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RÉSUMÉ

La consommation existe depuis toujours, mais elle a atteint de nouveaux sommets avec la mondialisation des marchés. Les politiques de frontières ouvertes ont contribué à la régionalisation et à l'internationalisation des marchés de consommation. En théorie du moins, ces politiques procurent pour le consommateur des bénéfices en offrant un plus grand choix, une concurrence accrue, et donc des prix plus avantageux. Cependant, ces mêmes politiques ont rendu plus vulnérable le consommateur, car les mesures nationales de protection du consommateur se trouvent limitées.

Bien que pendant les décennies précédentes les mesures de protection du consommateur aient été adéquates, ce n'est plus le cas avec les conditions actuelles des marchés. La régionalisation et internationalisation des marchés sont devenues un défi de taille du droit et des politiques contemporains sur la consommation. La communauté internationale est parvenue à conclure que les instruments nationaux de protection du consommateur sont limités et ne peuvent plus garantir au consommateur une protection adéquate. Seules des initiatives régionales ou internationales peuvent assurer les résultats voulus. Le consommateur est maintenant un consommateur international, et afin de maintenir un équilibre entre le marché international et le consommateur international, le droit sur la consommation doit aussi être obligatoirement international.

Étrangement, malgré la nature universelle de la consommation et l'existence de graves problèmes pour le consommateur sur les marchés internationaux, un système juridique international sur la consommation n'existe pas.

À date, la recherche de remèdes légaux visant la protection du consommateur s'est limitée surtout au niveau national. Ce travail évalue le besoin d'internationaliser les lois et politiques sur la consommation, en plus d'essayer d'identifier les sources internationales existantes de protection du consommateur.

Ce travail se veut un premier effort visant à contribuer à la conception future de droit international sur la consommation. Le but de ce mémoire n'est pas d'énumérer toutes les conditions et exigences requises pour établir un cadre efficace de protection du consommateur au niveau international. Le but visé est beaucoup moins ambitieux. Ce travail vise plutôt à identifier et systématiser les initiatives internationales existantes qui sont les plus propices à influencer la protection des intérêts du consommateur.

Sous le régime actuel de mondialisation, les marchés régionaux sont devenus une réalité beaucoup plus tangible pour le consommateur que les marchés internationaux. La première partie de ce travail examine si et comment la régionalisation des marchés peut contribuer à la protection juridique des intérêts du consommateur. Les succès réalisés et les initiatives prises en faveur du consommateur par certaines institutions internationales sont ensuite présentés dans la deuxième section. Enfin, la troisième partie offre quelques conclusions sur l'état actuel du droit international de protection du consommateur et sur la possibilité que celui-ci puisse offrir au consommateur une protection adéquate sur les marchés globaux.

CONSOMMATION--- PROTECTION DU CONSOMMATEUR--- DROIT RÉGIONALES SUR LA CONSOMMATION--- UE--- CEI--- DROIT INTERNATIONAL SUR LA CONSOMMATION--- ONU

SUMMARY

Consumption has existed forever, but it has more recently reached new heights as a result of market globalization. Open-border policies make consumer markets more regional and international. In theory at least, they bring benefits to the consumer in terms of greater choice, higher competition, and hence lower prices. However, they also make consumers more vulnerable in the marketplace since they limit national consumer protection measures.

While national consumer protection measures may have been sufficient in past decades, this is not the case anymore under contemporary market conditions. The regionalization and internationalization of markets has become one of the main challenges of modern consumer law and policy. The international community has reached the point where it has become obvious that state consumer protection instruments are limited and no longer guarantee sufficient protection to consumers. Only regional or international initiatives can produce the desired results. Consumers are now international consumers, and to maintain a balance between the international market and international consumers, consumer law should truly be international.

Surprisingly, despite the universal nature of consumption and severe consumer-related problems on the international markets, international consumer law does not exist.

To date, the search for legal remedies aimed at protecting consumers has remained mostly national. This work intends to assess the need for consumer law and policy to become more international and attempts to identify existing international sources of consumer protection.

