAPEX. During 80s and 90 less than 100 notifications were sent annually. Approximately 90 Canada-US joint recalls are observed annually.

Recent developments have shown that in the very near future a system similar to RAPEX will be a part of consumer safety arrangements in the scope of the EAEU. The only obvious drawback is that EAEU membership is limited to five states and for political reasons many CIS members might never be a part of the Union. It might also be projected that when EAEU RAPEX will be operational, lax legal and technical agreements will be made to let other states be a part of an information exchange scheme, similar to RAPEX-China model.

CONCLUSIONS

1. Safety as a Priority Need on International Consumer Markets

The internationalization and regionalization of the legal framework for consumer safety is being universally admitted as essential for a number of obvious reasons, among which the development of international trade, cost-efficiency rationales, and the willingness to protect national consumers against the increased safety risks associated with the opening of national borders and the resultant ever wider range of imported products made available on national consumer markets.

The merit of safety is universal. Consumer safety has always been the pinnacle of the consumer agenda through the world. Depending on the level of socio-economic development and political support, every country has developed its own pattern of consumer safety agenda. Unavoidably, diverging national safety laws, regulations and product standards create barriers to trade. Hence, the facilitation of cross-border trade of products and services calls for international legal frameworks. Requests for legal harmonization have become louder as globalization requires easier circulation of consumer goods and services across national borders. Even if international consumer safety law has been around for a long time, increased transnational trade has accelerated the process of further internationalization and regionalization of consumer safety legislation.

The need for urgent legal harmonization becomes even more obvious when consumer safety laws and regulations are admitted as legitimate obstacles to trade under international and regional trade rules. Indeed, law harmonization becomes the only way to open borders without dismantling or reducing the level of protection granted to consumers under national safety policies.

Moreover, it has long been acknowledged that action to improve consumer safety is more effective if carried out at the international level rather than by individual countries acting unilaterally and without co-ordination. There is a strong economic rationale to have safety regulations and standards agreed, implemented and put into operation on an international basis. With the present level of globalization and production outsourcing, even the most resourceful state cannot fully protect its own consumers from unsafe products or services. The regulatory landscape in many states is still erratic. National authorities often refrain from cooperation. Therefore, only universally recognizable legal instruments can guarantee consumer safety.

Furthermore, any comprehensive, far-reaching and operational safety-related framework is very costly and laborious to develop and maintain for both governments and industry. International sharing of the expenditures of consumer safety schemes eliminates unnecessary overheads. This is particularly crucial for economies in transition.

Finally, differences in laws, technical regulations and standards discourage research, innovation and growth, as new products or services may only be admitted in the country or countries that apply identical safety standards; they also delay the placing of safer products and services on the market.

Hence, the internationalization and regionalization of consumer safety law are not only needed for protecting consumers against dangerous products or services, but they also encourage the industry to develop new sounder products, provide governments with lower-cost consumer safety schemes, and encourage cross-border trade.

2. A Dispersed, Fragmented and Restrictive Vision of Consumer Safety

Regrettably, existing international and regional agreements on consumer safety for non-food products in most instances do not provide for a global and full treatment of the issue of dangerous products and services made available on national consumer markets. Our research revealed that the existing policy approach has remained dispersed, sector-specific, limited in scope and slow-moving. To date, thousands of potentially dangerous consumer products and services remain unregulated under international and regional safety schemes. A horizontal and comprehensive vision of consumer safety, including general safety legislation applicable to all products (and eventually all services) available on consumer markets has emerged only recently in some countries, among which Canada, or regions such as the European Union. Such a global safety net remains unknown or undeveloped in most regions as well as at the international level.

This lack of global vision has three main causes: (i) the absence of an international institutional framework on consumer safety; (ii) conflicts between free trade rules and the consumer safety agenda; and (iii) the lack of common ground among countries for assessing safety hazards and risks.

(i) Institutional deficit

To date, only the EU possesses a vigorous and comprehensive structure to guarantee consumer safety. All three branches of power (the European Commission, the European Parliament and the European Court of Justice) have taken an active part in the development of a vigorous consumer safety policy at the EU level. Regional standardization bodies, EU-managed exchanges of information on dangerous products through the RAPEX system, and enhanced cooperation among national market surveillance authorities have also contributed to the building up of an EU-wide product safety policy.

Some progress in setting up bodies responsible for consumer affairs, including consumer safety, has been done in the newly formed EAEU. As an example, the Consumer Rights Protection Consultative Committee in the Eurasian Economic Union Member States has been created with the mandate to implement regionally agreed consumer protection measures in the Union states; so far however, this Committee has only advisory power. Additionally, the EAEU agreement gives a legal basis for setting-up a regional "RAPEX" in upcoming years. It may be projected that in the very near future the EAEU will inaugurate an institutional network on consumer safety with a legal framework and functions similar to those of the EU.

In contrast, very limited developments have been observed on the North American continent. No institutions in charge of consumer safety have been introduced in the scope of NAFTA. In fact, the free trade agreement in North America did not lay down a legal basis for any institutional setups and nothing indicates that this situation will change any time soon. However, technical work in the area of consumer safety has been carried out under the North America Cooperative Engagement Framework

on Consumer Product Safety parallel to NAFTA. Also joint recalls have been conducted since 2011 under a quasi-RAPEX voluntary scheme.

As for the international level, no visible work has been done or incentives created to establish a UN institution exclusively responsible for consumer protection and/or consumer safety; nor have prerequisites yet been laid down on the legal and technical features of such a body. Such a gap is difficult to justify, considering the fact that the basic consumer need for safety stated in the UN Guidelines is universally proclaimed and has received priority attention in all countries worldwide.

Without such an institutional driving force, the consumer safety agenda has not been given sufficient importance worldwide. New international and regional instruments on consumer safety have been adopted at an unforgivably slow pace; whereas existing ones have not always been updated accordingly. Cooperation on consumer safety matters between governments remains limited, and not organized.

(ii) Conflicting interests

Conflicts of interest between free trade and consumer safety have further diminished the efficiency of basic mechanisms for the protection of consumers' life and health. As a rule, international and regional open-border agreements are not consumer "friendly", as their main goal remains the facilitation of trade. Consumer protection and safety policies are seen as a threat to cross-border commerce and treated as by-products of the free trade agenda. Hence, consumer interests are often overlooked or given less importance compared with business interests. Consumer protection is not regarded as an explicit goal of WTO agreements, nor is it admitted as a legitimate exception from the application of the free trade rules. While the protection of life and health may be admitted as such an exemption, this remains subject to several

conditions and strict interpretation. In this sense, consumer safety remains a by-product of trade and not a policy goal *per se*.

In the regional realm, only the EU has adopted a far-reaching and separate framework for consumer safety. Through a broad range of detailed harmonization measures, free trade goals have been reconciled with the need to ensure a high level of protection for consumers, including with regard to product safety. Over the years, the EU fundamental treaties have shifted from the establishment and functioning of a free trade zone to a social-economic Union. Therefore, it would be difficult to apply the EU model universally.

In NAFTA, where a free market is perceived as the primary goal, consumer safety is and will be given attention only under exceptional circumstances and no harmonization attempts will be made to regulate safety on the regional North-American market as opposed to the national markets of the Contracting Parties.

Meanwhile, the newly formed EAEU has explicitly admitted consumer protections and safety as a separate union policy in the founding treaty. Yet, the legal and institutional set-ups have to be still developed in upcoming years.

(iii) A fragmented perception of safety risks

Although safety is universally proclaimed as a basic consumer need, the safety properties of a particular product or service may vary from state to state, from region to region, and from one social group to another. Such differences in safety standards stem predominately from dissimilarities in socio-economic development among countries. Most of the world's population does not have the financial ability to live in accordance with the elevated "western safety model". A toy with lead paint outlawed for safety concerns in Australia may be accepted as legally safe in Asia. A car

withdrawn from the market in Europe due to unsafe design may be deemed a perfectly safe vehicle in most African countries. A hotel without a proper fire escape would never be officially permitted in Canada but is lawfully operated in South America. Hence, depending on socio-economic circumstances every country develops its own suitable legal blueprint for consumer safety. In such circumstances, it is challenging to reach an agreement on universal safety standards and risk assessment techniques.

Horizontal international instruments with a general obligation on economic operators to market only safe consumer products, if adopted, would remain subject to various interpretations in different parts of world. The same is true among states that are members of the same regional agreement. In many respects the concept of safety in Mexico and Canada is rather dissimilar despite the fact that both states are members of NAFTA.

3. Searching for Long-Term and Short-Term Responses

Reforms that are needed to address the problem of product safety on international markets are far-reaching and will be long-term commitments. However, some responses that could quickly contribute in a significant way to the increase of safety of products made available on consumer markets worldwide seem feasible without too much effort.

The following four recommendations are formulated:

(i) To designate one international institution as competent to deal with consumer safety maters (3.1).

(ii) To work on a new generation of trade agreements, whether multilateral or bilateral ones, that would formally include consumer protection as one of

their policy objectives and hence admit consumer protection as a legitimate exception from the application of the agreement free trade rules (3.2).

(iii) To promote a global and common understanding of product safety parameters through a mix of hard law and soft law initiatives (3.3).[1310]

(iv) To design a worldwide knowledge-based policy tool in the area of product safety and make it operational (3.4).

3.1. Designation of one international institution as competent to deal with consumer safety maters

The ideal action would be to create a new, or to designate one existing, international institution as fully and exclusively in charge of consumer affairs, including consumer safety.

One international body exclusively competent in the area of consumer protection would not only consolidate global efforts on consumer safety but also galvanize new incentives to fill existing legal and technical gaps on the matter. Its autonomy would prevent conflicts with related areas such as competition and trade. It would ensure actual and strong consumer inputs into an area commonly dominated by business interests.

[1310]Soft law refers to rules that are neither strictly binding in nature nor completely lacking legal significance. In the context of international law, soft law refers to guidelines, policy declarations or codes of conduct which set standards of conduct. However, they are not directly enforceable. Hard law refers to binding laws. In the context of international law, hard law includes treaties or international agreements, as well as customary laws. These documents create enforceable obligations and rights for countries (states) and other international entities. (*Soft Law: Law and Legal Definition*, online: US Legal <https://definitions.uslegal.com/s/soft-law/>). More on soft/hard laws see: Andrew T. Guzman & Timothy L. Meyer, "International Soft Law", *Legal Analysis* 171, (1 January 2010), online: Berkeley Law Scholarship <http://scholarship.law.berkeley.edu/cgi/viewcontent.cgi?article=1694&context=facpubs>.

However, one has to observe that such an institution, acting with full autonomy in the area of consumer protection, does not exist so far on the international scene.

Some scholars see the WTO as the "ideal vehicle" to carry out work in the field of consumer safety, mainly because of the organization's experience dealing with product safety.[1311] Nevertheless, although some arbitration made by WTO may prove to admit consumer safety as an imperative requirement, the primary purpose of the organization is to endorse free trade by removing tariff and non-tariff barriers, including at times national safety-related measures. WTO agreements do not call for a comprehensive and independent policy regarding consumer protection in general and consumer safety in particular.

A more desirable development would be the establishment of a new UN institution that would be exclusively in charge of consumer protection and consumer safety. Nevertheless, this scenario is most improbable. Taking into account how problematic the process was to make recent minor amendments in the UN Guidelines, it is difficult to imagine that in the near future the international community would agree on the status, functions and operation of a new UN body dealing exclusively with consumer protection.

Nowadays, within the UN system, consumer policy falls under the scope of competences of the UN Conference on Trade and Development (UNCTAD). No UN institution has been mandated with consumer protection policy *per se*; consumer protection has not been confirmed as a field of policy separate from trade and competition matters. Despite possible conflicts of goals and interests, UNCTAD has proved to be active in the area of consumer protection. In particular, it did prepare and supervise the revision process of the UN Guidelines on consumer protection of

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[1311] *Op. cit.* 3 (Cary Coglianese, Adam Finkel & David Zaring) at 259 to 261.

1985, which led to the adoption of extended Guidelines in December 2015. These new Guidelines also provide for the establishment of an Intergovernmental Group of Experts on Consumer Protection Law and Policy, which met for the first time in October 2016. The fact that for the first time one body within the UN system is designated as exclusively competent on consumer protection matters, including consumer safety, can be seen as a positive development. Still the main functions of the Committee remain limited to giving advice to national governments and enhancing cooperation among them on consumer policy issues, including safety matters. Besides, this Intergovernmental Group will operate within the framework of the existing Commission for Trade and Development Board of the UN Conference on Trade and Development.

Whether this Group of experts will be willing, allowed and capable to have a direct impact on the development of international instruments to protect consumers against unsafe products is too early to assess.

Another UN organization that might be considered is the United Nations Economic Commission for Europe (UNECE). Nevertheless, a closer look revealed the UNECE has very limited arrangements on consumer protection and even less on consumer safety. The work of UNECE on consumer protection has been concentrated on the harmonization of technical regulations on motor vehicles and transport of dangerous goods; also, UNECE regularly hosts forums on market surveillance.[1312] Hence, the UN does not possess any dedicated body to fulfill work in fields of consumer protection and safety.

Our research concentrates solely on organizations under the UN umbrella. Yet, it would be beneficial to look outside of the UN network to suggest an alternative

[1312]For more information please consult the UNECE webpage online: UNECE <http://www.unece.org/info/ece-homepage.html>.

institution. From all existing international bodies, so far, the Organization for Economic Co-operation and Development (OECD) looks as most suitable to carry out additional work in the field of consumer safety.

With the mission to promote policies that improve the economic and social well-being of people around the world, the 35 OECD Member States have already developed an extensive framework on consumer safety. For years, the OECD has successfully conducted work on consumer product safety-related matters aiming to improve co-operation amongst jurisdictions in areas of mutual interest. Since 2010, the Working Party on Consumer Product Safety, a newly created specialized OECD body, focuses on several key issues related to product safety, such as information sharing and cooperation among regulatory and market surveillance authorities, sharing practices and policy law developments and supporting global and regional fora.[1313] In October 2012 the web portal "*GlobalRecalls*" was launched under the OECD umbrella.[1314] More recently, initiatives in the field of consumer safety have intensified as new tasks have been assigned to the OECD. In 2014, the International Consumer Product Safety Caucus, a global platform for consumer product safety regulators and market surveillance authorities did transfer to the OECD Working Party on Consumer Product Safety most of its substantive work items.[1315]

Undeniably, the OECD possesses sufficient credentials to serve as a driving force for consumer safety agenda around the globe. The only severe drawbacks are the limited

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[1313]OECD, *Mandate of the Working Party on Consumer Product Safety*, online: OECD <http://www.oecd.org.proxy.bibliotheques.uqam.ca:2048/sti/consumer/WPCPS%20Mandate.pdf>.
[1314]In many respects the portal mimics European RAPEX. Nevertheless, the legal and technical bases are very different. For instance, the portal is only for informational purpose. It does not create any obligations to report or take actions. For more details see: GlobalRecalls online: OECD <http://globalrecalls.oecd.org/Content.aspx?Context=AboutThePortal_Introduction&lang=En>.
[1315]For more information on the International Consumer Product Safety Caucus see; ICPSC, online <http://www.icpsc.org/Home_Page.html>.

membership and current non-UN status of the organization. As of today, the OECD counts only 35 members, predominantly developed states from Europe and North America.[1316]

Yet, the OECD has already worked closely for years with many emerging and developing economies in Africa, Asia, Latin America and the Caribbean. If needed, a specific model of cooperation on consumer safety matters with non-OECD states might be introduced in the scope of the future global safety framework.

As for the status, OECD is, indeed, not a part of the UN network. Nevertheless, both institutions share similar fundamental principles and goals, and have worked together for years on numerous global projects. In fact, many UN initiatives have been complimented by OECD ones.[1317] Hence, one ideal solution, for the time being, could be to encourage the OECD and the UN Intergovernmental Group of Experts on Consumer Law and Policy to cooperate and coordinate their works in the area of consumer safety.

[1316]OECD Members States are Australia, Austria, Belgium, Canada, Chile, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Luxembourg, Mexico, Netherlands, New Zealand, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom, and United States. OECD also works closely with emerging economies like the People's Republic of China, India and Brazil and developing economies in Africa, Asia, Latin America and the Caribbean. For more information on OECD membership see OECD, online, OECD <http://www.oecd.org/>.

[1317]For instance, UN Global Compact project which promotes responsible corporate practices through a variety of engagement mechanisms, is complemented and reinforced by the OECD Guidelines for Multinational Enterprises. Together they are the world's foremost comprehensive, voluntary corporate responsibility initiatives. For more details on the Global Compact project and UN-OECD joint venture please see: OECD, *The UN Global Compact and the OECD Guidelines for Multinational Enterprises: Complementarities and Distinctive Contributions*, Investment Division: Directorate for Financial and Enterprise Affairs Organisation for Economic Co-operation and Development, (April 2005), online: OECD <http://www.oecd.org/corporate/mne/34873731.pdf>.

3.2. Working on a New Generation of Free Trade Agreements

It would be naïve to expect that international and regional bodies as WTO or NAFTA self-implement proactive polices on consumer protection, or at least consumer safety. Simply put, consumer protection and consumer safety have never been a part of free trade DNA.

However, as shown recently by the ratification process of the Comprehensive and Economic Trade Agreement between Canada and the European Union (CETA) and the negotiation of the Transatlantic Trade and Investment Partnership (TTIP), there is a growing demand for a new generation of trade agreements, whether multilateral, regional or bilateral ones.[1318] Pressures have intensified from some national policy-makers, civil society organizations and academics for more socially oriented agreements, giving equal attention to other public interests such as the protection of labour, environment protection, sustainable development and consumer protection.[1319]

[1318]The Comprehensive Economic and Trade Agreement (CETA) is a free trade agreement between Canada and the European Union. If enacted, the agreement will eliminate 98% of the tariffs between Canada and the EU. More on CETA see: CETA, online: European Commission <http://ec.europa.eu/trade/policy/in-focus/ceta/>; The Transatlantic Trade and Investment Partnership (TTIP) is a proposed trade agreement between the European Union and the United States, with the aim of promoting trade and multilateral economic growth. More on TTIP see: TTIP, online: European Commissions <http://ec.europa.eu/trade/policy/in-focus/ttip/>&
Christian Deblock, Michele Rioux, *NAFTA – a Model Running out of Breath?* (January 2010), online: Research Gate <https://www.researchgate.net/publication/227384039> & Parliamentary Assembly, *"New Generation" Trade Agreements and their Implications for Social Rights, Public Health and Sustainable Development,* Report: Doc. 14219, (14 December 2016), online: Parliamentary Assembly <http://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-en.asp?fileid=23232&lang=en>.

[1319]Thierry Bourgoignie, *Accords de libre-échange et intégration des marchés: les consommateurs oubliés*, proceedings of conference: Les partenariats transatlantique et transpacifique à l'ère de l'interconnexion, (16- 17 November 2016), UQAM, Montreal, online: CEIM-UQAM <http://www.ieim.uqam.ca/IMG/pdf/bourgoignie_uqam_nov_2016.pdf>.

As constituents, consumers through consumer associations should increase social pressure on politicians to include consumer groups as equal stakeholders in the negotiations of new trade agreements. They should also mobilize scattered forces to pursue the agenda on consumer safety in score of already existing free trade deals.

Intensive campaigns and awareness raising events will help in such a mobilization process.

3.3. Building a Global and Common Legal Framework for Consumer Safety

Common legal policy tools should be promoted at the international level in order to encourage and facilitate a common understanding and perception of safety, the main features of a comprehensive policy in the area of product safety and ways to prevent, reduce or eliminate risks on consumer markets.

It is our recommendation that the international institution designated as competent to deal with consumer safety – currently the OECD acting in close cooperation with the UN Intergovernmental Group of experts on consumer law and policy – elaborates a model legal framework for consumer safety that could give guidance to national governments in designing and implementing their national policies in the area of consumer safety.

In order to be comprehensive, such a Consumer Safety Package should comprise the following tools[1320]:

(i) A draft model law on general product safety: this law would act as umbrella legislation applicable to all products made available on the

[1320]Thierry Bourgoignie, *Quality Infrastructure System: The legal pilar*, Summer Programme in Consumer Law and Policy, UQÀM-GREDICC (6 July 2016), Montreal.

market place, whether regulated or unregulated ones, and eventually services, intended or likely to be used by consumers. The goal is to suggest a minimum common safety net that will benefit all consumers of all products and services worldwide.

In recent years, several countries across the globe have opted for such a comprehensive approach towards product safety and introduced into their legal order a new legislation on general product safety. Namely, this is the case in all Member States of the European Union[1321], Canada[1322] and Australia[1323] and has recently emerged in EAEU.

Based on this experience, the model law that we suggest shall, among others:

- Confirm the broad and horizontal scope of application of the law provisions;
- Propose a uniform glossary of terms and definitions used in the area of consumer safety;
- Impose upon all economic operators to place only safe products and services on the market place;

[1321]EC, *Commission Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety (Text with EEA Relevance)*, [2001] O.J. L 011/4, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0095:EN:HTML>; EC, *Regulation No 765/2008 of the European Parliament and of the Council of 9 July 2008 Setting out the Requirements for Accreditation and Market Surveillance Relating to the Marketing of Products and Repealing Regulation (EEC) No 339/93 (Text with EEA Relevance),* [2008] O.J.L 218, online: EUR-Lex <http://europa.eu/legislation_summaries/consumers/consumer_safety/l33248_en.htm>; New Package (*Reinforcing Product Safety and Market Surveillance*, online: European Council http://www.consilium.europa.eu/en/policies/product-safety-market-surveillance/).

[1322]*Canada Consumer Product Safety Act 2011*, (S.C. 2010, c. 21),

[1323]*The Australian Consumer Law* (2011), online: Government of Australia <http://consumerlaw.gov.au/>.

- Confirm a broad definition of safety that would go beyond conformity with safety standards and also include consumer expectations and needs;
- State additional general safety obligations imposed upon economic operators, such as performing premarket controls, assessing the product-associated safety risks, informing potential users about the product-related risks, monitoring the safety of the product once this placed on the market, taking action if and when the product is found unsafe or a risk is detected (including product recalls), informing the public and notifying market surveillance authorities about detected risks, occurred accidents and remedial action taken, and cooperating with market surveillance authorities.
- Include a range of obligations imposed upon the state authorities in relation to the establishment and operation of an adequate market surveillance system, including inspection activities and remedial action.
- Give legal basis to the creation of national knowledge-based policy tools (collecting information about dangerous products, product-related accidents, product recalls, consumer complaints, etc.)
- Suggest the institutional arrangements needed in order to make the market surveillance system most effective, coordinated and participative.
- Empower the competent authorities to adopt vertical or sector-by-sector regulations as well as implementing legislation.

(ii) Drafts of legal instruments on related areas such as standardization, market surveillance, conformity assessment procedures, accreditation, and metrology.

(iii) Guidelines on more specific matters such as legal and technical terminology, core market surveillance practices, risk assessment methodologies, voluntary and mandatory product withdrawals and recalls, cross-border cooperation among regulatory and market surveillance authorities, and cooperation with customs.

(iv) Legal guidance documents.

The above legal instruments would not create any obligation for national authorities to introduce them into their legal order, but rather serve as referential or guidance tools for national and regional policy-makers and economic operators, as well as consumers. Needless to say that such minimum standards in the form of Guidelines would not prevent any state from imposing more protective safety measures.

Furthermore, such a model safety package would be a driving force to approximate main safety legislation around the globe. A common perception of the concept of safety, safety features, safety obligations and requirements, a common understanding of the terminology used in product safety policies, and common guidelines on closely-related matters such as standardization and market surveillance would directly and significantly contribute to a minimum common safety culture worldwide.