This work is a first effort to contribute to the design of future international consumer law. The purpose of this paper 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 and to systemize existing international initiatives most likely to have an impact on the protection of consumer interests.

Under the current globalization process, regional markets have become a closer reality for consumers than international ones. Therefore, whether and how market regionalization does contribute to the legal protection of consumer interests is the subject of Part 1. The achievements made or initiatives taken in favor of consumers

by some institutions at the international level are then identified and described in Part 2. Part 3 formulates some conclusive remarks about the current state of international consumer law and its potential to provide consumers with adequate consumer protection on global markets.

INTRODUCTION

Consumption has existed forever, but it has more recently reached new heights as a result of market globalization. Open-border policies make consumer markets more regional and international. In theory at least, they bring benefits to the consumer in terms of greater choice, higher competition and hence lower prices. However, they also make consumers more vulnerable in the marketplace. To date, the search for legal remedies aimed at protecting consumers has remained mostly national. This work intends to assess the need for consumer law and policy to become more international and attempts to identify existing international sources of consumer protection.

Nothing or little was done for consumers before 1960. The paradox is that although consumers have always existed, they were perceived as marketing targets rather than as subjects of legal rights. 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 absence of consumers from the legal sphere translated into constant abuses of consumers, who ultimately paid the price, while producers got away with staggering profits. This situation could not endure.

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 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 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.*

This 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 did proclaim four basic consumer rights:

1.The right to safety--protection against product hazards to life or health.
2.The right to choose--consumer access to a variety of products and services at fair prices.
3.The right to information--protection against dishonest or misleading information or practices which could affect consumers' ability to make the right choice.
4.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.[1] 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 recognized and proclaimed now for 45 years and certain steps have been taken on different levels of governance toward development and implementation of comprehensive consumer policy, consumers are

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[1]Centre for Consumer Action Research and Training, "Consumer rights and its expansion", on line: Centre for Consumer Action Research and Training <http://www.cuts-international.org/Consumer-Rights.htm>.

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 some producers' actions may lead to physical harm or even death.

There are strong political, economic, and social considerations which call for the adoption of active consumer protection policies and strategies at the national level.[2]

There may also be significant opposition to such a move. Among others, two factors explain why consumer protection is often overlooked by government. 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.[3] Second, consumer law is regarded by some within the legal sphere as an unnecessary luxuriance.[4] One believes that a legal instrument such as a civil code or contract law should have enough authority to regulate and solve any crisis arising from consumer-professional contractual relations. Moreover, because different state policies, such as for health, trade, competition, etc., include many elements related directly or indirectly to consumer protection, there is an illusion that consumer policy and law can exist as part of other pertinent state affairs. Nevertheless, consumer

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[2] 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, QC: Yvon Blais Inc, 2006) at 1-18.

[3] We must also keep in mind that consumer protection regulations can have tremendous economic implications not only for producers but also for consumers. The greatest disadvantage for producers 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. As for consumers, the extra cost of safety measures, for example, can make products too expensive to buy.

[4] 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 would 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 and meticulously follow it. However, it is not very 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.

protection law has all the essential features to exist and be treated as autonomous law by virtue of its specific nature, goals, basic principles and instruments.[5] Other pertinent laws have failed to provide adequate consumer protection because they are too broad in scope. For example, a civil code or contract law assumes "that the parties to contract are *legally equal* in terms of power and information."[6] This concept works well for commercial contacts where parties exercise comparable powers, but it does not work for most consumer contracts, as consumers do not have the same economic clout and information as professionals. Contrary to a civil code or contract law, consumer law presumes unequal relations between consumers and professionals, with the latter always enjoying a superior position.[7] Thus, only specific consumer law can provide adequate consumer protection.[8] Moreover, some aspects of consumer law, such as consumer education or market surveillance, have never been a part of a civil code or contract law. Therefore, the institution of autonomous consumer law would be an essential and logical step for any state seeking to create efficient consumer protection.

Despite such controversies, most countries throughout the world have put key elements of consumer regulations into place.[9] In most states, consumer law exists as a

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[5]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.