3.4. Making an International System for the Exchange of Information on Dangerous Products Operational

Our research has shown that the exchange of information on dangerous consumer products is regarded as a privileged tool to deal with safety risks and in particular urgent threats on consumer health and safety. The main international legal instruments such as the Rotterdam or Basel conventions provide for such mechanisms. The European Union introduced a system for

the rapid exchange of information on dangerous products already in 2004. Under regional incentives on consumer safety, North American States have conducted information exchange, resulting in the recall of millions of dangerous products from the market since 2011.

Similar rapid alert platforms have been set up elsewhere around the globe. The Caribbean model, CARREX – CARICOM Rapid Exchange system, was launched in 2011.[1324] More recently, the Inter-American Rapid Alerts System (SIAR) - the first hemispheric integrated system for the generation, management and rapid exchange of information on consumer safety alerts, was established in 2014.[1325] Finally, ex-soviet states are about to set up system similar in spirit to the European one under the umbrella of the newly born EAEU.

While the technical specifications and operational rules of these various schemes differ, they all share a common goal: to share information about the safety risks of products circulating on national consumer markets in order either to prevent the entry of dangerous products into the national market or to take action against such products when already made available to consumers.

There are a few reasons why informational exchange has been a prevalent choice over other consumer safety schemas.

First, informational exchange is flexible legal instrument and does not require scrupulous laws approximation between the states. Of course exchange schemas like RAPEX do indeed constitute direct obligations for Member States to harmonize

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[1324]More on CARREX – CARICOM Rapid Exchange System see: *CARREX – CARICOM*, online: CARREX – CARICOM <http://carrex.caricom.org/>.
[1325]More on SIAR see: *Inter-American Rapid Alerts System*, online: OAS <https://www.sites.oas.org/rcss/EN/Pages/about/siar.aspx>.

national legal and technical bases on informational exchange, risk assessment mythology, product recall and reporting. Nevertheless, other schemas like *Global Recall* or North American informational exchange model do require only rudimentary consensus on technical aspects regarding how and in what form the data on dangerous consumer products should be disseminated. Under such schemas the recipient states is not obliged to take any measures or to report back. Any corrective actions taken would be solely at the state's discretion. Moreover, such flexibility does not require international consent on safety risk assessment. After a notification is disseminated, every state unilaterally evaluates the safety risks associated with the named consumer product and takes corrective actions, if required, in accordance with national consumer safety regulation.

Second, the information exchange on dangerous consumer products does not violate the terms of international or regional free trade treaties. In fact, free trade agreements are silent or neutral on the matter, since informational exchange *per se* does not constitute a barrier to cross-border movement. Only corrective measures taken as a response to information received could create such barriers.

Additionally, the national framework on informational exchange requires minimum financial and human resources. A national office on data exchange needs only a few workstations and technical personal with a very basic training. Hence, even developing states might set up and operate such office quickly and at little cost.

Finally, during our research it has been observed that each Member State has already put in operation a market surveillance authority which collects and disseminates national data on hazardous consumer products. Hence, already existing resources might be used for informational exchange.

Regrettably, all existing regional rapid alert systems have deficiencies, since they cover limited geographic area or only a few states. Many countries, especially from the developing world where mass production is concentrated, are not a part of any information exchange schemas and, in most cases, no formal mechanisms have been put in place to exchange data on dangerous consumer products from such regions. So far only the RAPEX-CHINA partnership taskforce has been a successful attempt to extend regional initiatives toward mass manufacturing territories. No other blanket projects, covering all states worldwide, have been entertained on the regional level. Hence, an all-encompassing rapid alert framework should be designed to overcome such shortcomings.

The first step towards a universal RAPEX network was already made in October 2012 when the *GlobalRecall* portal was inaugurated under the patronage of the OECD. The portal was introduced to provide information on mandatory and voluntary product recalls being issued around the world, on a regular basis, together in one place. It enhances information sharing across jurisdictions and supports regulators in taking corrective actions. Information on product recalls comes currently from Australia, Canada, the European Commission, Japan and the United States. In the near future, additional OECD and non-OECD jurisdictions will be joining the initiative.

The portal is beneficial for consumers and businesses. Consumers can use this portal to check whether there are safety concerns about the products they intend to buy. It might be particularly useful when making cross borders online purchases. Businesses can improve tracking of emerging hazards from around the world, which will help them to move quickly to address problems.

The next steps for the project encompass: *i)* enhancing translation and searching capabilities, *ii)* adding historical data into the portal, *iii)* automating regular updates

and iv) gathering data from additional jurisdictions. Work also has commenced on a mobile application which would facilitate the use of the portal. Eventually, consumers will be able to report a health and safety concern or raise other product-safety related issues through the portal tools. Finally, efforts will be also made to develop a customized interface for those jurisdictions which do not have their own database in place.[1326]

Since the launch, this ambitious project has shown encouraging results. The information on recalls has regularly been updated[1327] and presented in English (with limited content in French).[1328] Already more than 15,000 notifications have been posted on the portal; including 2462 from Canada alone.[1329] In contrast, only a few notifications were sent annually through the European RAPEX during its first years. The portal also provides contact information to communicate to the authorities in every participating jurisdiction. Everyone has unrestricted access to the *GlobalRecall* webpage and can easily look up with help of search engine if a specific product has been ever recalled by participating jurisdictions. Eventually, when more and more states join to this project, it has all chances to become an indispensable universal tool, somewhat of a global analog to RAPEX, to contribute product safety in every part of the word by providing rapid alerts on dangerous consumer products to authorities, to businesses, and of course to consumers.

[1326]More on GlobalRecalls Portal see: GlobalRecalls online: OECD, <http://globalrecalls.oecd.org/Content.aspx?Context=AboutThePortal_Introduction&lang=En>.)

[1327]A web service is being developed so that information can be collected automatically from participating jurisdictions. Each jurisdiction decides how often and when it sends information to the portal, so the updates timespan may vary from daily to weekly or monthly.

[1328]In the future additional languages will be added as will an automatic translation facility which will enable translation into more than one hundred languages. Users will then be able to access information in the language of their choice. The portal will also link recalls for items with related names. For example, an Australian consumer might launch a search for a "*pram*". In this example, the consumer would also receive results on "*stroller*" (the term used in the United States) and "*pushchair*" (the term used in Europe).

[1329]As December 2016.

4. Existing Challenges and Technological Solutions: Designing a New Generation Rapid Alert Framework

The positive impact of rapid alert systems on consumer safety is undeniable. Millions of consumers around the world have been already saved from potential death or injury by means of corrective actions triggered due to simple informational exchange. Yet, it is important to point out that all existing rapid alert systems, be they national, regional or global, possess identical drawbacks that diminish their effectiveness.

(i) existing rapid alert systems are not user "friendly".

Everyone would agree that the idea of inviting consumers to go online every time to confirm that a product he or she is about to buy (or has already bought) is not listed as dangerous on national, regional or global portals is simply erroneous. No one has the time or desire to navigate through hundreds and thousands of alerts every single day. Existing rapid alert frameworks are not user "friendly", since from the start their design has been rather intended for professional users, such as authorities or businesses.

(ii) existing rapid alert systems do not have a direct channel to communicate the alert massage to a passive consumer in possession of a recalled product.

In general, consumers are quite passive players on the market. Just ask yourself when was the last time you checked any product recall database. Hence, any information designated to a consumer, such as recall alerts, should be prepared in the form of an easily understood message and delivered directly through mass media outlets. Yet, mass media broadcasts only extraordinary product recalls, when thousands or millions lives are at stake, such as crises like Samsung's or Takata's products. Other smaller scale crises have never made their ways from official alerts notifications to headlines,

leaving many passive consumers unaware of the imminent danger from product in their hands.

(iii) existing rapid alert systems leave consumers one-on-one with danger when individual purchases are made online.

As a rule, the regulators initiate a recall or release an alert notification only when they know that a hazardous product was sold on the market. When an unsafe product, never marketed locally, is shipped from an overseas distributor directly to consumers, authorities may not be aware of this transaction. Hence, no recall would be initiated or alerts notification published. Even a proactive consumer would also face a predicament to find comprehensive information on a product recall launched by a foreign government if an alert notification was never posted online or published only in an unfamiliar language. This problem especially calls for urgent intervention, since more and more consumers have opted for online shopping.

(iv) existing rapid alert systems are not all-embracing: corrective actions, in one jurisdiction do not automatically trigger similar action at another.

After receiving information on the hazardous properties of a certain consumer product, the national authority conducts a risk assessment to confirm that local criteria for recall are met. Since those criteria vary greatly from state to state and from region to region, there is no guarantee that in the end the hazardous product will be recalled and an alert notification will be disseminated. As a result consumers would not be informed of potential danger.

To summarize, the desirable rapid alert platform should directly notify a consumer when a product in his/her possession has been recalled anywhere in the world. Present rapid alert models have failed to deliver immediate prompt notifications. This

ambitious and seemingly almost utopic mission surprisingly has a simple technological solution.

Not too long time ago, there were no means to directly alert the consumer regarding a danger from a product in his/her hands. In recent years, the situation has changed dramatically with the introduction of new technologies, especially smartphones.

The number of smartphone users is forecast to grow exponentially, from 1.5 billion in 2014 to around 2.5 billion in 2019. Already in 2016 the total number of smartphone users worldwide reached 2.1 billion. Just in two years around half of the Chinese population is projected to use a smartphone. By 2019, in the U.S more than 80% population above the age of 10, or 236 million consumers, will possess a smartphone. India is projected to pass the United States in number of smartphone users in 2017 with nearly 244 million units sold.[1330] Needless to say that the proportion of the population with real access to smartphones is even higher taking into consideration that presented statistics do not provide data on how many households are in possession of at least a single unit.

The encouraging fact is that the trend is universal for both developed and developing courtiers. Fierce competition on the global communication market drives prices for smartphones down making them accessible for consumers even with very low income in place like Asia or Africa. As a result more and more people are connected to a global network to study, to work, to communicate, to stay informed, and of course to shop.

[1330] *Number of Smartphone Users Worldwide from 2014 to 2020)*, online: Statista <https://www.statista.com/statistics/330695/number-of-smartphone-users-worldwide/>; *2014 National Population Projections: Summary Tables*, United States Census Bureau, at Table 4, online: United States Census Bureau <https://www.census.gov/population/projections/data/national/2014/summarytables.html>.

Understanding the power of informational tools with direct access to consumers, regulators have already taken steps to develop IT platforms for mobile devices. In July 2010 the *U.S. Government's Products Recall* app for smartphones was inaugurated. Using data from several agencies across the government the Products Recall app puts information about any recalled products at consumers' fingertips. The app allows consumers both to view the most recent recall press releases and to search recalled products by product name or category. The app's "report incident" feature connects consumer directly with the government officials to report concerns of unsafe products.[1331]

Recently Health Canada has introduced a similar application. The *Recalls and Safety Alerts* app brings together the most recent recalls and advisories from Health Canada, Transport Canada and Canada Food Inspection Agency. Likewise, consumers might search recalls and safety alerts by categories (health and consumer products, food and vehicles) or by keywords (i.e. brand name, product type). Additionally, consumers can share recalls and safety alerts on social media and create a list of recalls and safety alerts that affect him/her. Analogously, Canadians might report health and safety concerns with products using the app's tools.[1332] A few other mobile applications developed by the private sector have similar functions and can be quite useful instruments for notifying the public on product hazards. Nevertheless, most recall applications for smartphones are intended only for proactive consumers who are willing to invest time searching through a vast database for alerts on a particular product.

[1331]More on the U.S. Government's Products Recall app see: *New Smartphone App Alerts Consumers to Food and Product Recall Info, Allows Reporting of Questionable Items*, United States Department of Agriculture's, 2 July 2010, online: United States Department of Agriculture's <http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=2010/07/0353.xml>.

[1332]For more on *Recalls and Safety Alerts* app see: *Recalls and Safety Alerts Mobile Application*, Government of Canada, online: Healthy Canadians <http://healthycanadians.gc.ca/connect-connectez/mobile-eng.php>

A breakthrough happened when a new generation of mobile applications with automatic direct alert function were introduced. For instance, *Retail Recall* app keeps a watch over products owned by a consumer and alerts him/her if there is a recall. The idea behind the app is straightforward. A consumer simply scans the UPS code, known as a barcode, of every product he/she already possesses or buys. The application then checks daily with the three most common recall databases (FDA, Department of Highway Safety and Motor Vehicles, and the Consumer Product Safety Commission) to see if any of products in consumer' hands have been recalled. If a match is ever made an alert will be send immediately.[1333]

The idea behind mobile applications with automatic direct alert function is as genial as simple and requires very modest participation of consumer. This effortless solution eliminates the challenge for passive consumers to know when a recall takes place. The only visible downside is that no smartphone applications linked to universal database, such as *Global Recall*, have been introduced so far. Consumers who already possess or intend to buy products unfamiliar on local market still might face an imminent danger.

The OECD has been working on a mobile *Global Recall* application for a while. No information on technical or legal blueprint of the future app has been yet released. Ideally, the following key parameters should be integrated into the app:

(i) automatic direct alert function. To date, already more than 15,000 notifications are posted on the *Global Alert* portal. Eventually, when new jurisdictions commence reporting and the historical data are added, consumers will be overwhelmed with an avalanche of alerts. This function will be an

[1333]More on Retail Recall app see: *Retail Recall*, online: iTunes <https://itunes.apple.com/ca/app/retail-recall/id879467473?mt=8>.

essential tool to disseminate alerts directly to consumer owning recalled products;

(ii) enhanced automatic product adding function. The process of adding a purchased product to the app though a barcode scan should be complimented by other techniques. For instance, the *Global Alert* app might be linked to shopping apps such as Amazon, Apple pay, or credit card terminal. A product would be added automatically any time a consumer makes a purchase;

(iii) multi-language and translation functions. Alert notification should be available in a few common languages. When an alert is sent in an unfamiliar language an automatic translation should be available to common languages. The translation could be done automatically through an existing platform such as Google Translate.

(iv) be preinstalled on smartphones by default and be ready to use. Smartphone producers should be persuaded to include the *Global Recall* app as a standard setting for the operational system;

(v) app with open platform. Every state should have ability to tailor the *Global Recall* app to national needs (linguistic, religious, cultural and etc.) without changing the core functions;

(vi) direct reporting function. With the help of the app, the consumer should have the ability to report on adverse effects from consumer products directly to both local authorities and *GlobalRecall*. Direct data collection on potential threats worldwide would trigger appropriate corrective actions in a timely manner.

From technical standpoint, all of the above parameters are easily achievable. Moreover, at the first stage, the application might only possess the automatic direct alert function. Eventually, more functions might be added.

From a legal standpoint, the launch of such an application does not pose any visible problems. The international informational exchange on hazards from consumer products has already existed for decades. The right of a consumer to information was proclaimed by the UN Guidelines for Consumer Protection as a basic right more than three decades ago and has been overwhelmingly supported by the international community ever since. In fact, the mobile application would only change the means to communicate product hazards to a consumer without changing the content of the warning.

Lastly, by informing the consumer on potential risks in a convenient and prompt manner the proposed application for a smartphone would certainly raise the level of product safety around the world. The direct data collection function would also elevate localized threats into the global realm, keeping the political elite in every part of the world under constant pressure to take appropriate corrective actions for consumer safety sake.

BIBLIOGRAPHY

LEGISLATION

Agreement Between the Government of Canada and the Government of the United States of America Concerning the Transboundary Movement of Hazardous Waste 1986, online: Environment and Climate Change Canada <http://www.ec.gc.ca/gdd-mw/default.asp?lang=en&n=C59BCC26-1>.

A Guide for Exporters of Used Goods 2009, Norwegian Pollution Control Authority, online: Norwegian Environmental Agency, <http://www.miljodirektoratet.no/old/klif/publikasjoner/2516/ta2516.pdf>.

Amendments to the Annex to the International Convention for the Safety of Life at Sea (SOLAS) 1974, (12 December 2002), online: Admiralty Law Guide <http://www.admiraltylawguide.com/conven/amendsolas2002.pdf>.

Amendments to Consumer Protection Law Allows for Public Interest Lawsuits With Limitations, online: Congressional Executive Committee on China <http://www.cecc.gov/publications/commission-analysis/amendments-to-consumer-protection-law-allows-for-public-interest>.

Amsterdam Treaty, OJ C 325, 24.12.2002, p. 33–184, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A12002E%2FTXT>.

Athens Convention relating to the Carriage of Passengers and their Luggage by Sea, 1974, online: Admiralty and Maritime Law Guide <http://www.admiraltylawguide.com/conven/passengers1974.html>.

The Australian Consumer Law (2011), online: Government of Australia <http://consumerlaw.gov.au/>.

Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, online: Basel Convention <http://www.basel.int/Portals/4/Basel%20Convention/docs/text/BaselConventionText-e.pdf>.

Brussels Convention on Jurisdiction and the Enforcement of Judgments in Civil and Commercial Matters (1968) online: Oslo University <http://www.jus.uio.no/lm/brussels.jurisdiction.and.enforcement.of.judgments.in.civil.and.commercial.matters.convention.1968/doc.html>.

Canada Consumer Product Safety Act 2011, (S.C. 2010, c. 21), online: Department of Justice Canada <http://laws-lois.justice.gc.ca/eng/acts/C-1.68/index.html>.

Canadian Environmental Protection Act, 1999, (S.C. 1999, c. 33), online: Canadian Legal Information Institute <https://www.canlii.org/en/ca/laws/stat/sc-1999-c-33/latest/sc-1999-c-33.html>.

Canada Shipping Act, 2001, (S.C. 2001, c 26), online: Justice Laws Website <http://laws-lois.justice.gc.ca/PDF/C-10.15.pdf>.

Charter of Fundamental Rights of the European Union, OJ C 303, 14.12.2007.p.1.

CIS, *Актуальные Вопросы Защиты Прав Потребителей в Государствах - Участниках СНГ (информационно-аналитический обзор),* (*Actual Questions Regarding Consumer Protection in the CIS Member States (Informative- Analytical Review)* [translated by author]), online: CIS Executive Committee <http://www.e-cis.info/page.php?id=23359>.

CIS, *The Charter of the Commonwealth of Independent States*, online: Dipublico, <http://www.dipublico.org/100617/charter-establishing-the-commonwealth-of-independent-states-cis/>.

CIS, *Договор о Проведении Согласованной Антимонопольной Политики* (Implementation of Coordination Regarding Common Practices in Competition [translated by author]), online: CIS Executive Committee, <http://cis.minsk.by/page.php?id=1938>.

CIS, *О Рекомендательном Законодательном Акте "Об Общих Принципах Регулирования Защиты Прав Потребителей в Государствах - Участниках Межпарламентской Ассамблеи* (The *Recommendation on Common Principles Regulating Consumer Protection in Member States* [translated by author]), online:

CIS Executive Committee, <http://www.lawbelarus.com/world/sub02/texa3945.htm>.

CIS, *Протокол о Внесении Изменений в Соглашение об Основных Направлениях Сотрудничества Государств – Участников Содружества Независимых Государств в Области Защиты Прав Потребителей от 25 января 2000 года (Protocol Amending* the *Accord Regarding the Basic Directions of Cooperation among Members of the CIS within the Sphere of Consumer Protection, January 25, 2000* [translated by author]), online: CIS Executive Committee <http://www.e-cis.info/page.php?id=20676>.

CIS, *Соглашение об Основных Направлениях Сотрудничества Государств Участников Содружества Независимых Государств в Области Защиты Прав Потребителей* (The Accord Regarding the Basic Directions of Cooperation Among Members of the CIS within the Sphere of Consumer Protection [translated by author]), online: CIS Executive Committee <http://e-cis.info/page.php?id=21315 >.

CIS, *Соглашение о Создании Содружества Независимых Государств* (*The Agreement on creation of the Commonwealth of Independent States* [translated by author]), online: CIS Executive Committee <http://cis.minsk.by/page.php?id=176 >.

Civil Code of Québec (S.Q., 1991, c. 64.), online: Justice Québec <http://www.justice.gouv.qc.ca/English/sujets/glossaire/code-civil-a.htm>.

Consumer protection (Guidelines for Consumer Protection), GA Res.39/248, UN GAOR, 1985, UN Doc. A/RES/39/248, online: UN <http://www.un.org/documents/ga/res/39/a39r248.htm>.

Consolidated Version of the Treaty on the Functioning of the European Union, [2012] O.J. L 326/01, online: EUR-Lex <http://eur-lex.europa.eu/JOHtml.do?uri=OJ:C:2012:326:SOM:EN:HTML>.

Convention for the Unification of Certain Rules for International Carriage by Air Signed at Montreal on 28 May 1999, (Montreal Convention), online: Lex Mercatoria <http://www.jus.uio.no/lm/air.carriage.unification.convention.montreal.1999/>.

Convention for the Unification of Certain Rules Relating to International Carriage by Air, Signed at Warsaw on 12 October 1929 (Warsaw Convention), online: McGill <https://www.mcgill.ca/iasl/files/iasl/warsaw1929.pdf>.

Convention on the Law Applicable to Contractual Obligations Opened for Signature in Rome on 19 June 1980 (1980), online: Eur-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV%3Al33109>.

Convention Relating to the Regulation of Aerial Navigation Signed at Paris, October 13, 1919, online: Space Law <http://www.spacelaw.olemiss.edu/library/aviation/IntAgr/multilateral/1919_Paris_conevention.pdf>.

Code de la consummation, online: Legifrance <http://www.legifrance.gouv.fr/affichCode.do;jsessionid=14D18F0AE4A372668F5BE9F55FB08FC6.tpdjo03v_1?cidTexte=LEGITEXT000006069565&dateTexte=20130728>.

Codex Alimentarius, FAO, online: Codex Alimentarius Net <http://www.fao.org/fao-who-codexalimentarius/en/>.

Commission on Sustainable Development, *Consumer Protection and Sustainable Consumption: New Guidelines for the Global Consumer, Background Paper for the United Nations Inter-Regional Expert Group Meeting on Consumer Protection and Sustainable Consumption*, UN ECOSOCOR, 1998, online: UN <http://www.un.org/documents/ecosoc/cn17/1998/background/ecn171998-consumer.htm>.

Código Brasileiro de Defesa do Consumidor, online: Biblioteca do Senado Federal <<https://www2.senado.leg.br/bdsf/bitstream/handle/id/496457/000970346.pdf?sequence=1>.

Consumer Product Safety Act, 1972, (PL 92-573; 86 Stat.1207).

Consumer Protection Act (R.S.Q. c. P-40.1, 1978) online: Legis Quebec <http://legisquebec.gouv.qc.ca/en/showdoc/cs/P-40.1l>.

Convention for the Unification of Certain Rules Relating to International Carriage by Air, Signed at Warsaw on 12 October 1929 (Warsaw Convention), online: McGill, <https://www.mcgill.ca/iasl/files/iasl/warsaw1929.pdf>.

Council of Europe, *Council Resolution of 14 April 1975 on a Preliminary Programme of the European Economic Community for a Consumer Protection and Information Policy,* OJ C 92, 25.4.1975, online: Eur-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:1975:092:0001:0001:EN:PDF>.

Council of Europe, *Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety*, OJ L 11, 15.1.2002, p. 4–17, online: Eur-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0095:EN:NOT>.

CPSC, *Consumer Product Safety Act,* online: CPSC <http://www.cpsc.gov//PageFiles/105435/cpsa.pdf>.