[6]John Goldring, "Consumer protection, the National-State, Law, Globalization, and Democracy", on line: School of law, University of Wollongong <http://jcmc.indiana.edu/vol2/issue2/goldring.html >.

[7]Denis Mazeaud, *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) at 701

[8]Consumer protection law seems more like a mechanism of prevention of possible consumer abuse or danger. In other words, the law must protect consumers from unfair commercial practices and dangerous products before they even reach the marketplace. Civil codes and contract law have failed to provide such a mechanism because there is no such requirement for commercial operations between professionals.

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

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 consumer protection. The trend is universal, and it does not really matter what kind of background or social or economical structure a state may have: developed, as in the case of France;[10] in transition, as in Russia;[11] developing, as in Brazil;[12] or communist, as in China.[13] Every state confirms the need to protect

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[10]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.

[11]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.

[12]Consumer protection law was created in Brazil as a result 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 Protection in Brazil, A General View" (2002), on line: George Washington University, Institute of

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

Incentives for governments to act in favor of consumers have also arisen from international pressure.

Some elements of international consumer protection law appeared long before the recognition of consumer law as a branch of the legal sphere. 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.[14] The Warsaw Convention was not only the first international document that set out consumer rights, but it was also one of the rare agreements with an impact on the protection of consumers' economic interests. Moreover this convention was one of the few consumer-related documents of a binding nature. 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

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Business and Public Management Issues
<http://www.gwu.edu/~ibi/minerva/Fall2002/Luciano.Maia.pdf>.

[13]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*. (Consumer International, Asia Pacific Office "Law of the People's Republic of China on the Protection of Consumer Rights and Interests", on line: Consumer International, Asia Pacific Office <http://www.ciroap.org/apcl/country_more.php?id=30>.) For more on consumer protection in China, see Anne Meunier-Bihl, *Le droit de la consommation en Republique polulaire de Chine* (Louvain: Centre de droit de la consommation,1997).

[14]*Convention for the Unification of Certain Rules Relating to International Carriage by Air, Signed at Warsaw on 12 October 1929 (Warsaw Convention*), on line: Faculty of Law, University of Oslo, <http://www.jus.uio.no/lm/air.carriage.warsaw.convention.1929/portrait.pdf>.

standards and guidelines.[15] The Commission became the first international institution to take the matter of consumer safety seriously. Unfortunately, documents adopted by the Commission are not binding and their applications are limited to the safety of food.

Despite the adoption of a few international agreements regarding consumer protection, the work in this field was sporadic and of very limited scope since there was no universal document that standardized the international view on this problem to put governments on the right track. The adoption of the UN Guidelines on Consumer Protection in 1985 did constitute a major step forward, as the Guidelines suggest a universal model framework for consumer protection policy.[16] With one of the objectives being *to assist countries in achieving or maintaining adequate protection for their population as consumers*, the guidelines integrate six basic consumer rights: 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 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. Thus, since 1985, governments around the globe have had a handbook that gives detailed directions to pursue and develop effective national consumer protection policy. The UN guidelines did have a decisive impact on the decision by several members of the international community to adopt consumer protection measures and the choice

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[15]*Codex Alimentarius*, FAO, on line: Codex Alimentarius net <http://www.codexalimentarius.net/web/index_en.jsp>.

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

thereof.[17]

While initiatives taken at the international level have benefited the development of national consumer policies, some regional developments have played an important role as well.

The regional economic integration process that started in Europe after World War II with the creation of the European communities has spread across the globe. There are now several other regional unions, such as the Commonwealth of Independent States (CIS), the North American Free Trade Agreement (NAFTA) zone, and the Southern Common Market (MERCOSUR). Although these regional systems have different goals and different levels of political and economic integration, they all involve some degree of law approximation designed to support the integration process. Namely, in order to become a member of the European Community, candidate countries must make their laws and rules compatible with the regional standards and rules or *Acquis communautaire.*[18] Existing national policies on consumer protection must be modified to meet common standards and measures adopted by the European Community to ensure consumers a high level of protection in the regional

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[17]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 6.