Cracking Down on Tobacco Marketing Aimed at Youth Act (S.C. 2009, c. 27), online: Justice Law Website <http://laws.justice.gc.ca/eng/AnnualStatutes/2009_27/page-1.html>).

Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs: General, (Title 21, Volume 4) online: FDA <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=210&showFR=1>.

Décret no. 96-1133 relatif à l'interdiction de l'amiante, pris en application du code de travail et du code de la consummation, (Journal officiel of 26 December 1996).

Decision of Inter-Parliament Assembly of the Member States of the Commonwealth of Independent States on 15 June 1998 №11-9.

Dietary Supplement and Nonprescription Drug Consumer Protection Act, 2006, Public Law 109–462 (S. 3546), online: FDA<http://www.fda.gov/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAct/ucm148035.htm >.

Dietary Supplement Health And Education Act of 1994, (Public Law 103-417), FDA, (1994), online: FDA <https://ods.od.nih.gov/About/DSHEA_Wording.aspx>.

Drug Applications and Current Good Manufacturing Practice (CGMP) Regulations, online: FDA <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm090016.htm>.

EAEU, *Treaty on the Eurasian Economic Union*, online: EAEU <https://docs.eaeunion.org/en-us/Pages/DisplayDocument.aspx?s=bef9c798-3978-42f3-9ef2-d0fb3d53b75f&w=632c7868-4ee2-4b21-bc64-1995328e6ef3&l=540294ae-c3c9-4511-9bf8-aaf5d6e0d169&EntityID=3610>.

EAEU, Положение *от 25.05.15 № 59 "О Консультативном Комитете по Вопросам Защиты Прав Потребителей Государств – Членов Евразийского*

Экономического Союза" (Decision of 25.05.15 № 59 on the Advisory Committee on Consumer Protection in Member States of the Eurasian Economic Union [translated by author]), online: Eurasian Commission <http://www.eurasiancommission.org/ru/act/texnreg/depsanmer/kk/Documents/Решение%20Коллегии%20№%2059%20от%2025%20мая%202015%20г.pdf>.

EAEU, *Распоряжение Коллегии ЕЭК от 28.09.2015 № 101 " О Составе Консультативного Комитета по Вопросам Защиты Прав Потребителей Государств - Членов Евразийского Экономического Союза"* (EA Commission Regulation of 28.09.2015 № 101 "On the Composition of the Eurasian Economic Union Advisory Committee on Consumer Protection" [translated by the author]), online: Eurasian Commission <http://www.eurasiancommission.org/ru/act/texnreg/depsanmer/kk/Documents/Распоряжение%20Коллегии%20№%20101%20от%2028%20сентября%202015%20г.pdf>.

EC, *Commission Decision 2008/721/EC of 5 August 2008 Setting up an Advisory Structure of Scientific Committees and Experts in the Field of Consumer Safety, Public Health and the Environment and Repealing Decision 2004/210/EC* [2008] O.J.L 241, online: EUR-Lex <http://europa.eu/legislation_summaries/consumers/consumer_safety/l28153_en.htm>.

EC, *Amended by Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 Amending, as Regards Traditional Herbal Medicinal Products, Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use*, OJ L 136, 30.4.2004, p. 85-90., online: European Commission <http://ec.europa.eu/health/files/eudralex/vol-1/dir_2004_24/dir_2004_24_en.pdf>.

EC, *Annex to the Commission Implementing Decision Concerning the Adoption of the Work Programme for 2015 and the Financing for the Implementation of the Multiannual Consumer Programme for the Years 2014-2020*, C(2014) 9323 final, 11.12.2014 ; online: EC <http://ec.europa.eu/consumers/eu_consumer_policy/financial-programme/docs/c_2014_9323_f1_annex_v2_p1_791657_en.pdf>.

EC, *Commission Decision 2004/418/EC of 29 April 2004 Laying Down Guidelines for the Management of the Community Rapid Information System (RAPEX) and for Notifications Presented in Accordance with Article 11 of Directive 2001/95/EC,* [2004], OJ L 151, 30.4.2004, p. 83–117, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0418:EN:NOT>.

EC, *Commission Decision 2008/721/EC of 5 August 2008 Setting up an Advisory Structure of Scientific Committees and Experts in the Field of Consumer Safety, Public Health and the Environment and Repealing Decision 2004/210/EC*, [2008] O.J.L 241, online: EUR-Lex

EC, *Commission Decision 2008/911/EC of 21 November 2008 Establishing of a List of Herbal Substances, Preparations and Combinations thereof for Use in Traditional Herbal Medicinal Products*, OJ L 328, 6.12.2008, p. 42–48., online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:328:0042:0048:en:PDF>.

EC, *Commission Decision 2010/15/ of 16 December 2009 Laying Down Guidelines for the Management of the Community Rapid Information System RAPEX Established under Article 12 and of the Notification Procedure Established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive)*, [2010], OJ L 22, 26.1.2010, p. 1–64,, online: Eur-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010D0015:EN:NOT>.

EC, *Commission Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999 Amending Council Directive 85/374/EEC on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products*, [1999] O.J. L 141/20, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31999L0034>.

EC, *Commission Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety (Text with EEA Relevance)*, [2001] O.J. L 011/4, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0095:EN:HTML>.

EC, *Commission Directive 2003/94/EC of 8 October 2003 Laying down the Principles and Guidelines of Good Manufacturing Practice in Respect of Medicinal Products for Human Use and Investigational Medicinal Products for Human Use*, OJ L 262, 14.10.2003, p. 22–26, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32003L0094>.

EC, *Commission Directive 2010/36/EU of 1 June 2010 Amending Directive 2009/45/EC of the European Parliament and of the Council on Safety Rules and Standards for Passenger Ships*, OJ L 162, 29.6.2010, p. 1–135, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1432920816969&uri=CELEX:32010L0036>.

EC, *Commission Directive 93/13/EEC of 5 April 1993 on Unfair Terms in Consumer Contract*, [1993], O.J. L 095/29, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0013:EN:HTML>.

EC, *Commission Implementing Decision of 11.12.2014 Concerning the Adoption of the Work Program for 2015 and the Financing for the Implementation of the Multiannual Consumer Program for the Years 2014-2020*, C (2014) 9323 (final), online: European Commission <http://ec.europa.eu/consumers/eu_consumer_policy/financial-programme/docs/c_2014_9323_f1_commission_implementing_decision_v2_p1_791655_en.pdf>.

EC, *Commission Implementation Regulation (EU) No 699/2014 of 24 June 2014 on the Design of the Common Logo to Identify Persons Offering Medicinal Products for Sale at a Distance to the Public and the Technical, Electronic and Cryptographic Requirements for Verification of its Authenticity*, OJ L 184, 25.6.2014, p. 5–7, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2014_184_R_0004&qid=1403861374882&from=EN>.

EC, *Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee:20 Actions for Safer and Compliant Products for Europe: a Multi-Annual Action Plan for the Surveillance of Products in the EU,* COM/2013/076 (final), online: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013DC0076>.

EC, *Communication from the Commission to the European Parliamnet, the Council and the European Economic and Social Committee, More Product Safety and Better Market Surveillance in the Single Market for Products*, COM/2013/074 final, online: Eur-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013DC0074>.

EC, *Community Implementation Plan for the Stockholm Convention on Persistent Organic Pollutants,* SEC (2007) 341, online: European Commission <http://ec.europa.eu/environment/chemicals/international_conventions/pdf/sec_2007_341.pdf>.

EC, *Consolidated Version of the Treaty on the Functioning of the European Union*, OJ C 326, 26.10.2012, p. 47–390, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:12012E/TXT>.

EC, *Council Decision 84/133/EEC of 2 March 1984 Introducing a Community System for the Rapid Exchange of Information on Dangers Arising from the Use of Consumer Products*, [1984], J.O. L 70/16, online: EUR-Lex <http://europa.eu/legislation_summaries/other/l32039_en.htm>.

EC, *Council Decision of 1 February 1993 on the Conclusion, on behalf of the Community, of the Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (Basel Convention)*, OJ L 39, 16.2.1993, p. 1–2, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31993D0098>.

EC, *Council Directive 65/65/EEC of 26 January 1965 on the Approximation of Provisions Laid down by Law, Regulation or Administrative Action relating to Proprietary Medicinal Products*, O.J 02, 09.02.1965, p. 369–373, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31965L0065:EN:HTML>.

EC, *Council Directive 85/374/EEC of 25 July 1985 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products*, OJ L 210, 7.8.1985, p. 29–33, online: Eur-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:31985L0374>.

EC, *Council Directive 91/689/EEC of 12 December 1991 on Hazardous Waste*, OJ L 377, 31.12.1991 p.20-27, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31991L0689:EN:HTML>.

EC, *Council Directive 92/59/EEC of 29 June 1992 on General Product Safety*, [1992], OJ L 228, 11.8.1992, p. 24–32, online: EUR-Lex, <http://eur-lex.europa.eu/Result.do?T1=V3&T2=1992&T3=59&RechType=RECH_naturel&Submit=Search>.

EC, *Council Directive 98/18/EC of 17 March 1998 on Safety Rules and Standards for Passenger Ships*, OJ L 144, 15.5.1998, p. 1–115, online: Eur-Lex <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31998L0018>.

EC, *Council Resolution of 14 April 1975 on a Preliminary Programme of the European Economic Community for a Consumer Protection and Information Policy*, OJ C 92, 25.4.1975, p. 1–1, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31975Y0425(01)>.

EC, *Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a Common Framework for the Marketing of Products, and Repealing*

Council Decision 93/465/EEC, [2008] O.J.L 218, online: EUR-Lex <http://europa.eu/legislation_summaries/consumers/consumer_safety/l10141_en.htm >.

EC, *Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 Concerning the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Relating to the Classification, Packaging and Labeling of Dangerous Preparations*, OJ L 200, 30.7.1999, p. 1–68, online, EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31999L0045>.

EC, *Directive 67/548/EEC of 27 June 1967 on the Approximation of Laws, Regulations and Administrative Provisions Relating to the Classification, Packaging and Labeling of Dangerous Substances OJ 196, 16.8.1967, p. 1–98,* online: European Commission <http://ec.europa.eu/environment/archives/dansub/pdfs/67_548_en.pdf>.

EC, *Directive 90/385/EEC of 20 June 1990 on the Approximation of the Laws of the Member States Relating to Active Implantable Medical Devices*, [1990] O.J. L 189.

EC, *Directive 93/42/EEC of 14 June 1993 Concerning Medical Devices*, [1993], O.J. L 169.

EC, *Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in Vitro Diagnostic Medical Devices*, [1998], O.J. L 331.

EC, *Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Veterinary Medicinal Products*, [2001], O.J. L 311.

EC, *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001, on the Community Code Relating to Medicinal Products for Human Use*, [2010], O.J. L 311, 28.11.2001, p. 67–128, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1479458852043&uri=CELEX:32001L0083>.

EC, *Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety*, [2002], OJ L 11, 15.1.2002, p. 4–17, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32001L0095 >.

EC, *Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications*, OJ L 255,

30.9.2005, p. 22–142, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32005L0036>.

EC, *Directive 2008/98/EC of the European Parliament and the Council of 19 November 2008 on Waste and Repealing Certain Directives*, OJ L 312/3, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:312:0003:0030:en:PDF>.

EC, *Directive 2009/21/EC of the European Parliament and of the Council of 23 April 2009 on Compliance with Flag State Requirements,* OJ L 131, 28.5.2009, p. 132–135, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32009L0021>.

EC, *Directive 2009/15/EC of the European Parliament and of the Council of 23 April 2009 on Common Rules and Standards for Ship Inspection and Survey Organisations and for the Relevant Activities of Maritime Administrations*, OJ L 131, 28.5.2009, p. 47–56 online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:131:0047:0056:EN:PDF>.

EC, *Directive 2009/16/EC of the European Parliament and of the Council of 23 April 2009 on Port State Control*, OJ L 131, 28.5.2009, p. 57–100, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:131:0057:0100:EN:PDF>.

EC, *Directive 2009/17/EC of the European Parliament and of the Council of 23 April 2009 Amending Directive 2002/59/EC Establishing a Community Vessel Traffic Monitoring and Information System*, OJ L 131, 28.5.2009, p. 101–113, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:131:0101:0113:EN:PDF>.

EC, *Directive 2009/18/EC of the European Parliament and of the Council of 23 April 2009 Establishing the Fundamental Principles Governing the Investigation of Accidents in the Maritime Transport Sector and Amending Council Directive 1999/35/EC and Directive 2002/59/EC of the European Parliament and of the Council*, OJ L 131, 28.5.2009, p. 114–127, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:131:0114:0127:EN:PDF>.

EC, *Directive 2009/20/EC of the European Parliament and of the Council of 23 April 2009 on the Insurance of Shipowners for Maritime Claims*, OJ L 131, 28.5.2009, p. 128–131, online: EUR-lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:131:0128:0131:EN:PDF>.

EC, *Directive 2009/45/EC of the European Parliament and of the Council of 6 May 2009 on Safety Rules and Standards for Passenger Ships*, OJ L 163, 25.6.2009, p. 1–140, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009L0045>.

EC, *Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the Application of Patients' Rights in Cross-Border Healthcare*, OJ L 88, 4.4.2011, p. 45–65, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0024>.

EC, *Directive 2011/62/EU of the European Parliament and of the Council Amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, as Regards the Prevention of the Entry into the Legal Supply Chain of Falsified Medicinal Products*, OJ 174.74.2011, online: European Commission, <http://ec.europa.eu/health/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf>.

EC, *EU Consumer Policy strategy 2007-2013, Empowering Consumers, Enhancing their Welfare, Effectively Protecting them,* Brussels, 13.3.2007, COM (2007) 99 (final), online: European Commission <http://ec.europa.eu/consumers/overview/cons_policy/doc/EN_99.pdf>.

EC, *Green Paper on Consumer Protection in the European Union*, Brussels, (COM (2001) 531 (final)), at 10&11, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52001DC0531&from=EN>.

EC, *Guidance Document on the Relationship between the GPSD and Certain Sector Directives*, online: European Commission <http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/guidance_gpsd_en.pdf>.

EC, *Guidelines for Information Exchange and on Administrative Cooperation between the U.S. Consumer Product Safety Commission and the Directorate- General Health and Consumer Protection of the European Commission*, online: European Commission <http://ec.europa.eu/consumers/archive/cons_safe/prod_safe/coop_USA_guidelines.pdf>.

EC, *Joint Statement of Extension of Memorandum of Understanding on Administrative Cooperation Arrangements Between DG SANCO and AQSIG*, online: European Commission <http://ec.europa.eu/consumers/archive/safety/int_coop/docs/joint_statement_of_extention_of_mou_on_adm_coop_arrangements_between_sanco__aqsiq_en.pdf>.

EC, *Memorandum of Understanding on Administrative Cooperation Arrangements Between DG SANCO and AQSIG*, online: European Commission <http://ec.europa.eu/consumers/archive/safety/int_coop/docs/memorandum_china_annexes.pdf>.

EC, *Product Safety and Market Surveillance Package*, online: European Commission <http://ec.europa.eu/consumers/consumers_safety/product_safety_legislation/product_safety_and_market_surveillance_package/index_en.htm>.

EC, *Product Safety and Market Surveillance Package Proposal for a Regulation of the European Parliament and of the Council on Market Surveillance of Products and Amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC,2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EU) No 305/2011, Regulation (EC) No 764/2008 and Regulation (EC) No765/2008 of the European Parliament and of the Council*, online: Council of the EU <http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%205890%202013%20INIT>.

EC, *Product Safety and Market Surveillance package, Proposal for a Regulation of the European Parliament and of the Council on Consumer Product Safety and Repealing Council Directive 87/357/EEC and Directive 2001/95/EC*, 2013/0049 (COD), online: Council of the EU <http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%205892%202013%20INIT>.

EC, *Proposal for a Council Decision Introducing a Community System for the Rapid Exchange of Information on Dangers Arising from the Use of Consumer Products*, J.O. L 79/C 321/04, online: EUR-Lex <http://eur-lex.europa.eu/JOHtml.do?uri=OJ:C:1979:321:SOM:en:HTML>.

EC, *Proposal for a Regulation of the European Parliament and of the Council on Consumer Product Safety and Repealing Council Directive 87/357/EEC and Directive 2001/95/EC,* COM/2013/078 (final), 2013/0049 (COD), online: EUR-Lex <http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:52013PC0078>.

EC, *Proposal for a Regulation of the European Parliament and of the Council on Market Surveillance of Products and Amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EU) No 305/2011, Regulation (EC) No 764/2008 and Regulation (EC)*

No 765/2008 of the European Parliament and of the Council, COM/2013/075 (final), 2013/0048 (COD), online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52013PC0075>.

EC, *Regulation No 178/2002 of the European Parliament and of the Council of 28 January 2002 Laying down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority and Laying down Procedures in Matters of Food Safety*, OJ L 31, 1.2.2002, p. 1–24, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32002R0178>.

EC, *Regulation No 254/2014 of the European Parliament and of the Council of 26 February 2014 on a Multiannual Consumer Programme for the Years 2014-20 and Repealing Decision No 1926/2006/EC*, JO L84/42 20.3.2014, p. 44 online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2014:084:0042:0056:EN:PDF>.

EC, *Regulation 304/2003 of the European Parliament and of the Council of 28 January 2003 Concerning the Export and Import of Dangerous Chemicals*, OJ L 63, 6.3.2003, p. 1.

EC, *Regulation No. 391/2009 of the European Parliament and of the Council on Common Rules and Standards for Ship Inspection and Survey Organisations*, O.J. L 131, 28 May 2009, p. 11-23, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:131:0011:0023:EN:PDF>.

EC, *Regulation No 392/2009 of the European Parliament and of the Council of 23 April 2009 on the Liability of Carriers of Passengers by Sea in the Event of Accidents*, OJ L 131, 28.5.2009, p. 24–46, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:131:0024:0046:EN:PDF>.

EC, *Regulation 649/2012 of the European Parliament and of the Council of 4 July 2012 Concerning the Export and Import of Hazardous Chemicals*, OJ L 201, 27.7.2012, p. 60-106, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:201:0060:0106:en:PDF>.

EC, *Regulation 689/2008 of the European Parliament and of the Council of 17 June 2008 Concerning the Export and Import of Dangerous Chemicals*, OJ L 204, 31.7.2008, p. 1-35, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32008R0689>.

EC, *Regulation 765/2008 of the European Parliament and of the Council of 9 July 2008 Setting out the Requirements for Accreditation and Market Surveillance Relating to the Marketing of Products and Repealing Regulation (EEC) No 339/93*,

OJ L 218, 13.8.2008, p. 82- 128, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:l10141>.

EC, *Regulation 850/2004 of the European Parliament and of the Council of 29 April 2004 on Persistent Organic Pollutants and Amending Directive 79/117/EEC*, OJ L 158, 30.4.2004, p. 7–49, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32004R0850>.

EC, *Regulation 1272/2008 of the European Parliament and of the Council of 16 December 2008 on Classification, Labeling and Packaging of Substances and Mixtures, Amending and Repealing Directives 67/548/EEC and 1999/45/EC, and Amending Regulation 1907/2006*, 31.12.2008, L 353/1, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF>.

EC, *Regulation 1406/2002 of the European Parliament and of the Council of 27 June 2002 Establishing a European Maritime Safety Agency*, OJ L 208, 5.8.2002, p. 1–9, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32002R1406>.

EC, *Regulation No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed*, [2003] O.J.L 268, online: EUR-Lex <http://europa.eu/legislation_summaries/consumers/consumer_safety/l21154_en.htm >.

EC, *Regulation 1907/2006 of the European Parliament and of the Council of 18 December 2006 Concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Establishing a European Chemicals Agency, Amending Directive 1999/45/EC and Repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC*, OJ L 396, 30.12.2006, p. 1–850, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32006R1907>.

EC, *Regulation 2111/2005 of the European Parliament and of the Council of 14 December 2005 on the Establishment of a Community List of Air Carriers Subject to an Operating Ban within the Community and on Informing Air Transport Passengers of the Identity of the Operating Air Carrier, and Repealing Article 9 of Directive 2004/36/EC*, OJ L 344, 27.12.2005, p. 15–22, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32005R2111>.

EC, *The Blue Guide on the Implementation of EU Product Rules*, 2016, J.O. 2016/C 272/01, online: European Commission <http://ec.europa.eu/DocsRoom/documents/18027>.

EC, *The Proposal for a Regulation of the European Parliament and of the Council on Classification, Labelling and Packaging of Substances and Mixtures, and Amending Directive 67/548/EEC and Regulation (EC) No 1907/2006 - Legislative Text as Adopted on 27 June 2007 by the European Commission*, COM (2007) 355 (final), online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52007PC0355>.

EC, *The Rules Governing Medicinal Products in the European Union EU: Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use*, SANCO/C8/AM/sl/ares, (2010), European Commission: Health and Consumer Directorate-General, online: European Commission <http://ec.europa.eu/health/files/eudralex/vol-4/2011_intro_en.pdf>.

EC, *Treaty Establishing the European Economic Community: EEC Treaty - original text (non-consolidated version)*, Rome, (25 March 1957), online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3Axy0023>.

European Council, *Reinforcing Product Safety and Market Surveillance*, online: European Council <http://www.consilium.europa.eu/en/policies/product-safety-market-surveillance/>.

European Parliament, *Resolution on the Status of Non-Conventional Medicine* (A4-0075/97), (6 March 1997), online: Euro-CAM <http://www.cam-europe.eu/dms/files/Parliament_documents/EuropeanParliamentResolution1997.pdf>.

Export and Import of Hazardous Waste and Hazardous Recyclable Material Regulations, SOR/2005-149, online: Justice Laws Website <http://laws-lois.justice.gc.ca/eng/regulations/SOR-2005-149/>.

Export Control List Notification Regulations, SOR/2000-108, online: Canadian Legal Information Institute <https://www.canlii.org/en/ca/laws/regu/sor-2000-108/latest/sor-2000-108.html>.

Export of Substances on the Export Control List Regulations, SOR/2013-88, online: Canadian Legal Information Institute <https://www.canlii.org/en/ca/laws/regu/sor-2013-88/latest/sor-2013-88.html>.

Export of Substances Under the Rotterdam Convention Regulations, SOR/2002-317, online: Canadian Legal Information Institute <https://www.canlii.org/en/ca/laws/regu/sor-2002-317/latest/sor-2002-317.html>.

Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (codified in scattered sections of 21 U.S.C.).

FAO, *International Code of Conduct on Pesticide Management,* (2012), online: FAO <www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/code/en>.

Federal Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906), online: FDA <http://www.fda.gov/regulatoryinformation/legislation/ucm148690.htm>.

Food and Drugs Act, (R.S.C., 1985, c. F-27), online: Justice Law <http://laws-lois.justice.gc.ca/eng/acts/F%2D27/>.

Good Manufacturing Practices (GMP) Guidelines: *Health Products and Food Branch Inspectorate*, (GUI-0001), (2009), Health Canada, online: <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/compli-conform/gmp-bpf/docs/gui-0001-eng.pdf>.

Hazardous Products Act 1985, (R.S.C., 1985, c. H-3), online: Justice Laws <http://laws-lois.justice.gc.ca/eng/acts/H-3/>.

Hazardous Products Regulations (SOR/2015-17), online: Justice Laws <http://laws-lois.justice.gc.ca/eng/regulations/SOR-2015-17/>.

ICAO, *The Council decision C-DEC 197/4.*

ICAO, *Convention on International Civil Aviation*, online: ICAO <http://www.icao.int/publications/Documents/7300_cons.pdf>.