[18]The accession criteria, or Copenhagen criteria, are the essential conditions all candidate countries must satisfy to become a Member State of the EC. They were set at the Copenhagen European Council in 1993 and at the Madrid European Council in 1995 and comprise: (1) political criteria: stability of institutions guaranteeing democracy, the rule of law, and respect for human rights, including the rights of minorities; (2) economic criteria: a functioning market economy and the capacity to cope with competition and market forces; the capacity to take on the obligations of membership, including adherence to political, economic, and monetary objectives; (3) creation of the conditions for integration through the adjustment of administrative and institutional structures guaranteeing effective implementation of *Acquis Communautaire.* The *Acquis Communautaire* is the total body of European Union law applicable in the EU member states. The Acquis comprises various topics, and consumer and health protection is one of them. For more on this subject, see EC *Accession criteria*, on line: European Commission <http://ec.europa.eu/enlargement/enlargement_process/accession_process/criteria/index_en.htm>.

marketplace. Regional integration thereby directly benefits the recognition of consumer rights on the national stage.[19]

Under current market conditions, consumer policy will have to become increasingly international. Global thinking is a must in this field as it is in others.

While national consumer protection measures may have been sufficient in past decades, this is not the case anymore under contemporary market conditions. The regionalization and internationalization of markets has become one of the main challenges of modern consumer law and policy[20]. The effectiveness of national rules appears more and more limited, and a global approach to consumer policy is now needed.

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, and 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.[21] Globalization has brought about new means of production, marketing, and commerce that have radically affected how countries can impose control on the marketplace.

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[19]Another good example of how regional integration benefits the recognition of consumer rights on a national level is the CIS agreement on consumer protection. "The accord regarding the basic directions of cooperation among members of the CIS within the sphere of consumer protection" that forces member-states to make the necessary legal and administrative changes on the national level to comply with the CIS standards. For more on this subject, see part 1.3 of this work.

[20]*Ibid.*2 at 26-34.

[21]Online fraud is the biggest problem facing consumers. As of 2003, "one of every 20 consumers has been the victim of credit card fraud ... and one in 50 has been the victim of identity theft." Total losses related to online fraud reached a staggering $700 million, which is 19 times more then offline fraud losses. Peter Thiruselvam, "The Facts About Online Fraud" (2003), on line: Webpronews <http://www.webpronews.com/topnews/2003/04/18/the-facts-about-online-fraud>.

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 a result of regional or international 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 transborder shopping,[22] but the impact thereof remains limited. Many countries, including Canada, have not ratified these international conventions, the scope of which exclude several contracts and give protection only to certain groups of consumers (the so-called passive consumers).[23] Transborder litigation remains for individual consumers an unaffordable, uncertain, and much too risky move.[24] 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 declared imperative.[25] Consumer legislation commonly declares unfair a contract

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[22] *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, on line: Oslo University <http://www.jus.uio.no/lm/brussels.jurisdiction.and.enforcement.of.judgments.in.civil.and.commercial.matters.convention.1968/doc.html> and *Convention on the law applicable to contractual obligations opened for signature in Rome on 19 June 1980*, 1980, at Art. 5, *Certain consumer contracts*, on line: Rome convention <http://www.rome-convention.org>.

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

[24] *Ibid.* 20.

[25] "*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, on line: 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*

clause by the effect of which the consumer would be deprived of the protection he would be granted under national law.[26]

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 give up certain powers to regional or international authorities, with the result being to limit the state's authority to set up national schemes conferring to their consumers a high or the highest level of protection. International trade and open-borders policies may threaten national consumer protection measures as these would be regarded as an obstacle to the free circulation of goods and services, thus calling for the dismantling of national consumer protection framework.[27] Nowadays, it is important to realize that internationalization has shifted control over national consumer markets from the state level to the regional or international realm.

It remains that as a result of globalization, national consumer protection measures are no longer sufficient to effectively protect consumer interests. Only regional or international initiatives can produce the desired results. Some consider that the

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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, on line: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0013:EN:HTML>.