ICAO, *Resolution A36-13: Consolidated Statement of ICAO Policies and Associated Practices Related Specifically to Air Navigation*, (Doc. 9902), online: ICAO

Law of the People's Republic of China on the Protection of Consumer Rights and Interests, online: World Intellectual Property Organization <http://www.wipo.int/wipolex/en/details.jsp?id=8745>.

IMO, *Convention on the International Regulations for Preventing Collisions at Sea*, 1972, online: IMO <http://www.imo.org/About/Conventions/ListOfConventions/Pages/COLREG.aspx>.

IMO, *International Convention on Standards of Training, Certification and Watchkeeping for Seafarers*, 1978, online: IMO <http://www.imo.org/About/Conventions/ListOfConventions/Pages/International-Convention-on-Standards-of-Training,-Certification-and-Watchkeeping-for-Seafarers-(STCW).aspx.>.

IMO, *International Maritime Dangerous Goods Code*, online: IMO <http://www.imo.org/blast/mainframe.asp?topic_id=158>.

IMO, *The International Convention on Tonnage Measurement of Ships*, 1969, online: Admiralty Law Guide <http://www.admiraltylawguide.com/conven/tonnage1969.html>.

Memorandum of Understanding between the Healthy Environments and Consumer Safety Branch of the Department of Health of Canada and the Consumer Product Safety Commission of the United States of America Regarding Cooperation Related to the Safety of Consumer Products, online: CPSC <https://www.cpsc.gov/PageFiles/64600/05212.pdf>.

MERCOSUR, *Declaration presidencial de derechos fundamentales de los consumidores del MERCOSUR*, (2000), ATA 02/2000 MERCOSUR/CCM/CT7, Comite de Defensa del Consumidor.

MERCOSUR, Resolution N 23/04 - *Technical Standard on Toy Safety*, NM-300-1:2002, online: International Council of Toy Industries <http://www.toy-icti.org/PDFs/NM300-1_2002.pdf>.

Minamata Convention on Mercury, online: Mercury Convention <http://www.mercuryconvention.org/Portals/11/documents/Booklets/Minamata%20Convention%20on%20Mercury_booklet_English.pdf>.

Motor Vehicle Safety Act 1993, (S.C. 1993, c. 16), online: Justice Laws <http://laws-lois.justice.gc.ca/eng/acts/M-10.01/>.

NAFTA, *North American Free Trade Agreement*, online: NAFTA Secretariat <https://www.nafta-sec-alena.org/Home/Legal-Texts/North-American-Free-Trade-Agreement>.

Natural Health Products Regulations, (SOR/2003-196), online: Justice Laws <http://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/page-1.html#docCont>.

Navigation and Vessel Inspection Circular N 2-84: Amendments to the 1974 Safety of Life at Sea (SOLAS) Treaty, Department of Transportation: US Coast Guard, online: US Coast Guard <https://www.uscg.mil/hq/cg5/nvic/pdf/1984/n2-84.pdf>).

Norma Mexicana (NMX-R-019-SCFI-201) Sistema Armonizado de Clasificacion y Comunicacion de Peligros de los Productos Quimicos, [Spanish] online: Diario Oficial de la Federation <http://dof.gob.mx/nota_detalle.php?codigo=5166277&fecha=04/11/2010>.

Norma Oficial Mexicana (NOM-018-STPS-2000), Sistema para la identificación y comunicación de peligros y riesgos por sustancias químicas peligrosas en los centros de trabajo, [Spanish] online: Secretaria del Trabajo y Previsión Social <http://www.stps.gob.mx/bp/secciones/dgsst/normatividad/normas/Nom-018.pdf>.

OECD, *Guidelines for Consumer Protection in the Context of E-commerce* (1999), OECDOR, online: OECD <http://www.oecd.org/fr/sti/consommateurs/oecdguidelinesforconsumerprotectionintheconteXtofelectroniccommerce1999.htm>.

OECD, *The UN Global Compact and the OECD Guidelines for Multinational Enterprises: Complementarities and Distinctive Contributions*, Investment Division: Directorate for Financial and Enterprise Affairs Organisation for Economic Co-operation and Development, (April 2005), online: OECD <http://www.oecd.org/corporate/mne/34873731.pdf>.

Parliamentary Assembly, *Resolution 1206 (1999), A European Approach to Non-Conventional Medicines*, (4 November 1999), online: Parliamentary Assembly <http://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-en.asp?fileid=16727&lang=en>.

Pathway for Licencing NHPs Making Modern Health Claims, Health Canada: Natural and Non-prescription Health Products Directorate, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodnatur/legislation/docs/modern-eng.pdf>.

Pest Control Products Act (S.C. 2002, c. 28), online: Justice Laws Website <http://laws-lois.justice.gc.ca/eng/acts/P-9.01/>.

Practical guide 7: How to Notify Substances to the Classification and Labelling Inventory, European Chemicals Agency, 2012, online: European Chemicals Agency <http://echa.europa.eu/documents/10162/13643/pg_7_clp_notif_en.pdf>.

Privacy Act 1985, (R.S.C., 1985, c. P-21), online: Justice Laws <http://laws-lois.justice.gc.ca/eng/acts/P-21/index.html>

The Protocol of 2002 to Amend the Athens Convention Relating to the Carriage of Passengers and their Luggage by Sea, 1974, online: UK Government <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/261628/Misc.6.2013_Prot_2002_Athens_8760.pdf >.

Protocol to Amend the Convention for the Unification of Certain Rules Relating to International Carriage by Air, Signed at Warsaw on 12 October 1929, Done at The Hague on 28 September 1955, online: McGill <https://www.mcgill.ca/iasl/files/iasl/hague1955.pdf>.

Protocol to the Athens Convention Relating to the Carriage of Passengers and their Luggage by Sea of 13 December 1974, online: Admiralty and Maritime Law Guide <http://www.admiraltylawguide.com/conven/protopassengers1976.html>.

Quality of Natural Health Products Guide, (1 May 2015), Health Canada: Natural and Non-prescription Health Products Directorate, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodnatur/legislation/docs/eq-paq-eng.pdf>.

Recall Handbook, A Guide for Manufacturers, Importers, Distributors and Retailers on Reporting Under Sections 15 and 37 of the Consumer Product Safety Act and Section 102 of the Child Safety Protection Act and Preparing for, Initiating Including CPSC Fast Track Product Recall Program and Use of Social Media, online: CPSC <https://www.cpsc.gov/s3fs-public/8002.pdf>.

Report an Incident Involving a Consumer Product, online: Health Canada <http://www.hc-sc.gc.ca/cps-spc/advisories-avis/incident/index-eng.php>.

Ship Safety: Passenger Ship Operations and Damaged Stability Standards: Convention Ships, (TP 10405 E), online: Transport Canada <https://www.tc.gc.ca/eng/marinesafety/tp-tp10405-menu-1045.htm>.

Standard for the Tonnage Measurement of Vessels (TP 13430 E), Transport Canada, online: Transport Canada <https://www.tc.gc.ca/eng/marinesafety/tp-tp13430-menu-332.htm>.

Stockholm Convention on Persistent Organic Pollutants, 2001, online: Stockholm Convention <www.pops.int >.

Technical Guidance on the Requirements of the Hazardous Products Act (HPA) and the Hazardous Products Regulations (HPR) - WHMIS 2015 Supplier Requirements - Phase 1, online: Health Canada <http://www.hc-sc.gc.ca/ewh-semt/occup-travail/whmis-simdut/ghs-sgh/classification/hazardous-products-produits-dangereux/index-eng.php>.

The Canadian Supplement to the SOLAS Convention, online: Transport Canada <https://www.tc.gc.ca/eng/marinesafety/tp-menu-515-4289.htm>.

The Pathway for Licensing Natural Health Products Making Modern Health Claims, Health Canada: Natural and Non-prescription Health Products Directorate, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodnatur/legislation/docs/modern-eng.pdf>.

The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, 1996, online: Rotterdam Convention <http://www.pic.int/TheConvention/Overview/TextoftheConvention/tabid/1048/language/en-US/Default.aspx >.

Toxic Substances Management Policy, online: Environment and Climate Change Canada <https://www.ec.gc.ca/toxiques-toxics/default.asp?lang=En&n=2A55771E-1>.

Toy Safety Standards, online: ICTI <http://www.toy-icti.org/info/toysafetystandards.html>.

Trilateral Cooperation Charter Between The Health Products and Food Branch, Health Canada, Canada, The Food and Drug Administration, Department of Health and Human Services, the United States of America, and the Federal Commission for the Protection from Sanitary Risks, Secretaria de Salud Mexico, (27 February 2004), online: Wayback <http://web.archive.org/web/20061020024258/http://www.fda.gov/oia/charter.html>.

Trilateral Cooperation Charter between the Secretariat of Health of the Mexican United States, through the Federal Commission for the Protection from Sanitary Risks; the Health Products and Food Branch of the Department of Health of Canada; and the Food and Drugs Administration within the Department of Health and Human Services of the United States of America, (14 October 2009).

United Nations Guidelines for Consumer Protection, GA Dec. 54/449, UN GAOR, 1999, online: UN <http://www.un.org/esa/sustdev/sdissues/consumption/cpp14.htm#54-449>.

UN Commission on Sustainable Development, *Consumer Protection and Sustainable Consumption, New Guidelines for the Global Consumer, Background paper for the United Nations Inter-Regional Expert Group Meeting on Consumer Protection and Sustainable Consumption*, UN Commission on Sustainable Development OR, 1998, online: UN <http://www.un.org/documents/ecosoc/cn17/1998/background/ecn171998-consumer.htm>.

UNCTAD, *Draft Resolution on Consumer Protection for Consideration by the General Assembly* (June 2015), online: UNCTAD <http://unctad.org/Sections/ditc_ccpb/docs/UNGCP_DraftResolution2015_en.pdf>.

UNCTAD, the *United Nations Guidelines on Consumer Protection*, 2015, online: UNCTAD <http://unctad.org/en/PublicationsLibrary/ditccplpmisc2016d1_en.pdf>.

UNEP, *Strategic Approach to International Chemicals, Management (Comprising the Dubai Declaration on International Chemicals Management, the Overarching Policy Strategy and the Global Plan of Action)*, Dubai, 2006, online: <http://www.saicm.org/images/saicm_documents/saicm%20texts/standalone_txt.pdf>.

UN Commission on Transnational Corporations, "Informational Paper on the Negotiations to Complete the Code of Conduct on Transnational Corporations, *International Legal Materials* 22:1 (January 1983), online: JSTOR <https://www.jstor.org/stable/20692548?seq=1#page_scan_tab_contents>.

UN, *Consolidated List of Products whose Consumption and/or Sale have been Banned, Withdrawn, Severely Restricted or Not Approved by Governments*, online: UN <http://www.un.org/esa/coordination/CL11.pdf>.

UN Department of Economic and Social Affairs, Division for Sustainable Development, *Agenda21*, 1992, online: UN-DESA <https://sustainabledevelopment.un.org/index.php?page=view&type=400&nr=23&menu=35>.

UNECE, *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*, 2011, (ST/SG/AC.10/30/Rev.4), online: <https://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev04/English/ST-SG-AC10-30-Rev4e.pdf>.

UN ECOSOC, *The Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or Not Approved by*

Governments (Pharmaceuticals), (ST/ESA/322) online: UN ECOSOC <http://www.un.org/esa/coordination/CL-14-Final.for.Printing.pdf>.

UN Economic and Social Council, *Consumer Protection*, ECOSOC Res. 1995/53, UN ECOSOCOR, 1995, online: UN <http://www.un.org/documents/ecosoc/res/1995/eres1995-53.htm>.

UNEP, *Rio Declaration on Environment and Development*, 1992, online: UNEP <http://www.unep.org/Documents.Multilingual/Default.asp?DocumentID=78&ArticleID=1163>.

UNEP, *The London Guidelines for the Exchange of Information on Chemicals in International Trade,* (1987), online: UNEP <http://www.chem.unep.ch/ethics/english/longuien.htm>.

UN GAOR, *Exchange of Information on Banned Hazardous Chemicals and Unsafe Pharmaceutical Products*, GA Res. 34/173, UN GAOR, 1979, UN Doc. A/RES/34/173, online: UN <http://www.un.org/documents/ga/res/34/a34res173.pdf>.

UN GAOR, *Exchange of Information on Banned Hazardous Chemicals and Unsafe Pharmaceutical Products*, GA Res. 35/186, UN GAOR, 1980, UN Doc. A/RES/35/186, online: UN <http://www.un.org/documents/ga/res/35/a35r186e.pdf>.

UN GAOR, *Exchange of Information on Banned Hazardous Chemicals and Unsafe Pharmaceutical Products*, GA Res. 36/166, UN GAOR, 1981, UN Doc. A/RES/36/166, online: UN <http://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/36/166>.

UN GAOR, *Nineteenth Special Session, the Earth Summit+5*, GA, UN GAOR, online: UN <http://www.un.org/esa/earthsummit/>.

UN GAOR, *Programme for the Further Implementation of Agenda 21*, GA Res19/2, UN GAOR, 1997, UN Doc. A/RES/S-19/2, online: UN <http://www.un.org/documents/ga/res/spec/aress19-2.htm>.

UN GAOR, *Protection Against Products Harmful to Health and the Environment*, GA Res.37/137, UN GAOR, 1982, UN Doc. Res. 37/137, online: UN <http://daccessdds.un.org/doc/RESOLUTION/GEN/NR0/426/15/IMG/NR042615.pdf?OpenElement>.

UN GAOR, *Protection Against Products Harmful to Health and the Environment,* GA Res.39/229, UN GAOR, 1984, UN Doc. A/RES/39/229, online: UN <http://www.un.org/documents/ga/res/39/a39r229.htm>.

UN, *International Convention for the Safety of Life at Sea* (SOLAS), 1974, online: UN <https://treaties.un.org/doc/Publication/UNTS/Volume%201184/volume-1184-I-18961-English.pdf>.

UN Office on Drugs and Crime, *The Convention on Psychotropic Substances*, 1971, online: UN Office on Drugs and Crime <https://www.unodc.org/pdf/convention_1971_en.pdf>,

UN Office on Drugs and Crime, *The Single Convention on Narcotic Drugs*, 1961, online: UN Office on Drugs and Crime <http://www.unodc.org/pdf/convention_1961_en.pdf>.

UN Office on Drugs and Crime, *The United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances*, 1988, online: UN Office on Drugs and Crime <http://www.unodc.org/pdf/convention_1988_en.pdf>.

U.S. Code: Title 33 Navigation and Navigable Waters, online: Law Cornell <https://www.law.cornell.edu/uscode/text/33>.

U.S. Code: Title 46 Shipping, online: Law Cornell <https://www.law.cornell.edu/uscode/text/46>.

WHA, *Cross-Border Advertising, Promotion and Sale of Medical Products Using the Internet*, Res. WHA51.9 (1998), online: WHO <http://apps.who.int/medicinedocs/en/d/Js21471ru/>.

WHA, *Traditional Medicine*, Res. WHA56.31 (2003) online: WHO <http://apps.who.int/gb/archive/pdf_files/WHA56/ea56r31.pdf>.

WHO, *Constitution of the World Health Organization*, online: WHO <http://www.who.int/governance/eb/who_constitution_en.pdf>.

WHO, *Good Manufacturing Practices for Pharmaceutical Products: Main Principles*, 2014, online: WHO <http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS986annex2.pdf?ua=1>.

WHO, *Guidelines for Appropriate Use of Herbal Medicines*, 1997, online: WHO <http://apps.who.int/medicinedocs/en/d/Jh2945e/>.

WHO, *Guidelines for Drug Donations*, 1999, (WHO/EDM/PAR/99.4), online: WHO <http://www.who.int/hac/techguidance/guidelines_for_drug_donations.pdf>.

WHO, *Guidelines for Inspection of Drug Distribution Channels*, WHO: Expert Committee on Specifications for Pharmaceutical Preparations, WHO: Technical Report Series, No. 885, 1999, online: WHO <http://apps.who.int/prequal/info_general/documents/TRS885/WHO_TRS_885-Annex6.pdf>.

WHO, *Guidelines for Medicine Donations*, 2010, online: WHO <http://whqlibdoc.who.int/publications/2011/9789241501989_eng.pdf?ua=1>.

WHO, *Guidelines for the Development of Measures to Combat Counterfeit Drugs*, (WHO/EDM/QSM/99.1), WHO: Department of Essential Drugs and Other Medicines, 1999, online: WHO <http://apps.who.int/iris/bitstream/10665/65892/1/WHO_EDM_QSM_99.1.pdf.>.

WHO, *Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine,* 2004, online: WHO <http://www.who.int/medicinedocs/collect/edmweb/index/assoc/s7149e/s7149e.pdf>.

WHO, *Guidelines on the Implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce*, online: WHO <http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/guidelines/en/index.html>.

WHO, *International Code of Marketing of Breastmilk Substitutes*, online: WHO <http://www.who.int/nutrition/publications/code_english.pdf>.

WHO, *Pharmaceuticals: Restrictions in Use and Availability* (WHO/EMP/QSM/2010.3), 2010, online: WHO <http://apps.who.int/medicinedocs/documents/s17126e/s17126e.pdf>.

WHO, *Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials. Good Manufacturing Practices and Inspection,* Vol. 2, Geneva: WHO, 2003, online: WHO <http://apps.who.int/medicinedocs/pdf/s4900e/s4900e.pdf>.

WHO, *Supplementary Guidelines on Good Manufacturing Practices for the Manufacture of Herbal Medicines,* WHO Technical Report Series: No. 937, 2006, online: WHO <http://www.who.int/medicines/areas/quality_safety/quality_assurance/SupplementaryGMPManufactureHerbalMedicinesTRS937Annex3.pdf?ua=1>.

WTO, *Agreement on the Application of Sanitary and Phytosanitary Measures*, online: WTO <https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm>.

WTO, *Agreement on Technical Barriers to Trade*, online: WTO <https://www.wto.org/english/docs_e/legal_e/17-tbt.pdf>.

WTO, *Decisions and Recommendations Adopted by the WTO Committee on Technical Barriers to Trade Since 1 January 1995*, Doc. G/TBT/1/Rev.11, (December 2013), online: WTO <https://www.wto.org/english/tratop_e/tbt_e/tbt_work_docs_e.htm>.

WTO, *Decision on the Implementation of Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures'*, WTO Doc. G/SPS/19/Rev.2., online: WTO <https://www.wto.org/english/tratop_e/sps_e/decisions06_e.htm>.

WTO, *European Communities – Measures Affecting Asbestos and Asbestos*, Dispute Settlement, WTO Doc. DS135, online: WTO <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds135_e.htm>.

WTO, *Guidelines to Further the Practical Implementation of Article 5.5'*, WTO Doc.G/SPS/15, online: WTO <https://www.wto.org/english/tratop_e/sps_e/decisions06_e.htm>;

WTO, *Marrakesh Agreement Establishing the World Trade Organization*, 1994, online: WTO <https://www.wto.org/english/docs_e/legal_e/04-wto_e.htm>.

WTO, *Standards and Safety*, online: WTO <https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm4_e.htm#TRS>.

WTO, *The WTO Agreement on the Application of Sanitary and Phytosanitary Measures,* online: WTO <http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm>.

ГОСТ 31340-2013 Предупредительная Маркировка Химической Продукции. Общие Требования [GOST 31340-2013 Labelling of Chemicals. General Requirements], online: Электронный Фонд <http://docs.cntd.ru/document/1200107846>.

ГОСТ Р 52249-2004, Правила Производства и Контроля Качества Лекарственных Средств (GOST R 52249-2004 Rules of Production and Quality Control of Medicines [translated by author]), online: VSEGOST <http://vsegost.com/Catalog/54/5420.shtml>.

ГОСТ Р 52249-2009, Правила Производства и Контроля Качества Лекарственных Средств (GOST R 52249-2009 Rules of Production and Quality Control of Medicines [translated by author]), online: VSEGOST <http://vsegost.com/Catalog/48/48198.shtml>.

Договор о Евразийском Экономическом Союзе (EAEU Treaty [translated by author]), online: EAEU <https://docs.eaeunion.org/Pages/DisplayDocument.aspx?s=bef9c798-3978-42f3-9ef2-d0fb3d53b75f&w=632c7868-4ee2-4b21-bc64-1995328e6ef3&l=540294ae-c3c9-4511-9bf8-aaf5d6e0d169&EntityID=3610>.

Договора о Правилах и Порядке Обеспечения Безопасности и Обращения Продукции, Требования к Которой не Установлены Техническими Регламентами Евразийского Экономического Союза (Проект), (International Treaty on the Rules and Procedures to Ensure the Safety and Handling of Products, the Requirements for which are not Established by the Technical Regulations of the Eurasian Economic Union (draft)), online: Комитет РСПП по Техническому Регулированию, Стандартизации и Оценке Соответствия <http://docs.cntd.ru/document/420295691>.

Закон РФ "О Защите Прав Потребителей", [The Consumer Protection Act of the Russian Federation], online: Общество защиты прав потребителей <http://ozpp.ru/laws/zpp.php>.

О Безопасности Химической Продукции [On Safety of Chemical Products], online: Eurasian Commission <http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/tr/Documents/TRHimiyaVGS.pdf>.

Кодекс Моргового Мореплавания Российской Федерации" от 30.04.1999 N 81-ФЗ, [Merchant Shipping Code of the Russian Federation, 30.04.1999, Federal Law 8,] online: Consultant <http://www.consultant.ru/document/cons_doc_LAW_177298/>).

Об Утверждении Правил Морской Перевозки Пассажиров [Regarding the Rules on Maritime Carriage of Passengers], online: Министерство Экономического Развития Российской Федерации <http://economy.gov.ru/minec/about/structure/depregulatinginfluence/doc20120216_03>.

О Введении в Действие Стандарта Отрасли ОСТ 42-510-98 "Правила Организации Производства и Контроля Качества Лекарственных Средств (GMP)" (On Introduction of the Industry Standard OST 42-510-98 "Rules of

Production and Quality Control of Medicines (GMP)" [translated by author]), online: CNTD <http://docs.cntd.ru/document/901755081>.

О Модельном Законе "Об Отходах Производства и Потребления" [Model Law "On Production and Consumption Waste"], online: Pravo Levonevsky <http://pravo.levonevsky.org/bazaby/org327/basic/text0170.htm>.

О Принципах Экологической Безопасности в Государствах Содружества, 1992 [On Principles of Ecological Safety in the States of the Commonwealth, 1992], online: Priroda <http://www.priroda.ru/law/detail.php?ID=6382>.

Постановление Правительства РФ от 06.02.2002 N 81 О Внесении Изменений и Дополнений в Правила Продажи Отдельных Видов Товаров (Government Decree of 06.02.2002 N 81 On Amendments and Additions to the Rules of the Sale of Certain Goods [translated by author]), online: Консультант <http://www.consultant.ru/document/cons_doc_LAW_136273/>.

Федеральный закон Российской Федерации от 8 марта 2011 "О Присоединении Российской Федерации к Роттердамской Конвенции о Процедуре Предварительного Обоснованного Согласия в Отношении Отдельных Опасных Химических Веществ и Пестицидов в Международной Торговле " (the Federal Law of the Russian Federation N30- ФЗ "On Accession of the Russian Federation to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade" [translated by author]), online: Российская Газета <https://rg.ru/2011/03/11/pesticidy-dok.html>.

Постановление Правительства Российской Федерации от 3 ноября 2007 г. N 746 "О Реализации Положений главы XI-2 Международной Конвенции по Охране Человеческой Жизни на Море 1974 года и Международного Кодекса по Охране Судов и Портовых средств (Resolution of the Government of the Russian Federation, November 3, 2007 N 746 "On the Implementation of the Provisions of Chapter XI-2 of the International Convention for the Safety of Life at Sea, 1974 and the International Code for the Security of Ships and Port Facilities [translated by author]), online: Morflot <http://www.morflot.ru/transportnaya_bezopasnost/solas_74.html>.

Постановление Правительства РФ от 03.07.97 N 813 "О Создании и Функционировании Глобальной Морской Системы Связи при Бедствии и для Обеспечения Безопасности", [RF Government Directive N 813, 03.07.97 "Regarding the Establishment and Operation the Global Maritime Distress and Safety System "], online: Законодательная База Российской Федерации, <http://zakonbase.ru/content/nav/22355>.

Постановление Правительства РФ от 12 августа 2010 г. No 620 "Об Утверждении Технического Пегламента о Безопасности Объектов Морского Транспорта" [Government Directive of August 12, 2010 No 620 "On Approval of Technical Regulations on Safety of Maritime Transport", online: ГОСТ <http://www.gost.ru/wps/wcm/connect/85e03a00455e487cb079b5e4dfffd2ca/Post_Prav_09.08.2010_№+620.pdf?MOD=AJPERES>.

Постановление Правительства РФ от 19 января 1998 г. N 55 Об Утверждении Правил Продажи Отдельных Видов Товаров (The Government of Russian Federation Resolution January 19, 1998 N 55 On the Rules of the Sale for Certain Goods [translated by author]), online: Гарант <http://base.garant.ru/12108380/>.

Постановление Совета Министров СССР от 2 ноября 1979 г. N 975 "О Принятии СССР Международной Конвенции по Охране Человеческой Жизни на Море, 1974 года", [Resolution of the Council of Ministers of the USSR, November 2, 1979, Regarding Ratification International Convention SOLAS 1974], online: Consultant <http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=ESU;n=21174>.

Постановление от 26 января 2012 Года, О мерах по Обеспечению Выполнения Обязательств Российской Федерации, Вытекающих из Роттердамской Конвенции о Процедуре Предварительного Обоснованного Согласия в Отношении Отдельных Опасных Химических Веществ и Пестицидов в Международной Торговле [The Directive of the Government of Russian Federation n. 22 January, 26, 2012 Regarding Measures to Implement the Obligation under the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade], online: Российская Газета <https://rg.ru/2012/02/07/pesticidy-site-dok.html>.

Постановление от 27 Октября 2008 года О Федеральной Целевой Программе "Национальная Система Химической и Биологической Безопасности Российской Федерации (2009- 2013 годы)", Directive of the Government of the Russian Federation October 27, 2008 N 791, Regarding the Federal Program the National System of Chemical and Biological Security of Russian Federation 2009 – 2013] (Russian), online: EMERCOM of Russia <http://www.mchs.gov.ru/document/3591324>.

Постановление от 30 Июля 2014 Года №720, О Мерах по Обеспечению Выполнения Российской Федерацией Обязательств, Предусмотренных Стокгольмской Конвенцией о Стойких Органических Загрязнителях от 22 Мая 2001 г. [Directive №720, 30 July, 2014, Regarding the Measure to Implement Russian Federation's Obligations under the Stockholm Convention on Persistent Organic Pollutants at 22 May, 2001], online: Government of Russia

<http://government.ru/docs/14081/>.

Пояснительная Записка к Проекту Федерального Закона «О Присоединении Российской Федерации к Роттердамской Конвеции о Процедуре Предварительного Обоснованного Согласия в Отношении Отдельных Опасных Химических Веществ и Пестицидов в Международной Торговли от 10 Сентября 1998 Года» [Explanatory Note on the Federal Law Draft: Regarding the Accession of the Russian Federation to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, September 10, 1998], online: Консультант Плюс <http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=PRJ;n=82457>.

Правила Надлежащей Производственной Практики (GMP) ЕАЭС, Версия 4.0 от 20.02.2015 (Rules for Good Manufacturing Practices (GMP) EAEU, Draft 4.0, (20 February 2015) [translated by author]), online: Eurasian Commission <http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/konsultComitet/Documents/Проект%20Правил%20GMP%20редакция%20от%202015%2002%2020%20на%20сайт.pdf>.

Приказ Министерства Промышленности и Торговли РФ от 14 июня 2013 г. № 916 (The Directive of the Ministry of Industry and Trade of the Russian Federation on June 14, 2013 № 916 [translated by author]), online: Качество РФ <http://качество.рф/documents/order>.

Соглашение Стран СНГ о Контроле за Трансграничной Перевозкой Опасных и Других Отходов, 1996 [Agreement of the CIS States on Control of Transboundary Movement of Hazardous and Other Waste, 1996], online: Pravo Levonevsky <http://pravo.levonevsky.org/bazaby09/sbor79/text79354.htm>.

Федеральный Закон Российской Федерации от 12 Апреля 2010 г. N 61-ФЗ Об Обращении Лекарственных Средств (Federal Law of Russian Federation on April 12, 2010, N 61, On the Circulation of Pharmaceuticals [translated by author]), online: Российская Газета <http://www.rg.ru/2010/04/14/lekarstva-dok.html>.

Федеральный Закон от 12.04.2010 N 61-ФЗ "Об Обращении Лекарственных Средств" (The Federal Law of 12.04.2010 N 61-FZ "On Circulation of Medicines" [translated by author]) online: Consultant <http://www.consultant.ru/document/cons_doc_LAW_176361/>.

Федеральный Закон от 21.11.2011 N 323-ФЗ "Об Основах Охраны Здоровья Граждан в Российской Федерации" (On the Fundamentals of Health Protection in the Russian Federation [translated by author]) online: Российская Газета <http://www.rg.ru/2011/11/23/zdorovie-dok.html>).

JURISPRUDENCE

Agreement Under Article 21.3(b) of the DSU, United States–Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products (Complaint by Mexico), (2008), WTO Doc. WT/DS381, (Dispute Settlement), online: WTO <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds381_e.htm>.

Appellate Body Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes (Complaint by Indonesia)*, (2012), WTO Doc. WT/DS406/AB/R, online: WTO <https://www.wto.org/english/tratop_e/dispu_e/406abr_e.pdf>.

European Communities — Measures Affecting the Approval and Marketing of Biotech Products (Complaint by Argentina), (2006), WTO Doc. DS293, (Dispute Settlement) online: WTO <http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds293_e.htm>.

European Communities – Measures Affecting Asbestos and Asbestos – Containing Products (Complaint by Canada), (2000), WTO Doc. WT/DS135/R (Report of the Panel), online: WTO <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds135_e.htm>.

European Communities — Measures Concerning Meat and Meat Products (Hormones) (Complaint by the United States), (1999), WTO Doc. DS26, (Dispute Settlement), online: WTO <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds26_e.htm>.

United States—Measures Affecting the Production and Sale of Clove Cigarettes (Complaint by Indonesia), (2014), WTO Doc. WT/DS406/12, (Dispute Settlement), online: WTO <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds406_e.htm>.

Recourse to Article 22.2 of the DSU by Indonesia, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, WTO Doc. WT/DS406/12 (2013).

Recourse to Article 22.2 of the DSU by Indonesia, Communication from the Arbitrator, *United States—Measures Affecting the Production and Sale of Clove Cigarettes (Complaint by Indonesia)*, WTO Doc. WT/DS406/16 (24 June 2014), online: WTO <https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=125508,122599,119011,118886,118743,118

023,117359,116708,116125,115577&CurrentCatalogueIdIndex=0&FullTextSearch=>.

Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein Case, Reference for a Preliminary Ruling: (Hessisches Finanzgericht - Germany), Measures Heaving an Effect Equivalent to Quantitative Restrictions, (20 February1979), No.120/78, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:61978J0120:EN:HTML>.

United States–Certain Country of Origin Labeling (Complaint Canada), (2012) WTO Doc. WT/DS384/24 & WT/DS386/23 (Dispute Settlement), online: WTO <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds384_e.htm>.

SECONDARY MATERIAL: MONOGRAPHS

Barrios, Paula. *The Rotterdam Convention on Hazardous Chemicals: A Meaningful Step Toward Environmental Protection?* (University of British Colombia, 2004) online: University of British Colombia <https://open.library.ubc.ca/cIRcle/collections/ubctheses/831/items/1.0077646>.

Bartlett, W.B., *Titanic: 9 Hours to Hell, the Survivors' Story*, (Stroud, Gloucestershire: Amberley Publishing, 2011).

Barnard, Catherine. *The Substantive Law of the EU: The Four Freedoms* (Oxford University Press, 2007).

Benohr, Iris. *EU Consumer Law and Human Rights*, (Oxford, U.K.: Oxford University Press, 2013).

Bourgoignie, Thierry. *Droit et politique communautaires de la consommation: une évaluation des acquis* in *Melanges Claude Masse*, ed. by Pierre-Claude Lafond (Cowansville: Yvon Blais, 2003)

Bourgoignie, Thierry. *La protection des consommateurs économiquement faibles ou le consommateur oublié*, in *Droits des pauvres. Pauvre droit ?,* Editions du Jeune Barreau, Cabay (Louvain-la-Neuve, 1984).

Bourgoignie, Thierry. *Lois générales sur la protection du consommateur et codes de la consommation en Europe*, in *Pour une réforme du droit de la consommation au Québec,* ed. by François Maniet (Cowansville,Qc.: Yvon Blais Inc., 2005).

Bourgoignie, Thierry. *Un droit de la consommation est-il encore nécessaire en 2006?*, in *Regards croisés sur les enjeux contemporains du droit de la consommation*, ed. by Bourgoignie, Thierry (Cowansville, Quebec: Yvon Blais Inc, 2006).

Bourgoignie, Thierry & St-Pierre, Julie. "Le statut de politique de protection du consommateur dans les systèmes régionaux économiquement intégrés. Une première évaluation comparative", *Québec Journal of International Law*, 20:1, (2007), online: Revue Québécoise de Droit International <http://www.sqdi.org/wp-content/uploads/20.1_bourgoignie.pdf>.

Bourgoignie, Thierry. & Trubek, David. *Consumer Law, Common Markets and Federalism* (Berlin: Walter de Gruyter, 1987).

Calabresi, Guido. *The Cost of Accidents: A Legal and Economic Analysis*, (Yale University Press, 2008).

Choo TA, Goh. *et al. A Comparison of Mandatory and Voluntary Approaches to the Implementation of Globally Harmonized System of Classification and Labeling of Chemicals (GHS) in the Management of Hazardous Chemicals.*, Industrial Health (20 October 2011), online: Academia <https://www.academia.edu/3013741/A_Comparison_of_Mandatory_and_Voluntary_Approaches_to_the_Implementation_of_Globally_Harmonized_System_of_Classification_and_Labelling_of_Chemicals_GHS_in_the_Management_of_Hazardous_Chemicals>.

Coglianese, Cary. Finkel, Adam. & Zaring, David. *Import Safety: Regulatory Governance in the Global Economy.* (Philadelphia: University of Pennsylvania Press, 2009).

Conway, Emilie. *La protection du consommateur à l'épreuve de l'Organisation mondiale du commerce* (Cowansville, Qc.: Yvon Blais Inc., 2012).

Cseres, Katalin Judit. *Competition Law and Consumer Protection*, (Kluwer Law International, 2005).

Deblock, Christian. Rioux, Michele. *NAFTA – a Model Running out of Breath?* (January 2010), online: Research Gate <https://www.researchgate.net/publication/227384039_NAFTA_-_A_model_running_out_of_breath>.

De Very, Rogier W. *Towards a European Unfair Competition Law: A Clash Between Legal Families: a Comparative Study of English, German and Dutch Law in Light of Existing European and International Legal Instruments a Comparative* (Leiden/Boston: Martinus Nijhoff, 2006)

Grosz, Mirina. *Sustainable Waste Trade under WTO Law: Chances and Risks of the Legal Frameworks' Regulation of Transboundary Movements of Wastes*, (Leiden/ Boston: Martinus Nijhoff Publishers, 2011).

Harland, David. *The United Nations Guidelines for Consumer Protection: Their Impact in the First Decade* in *Consumer Law in the Global Economy—National and International Dimensions* ed. by Iain Ramsay (Aldershot: Ashgate, 1997).

Havel, Brian F. Sanchez, Gabriel S. *The Principles and Practice of International Aviation Law*, (Cambridge University Press, 2014).

Huang, Jiefang. *Aviation Safety and ICAO,* (The Netherlands: Kluwer Law International BV, 2009).

Hutchings, David F., & de Kerbrech, Richard P. *RMS Titanic 1909–12 (Olympic Class): Owners' Workshop Manual.* (Sparkford, Yeovil: Haynes 2011)

Hoekman, Bernard. & Kostecki, Michel. *The Political Economy of the World Trading System: WTO and Beyond,* 2d ed. (OUP Oxford, 2001) online: Oxford Scholarship <http://www.oxfordscholarship.com/view/10.1093/019829431X.001.0001/acprof-9780198294313>.

Howells, Geraint. & Weatherill, Stephen. *Consumer Protection Law*, (Aldershot: Ashgate, 2005).

Liz, Jorge Pegado. *Compatibility of National Consumer Protection Measures with Free Trade Rules in the EU 2007* (Montreal: UQAM, GREDICC, 2007).

MacKenzie, David. *ICAO: A History of the International Civil Aviation Organization*, (University of Toronto Press, 2010),

Françoise Maniet, *Nanotechnologies et produits de consommation Quels risques ? Quels encadrements ?,* (Cowansville (Québec):Yvon Blais), (2012).

Maniet, F. & Dunaj, B. eds., *The Implementation Process of E.U. Directives on Product Safety, Product Liability and Unfair Contract Terms: The European Directive on General Product Safety and its Implementation in the E.U Member*

States. (Lauvain: Centre de Droit de la Consommation, Université Catholique de Lauvain, 1994).

Mackaay, Ejan. *L'analyse économique du droit de la consommation, dans Propos autour de l'effectivité du droit de la consommation*, ed. by Thierry Bourgoignie (Cowansville, Quebec: Yvon Blais Inc, 2008).

McClean, David. *et al, Shawcross and Beaumont on Air Law* (London: LexisNexis Butterworths, 2014).

Mazeaud, Denis. *Droit commun du contrat et droit de la consommation. Nouvelles frontières?* in *Études de droit de la consommation*, ed. by Liber Amicorum & Jean Calais-Auloy (Paris: Dalloz, 2004).

Molchanov, Mikhail A. *Eurasian Regionalisms and Russian Foreign Policy*, (Surrey: Ashgate Publishing, 2015).

Micklitz, Hans-W. Stuyck, Jules. & Terryn, Evelyn. *Consumer Law: Ius Commune Casebooks for a Common Law of Europe*, (Bloomsbury Publishing, 2010).

Nally, Joseph D. *Good Manufacturing Practices for Pharmaceuticals*, CRC Press (26 December 2006).

Nehf, James P. "Principles of Consumer Protection in the North American Free Trade Agreement" in Thierry Bourgoignie dir., *Integration économique régionale et politique de protection du consommateur* (Cowansville (Québec):Yvon Blais, 2009).

Paisant, Gilles. *Défense et illustration du droit de la consummation*, (Paris: LexisNexis, 2016).

Papadopoulos, Thomas. *EU Law and the Harmonization of Takeovers in the Internal Market*, (Kluwer Law International, 2010).

Peterson, Esther. *The United Nations and Consumer Guidelines* in *Consumers, Transnational Corporations and Development,* ed. by T. Wheelwright, (Sydney: Transnational Corporations Research Project, University of Sydney, 1986).

Ramsay, Iain. *Consumer Law and Policy: Text and Materials on Regulating Consumer Markets*, (Oxford and Portland, Oregon: Bloomsbury Publishing, 2012).

Reich, Norbert *et al.*, *European Consumer Law*, (Cambridge: Intersentia, 2014).

Shinkuma, Takayoshi. & Managi, Shunsuke. *Waste and Recycling: Theory and Empirics*, (Oxford: Routledge, 2011).

Schulze, Reiner. Schulte-Nolke, Hans. Jones, Jackie. *A Casebook on European Consumer Law*, (Oxford/Portland: Hart Publishing, 2002)

Sjöström, H. *Thalidomide and the Power of the Drug Companies* (Manchester: Penguin, 1972).

Van Calster, Geert. & Prevost, Denise. *Research Handbook on Environment, Health and the WTO*, (Northampton: Edward Elgar Publishing, 2013).

Weatherill, Stephen. *EU Consumer Law and Policy,* (Northampton: Edward Elgar, 2013).

SECONDARY MATERIAL: COMMUNIQUES AND REPORTS

2015 Passenger Capacity, online: Cruise Market Watch <http://www.cruisemarketwatch.com/capacity/>.

17th Japan-EU Summit Tokyo: 23 April 2008 Joint Press Statement, online: EU-Asia <http://www.eu-asiacentre.eu/links.php?cat_id=25&level=0&tree=25&code=4 >.

Adaptations to Technical Progress to the CLP Regulation, online: REACH <http://www.reach.lu/mmp/online/website/menu_hori/news/93/900_EN.html>.

Agreement on Free Trade Zone between the EAEU and Socialist Republic of Vietnam Signed According to the Results of the Second Session of the Eurasian Intergovernmental Council, (29 May 2015), Eurasian Commission, online: Eurasian Commission <http://www.eurasiancommission.org/en/nae/news/Pages/29-05-2015-5.aspx>.

Alert: Graco Children's Products Inc. Recalls Strollers & Travel Systems, (20 November 2014), online: Health Canada <http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2014/42149r-eng.php?_ga=1.186515818.216261415.1445610077>.

Americans Spend 34 Billions Dollars on Alternative Medicine, Pacific College of Oriental Medicine (6 May 2015), online: Pacific College of Oriental Medicine <http://www.pacificcollege.edu/acupuncture-massage-news/press-releases/718-americans-spend-34-billion-dollars-on-alternative-medicine-.html>.

Asher, Radha. Gray, Robin. & Hogerzeil, Hans. *First-Year Experiences with the Interagency Guidelines for Drug Donations*, WHO: Department of Essential Drugs and Medicines Policy, Geneva, 2000, online: WHO <http://whqlibdoc.who.int/hq/2000/WHO_EDM_PAR_2000.1.pdf>.

Asbestosis, online: Medline Plszus <http://www.nlm.nih.gov/medlineplus/ency/article/000118.htm>.

Annual Reporting on PIC Exports and Imports, online: European Chemicals Agency <https://echa.europa.eu/regulations/prior-informed-consent/annual-reporting-on-pic-exports-and-imports>.

Buying Drugs over the Internet, online: Health Canada, <http://healthycanadians.gc.ca/drugs-products-medicaments-produits/drugs-medicaments/internet-eng.php>.

Buying Medicines Over the Internet: Quick Tips for Buying Online, FDA, online: FDA <http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/buyingmedicinesovertheinternet/default.htm>.

BC-10/3: Indonesian-Swiss Country-led Initiative to Improve the Effectiveness of the Basel Convention, online: Basel Convention <http://www.basel.int/Implementation/LegalMatters/CountryLedInitiative/tabid/1339/Default.aspx>.

BC-11/1: Follow-up to the Indonesian-Swiss country-led initiative to improve the effectiveness of the Basel Convention, online: Basel Convention: <http://www.basel.int/Implementation/LegalMatters/CountryLedInitiative/tabid/1339/Default.aspx>.

Canada Acting to Improve the Regime for Donations of Medicines to the Developing World, (16 May 2008) online: Department of Finance Canada <https://www.fin.gc.ca/n08/08-038-eng.asp >.

Canada and Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, online: Environment and Climate Change Canada <http://www.ec.gc.ca/gdd-mw/default.asp?lang=en&n=1C6F3B4C-1>.

Canadian Motor Vehicle Traffic Collision Statistics 2012, Transport Canada, 2014, online: Transport Canada <https://www.tc.gc.ca/media/documents/roadsafety/cmvtcs2012_eng.pdf>.

Canada's National Implementation Plan under the Stockholm Convention on Persistent Organic Pollutants, online: Stockholm Convention <http://chm.pops.int/Implementation/NIPs/NIPSubmissions/tabid/253/>.

Canada Shipping Act, 2001, online: Transport Canada <https://www.tc.gc.ca/eng/marinesafety/rsqa-csa2001-menu-1395.htm>.

Canada-United States Regulatory Cooperation Council Joint Forward Plan August 2014, online: Health Canada <http://www.hc-sc.gc.ca/ahc-asc/legislation/acts-reg-lois/rcc-ccmr/index-eng.php>.

Canada-US Agreement Concerning the Transboundary Movement of Hazardous Waste, online: Environment and Climate Change Canada <http://www.ec.gc.ca/gdd-mw/default.asp?lang=En&n=EB0B92CE-1>.

CARICOM, *Rapid Alert System for Exchange of Information on Dangerous (non-food) Consumer Goods* (CARREX), (23 May 2015), online: CARICOM <http://caricom.org/projects/detail/caricom-rapid-exchange-system-for-dangerous-non-food-consumer-goods-carrex>.

CETA, online: European Commission <http://ec.europa.eu/trade/policy/in-focus/ceta/>.

Chemicals Management Plan Progress Report, online: Environment and Climate Change Canada <http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=FEB6CAEE-1#s6>.

Chemicals Proposed for Listing under the Convention, online: Stockholm Convention <http://chm.pops.int/TheConvention/ThePOPs/ChemicalsProposedforListing/tabid/2510/Default.aspx>.

Compilation of Responses to the Temporary Questionnaire for Reporting on SAICM Implementation: European Union, online: SAICM <http://www.saicm.org/index.php?option=com_content&view=article&id=390:responses-second-session-of-the-international-conference-on-chemicals-management-iccm2&catid=89:iccm-2>.

Compilation of Responses to the Temporary Questionnaire for Reporting on SAICM Implementation: United States, online: SAICM <http://www.saicm.org/index.php?option=com_content&view=article&id=390:responses-second-session-of-the-international-conference-on-chemicals-management-iccm2&catid=89:iccm-2>.

Complementary, Alternative, or Integrative Health: What's In a Name?, National Center for Complementary and Integrative Health, online: NCCIH <https://nccih.nih.gov/health/whatiscam>.

Complementary Medicine Popular Across Europe, online: European Commission <http://ec.europa.eu/research/infocentre/article_en.cfm?artid=28813>.

Consumers International, *Proposals for Amendments to the UN Guidelines for Consumer Protection* [In advance of the Ad Hoc Expert Meeting on Consumer Protection, UNCTAD, Geneva, July 2013] (2013), online: Consumer International <http://www.consumersinternational.org/media/1362222/ci_proposal_annex_a_eng.pdf>.

Commission on Sustainable Development, *Consumer Protection: Guidelines for Sustainable Consumption, Report of the Secretary-General*, ECOSOC, UN ECOSOCOR, 1998, UN Doc. E/CN.17/1998/5, online: UN <http://www.un.org/esa/documents/ecosoc/cn17/1998/ecn171998-5.htm>.

CPHA Applauds the Government of Canada on Chrysotile Asbestos Decision, (14 September 2012), online: Canadian Public Health Association *<http://www.cpha.ca/en/about/media/asbestos.aspx>*.

Cruise Industry Overview – 2013: State of Cruise Industry, Florida Caribbean Cruise Association, online: Florida Caribbean Cruise Association <http://www.f-cca.com/downloads/2013-cruise-industry-overview.pdf>.

Cruise Ship Orderbook, online: Cruise Industry News <http://www.cruiseindustrynews.com/cruise-news/cruise-ship-orderbook.html>.

DDT - A Brief History and Status, United States Environmental Protection Agency, United States Environmental Protection Agency online: United States Environmental Protection Agency <http://www2.epa.gov/ingredients-used-pesticide-products/ddt-brief-history-and-status>.