[26] *"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, on line: Canadian Legal Information Institute <http://www.canlii.org/qc/laws/sta/p-40.1/20050513/whole.html>.

[27] Thierry Bourgoignie & David Trubek, *Consumer law, common markets and federalism* (Berlin: Walter de Gruyter, 1987) at 1 to14.

survival itself of consumer protection at the national level requires that initiatives be taken for consumers at the international level.[28]

Consumers are now international consumers, and to maintain a balance between the international market and international consumers, consumer law should truly be international.

The international community has reached the point where it has become obvious that state consumer protection instruments are limited and no longer guarantee sufficient protection to consumers. 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. And it is without a doubt a very important matter. However, as such agreements are silent regarding consumer protection measures, they also play the role of a Trojan horse by bringing into the national market more consumer problems then benefits. It is crystal clear that, the more a state integrates into the international market, the more often national measures will fail. There is only one possible way to eliminate present and future consumer problems: standardize legal tools of consumer protection.

Public international law is the spinal cord of the international legal order. Recently, by virtue of globalization, public international law has become increasingly important, especially as an international trade regulator.[29] Today, public international

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[28] *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*: *Proceedings of Conference on economic regional integration and consumer protection in the Americas and Europe, Montreal, 18 -19 October 2007* (Montreal: UQAM, GREDICC, 2007).

[29] Even so, the main actor of public international law is the state, and it affects to a minor degree subjects within state borders (professionals and individuals) when international legal obligations taken voluntarily by states transform and amalgamate national legislation. Moreover, recent developments show that certain branches of public international law, such as international human rights law, international humanitarian law, and international trade law also include corporations and individuals (for example Chapter 11 of North American Free Trade Agreement, NAFTA). The principal sources of public international law are international conventions, international customs, general principles,

law comprises specific branches, such as international criminal law, diplomatic law, and international trade law. Environmental law has also become a branch of international public law.

Surprisingly, despite the universal nature of consumption and severe consumer-related problems on the international markets, international consumer law does not exist.

Also astonishing is the fact that although the environmental and consumer movements were born at the same time and are deeply intertwined, they have received very different degrees of attention from the international community and have evolved at a different pace in recent decades.

The historical and political aspects of the development of international environmental and consumer protection law share common ground, as the consumer and environment movements both started in the 60s and 70s, and have since been constantly interrelated to a certain degree.[30] By 1985, both the environment and

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judicial decisions, and teachings. (*Statute of the International Court of Justice*, at Art. 38, on line: International Court of Justice <http://www.icj-cij.org/documents/index.php?p1=4&p2=2&p3=0>.) Even so, there is no established hierarchy, and all of them are generally equal in power. The Vienna Convention on the Law of Treaties 1969 pronounces in an imperative way the treaty as a prime source of international law. (Vienna Convention on the Law of Treaties, 23 May 1969, United Nations, *Treaty Series*, vol. 1155, at 331, on line: United Nations Treaty Collection <http://untreaty.un.org/ilc/texts/instruments/english/conventions/1_1_1969pdf>.) In addition to the state, other major players on the international stage include the UN and its institutional network, where every state is represented, and international organizations through which states agree to work on specific issues.

[30]The first crucial moment in the development of international environmental law was the 1972 United Nations Convention on the Human Environment, signed in Stockholm, Sweden. The conference issued the Declaration on the Human Environment, a statement containing 26 principles and 109 recommendations (now referred to as the Stockholm Declaration). (*Declaration of the United Nations Conference on the Human Environment*, UNEPOR, 1972, on line :UNEP <http://www.unep.org/Documents.multilingual/Default.asp?DocumentID=97&ArticleID=1503>.) The first major step toward the development of international consumer protection law was made by the UN Economic and Social Council in Resolution 1981/62 of July 23, 1981, in which the Council called upon the Secretary-General to continue consultations on consumer protection, with a view to developing a set of general guidelines for consumer protection. (*Consumer protection*, ECOSOC Res.1981/62, UN ECOSOCOR, 1981.) Four years later, the General Assembly adopted The