Development of Technical Guidelines on e-waste, online: Basel Convention <http://www.basel.int/Implementation/TechnicalMatters/DevelopmentofTechnicalGuidelines/Ewaste/tabid/2377/Default.aspx>.

Draft Technical Guidelines on Transboundary Movements of Electronic and Electrical Waste and Used Electrical and Electronic Equipment, in Particular Regarding the Distinction Between Waste and Non-waste, online: Basel Convention

<http://www.basel.int/Implementation/TechnicalMatters/DevelopmentofTechnicalGuidelines/Ewaste/tabid/2377/Default.aspx>.

Drug Identification Number (DIN), online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/fs-fi/dinfs_fd-eng.php>

Drug Safety: FDA Has Conducted More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but More Progress Is Needed, (GAO-10-961), (October 2010), online: United States Government Accountability Office <http://www.gao.gov/assets/320/310544.pdf>.

EAEU, *The EEC is Preparing a Treaty on Ensuring the Common Safety of Products*, online: Eurasian Commission <http://www.eurasiancommission.org/en/nae/news/Pages/08-10-2015-1.aspx>

EC, *2015 Annual Report on the Operation of the Rapid Alert System for Non-food Dangerous Products RAPEX*, 2016, online: the Directorate-General for Health and Consumers of the European Commission <http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/reports/docs/rapex_annual_report_2015_en.pdf >.

EC, *Analysis of the Potential Effects of the Proposed GHS Regulation on its EU Downstream Legislation*, Commission Services, (August 2006), online: European Commission <http://ec.europa.eu/geninfo/query/resultaction.jsp?SMODE=2&ResultCount=10&Collection=EuropaFull&Collection=EuropaSL&Collection=EuropaPR&ResultMaxDocs=200&qtype=simple&DefaultLG=en&ResultTemplate=%2Fresult_fr.jsp&page=1&QueryText=Analysis+of+the+Potential+Effects+of+the+Proposed+GHS+&y=0&x=0 >.

EC, *Bilaterral Cooperation*, online: European Commission <http://ec.europa.eu/consumers/consumers_safety/international_cooperation/bilateral_cooperation/index_en.htm>.

EC, *Commission Staff Working Paper: Impact Assessment: Accompanying the Document: Proposal for a Regulation of The European Parliament and of the Council on a Consumer Programme 2014-2020*, COM.2011.1320 (final), online: European Parliament <http://www.europarl.europa.eu/meetdocs/2009_2014/documents/imco/dv/com_sec(2011)1320__consp_/com_sec(2011)1320__consp_en.pdf>.

EC, *EU Air Safety List*, online: EC <http://ec.europa.eu/transport/modes/air/safety/air-ban/doc/list_en.pdf>.

EC, *European Maritime Safety Agency*, online: EC <http://ec.europa.eu/transport/modes/maritime/safety/emsa_en.htm>

EC, *EU RAPEX Annual Report 2015*, 2016, online: EC <http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/reports/docs/rapex_annual_report_2015_en.pdf>.

EC, *Herbal Medicinal Products*, online: European Commission <http://ec.europa.eu/health/human-use/herbal-medicines/index_en.htm#geninf>.

EC, *Impact Assessment of Implementing the GHS: Work Package 1, Final Report for the DG of Enterprise and Industry*, London: Risk & Policy Analysts Limited (2006), online: European Commission, <http://ec.europa.eu/growth/sectors/chemicals>.

EC, *Keeping European Consumers Safe 2011 Annual Report on the Operation of the Rapid Alert System for Non-Food Dangerous Products RAPEX*, 2011, online: the Directorate-General for Health and Consumers of the European Commission <http://ec.europa.eu/consumers/safety/rapex/docs/2011_rapex_report_en.pdf>.

EC, *Overview of EU-28 Air Passenger Transport by Member States in 2013 Passengers Carried (in 1000)*, online: EC <http://ec.europa.eu/eurostat/statistics-explained/index.php/File:Overview_of_EU-28_air_passenger_transport_by_Member_States_in_2013_passengers_carried_(in_1000)_.png>.

EC, *Procedures for Evaluating Medicinal Products and Granting Marketing Authorization,* online: European Commission <http://ec.europa.eu/health/authorisation-procedures_en.htm>.

EC, *Quality of Medicines and Good Manufacturing Practices (GMP),* online: European Commission <http://ec.europa.eu/health/human-use/quality/index_en.htm>.

EC, *Report from the Commisssion to the European Parliamnet, the Council and the European Economic and Social Committee on the Implementation of EC Regulation 765/2008 of the European Parliament and of the Council of 9 July 2008 Setting out the Requirements for Accreditation and Market Surveillance Relating to the Marketing of Products and Repealing Regulation (EEC) 339/93, COM/2013/077 final*, online: EUR-Lex <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013DC0077>.

EC, *RAPEX-CHINA Application*, online: European Commission <ec.europa.eu/consumers/cons_safe/news/rapex_china_en.pdf>.

EC, *RAPEX-CHINA System*, online: European Commission <http://eeas.europa.eu/delegations/china/eu_china/food_safety_and_consumer_protection/rapex_china_system/index_en.htm>.

EC, *Rapid Alert System for Non-Food Dangerous Products,* (RAPEX), online: EC <http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/index_en.htm>.

EC, *Safety of Passenger Ships*, online: EC <http://ec.europa.eu/transport/modes/maritime/safety-and-environment/safety-passenger-ships_en>.

ECOSOC, *Consumer Protection: Report of the Secretary-General*, UN ECOSOCOR (1995) UN Doc.E/1995/70, online: UN <http://www.un.org/documents/ecosoc/docs/1995/e1995-70.htm>.

ECOSOC, *Co-ordination Questions: Consumer Protection: Report of Secretary-General*, UN ECOSOCOR (1992) UN Doc.E/1992/48.

Eurasian Commission, *Eurasian Economic Integration: Facts and Figures*, online: Eurasian Commission <http://www.eurasiancommission.org/en/Documents/broshura26_ENGL_2014.pdf>.

European Chemical Industry Consul, *European Chemical Industry: Facts and Figures 2016*, online: European Chemical Industry Consul <http://asp.zone-secure.net/v2/index.jsp?id=598/765/42548&startPage=4>.

Executive Summary of the Review of the Existing National and International Legislation in the Field of Monitoring and Control of Transboundary Movement of Hazardous Wastes and their Environmentally Sound Management, Centre for International Projects, Moscow, 2005, online: Basel Convention <http://www.basel.int/Default.aspx?tabid=2345>.

Extended Producer Responsibility Evaluation: Final Report, Product Management Alliance, (February 2013), online: Product Management Alliance <http://www.productmanagementalliance.org/images/PMA.SAIC.EPR.Evaluation.pdf>.

Facts About the Current Good Manufacturing Practices, online: FDA <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm>.

Falsified Medicines, European Medicines Agency, online: EMA <http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000186.jsp&mid=WC0b01ac058002d4e8 >.

FDA History: The 1938 Food, Drug, and Cosmetic Act, online: FDA <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054826.htm>.

FDA Takes Action to Protect Consumers from Dangerous Medicines Sold by Illegal Online Pharmacies, FDA, (27 June 2013), online: FDA <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm358794.htm >.

First North America Consumer Product Safety Summit, (26 September 2011), online: CPSC <http://www.cpsc.gov/es/Business--Manufacturing/International/International-Activities/FIRST-NORTH-AMERICA-CONSUMER-PRODUCT-SAFETY-SUMMIT/>.

Flight Standard Service: International Aviation Safety Assessment Program, FAA, online: FAA <http://www.faa.gov/about/initiatives/iasa/media/IASAWS.xlsx>.

FY 2014 Inspectional Observation Summaries, online: FDA <http://www.fda.gov/ICECI/Inspections/ucm424098.htm#Drugs>.

Global Pharmaceutical Sales from 2011 to 2013, by Region, online: Statista <http://www.statista.com/statistics/272181/world-pharmaceutical-sales-by-region/>.

Government of Canada Launches the Canadian Initiative for the Economic Diversification of Communities Reliant on Chrysotile, (13 June 2013), online: Government of Canada <http://news.gc.ca/web/article-en.do?crtr.sj1D=&crtr.mnthndVl=6&mthd=advSrch&crtr.dpt1D=19&nid=750279&crtr.lc1D=&crtr.tp1D=1&crtr.yrStrtVl=2013&crtr.kw=&crtr.dyStrtVl=13&crtr.aud1D=&crtr.mnthStrtVl=6&crtr.page=1&crtr.yrndVl=2013&crtr.dyndVl=13&_ga=1.262906506.706984300.1398272198>.

Growth of the Cruise Line Industry, Cruise Market Watch, online: Cruise Market Watch <http://www.cruisemarketwatch.com/growth/>.

"Hazardous Products Regulations: Regulatory Impact Analysis Statement", Canada Gazette, Vol. 148, No. 32, (9 August 2014), online: Canada Gazette <http://gazette.gc.ca/rp-pr/p1/2014/2014-08-09/html/reg1-eng.php>.

Health Canada Warns Canadians about Buying Prescription Drugs Online from the Global Pharmacy Canada Website, Health Canada, (27 July 2010), online: Health

Canada <http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2010/13414a-eng.php>.

ICAO, *2013 ICAO Air Transport Result Confirm Robust Passenger Demand, Sluggish Cargo Market*, (December 2013), online: ICAO <http://www.icao.int/Newsroom/News%20Doc%202013/COM.43.13.ECON-RESULTS.Final-2.en.pdf>.

ICAO, *About ICAO*, online: ICAO <http://www.icao.int/about-icao/Pages/default.aspx>.

ICAO, *CMA Forum (FAQ)*, online: ICAO <http://www.icao.int/safety/CMAForum/Pages/FAQ.aspx>.

ICAO, *Convention for the Unification of Certain Rules for International Carriage by Air Montreal, 28 May 1999: Parties*, online: ICAO <http://www.icao.int/secretariat/legal/List%20of%20Parties/Mtl99_EN.pdf>.

ICAO, *Continuing Traffic Growth and Record Airline Profits Highlight 2015 Air Transport Results*, Montreal, (22 December 2015), online: ICAO <http://www.icao.int/Newsroom/Pages/Continuing-Traffic-Growth-and-Record-Airline-Profits-Highlight-2015-Air-Transport-Results.aspx>).

ICAO, *Global Aviation Safety Plan, 2014-2016*, (Doc.10004), online: ICAO <http://www.icao.int/NACC/Documents/Meetings/2014/SSPSMSANT/GASP.pdf>.

ICAO, *Safety Audit Information*, online: ICAO <http://www.icao.int/safety/Pages/USOAP-Results.aspx>.

ICAO, *Universal Safety Oversight Audit Programme*, online: ICAO <http://cfapp.icao.int/tools/38thAssyiKit/story_content/external_files/Flyer_US-Letter_ANB-USOAP_2013-08-30.pdff>.

ICAO, "Determination of a Definition of Aviation Safety", ICAO Working Paper AN-WP/7699 (11 December 2001).

IMO, *Introduction to IMO*, online: IMO <http://www.imo.org/About/Pages/Default.aspx>.

IMO, *Implications of the United Nations Conventions on the Law of the Sea for the International Maritime Organization*, (LEG/MISC.8), (30 January 2014), online: IMO

<http://www.imo.org/ourwork/legal/documents/implications%20of%20unclos%20for%20imo.pdf>.
IMO, *ISM Code and Guidelines on Implementation of the ISM Code 2014*, online: IMO <http://www.imo.org/OurWork/HumanElement/SafetyManagement/Pages/ISMCode.aspx>.

IMO, *Member States*, online: IMO <http://www.imo.org/About/Membership/Pages/MemberStates.aspx>.

IMO, *Passenger Ships*, online: IMO <http://www.imo.org/OurWork/Safety/Regulations/Pages/PassengerShips.aspx>.
IMO, *Structure of IMO*, online: IMO <http://www.imo.org/About/Pages/Structure.aspx>.

IMO, *Summary of Conventions*, online: IMO <http://www.imo.org/en/About/Conventions/StatusOfConventions/Pages/Default.aspx>.

IMO, *What it is*, (October 2013), online: IMO <http://www.imo.org/About/Documents/What%20it%20is%20Oct%202013_Web.pdf>.

ICAO, *Safety Audit Information*, online: ICAO <http://www.icao.int/safety/Pages/USOAP-Results.aspx>.

ICAO, *Safety Report 2014*, online: ICAO, <http://www.icao.int/safety/Documents/ICAO_2014%20Safety%20Report_final_02042014_web.pdf>.

ICAO, *Signatories to the Convention*, online: ICAO <http://www.icao.int/secretariat/legal/List%20of%20Parties/Chicago_EN.pdf>.

ICAO, *USOAP Continuous Monitoring Approach*, online: ICAO <http://www.icao.int/safety/CMAForum/Pages/default.aspx>.

IMO, *Passenger Ships*, online: IMO <http://www.imo.org/OurWork/Safety/Regulations/Pages/PassengerShips.aspx>.

IMO, *Port State Control*, online: IMO <http://www.imo.org/blast/mainframe.asp?topic_id=159>.

IMO, *Status of Multilateral Conventions and Instruments in Respect of Which the International Maritime Organization or its Secretary-General Performs Depositary or other Functions: As at 28 October 2016*, online: IMO <http://www.imo.org/en/About/Conventions/StatusOfConventions/Documents/Status%20-%202016.docx.pdf>).

INCB, *INCB Targets Illicit Sales of Drugs on Internet Pharmacies International Experts to Meet in Vienna to Discuss Solutions*, (UNIS/NAR/862), (18 October 2004), online: International Narcotics Control Board <https://www.incb.org/documents/Publications/PressRelease/PR2004/press_release_181004.pdf >.

Incident Trends data, online: Pharmaceutical Security Institute <http://www.psi-inc.org/incidentTrends.cfm>.

Inspections, Compliance, Enforcement, and Criminal Investigations, online: FDA <http://www.fda.gov/ICECI/default.htm>.
International Aviation Safety Assessment Program, FAA online: FAA <http://www.faa.gov/about/initiatives/iasa/media/FAA_Initiatives_IASA.pdf>.

International Prescription Drug Parity: Statement of William K. Hubbard, Associate Commissioner for Policy and Planning, before the Committee on Government Reform, U.S. House of Representatives, Hearing on Internet Drug Sales, U.S. Food and Drug Administration (FDA), (3 April 2004), online: FDA <http://www.fda.gov/NewsEvents/Testimony/ucm161404.htm>.

ITU Guidance for Administrations, online: International Telecommunication Union <http://www.itu.int/en/ITU-R/terrestrial/mars/Documents/Guidance.pdf>.

Joint Statement between: The International Pharmaceutical Federation (FIP) and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), Ensuring Quality and Safety of Medicinal Products to Protect the Patient: Approved by FIP Council in Barcelona in September 1999, online: FIP <https://www.fip.org/www/uploads/database_file.php?id=237&table_id=>.

Letter to Senator Frist (22 July 2005), online: Centre for International Environmental Law <http://www.ciel.org/Publications/POPs_Frist_22Jul05.pdf>.

Marketing Authorizations, European Medicines Agency, online: European Medicines Agency <http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000091.jsp&mid=WC0b01ac0580028a42>.

Mega Lifeboat, online: The Royal Institution of Naval Architects <http://www.rina.org.uk/mega-lifeboat.html>.

Mercury and Environment, online: Environment and Climate Change Canada <https://www.ec.gc.ca/mercure-mercury/>.

National GHS Implementation, online: United Nations Institute for Training and Research <https://www.unitar.org/cwm/ghs>.

National Pharmaceuticals Strategy: Progress Report, (June 2006), online: Health Canada <http://www.hc-sc.gc.ca/hcs-sss/pubs/pharma/2006-nps-snpp/index-eng.php>.

National Implementation Plan Submissions Log, online: Stockholm Convention <http://chm.pops.int/Implementation/NIPs/NIPSubmissions/tabid/253/>.

Natural Health Product Tracking Survey: Final Report 2010, Ipsos Reid, (13 January 2010), online: National Library of Canada Electronic Collection <http://epe.lac-bac.gc.ca/100/200/301/pwgsc-tpsgc/por-ef/health/2011/135-09/report.pdf >.

North America Consumer Product Safety Summit 2013 - Joint Statement, online: Health Canada <http://www.hc-sc.gc.ca/cps-spc/advisories-avis/info-ind/najs-nadc-eng.php>.

Obsolete Pesticides Technical Study in the Kyrgyz Republic, the Republic of Tajikistan, and the Republic of Uzbekistan, online: Obsolete Pesticides <https://obsoletepesticides.net/site/central-asian-technical-study-on-obsolete-pesticides/>.

OECD, *Extended Producer Responsibility*, online: OECD <http://www.oecd.org/env/tools-evaluation/extendedproducerresponsibility.htm>.

Parliamentary Assembly, "New generation" trade agreements and their implications for social rights, public health and sustainable development, Report: Doc. 14219, (14 December 2016), online: Parliamentary Assembly <http://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-en.asp?fileid=23232&lang=en>.

Persistent Organic Pollutants: A Global Issue, A Global Response, online: U.S. Environmental Protection Agency <http://www2.epa.gov/international-cooperation/persistent-organic-pollutants-global-issue-global-response>.

Policy of the U.S. Consumer Product Safety Commission on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), online: CPSC <https://www.cpsc.gov/About-CPSC/Policies-Statements-and-Directives />.

PQMD Guidelines for Quality Medical Product Donations, (April 2016), online: Partnership for Quality Medical Donations < http://www.pqmd.org/pillars/donation-guidelines/>.

President Bush Sends the Stockholm Convention on Persistent Organic Pollutants to Senate for Ratification, U.S. Environmental Protection Agency (11 April 2002), online: U.S. Department of State <http://2001-2009.state.gov/g/oes/rls/prsrl/press/jan/9748.htm>.

Projects in Central and Eastern Europe, online: Basel Convention <http://www.basel.int/Default.aspx?tabid=2345>.

Progress Report on the Chemicals in Products Project, Including Proposed Recommendations for Further International Cooperative Action: Implementation of the Strategic Approach to International Chemicals Management: Emerging Policy Issues, (International Conference on Chemicals Management Third session, Nairobi, 17–21 September 2012), online: SAICM <http://www.saicm.org/images/saicm_documents/iccm/ICCM3/Meeting%20documents/iccm3%2015/ICCM3_15_EN.pdf>.

Questions and Answers for Consumers, online: National Association of Pharmacy Regulatory Authorities <http://napra.ca/pages/Practice_Resources/QuestionsandAnswersConsumers.aspx?id=3177#Answer14>.

Questions and Answers for the Public Questions and Answers for the Public: Donating Drugs to International Humanitarian Relief Efforts, FDA, online: Food and Drugs Administration <http://www.fda.gov/downloads/NewsEvents/PublicHealthFocus/UCM249617.pdf>.

Recalling Consumer Products: A Guide For Industry, online: Health Canada online: <www.hc-sc.gc.ca/cps-spc/pubs/indust/recalling-guide-2005-04-rappel-eng.php>.

Report on Carcinogens, Eleventh Edition, Substance Profile, Asbestos CAS No. 1332-21-4, online: United States Department of Health and Human Services <https://web.archive.org/web/20110608211238/http://ntp.niehs.nih.gov/ntp/roc/eleventh/profiles/s016asbe.pdf>.

Report on Operational Incidents 2009 to 2013 for CLIA Global, G.P. Wild, (December 2014), online: Cruise Lines International Association <http://www.cruising.org/docs/default-source/market-research/report-on-operational-incidents-2009-to-2013.pdf?sfvrsn=0>

Report on Preparation of GHS Implementation by the OECD Countries, (ENV/JM/MONO(2007)8), Paris: OECD, 2007, online: OECD <http://www.oecd.org/chemicalsafety/testing/38735710.pdf>.

Request for Comments - Proposal to Implement the GHS in Canada, online: Health Canada <http://www.hc-sc.gc.ca/ewh-semt/consult/_2013/ghs-sgh/index-eng.php>.

Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, [communiqué]; online: U.S. Department of State, <http://www.state.gov/e/oes/eqt/chemicalpollution/83010.htm>.

Safety and Shipping 1912-2012: From Titanic to Costa Concordia: An Insurer's Perspective from Allianz Global Corporate & Specialty, Allianz Global Corporate & Specialty AG, 2012, online: Allianz Global Corporate & Specialty AG <http://www.agcs.allianz.com/assets/PDFs/Reports/AGCS_safety_and_shipping_report.pdf>.

Seven Countries Opposed the Listing of Chrysotile Asbestos in the Rotterdam Convention, (10 May 2013), online: Asbestos Disease Awareness <http://www.asbestosdiseaseawareness.org/archives/21214>.

Soft Law: Law and Legal Definition, online: US Legal <https://definitions.uslegal.com/s/soft-law/>.

Status of Ratifications, online: Stockholm Convention <http://chm.pops.int/Countries/StatusofRatifications/PartiesandSignatories/tabid/252/Default.aspx#a-decl-RU>.

Summary report of the Drug Good Manufacturing Practices (GMP): Inspection Program (April 1, 2006 to March 31), (21 December 2011), online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/compli-conform/gmp-bpf/summary-report-sommaire-eng.pdf>.

Surveillance of Implementation of Recommendations Adopted by the DSB: United States-Measures Affecting the Production and Sale of Clove Cigarettes: Status Report by the United States, WT/DS406/11/ADD.4, 2013, online: <http://geneva.usmission.gov/wp-content/uploads/2013/07/July23-DSB.pdf>.

Tajikistan Paves the Way to Eurasian Union Cental Asia-Caucasus Analyst, (7 January 2015), online: Cental Asia-Caucasus Analyst <http://www.cacianalyst.org/publications/field-reports/item/13113-tajikistan-paves-the-way-to-eurasian-union.html>.

The Approach to Natural Health Products, Health Canada: Natural and Non-prescription Health Products Directorate, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/nhp-new-nouvelle-psn-eng.php>.

The Contribution of the North American Cruise Industry to the U.S. Economy in 2013, Business Research & Economic Advisors, (September 2014), online: Cruise Lines International Association <http://www.cruising.org/docs/default-source/research/us-economic-impact-study-2013.pdf?sfvrsn=2>.

The Goal of Minimizing Hazardous Wastes, online: Basel Convention <http://www.basel.int/pub/simp-guide.pdf>.

The Hazard Communication, online: United States Department of Labor <https://www.osha.gov/dsg/hazcom/index.html>.

The New POPs under the Stockholm Convention, online: Stockholm Convention <http://chm.pops.int/TheConvention/ThePOPs/TheNewPOPs/tabid/2511/Default.aspx>.

The North American Free Trade Agreement Technical Working Group on Pesticides, online: Health Canada < http://www.hc-sc.gc.ca/cps-spc/pest/part/int/_nafta-alena/index-eng.php >.

The Possible Dangers of Buying Medicines over the Internet, online: FDA <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048396.htm>.

The Third America Consumer Product Safety Summit Joint Statement, (19 November 2015), online: CPSC <http://www.cpsc.gov/en/Business--Manufacturing/International/International-Activities/The-Third-America-Consumer-Product-Safety-Summit-Joint-Statement/>.

The White Paper: Strategy for a Future Chemicals Policy, COM(2001) 88 (final), online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2001:0088:FIN:EN:PDF>.

To Harmonize the Rules in Order to Guarantee the Safety of Pharmaceutical Products and the Citizen's Health: why are Mandatory Inspections Needed?,

European Fine Chemicals Group, (12 November 2012), online: European Fine Chemicals Group <http://www.efcg.cefic.org/publications>.

Trust Fund for the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (BC), online: Basel Convention <http://www.basel.int/TheConvention/FinanceBudget/TrustFund(BC)/ContributionsStatus/2014/tabid/3787/Default.aspx>.

Trust Fund to Assist Developing Countries and other Countries in Need of Technical Assistance (BD), online: Basel Convention <http://www.basel.int/TheConvention/FinanceBudget/TechnicalCooperationTrustFund(BD)/ContributionsStatus/2014/tabid/3788/Default.aspx>.

TTIP, online: European Commissions <http://ec.europa.eu/trade/policy/in-focus/ttip/>.

UN, *Canada National Reporting to CSD-18/19: Thematic Profile on Chemicals*, online: UN <http://www.un.org/esa/dsd/dsd_aofw_ni/ni_pdfs/NationalReports/canada/Chemicals.pdf>.

UN, *Macroeconomic Policy Questions: International Trade and Development*, A/70/470/Add.1, online: UN <http://www.un.org/ga/search/view_doc.asp?symbol=A/70/470/Add.1>.

UNCTAD, *The Implementation Report on the United Nations Guidelines on Consumer Protection 1985–2013*, TD/B/C.I/CLP/23, (29 April 2013), online: UNCTAD <http://unctad.org/meetings/en/SessionalDocuments/ciclpd23_en.pdf>.

UNCTAD, *The Revision of the United Nations Guidelines on Consumer Protection,* (November 2015), UNCTADOR, online: <http://unctad.org/en/Pages/DITC/CompetitionLaw/UN-Guidelines-on-Consumer-Protection.aspx>.

UNEP, *Global Monitoring Report under the Global Monitoring Plan for Effectiveness Evaluation. Matters for Consideration or Action by the Conference of the Parties: Effectiveness Evaluation*, Conference of the Parties of the Stockholm Convention on Persistent Organic Pollutants Fourth meeting, Geneva, 4–8 May 2009, UNEP/POPS/COP .4/33, (30 January 2009), online: Stockholm Convention <http://chm.pops.int/Implementation/GlobalMonitoringPlan/Overview/tabid/83/Default.aspx>.

UNEP/FAO, *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade Chemical Review Committee: Listing of Chemicals in Annex III of the Rotterdam Convention: Consideration of the Draft Decision Guidance Document for Chrysotile asbestos*, (UNEP/FAO/RC/CRC.2/19) online: Rotterdam Convention <http://www.pic.int/Portals/5/incs/crc2/s19)/English/CRC-2-19.%20chrysotile%20DGD%20rev%201pdf.pdf>.

UNEP, *Progress Report on the Chemicals in Products Project, Including Proposed Recommendations for Further International Cooperative Action*, (SAICM//ICCM.3/15), 2012, online: SAICM <http://www.saicm.org/images/saicm_documents/iccm/ICCM3/Meeting%20documents/iccm3%2015/ICCM3_15_EN.pdf>.

UNEP, *Supplementary Report Prepared by the President of the Stockholm Convention Pursuant to Decision SC-2/15 of the Second Meeting of the Conference of the Parties of the Stockholm Convention,* Ad hoc joint working groups on enhancing cooperation and coordination among the Basel, Rotterdam, and Stockholm conventions (AHJWG), online: AHJWG <http://ahjwg.chem.unep.ch/index.php?option=com_content&task=section&id=6&Itemid=3>.

UNODC, *The Globalization of Crime: A Transnational Organized Crime Threat Assessment,* United Nations Office on Drugs and Crime: Vienna, 2010, online: UNODC <http://www.unodc.org/documents/data-and-analysis/tocta/TOCTA_Report_2010_low_res.pdf>.

US and Basel Convention, online: US Department of State <http://2001-2009.state.gov/g/oes/env/c18124.htm>.

US Department of Labor's OSHA Revises Hazard Communication Standard Regulation Protects Workers from Dangerous Chemicals, Helps American Businesses Compete Worldwide, (20 March 2012), online: United States Department of Labor <https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=2203>.

United States Coast Guard Top Cruise Ship Deficiencies of 2014, online: United States Coast Guard <http://www.uscg.mil/hq/cg5/csncoe/docs/Top%20Defs/Top%20Cruise%20Ship%20%20Deficiencies%20of%20%202014.pdf>.

U.S. Ratification of the Stockholm Convention: Analysis of Pending POPs Legislation, (13 March 2006), online: Center for International Environmental Law <http://www.ciel.org/Publications/POPs_Bills_28Feb2006.pdf>.

Vietnam - Eurasian Economic Union FTA, online: WTO Centre Vietnam <http://wtocenter.vn/other-agreement/vietnam-eurasian-economic-union-fta-full-content>.

Virta, Robert L. *Worldwide Asbestos Supply and Consumption Trends from 1900 through 2003*, 2013, online: U.S. Geological Survey <http://pubs.usgs.gov/circ/2006/1298/ >.

WHMIS 2015 — Variances between the HPR and the United States Hazard Communication Standard, 2012, online: Heath Canada <http://www.hc-sc.gc.ca/ewh-semt/occup-travail/whmis-simdut/ghs-sgh/classification/hazardous-products-produits-dangereux/variances-ecarts-eng.php>.

WHO, Asbestos Profile, online: WHO <http://www.who.int/ipcs/assessment/public_health/asbestos/en/>.

WHO, *Essential Medicines and Health Products: Challenges*, online: WHO <http://www.who.int/medicines/areas/quality_safety/challenges/en/>.

WHO, *Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review*, 2001, online: WHO <http://apps.who.int/medicinedocs/pdf/h2943e/h2943e.pdf>.

WHO, *Mercury and health*, online: WHO <http://www.who.int/mediacentre/factsheets/fs361/en/>.

WHO, *National Policy on Traditional Medicine and Regulation of Herbal Medicines: Report of a WHO Global Survey*, Geneva, (May 2005), online: WHO <http://apps.who.int/medicinedocs/pdf/s7916e/s7916e.pdf>.

WHO, *Norms, Standards and Guidance for Pharmaceuticals*, online: WHO <http://www.who.int/medicines/areas/quality_safety/quality_assurance/norms_standards/en/>.

WHO, Ong, C.K. *et al., WHO Global Atlas of Traditional, Complementary and Alternative Medicine*, Volume 1, (January 2005), online: WHO <http://apps.who.int/iris/bitstream/10665/43108/1/9241562862_map.pdf?ua=1>.

WHO Programme Members, online: *Uppsala Monitoring Centre* <http://www.who-umc.org/DynPage.aspx?id=100653&mn1=7347&mn2=7252&mn3=7322&mn4=7442>.

WHO, *Safety and Security on the Internet: Challenges and Advances in Member States: Based on the Findings of the Second Global Survey on eHealth*, WHO, 2011, online: WHO <http://www.who.int/goe/publications/goe_security_web.pdf>.

WHO, *Substandard and Counterfeit Medicines: Fact sheet N275*, (January 2016), online: WHO <http://www.who.int/mediacentre/factsheets/fs275/en/>.

World Bank, *GDP per capita, PPP: (current international $),* online: World Bank <http://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>.

WTO, Committee on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 5-6 November 2009*, G/TBT/M/49, (22 December 2009), online: WTO <https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=99791,89598,81738,80313,94266,103378,106242,104442,87898,62393&CurrentCatalogueIdIndex=5&FullTextSearch=>.

WHO, *Norms and Standards: Quality, Safety and Efficacy of Medicines*, online: WHO <http://www.who.int/medicines/areas/quality_safety/en/>.

WHO, *The Scientific Basis of Tobacco Product Regulation: Report of a WHO Study Group*, [WHO technical report series; no. 945], 2007, online: WHO <http://www.who.int/tobacco/global_interaction/tobreg/9789241209458.pdf>.

WHO, *Traditional Medicine: Definitions*, online: WHO <http://www.who.int/medicines/areas/traditional/definitions/en/>).

Wiesener, Solveig *et al. Legal Status and Regulation of CAM in Europe: Part I- CAM Regulations in the European Countries*, CAMbrella, 2012, online: Wien University <https://phaidra.univie.ac.at/detail_object/o:291583>.

WTO, *Review of the Operation and Implementation of the Agreement on the Application of SPS Measures*, WTO Doc. G/SPS/53, (May 2010), online: WTO <https://www.wto.org/english/tratop_e/sps_e/decisions06_e.htm>.

Выполнение СПМРХВ в Регионе ВЕКЦА, [SAICM Implementation in East Europe, Caucasus and Central Asia (EECCA) region] (Russian), online: MOGNOVSE <http://mognovse.ru/jrk-vipolnenie-spmrhv-v-regione-vekca.html>.

СГС в Техническом Регламенте [GHS in Technical Regulation] (Russian), online: REACH (Website Supporting Russian Exporters) <http://www.reach.ru/reglament-reach/pyblikachii/407-russian-face-of-reach>.

SECONDARY MATERIAL: ARTICLES

Andruszkiewcz, M. "Central and Eastern Europe: A Reference Point in Changing Times", *Consumer International*, 1 (1995).

Anisfeld, Michael H. *International GMPs*, online: Globepharm <http://www.globepharm.org/what-is-gmp/international-gmps.html>.

Angelo, Mary Jane. *Everywhere, All the Time: Why the U.S. Should Ratify 3 International Agreements on Persistent Organic Pollutants,* (9 March 2016), online: Centre for Progressive Reform <http://www.progressivereform.org/CPRBlog.cfm?fkScholar=6>.

Arendt, Susan. "Sony Battery Recall Costs $429 Million", *PC Mag* (26 October 2006), online: PC Mag <http://www.pcmag.com/article2/0,2817,2040936,00.asp>.

Attaran, Amir "How to Achieve International Action on Falsified and Substandard Medicines", *British Medical Journal*, (November 2012), online: British Medical Journal, <http://www.bmj.com/content/345/bmj.e7381.full.pdf+html>.

Attaran, Amir. Bate, Roger & Kendall, Megan. "Why and How to Make an International Crime of Medicine Counterfeiting", *Journal International Criminal Justice*, (February 2011), online: Social Science Research Network <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1652909>.

Balakrishnan, Anita. "Samsung, Safety Regulators Officially Recall about 1 Million Galaxy Note 7 Phones", *CNBC,* (15 September 2016), online: CNBC <http://www.cnbc.com/2016/09/15/consumer-safety-agency-plans-recall-of-samsung-galaxy-note-7-dj-citing-official.html>.

Ballet, Lucas. "Losing Flavor: Indonesia's WTO Complaint Against the U.S. Ban on Clove Cigarettes", *American University International Law Review,* 26: 2 (2011), online: Digital Commons (American University Washington College of Law) <http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1706&context=auilr>.

Stephen Barrett, "The Dietary Supplement Health and Education Act of 1994 Weakened the FDA", International Journal of Toxicology, 22:5, (September/October 2003), online: International Journal of Toxicology <http://ijt.sagepub.com/content/22/5/391.abstract>.

Bernard, Sophie. *Transboundary Movement of Waste: Second-Hand Markets and Illegal Shipments*, Montreal, (December 2011), {© [as requested the author]}, online: Cirano <http://www.cirano.qc.ca/pdf/publication/2011s-77.pdf>.

Blenman, Joy. *Adam Smith: The Father Of Economics,* (September 2016), online: Investopedia <http://www.investopedia.com/articles/economics/08/adam-smith-economics.asp>.

Bliss, Jeff. "U.S. Backs Off All-Cargo Scanning Goal With Inspections at 4%", *Bloomberg*, (13 August 2012), online: Bloomberg <http://www.bloomberg.com/news/articles/2012-08-13/u-s-backs-off-all-cargo-scanning-goal-with-inspections-at-4->.

Blyschak, Paul Michael *et al.* "The Canada Consumer Product Safety Act Now in Force", (21 June 2011), online: McCarthy Tétrault <http://www.mccarthy.ca/article_detail.aspx?id=5456>.

Brezhneva, Anna. & Ukhova, Daria. *Russia as a Humanitarian Aid Donor*, Oxfam, (July 2013), online: <http://www.oxfam.org/sites/www.oxfam.org/files/dp-russia-humanitarian-donor-150713-en.pdf>.

Bogdanich, Walt. "Heparin Find May Point to Chinese Counterfeiting", *N.Y. Times,* (20 March.2008), online: N.Y Times <http://www.nytimes.com/2008/03/20/health/20heparin.html?_r=0>.

Bero, Lisa *et al.* "To Give is Better than to Receive: Compliance with WHO Guidelines for Drug Donations During 2000–2008", *Bull World Health Organ*, 88:12, (1 December 2010), online: US National Library on Medicine, National Institutes of Health <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2995193/>.

Campbell, Colin. *Canada's Chrysotile Business is Dying Out*, (12 September 2103), online: Canadian Encyclopedia <http://www.thecanadianencyclopedia.ca/en/article/canadas-chrysotile-business-is-dying-out/>.

Carlone, Jonathan. "An Added Exception to the TBT Agreement After Clove, Tuna II, and Cool" *Boston College International and Comparative Law Review*, 37:1,

(February 2014), online: Law Digital Commons <http://lawdigitalcommons.bc.edu/cgi/viewcontent.cgi?article=1707&context=icl>.

Charles, Dan "Our Fertilized world", *National Geographic*, (May 2013).

Caro de Sousa, Pedro. "Negative and Positive Integration in EU Economic Law: Between Strategic Denial and Cognitive Dissonance?", *German Law Journal*, 13:8, (2012) online: German Law Journal <http://static1.squarespace.com/static/56330ad3e4b0733dcc0c8495/t/56b29e6586db4396b83ffdf3/1454546534135/GLJ_Vol_13_No_08_de+Sousa.pdf>.

Faust, Mike. *Couple Skips Muster Drill, Removed From Cruise*, Cruise Currents, (16 May 2012), online: Cruise Currents <http://www.cruisecurrents.com/archives/4117>.

Canada Poised to Launch, Enforce New Consumer Product Safety Act, Database, (20 June 2011), online: PRWeb <http://www.prweb.com/releases/2011/6/prweb8579747.htm>.

Christodoulou-Varotsi, Iliana. *Maritime Safety Law and Policies of the European Union and the United States of America: Antagonism or Synergy?,* Springer Science & Business Media, (2008).

CIS vs. EaEU?, (30 May 2014), online: Vestnik Kavkaza <http://vestnikkavkaza.net/articles/politics/55865.html>.

Consumer Rights and its Expansion, online: Centre for Consumer Action Research and Training <http://www.cuts-international.org/Consumer-Rights.htm>.

"Costa Concordia: What happened", BBC, (10 February 2015), online: BBC <http://www.bbc.com/news/world-europe-16563562>).

"Everything you Need to Know about the Takata Airbag Recall", (23 December 2015), online: Consumer Reports <http://www.consumerreports.org/cro/news/2014/10/everything-you-need-to-know-about-the-takata-air-bag-recall/index.htm>.

CPSC. "Port Surveillance News: CPSC Stops More Than 12.5 Million Units of Violative Products from Reaching Homes in Fiscal Year 2013", (5 May, 2014), online: CPSC <http://www.cpsc.gov/en/Newsroom/News-Releases/2014/Port-Surveillance-News-CPSC-Stops-More-Than-125-Million-Units-of-Violative-Products-from-Reaching-Homes-in-Fiscal-Year-2013/>.

CPSC. "Samsung Recalls Galaxy Note7 Smartphones Due to Serious Fire and Burn Hazards" (15 September, 2016), online: CPSC <http://www.cpsc.gov/en/Recalls/2016/Samsung-Recalls-Galaxy-Note7-Smartphones/>.

CPSC. "Sony Recalls Notebook Computer Batteries Due to Previous Fires", (23 October, 2006), online: CPSC <https://www.cpsc.gov/en/Recalls/2007/Sony-Recalls-Notebook-Computer-Batteries-Due-to-Previous-Fires/>.

Davis, Lucas W. & Kahn, Matthew E. *International Trade in Used Vehicles: The Environmental Consequences of NAFTA*, (January 2010), online: University of California (Hass School of Business) <http://faculty.haas.berkeley.edu/ldavis/Davis%20and%20Kahn%20AEJ%202010.pdf>.

Doyle, Sabrina. "Canada Lags behind United States in Drug Return, Reuse and Recycling Programs", Canadian Medical Association Journal 182:4, (9 March 2010) online: Canadian Medical Association Journal <http://www.cmaj.ca/content/182/4/E197.full>.

EAEU, *The 26th Session of the Eurasian Economic Council Board: On Creation of Joint Research Group to Study the Desirability of Conclusion of the Agreement on the Free Trade Area between the Customs Union and the Common Economic Space Member-States and the State of Israel*, online: Eurasian Commission <http://www.eurasiancommission.org/en/nae/events/Pages/03-09-2013-1.aspx>.

EEU, Iran Mull over Free Trade Agreement", Belarus News, (16 April 2015), online: Belarus News <http://eng.belta.by/economics/view/eeu-iran-mull-over-free-trade-zone-agreement-11708-2015 >.

"Egypt to Join Russia-Led Eurasian Free Trade Zone", Russia Today, (10 February 2015), online: Russia Today <https://www.rt.com/business/230987-egypt-russia-free-trade/>.

Exporting Consumer Goods – Second-Hand Articles or Waste?, Swiss Confederation, Federal office for the Environment, (April 2016), online: Federal Office for the Environment <http://www.bafu.admin.ch/publikationen/publikation/01613/?lang=en&download=NHzLpZig7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCGeoJ3hGym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.pdf>.

Fields, Simon. *The Beneficial Nature of the Second Hand Clothing Trade in Sub – Saharan Africa*, online: LMB <http://www.lmb.co.uk/images-news/pdf_9c219e8.pdf>.

Garrett, Laurie. *Ensuring the Safety and Integrity of the World's Drug, Vaccine, and Medicines Supply*, Policy Innovation: Memorandum 21, online: Council on Foreign Relation <http://www.cfr.org/pharmaceuticals-and-vaccines/ensuring-safety-integrity-worlds-drug-vaccine-medicines-supply/p28256>.

Getman, Myron. *United Nations Fails to Add Chrysotile to Rotterdam Convention – Again*, (27 May 2013), online: The Mad Skeptic <http://www.themadskeptic.com/2013/05/united-nations-fails-to-add-chrysotile.html>.

Goldman, Patti. *NAFTA and Consumer Rights: How NAFTA Jeopardizes Health, Safety and Environmental Standards*, (October 1993), online: Multinational Monitor <http://www.multinationalmonitor.org/hyper/issues/1993/10/mm1093_04.html>.

Goldring, John. "Consumer Protection, the National-State, Law, Globalization, and Democracy" Yeshiva University Cardozo Journal of International and Comparative Law, Spring Issue (1998), online: LexisNexis <https://litigation-essentials.lexisnexis.com/webcd/app?action=DocumentDisplay&crawlid=1&doctype=cite&docid=6+Cardozo+J.+Int%27l+%26+Comp.+L.+1&srctype=smi&srcid=3B15&key=929b4542c1edebb5e767369ccc3bde1d>.

Greenwood, Nigel S. *Passenger Ship Safety Since 1912*, BC Shipping News, (February 2013), online: BC Shipping News <http://www.bcshippingnews.com/magazine/feature-article/passenger-ship-safety-1912-nigel-s-greenwood>.

Gregory, Roxanne. *B.C. Ferries' Evacuation Systems Come under Fire,* Straight, (23 April 2014), online: Straight <http://www.straight.com/news/632216/bc-ferries-evacuation-systems-come-under-fire>.

Guzman, Andrew T. & Meyer, Timothy L. "International Soft Law", *Legal Analysis* 171, (1 January 2010), online: Berkeley Law Scholarship <http://scholarship.law.berkeley.edu/cgi/viewcontent.cgi?article=1694&context=facpubs>.

Henderson, Eugene. "African Countries Ripped off by Rag trader in Gift Charity Clothing", Express, (22 September 2013), online: Express <http://www.express.co.uk/news/world/431236/African-countries-ripped-off-by-rag-trader-in-gift-charity-clothing>.

Harland, David. "Legal Aspects of the Export of Hazardous products" *Journal of Consumer Policy* 8:3, (September 1985), online: Springer Link <http://link.springer.com/article/10.1007/BF00380383>.

Hachman, Mark. "Sony's Latest Battery Recall" *PC Mag,* (31 October 2008), online: PC Mag <http://www.pcmag.com/article2/0,2817,2333692,00.asp>.

Janischweski, Jorg. Henzler, Mikael P. & Kahlenborn, W. *The Export of Second-Hand Goods and the Transfer of Technology*, German Council for Sustainable Development, (May 2003), online: German Council for Sustainable Development <https://www.nachhaltigkeitsrat.de/fileadmin/user_upload/English/pdf/pdf/Study_Second-hand_goods_and_transfer_of_technology.pdf >.

Kallmyer, Kevin. *Basel Convention on the Control of Transboundary Movements of Hazardous Wastes*, University of Mary Washington, online: Cedadebate <http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCAQFjAA&url=http%3A%2F%2Fwww.cedadebate.org%2Fforum%2Findex.php%3Faction%3Ddlattach%3Btopic%3D749.0%3Battach%3D141&ei=Ho5nVLT8GoyigwSPvoPoCQ&usg=AFQjCNHSO9t2Rx5Zsszn_P7a9dGoPVhDOw&sig2=y2eJp5bL8oK8OmNB0xodbw&bvm=bv.79142246,d.eXY>.

Kazan-Allen, Laurie. *The Rotterdam Convention: Fighting for its Life*, (March 2008), online: International Ban Asbestos Secretariat <http://ibasecretariat.org/lka_rott_conv_fight_life_0308.php#3>.

Kojima, Michikazu. *Towards Appropriate International Recycling and Re-use*, online: Yumpu <https://www.yumpu.com/en/document/view/37133222/towards-appropriate-international-recycling-and-re-use>.

Liu, Chenglin. "Leaving the FDA Behind: Pharmaceutical Outsourcing and Drug Safety", *Texas International Law Journal*, 48:1, (2012), online: Texas International Law Journal <http://www.tilj.org/content/journal/48/num1/Liu1.pdf>.

Llamas, Tom. "Bogus Herbal Supplements Fail Ingredient Test: Investigation", ABC News, (3 February 2015), online: ABC <http://abcnews.go.com/Health/bogus-herbal-supplements-fail-ingredient-test-investigation/story?id=28684472>.

Malcolm, Jeremy. *Updating the UN Guidelines for Consumer Protection for the Digital Age,* Kuala Lumpur: Consumers International, (2013), online: Consumers International, <http://www.consumersinternational.org/media/1353300/updating-ungcp.pdf>.

Mackey, Tim K. & Liang, Bryan A. *Pharmaceutical Digital Marketing and Governance: Illicit Actors and Challenges to Global Patient Safety and Public Health*, (16 October 2013), online: Globalization and Health <http://www.globalizationandhealth.com/content/9/1/45#B36>.

Maniet, Françoise. "Le système d'échange rapide d'informations sur les produits dangereux (ou RAPEX) mis en place dans l'Union Européenne" *Revista de Direito do Consumidor,* 75, (2010).

McGrady, Benn. & Jones, Alexandra. "Tobacco Control and Beyond: The Broader Implications of United States— Clove Cigarettes for Non-Communicable Diseases", *American Journal of Law & Medicine* [American Society of Law, Medicine & Ethics Boston University School of Law] 39 (2013), online: Georgetown University <http://www.law.georgetown.edu/oneillinstitute/documents/SSRN-id2263270.pdf>.