consumers enjoyed recognition by the international community. However, both movements have not enjoyed equal recognition. The result of the 1972 United Nations Convention on the Human Environment (UNCHE) was the creation of the UN Environment Programme, which coordinates UN environmental activities. In contrast, adoption of the UN Guidelines for Consumer Protection did not yield similar results, as no body of the same type has ever been designated to coordinate UN initiatives regarding consumer protection. Further actions continued to shift the attention of the international community toward the environment, making consumer protection important but not a priority issue.[31] In recent years, environment protection has become a priority topic for politicians at all levels of governance, has been reinforced by legislation at regional and international levels, and has received very generous funding. In contrast, consumer protection has made little progress at the regional[32] and especially international level. The paradox is that although consumer protection forms an integral part of international affairs in such areas as health, trade, and the environment, it has mainly received attention from the state level, and not from the international community. Moreover, existing elements of international consumer legislation have never been systematized and appear more like a puzzle. Such an effort would certainly be a necessity in today's world, and the international

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Guidelines for Consumer Protection, a document in which the international community set out the basic principles of consumer protection.

[31]During the 1992 United Nations Conference on Environment and Development (UNCED), held in Rio de Janeiro, Brazil, also known as the Earth Summit, the parties adopted soft law, Agenda 21, in which the international community underlined the urgency of a shift toward sustainable patterns of consumption and production. 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; b) to develop a better understanding of the role of consumption and how to bring about more sustainable consumption patterns in everyday life. (UN Department of Economic and Social Affairs, Division for Sustainable Development, *Agenda21*, ECOSOCOR, 1992, on line: UN <http://www.un.org/esa/sustdev/documents/agenda21/index.htm>.) After long discussions and consultations in July 1999, the Economic and Social Council endorsed the Guidelines for Consumer Protection as a result of their relation to sustainable consumption, and later the same year the General Assembly adopted the amendments under Decision 54/449. Again, however, these amendments did not put consumer protection into the spotlight and did not lead to the creation of an international organization responsible for such matters.

[32] Only the European Community has had a comprehensive consumer policy since 1975.

community should endeavor to develop strong and comprehensible international consumer protection law and codify that which already exists.

In accordance with its statutes, the International Law Commission has included in its mandate "the more precise formulation and systematization of rules of international law in fields where there already has been extensive State practice, precedent and doctrine"[33]. Certainly, consumer protection should be qualified as a priority topic for the International Law Commission because consumer policy and legislation has been developed and implemented extensively by individual states.

The work hereunder is a first attempt to contribute to the design of future international consumer law. The purpose of this paper 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 and to systemize existing international initiatives most likely to have an impact on the protection of consumer interests. Such an inventory, although limited and still preliminary, will help in the building up of an effective international consumer protection law in the future. It is to be noted that to date such a work has not been done and no essay has been made to even suggest the nature, scope and sources of international consumer law.

Under the current globalization process, regional markets have become a closer reality for consumers than international ones. Therefore, whether and how market regionalization does contribute to the legal protection of consumer interests is the subject of Part 1. The achievements made or initiatives taken in favor of consumers by some institutions at the international level will then be identified and described in Part 2. This should allow us to formulate in Part 3 some conclusive remarks about the

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[33] *Statute of the International Law Commission*, ICJ, at Art. 15, on line: <http://untreaty.un.org/ilc/texts/instruments/english/statute/statute_e.pdf>.

current state of international consumer law and its potential to provide consumers with adequate consumer protection on global markets.

PART ONE

REGIONAL INTEGRATION AND CONSUMER PROTECTION

CHAPTER I

SELECTING REGIONAL SYSTEMS AND SETTING OUT EVALUATION CRITERIA

Recent works have shown that regional integration agreements operating in the Americas most commonly do not provide for any policy towards consumer protection.[34] For example, NAFTA[35] and the FTAA[36] have very restrictive provisions regarding sanitary and phytosanitary control that can benefit consumer protection to some degree. [37] Conversely, common, comprehensive consumer protection policy has never been on the NAFTA or FTAA political agenda.