Meltzer, Joshua. & Porges, Amelia. "Case Notes, Beyond Discrimination? The WTO Pases the TBT Agreement in US-Clove Cigarettes, US-Tuna II and US –COOL", *Melbourne Journal of International Law*, 14:2, (December 2013), online: Melbourne Law School <https://www.law.unimelb.edu.au/files/dmfile/11MeltzerPorges-Depaginated.pdf>.

Micklitz, Hanse W. "EC Regulation on the Export of Pharmaceuticals in Third World Countries", *Journal of Consumer Policy* 11:1 (March 1988), online: Springer Link <http://link.springer.com/article/10.1007/BF00411519>.

Milas, R. "La signification juridique de l'institution d'un système communautaire d'échange rapide d'informations sur les dangers découlant de l'utilisation de produits de consommation", *Revue du Marché Commun*, (1984).

Missions: *Maritime Safety*, online: U.S. Coast Guard <http://www.uscg.mil/top/missions/MaritimeSafety.asp>.

Mitchell, Andrew. & Voon, Tania. "Regulating Tobacco Flavors: Implications of WTO Law", *Boston University International Law Journal*, 29:2 (2011), online: Boston University School of Law <http://www.bu.edu/ilj/files/2014/05/MitchellVoon-finalpdf.pdf>.

"Necessary complications? Observations on the nexus between trade law and domestic regulation", *Frontier Economics*, (April 2015), online: Frontier Economics <http://www.frontier-economics.com/documents/2015/04/regulation-trade_frontier-report-april-2015.pdf>.

Ninan, Benson. & Wertheimer, Albert I. "Withdrawing Drugs in the U.S. Versus Other Countries", *Innovations in Pharmacy*, 3:3 (2012), online: University of Minnesota: College of Pharmacy <http://pubs.lib.umn.edu/cgi/viewcontent.cgi?article=1089&context=innovations>.

Novella, Steven. "Herbs Are Drugs: Science of Medicine", Skeptical Inquirer, 37:2, (March/April 2013), online: Skeptical Inquirer <http://www.csicop.org/si/show/herbs_are_drugs>.

OECD, *Safety of Consumer Products - Policy and Legislation in OECD Member Countries* Paris: OECD (1980).

O'Connor, Amy. *Tips for Buying Safe Medications On-line*, (21 March 2011), online: Lilly Pad <https://lillypad.lilly.com/entry.php?e=1574>.

Esteban Ortiz Ospina & Max Roser, *International Trade: Empirical View*, Our World in Data, online: Our World in Data <http://ourworldindata.org/data/global-interconnections/international-trade/>.

Outsourcing Excellence in China and India: Close Collaboration Effectively Manages Far-Flung Partnerships, (12 February 2013), online: Pharma Manufacturing <http://www.pharmamanufacturing.com/articles/2013/018/>.

Pharmaceutical Outsourcing: Maintaining Quality, Reducing Risk, online: CAN Canada <http://www.cnacanada.ca/web/wcm/connect/18d377a3-39a6-4d3b-842d-4db4a672eaff/PharmaceuticalOutsourcingMaintainingQualityReducingRisk.pdf?MOD=AJPERES>.

Pinheiro, Christina P. "Drug Donations: what Lies Beneath", *Bull World Health Organ*, 86(8): 580, (August 2008), online: National Center for Biotechnology Information <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2649461/>.

Pinto, Luciano. *Consumer Protection in Brazil, A General View* (2002), online: George Washington University, Institute of Business and Public Management Issues <http://www.gwu.edu/~ibi/minerva/Fall2002/Luciano.Maia.pdf>.

"Rapid Alert System on Dangerous Products - RAPEX 2013", *EU Business,* (25 March 2014), online: EU Business <http://www.eubusiness.com/topics/consumer/rapex-2013/>.

Sauvant, Karl P. "The Negotiations of the United Nations Code of Conduct on Transnational Corporations", *The Journal of World Investment & Trade*, 16, (2015), online: Columbia Center on Sustainable Investment, Columbia Law School

<http://ccsi.columbia.edu/files/2015/03/KPS-UN-Code-proof-2-Journal-of-World-Investment-and-Trade-March-2015.pdf>.

Noah M Sachs, *Out of Sight, Out of Mind: Ratifying the Basel Convention on Transboundary Waste*, (1 May 2012), online: Centre for Progressive Reforms <http://www.progressivereform.org/CPRBlog.cfm?idBlog=08A5B515-BA05-B72A-9AE04583A239DE21>.

Scheringer, Martin *et al, How Many Persistent Organic Pollutants Should We Expect?*, Atmospheric Pollution Research, 3, (2012), online: *Atmospheric Pollution Research* <http://www.atmospolres.com/articles/Volume3/issue4/APR-12-045.pdf>.

Schor, Elana. "Obama Admin Steps Up Pressure to Ratify Treaties on Toxics", The New York Times, (24 September 2010), online: The New York Times <http://www.nytimes.com/gwire/2010/09/24/24greenwire-obama-admin-steps-up-pressure-to-ratify-treati-73636.html>.

Schumacher, Keith B. *Marine Disasters and Merchant Ship Design*, online: USCG <http://www.uscg.mil/history/ops/marinesafety/docs/1958_Schumacher_MarineDisasters&MerchantShipDesign.pdf>.

Synergies Success Stories - Enhancing Cooperation and Coordination among the Basel, Rotterdam and Stockholm Conventions, online: Basel Convention <http://www.basel.int/Implementation/Publications/Other/tabid/2470/Default.aspx>.

Siegel, Michael. *The Rest of the Story: Tobacco News Analysis and Commentary: U.S. Thumbs Nose at World; Public Citizen Defends Ban on Clove Cigarettes*, (29 July 2013), online: Tobacco Analysis <http://tobaccoanalysis.blogspot.ca/2013/07/us-thumbs-nose-at-world-public-citizen.html>..

Sigman, Richard "Chemical safety" in OECD, *International Regulatory Co-operation: Case Studies*, 1: *Chemicals, Consumer Products, Tax and Competition*, OECD, (April 2013), online: OECD iLibrary <http://www.oecd-ilibrary.org/governance/international-regulatory-co-operation-case-studies-vol-1_9789264200487-en>.

Silver, Jake. "Canada Blocks UN from Declaring Asbestos a "Hazardous" Substance", (21 July 2011), online: WSWS <https://www.wsws.org/en/articles/2011/07/asbe-j21.html>.

Sinking Of The Titanic Influences Wireless Radio, online: Modesto Radio Museum <http://www.modestoradiomuseum.org/titanic.html>.

Slocum, Rebecca. *Rethinking Hazardous Waste under NAFTA*, Americas Program: Center for International Policy, (August 2009), online: Basel Action Network <http://ban.org/library/Features/090810_rethinking_hazardous_waste_under_nafta.html>.

SOLAS - The International Convention for the Safety of Life at Sea, online: Metal Safe Sign <http://www.mss-int.com/solas.html>.

Stanton, Oretchen H. "The SPS Agreement: WTO Agreement on the Application of Sanitary and Phytosanitary Measures", *International Trade Forum Magazine*, 3 (2010).

Story, Louise. "Putting Playthings to the Test" *New York Times*, (22 August 2007), online: New York Times <http://query.nytimes.com/gst/fullpage.html?res=9D0CE1DE1E3AF93AA1575BC0A9619C8B63&pagewanted=all>.

Teubner, Gunther. "Substantive and Reflexive Elements in Modern Law", *Law and Society Rev.*, 17:2, (1983).

Thomas, Mark. *Drug Donations: Corporate Charity or Taxpayer Subsidy?*, online: University of Essex <https://www.essex.ac.uk/armedcon/story_id/000068.pdf>.

Titanic vs. Oasis Of The Seas: Compare World's Biggest Cruise Ships, Then And Now", *Huffington Post*, (11 April 2012), online: Huffington Post <http://www.huffingtonpost.ca/2012/04/11/titanic-vs-oasis-compare-cruise-ships_n_1419368.html>.

Tucker, Todd "Summarizing WTO Appellate Body Decision on U.S. Flavored Tobacco Ban", (April 2012), online: Citizen <http://www.citizen.org/documents/memo-appellate-body-clove-ruling-04-12.pdf>.

Vamos-Goldman, Andras. "The Stagnation of Economic Regulation Under Public International Air Law: Examining Its Contribution to the Woeful State of the Airline Industry" (23 TRANSP.L.J 425, 431), (1996).

Vézina, N. Maniet, F. "La sécurité du consommateur au Québec... deux solitudes : mesures préventives et sanctions civiles des atteintes à la sécurité" *Les Cahiers de droit*, 49:1, (2008).

Vidal, John. "Toxic 'e-waste' Dumped in Poor Nations, says United Nations", *the Guardian*, (14 December 2013), online: the Guardian <http://www.theguardian.com/global-development/2013/dec/14/toxic-ewaste-illegal-

dumping-developing-countries>.

"Vietnam Airlines Mid-Air Scare: New Zealander Mark Ansley "Never Thought Twice" about Restraining Man Trying to Open Exit Door on Flight to Sydney", *ABC News*, (6 November 2014), online: ABC News <http://www.abc.net.au/news/2014-11-06/nz-man-restrained-by-passengers-for-trying-to-open-exit-door/5871750>.

Vincent, David. *API Manufacturing: Product Safety*, online: Pharmaceutical Canada <http://www.pharmaceuticalcanada.ca/article1.asp>.

UN Conference Approves POPs Convention in Stockholm, online: Our Stolen Future <http://www.ourstolenfuture.org/policy/pops/2001-0522popsconvention.htm>.

"US Rejects WTO Panel on Clove Cigarette Ban", *Reuters,* (22 June 2010), online: Reuters <http://uk.reuters.com/article/2010/06/22/trade-cigarettes-idUKLDE65L1O920100622>.

Walker, Jim. *20 Crew Members Injured During Cruise Ship Lifeboat Drill*, Cruise Law News, (22 November 2012), online: Cruise Law News <http://www.cruiselawnews.com/2012/11/articles/rescue-1/20-crew-members-injured-during-cruise-ship-lifeboat-drill/>.

Walker, Jim. *Titanic Redux? Can Royal Caribbean Safely Evacuate 8,500 Passengers & Crew from the Oasis of the Seas?*, Cruise Law News, (28 January 2013), online: Cruise Law News <http://www.cruiselawnews.com/2013/01/articles/sinking/titanic-redux-can-royal-caribbean-safely-evacuate-8500-passengers-crew-from-the-oasis-of-the-seas/>.

Weidenbaum, Murry. "The Case Against the UN Guidelines for Consumer Protection", 10, *Journal of Consumer Policy* , (1987) .

WTO, *Understanding on Rules and Procedures Governing the Settlement of Disputes*, online: WTO <https://www.wto.org/english/tratop_e/dispu_e/dsu_e.htm#11>.

Гармонизация Обращения Лекарственных Средств и Медицинских Изделий в Рамках Евразийского Экономического Союза (Harmonization of Drug and Medical Products Circulation within the Eurasian Economic Union [translated by author]), (17 December 2014), online: Esculap-Med <http://www.esculap-med.ru/news/details/garmonizaciya_obrashheniya_lekarstvennykh_sredstv_i_medicinskikh_izdelijj_v_ramkakh_evrazijjskogo_ehkonomicheskogo_soyuza>.

Данилова, Гульназ "В СНГ Создадут Единый Координирующий Орган в Сфере Технической Политики", (Danilova, Gulnaz. CIS Creates a Single Coordinating

Body in the Field of Technical Policies [translated by author]), (18 June 2013), *Russian Business Newspaper*, 901(23), online: Russian Business Newspaper <http://www.rg.ru/2013/06/18/tovari.html>.

Екатерина Дудина, "Участники Роттердамской Конвенции Отсрочили Вопрос о Запрете Хризотила" [Ekaterina Dunina, "The Participants of the Rotterdam Convention Conference Postponed Banning Chrysotile"], (20 May 2013). online: РИА Новости <http://ria.ru/economy/20130520/938391658.html>.

ЕАЭС Намерен Создать Общий Рынок Лекарственных Изделий и Медпрепаратов на Территории Стран-Участниц Союза , (EAEC Intends to Create a Common Market of Pharmaceuticals and Medicinal Products [translated by author]), ХИМРАР, (17 December.2014), online: ХИМРАР <http://www.chemrar.ru/i-news/index.php?ELEMENT_ID=19174>.

Законодательство по Препаратам на Основе Лекарственных Растений" Провизор 16 (2002) (Legislation on Medicinal Plants Formulations [translated by author]), Провизор, online: Провизор <http://www.provisor.com.ua/archive/2002/N16/art_21.php>.

Марианна Мирзоян, *GMP: Теперь в России* (Marianna Mirzoiyn, "GMP is Now in Russia"), [translated by author]), 6 November 2013, online: Медпортал, <http://medportal.ru/mednovosti/main/2013/11/06/243gmp/>.

Екатерина Чернышова, "Страна Двух Таблеток" (Ekaterina Chernishova, The Country of Two Pills [translated by author]) *Kommersant*, (9 December 2014), online: Kommersant <http://www.kommersant.ru/doc/2625142>.

SECONDARY MATERIAL: PROCEEDINGS OF CONFERENCE

Bourgoignie, Thierry. *Accords de libre-échange et intégration des marchés: les consommateurs oubliés*, proceedings of conference: Les partenariats transatlantique et transpacifique à l'ère de l'interconnexion, (16- 17 November 2016), UQAM, Montreal, online: CEIM-UQAM <http://www.ieim.uqam.ca/IMG/pdf/bourgoignie_uqam_nov_2016.pdf>.

Bourgoignie, Thierry. "Consumer Law and Policy Today: Everything Fine or Can We Do Better?", International Association of Consumer Law Conference, (2 July 2016), University of Amsterdam (The Netherlands), available on GREDICC website: <www.gredicc.uqam.ca>.

Bourgoignie, Thierry. *Quality Infrastructure System: The legal pilar*, Summer Programme in Consumer Law and Policy, UQÀM-GREDICC, (6 July 2016), Montreal.

Micklitz, Hans W. *Mohamed Aziz–Sympathetic and Activist, but Did the Court get it Wrong?*, European Constitutional Law Network (ECLN) Conference: When The ECJ Gets It Wrong, Florence (2013), online: European Constitutional Law Network <http://www.ecln.net/tl_files/ECLN/Florence%202013/Micklitz%20-%20The%20ECJ%20gets%20it%20wrong%20Aziz-30-11-14.pdf>.

Munn, Kevin. *The CiP Programme - an Overview* [Presentation], (March 2014), online: PREZI <https://prezi.com/9pwa5dxpwr6u/the-cip-programme-an-overview/>.

Trstenjak, Verica. *The Court of Justice of the EU (CJEU) and its Influence on Consumer Law,* Presentation to the Summer programme in consumer law and policy organized at UQAM by GREDICC, 4th to 9th July 2016.

UNEP, *Proceedings of the Twenty-Fifth Session of Governing Council/ Global Ministerial Environment Forum GC-25/GMEF: Decision 25/5,* (24 February 2011), online: Mercury Convention <http://www.mercuryconvention.org/Negotiations/Mandates/tabid/4223/Default.aspx>.

INTERNET WEB-CITES CONSULTED

About the GHS, online: UNECE <http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html>.

CARICOM, *Consumer Product Incident Reporting System*, online: CARICOM <carrex.caricom.org>.

Chemical Production Division, online: Environment and Climate Change Canada <http://www.ec.gc.ca/toxiques-toxics/Default.asp?lang=En&n=FB6BD2C0-1>.

Chemical Substances, online: Chemical Substances <http://www.chemicalsubstanceschimiques.gc.ca/index-eng.php?utm_source=VanityURL&utm_medium=URL&utm_campaign=chemicalsubstances.gc.ca>.

CIS, *CIS Advisory Commettee on Consumer Protection* [in Russian], online: Rospotrebnadzor <http://rospotrebnadzor.ru/deyatelnost/zpp/sng/>.

Codex Alimentarius, online: <http://www.fao.org/fao-who-codexalimentarius/codex-home/en/>.

Committee on Herbal Medicinal Products, online: European Medicines Agency <http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000264.jsp>.

Common Electronic Submission Gateway, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/cesg-pcde/index-eng.php>.

Consumers International, online: <http://www.consumersinternational.org>.

Consumer Product Safety Commission, online: CPSC <http://www.cpsc.gov/en/>.

Current Detentions, online: Paris MoU <https://www.parismou.org/detentions-banning/current-detentions>.

EC, *Rapid Alert System for Food and Feed of the European Union*, online: European Commission <http://ec.europa.eu/food/safety/rasff_en >.

EC, *RAPEX*, online: EC <http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/reports/index_en.htm >.

Eurasian Commission, online: EEC <http://eurasiancommission.org/en/Pages/default.aspx>.

Eurasian Development Bank [in English], online: EDB <http://www.eabr.org/e/>.

EMERCOM, online: <http://en.mchs.ru/>.

Estonia Ferry Disaster, online: Estonia Ferry Disaster <http://www.estoniaferrydisaster.net/estonia/index.html>.

EudraGMDP <http://eudragmdp.ema.europa.eu/inspections/displayWelcome.do>.

Eurasian Economic Commission, online: EEC <http://www.eurasiancommission.org/en/Pages/default.aspx>.

EUR-Lex: Consumer Safery, online: EUR-Lex <http://eur-

lex.europa.eu/summary/chapter/consumers/0903.html?root=0903>.

European Chemicals Agency, online: ECHA <http://echa.europa.eu>.

European Medicines Agency
<http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/Home_Page.jsp&mid=>
.

European Maritime Safety Agency (EMSA), online: EMSA
<http://www.emsa.europa.eu>.

EURMED, online: EURMED <http://www.eurmed.eu>.

e-PIC Database, online: ECHA <http://echa.europa.eu/information-on-chemicals/pic/chemicals>.

Federal Agency of Sea and River Transport, [in Russian] online: Morflot
<http://www.morflot.ru/ob_agentstve.html>.

Federal Institute for Occupational Safety and Health Federal Office for Chemicals (BAuA), online: <http://www.baua.de/en/Homepage.html>.

GHS Implementation, online: UNECE
<http://www.unece.org/trans/danger/publi/ghs/implementation_e.html#c25755>.

Inmarsat, online: Inmarsat <http://www.inmarsat.com/services/safety/gmdss/>.

Foreign & Offshore Compliance Division, online: U.S. Coast Guard
<http://www.uscg.mil/hq/cgcvc/cvc2/?BV_SessionID=@@@@0627973807.1432756504@@@@&BV_EngineID=cccdadggfkgmkmicfngcfkmdfhfdfgl.0>.

Ministry of Agriculture of the Russian Federation, [in Russian], online:
<http://www.mcx.ru>.

Ministry of Natural Resources and Environment of the Russian Federation, online:
<http://www.mnr.gov.ru/english/>.

National Cancer Institute, online:
<http://www.cancer.gov/cancertopics/types/malignantmesothelioma>.

North American Commission for Environmental Cooperation, online, CEC
<http://www.cec.org/Page.asp?PageID=1226&SiteNodeID=207&BL_ExpandID=566>.

Health Canada , online: <http://www.hc-sc.gc.ca/index-eng.php>.

ICAO, *GASP*, online: ICAO <http://www.icao.int/safety/SafetyManagement/Pages/GASP.aspx>.

IMF, online: <http://www.imf.org/external/>.

IMO, *List Of Conventions*, online: IMO <http://www.imo.org/About/Conventions/ListOfConventions/Pages/Default.aspx>.

International Consumer Protection and Enforcement Network, online: ICPEN <https://www.icpen.org>.

International Council of Toy Industries, (ICTI) online: <http://www.toy-icti.org/info/toysafetystandards.html>.

International Maritime Organization (IMO), online: IMO <http://www.imo.org>.

Institute for Health and Consumer Protection, online: <http://ihcp.jrc.ec.europa.eu>.

International Telecommunication Union, online: ITU <http://www.itu.int>.

Mario Negri Institute for Pharmacological Research, [in English], online: <http://www.marionegri.it/mn/en/>.

Ministero della Salute, [in Italian], online: <http://www.salute.gov.it>.

National Center for Complementary and Integrative Health, online: NCCIH <https://nccih.nih.gov>.

Natural Health Products, Health Canada: Natural and Non-prescription Health Products Directorate, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>.

NEFARMA, [in English], online: <http://www.nefarma.nl/website/engels/nefarma-english >.

NS Savannah, online: NS Savannah <http://www.nssavannah.net>.

OAS, *Consumer Safety and Health Network*, online: OAS <http://www.oas.org/en/sla/cshn/default.asp>.

OAS, *Inter-American Rapid Alerts System* (SIAR), online: OAS <https://www.sites.oas.org/rcss/en/Pages/about/siar.aspx>.

OECD, *Consumer Product Safety*, online: OECD <http://www.oecd.org/sti/consumer/consumer-product-safety.htm>.

OECD, *Global Recalls*, online: OECD <http://globalrecalls.oecd.org>.

On Safety of Chemical Products, online: EEC <http://www.eurasiancommission.org/en/act/texnreg/deptexreg/tr/Pages/bezopChemProd.aspx>

Oxford Dictionary, online: Oxford Dictionary <http://www.oxforddictionaries.com>.

Paris MoU, online: Paris MoU <https://www.parismou.org>.

Partnership for Quality Medical Donations, online: <http://www.pqmd.org>.

Pest Management Regulatory Agency, online: Health Canada <http://www.hc-sc.gc.ca/contact/cps-spc/pmra-arla/infoserv-eng.php>.

Pneumothorax, online: <http://www.pneumothorax.org/>.

Polar Cruises, online: Polar Cruises <http://www.polarcruises.com/arctic/ships/icebreaker/50-years-victory>.

Product Safety Summit, online: Product Safety Summit <http://productsafetysummit.com/en/home/>.

RAPEX Notifications, online: EFTA Authority <http://www.eftasurv.int/internal-market-affairs/notifications/rapex-notifications/>.

Russian Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing (Rospotrebnadzor), online: <http://www.rospotrebnadzor.ru/en/>.

The Approach to Natural Health Products, Health Canada, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/nhp-new-nouvelle-psn-eng.php>.

The *EU Consumer Law Acquis Database, online: EC Consumer Law Compendium* <http://www.eu-consumer-law.org/>.

The Interstate Council for Standardization, Metrology and Certification of the Commonwealth of Independence States (CIS), online: Euroasian Interstate Council <http://www.easc.org.by/english/mgs_org_en.php>.

The Wemos Foundation, [in English], online: <http://www.wemos.nl/Eng/>.

Titanic Lifeboats, online: Titanic Facts <http://www.titanicfacts.net/titanic-lifeboats.html>.

Transportation Safety Board of Canada, online: Transportation Safety Board of Canada <http://www.bst-tsb.gc.ca/eng/>.

UNEP, *Strategic Approach to International Chemicals Management* (SAICM), online: SAICM <http://www.saicm.org>.

United States Consumer Safety Commission, online: CPSC <http://www.cpsc.gov/en/>.

Uppsala Monitoring Centre, online: <http://www.who-umc.org/>.

U.S.-Canada Regulatory Cooperation Council, online: <http://trade.gov/rcc/>.

U.S. Pharmacopeial Convention, online: <http://www.usp.org>.

WHO, *International Nonproprietary Names*, online: WHO <http://www.who.int/medicines/services/inn/en/>.

WHO, *WHO Pharmaceuticals Newsletter*, online: WHO <http://www.who.int/medicines/publications/newsletter/en/index.html>.

WTO, *Sanitary and Phytosanitary Measures*, online: WTO <https://www.wto.org/english/tratop_e/sps_e/sps_e.htm#work>.

WTO, *Technical Barriers to Trade*, online: WTO <https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm>.

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