The same can be said about the other regional integration systems in the Americas, such as the *Southern Common Market* (MERCOSUR), the Andean Community, and albeit to a lesser degree, the *Caribbean Community* (CARICOM). On the American continent, the perception of consumer protection as an issue at regional levels is just emerging and there are no regional sources of consumer protection as of today,

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[34]Thierry Bourgoignie & Julie St-Pierre, *Le statut de la politique de protection du consommateur dans les systèmes régionaux économiquement intégrés. Une première évaluation comparative*: *Proceedings of the Conference on economic regional integration and consumer protection in the Americas and Europe, Montreal, 18 -19 October 2007* (Montreal: UQAM, GREDICC, 2007).
[35]The North American Free Trade Agreement members are the United States, Canada, and Mexico.
[36]The Free Trade Area of the Americas has currently being negotiated by 34 countries of the Americas. For more on the FTAA, see *Ibid.*34 at 38 to 41.

[37]*NAFTA*, at Art. 904, on line: NAFTA Secretariat <http://www.nafta-sec-alena.org/DefaultSite/index_e.aspx>; *FTAA, Draft Agreement*, Chapter XIII, at Art. 3.3 (a), on line: Free Trade of the Americas <http://www.ftaa-alca.org/FTAADraft03/Index_e.asp>.

though very recent developments toward more recognition of consumer interests in the regionalization process can be observed in MERCOSUR and CARICOM.[38]

The Cartagena Agreement, the principal treaty of the Andean Community of Nations,[39] has only very limited provisions that may be related to consumer protection. Article 73 provides the right to a member on import restriction *to protect the life and health of human beings.* The treaty also requires that members harmonize legislation to provide consumers a higher level of protection. Nevertheless, apart from the principal treaty, the Andean Community Commission has produced certain directives regarding food, cosmetics, telecommunications, and competition, as well as social and substantial development. Moreover, certain decisions of the Community Court of Justice have benefited consumer protection.[40]

MERCOSUR did not mention consumer protection as a common policy in its principal Treaty of Asunción, signed in 1991.[41] 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 five resolutions regarding consumer protection: (1) basic conception of consumer protection;[42] (2) fundamental consumer rights;[43] (3) protection of consumers' health and security;[44] (4)

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[38]*Ibid.*34 at 26 to 38 & at 15 to 21.
[39]The Community was founded in 1969 and presently counts four members: Bolivia, Colombia, Ecuador, and Peru
[40]For more on consumer protection in the Andean Community of Nations, see *Ibid.*34 at 10 to14.
[41]The members of MERCOSUR are Brazil, Argentina, Uruguay, Paraguay, and Venezuela.
[42]MERCOSUR, *Defensa do consumidor-Conceitos*, 13 December 1996, MERCOSUR/GMC/RES no.123/96, on line: < http://www.cari1.org.ar/spanish/mercosur/resoluciones/res1996/res12396.html>.
[43]MERCOSUR , *Defensa do consumidor-Direitos Básicos*, 13 December 1996, MERCOSUR/GMC/RES no.124/96, on line: <http://www.cari1.org.ar/spanish/mercosur/resoluciones/res1996/res12496.html>.
[44]MERCOSUR, *Defensa do consumidor-Proteção à saúde e segurança do consumidor*, 13 December 1996, MERCOSUR/GMC/RES no.125/96, on line: <http://www.cari1.org.ar/spanish/mercosur/resoluciones/res1996/res12596.html>.

advertising;[45] and (5) consumer contracts.[46] Just a year later, the Technical committee adopted a protocol on consumer protection. 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 such controversy, Brazil has never ratified it. In spite of the fact that the Union has not adopted a universal consumer policy, certain important initiatives have been taken. Firstly, the creation of a Commission on studies of consumer law. Secondly, one of the branches of the Technical committee has been put in charge exclusively of consumer protection with the objective to contribute to progressive harmonization of the legislations of the member states and to elaborate common norms.[47] Thirdly, consumer protection has received recognition on the political level. For example, the Declaration 2000 proclaimed consumer rights as fundamental human rights and listed most of the consumer rights from the UN Guidelines.[48] Fourthly, MERCOSUR has adopted numerous resolutions that directly or indirectly benefit common consumer protection policy inside the Union.[49] Finally, several decisions of the Ad Hoc Tribunal and the Permanent Court of the Revision of MERCOSUR have influenced consumer policy to a certain degree.[50]

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[45]MERCOSUR, *Defensa do consumidor-Direitos Publicidade*, 13 December 1996, MERCOSUR/GMC/RES no.126/96, on line: <http://www.cari1.org.ar/spanish/mercosur/resoluciones/res1996/res12696.html>.

[46]MERCOSUR, *Defensa do consumidor-Direitos Garantia contractual*, 13 December 1996, MERCOSUR/GMC/RES no.127/96, on line: <http://www.cari1.org.ar/spanish/mercosur/resoluciones/res1996/res12796.html>.

[47]For more on the Commission on studies of the consumer law and the Technical committee, see *Ibid.*34 at 26 to 38.

[48]MERCOSUR, *Declaration presidencial de derechos fundamentales de los consumidores del MERCOSUR*, [2000],ATA 02/2000 MERCOSUR/CCM/CT7 Comite de Defensa del Consumidor. For more on fundamental consumer rights in MERCOSUR, see *Ibid.*34 at 26 to 38.

[49]For a full list of resolutions, see *Ibid.*34 at 30 to 33.

[50]For more on the role of the Ad Hoc Tribunal and the Permanent Court of the Revision of MERCOSUR, see *Ibid.*34 at 33 to 38.

From its part, CARICOM[51] not only has integrated some provisions regarding consumer protection into a revised principal treaty, but 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 and environmental 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.[52] The Caribbean Court of Justice, established in 2005, plays a part in consumer protection by interpreting the treaty provisions.[53]

As noted above, even if some regional formations in the Americas like MERCOSUR have put certain elements of consumer protection policy in place, only CARICOM has made significant progress in giving an explicit legal basis to consumer protection policy and defining legal tools to protect consumers. Others systems like NAFTA promote only cooperation and have done little or nothing for consumer protection.

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. Also, in recent years, important initiatives have been taken by the Commonwealth of Independent States (CIS).

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[51]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.

[52]Revised Treaty of Chaguaramas establishing the Caribbean Community including the CARICOM Single Market and Economy. CARICOM, *Treaty of Chaguaramas*, 2001, at Chapter 8, on line: Caribbean Community Secretariat <http://www.caricomlaw.org/docs/revisedtreaty.pdf>.

[53]For more on the role of the Caribbean Court of Justice, see *Ibid.*34 at 20.

To observe just how well consumer protection policy works at the regional level, it would be preferable to chose and compare two organizations with different political and historical backgrounds but which also have a more or less comparable socio-economical level of development. The EU and CIS make the perfect pair. They developed in dissimilar manners and have different political levels of integration but at the same time have very similar levels of social and economic development. Thus, the approaches to consumer protection of the EU and CIS could give a good idea of the conditions that must be met at the regional level of governance in order to make such protection effective.

To assess the EU and CIS strategies regarding consumer protection policy and actual achievements made in terms of consumer legislation, the following four factors will be considered: 1) the main goals for building up an integrated regional system; 2) the degree of recognition by the main agreement establishing the regional system of consumer policy as being a specific or distinctive common policy; 3) actual achievements made at the regional level in the field of consumer protection; and 4) the existence or not of a regional institutional framework for consumer protection policy.[54]

[54] *Ibid.*34 at 1 to 4.

CHAPTER II.

CONSUMER PROTECTION IN THE EUROPEAN COMMUNITY

2.1 Emergence of consumer protection policy in the EU

Nowadays, the European Community consumer protection policy combines all necessary elements and mechanisms to guarantee adequate and efficient protection for consumers in all 27 members states.[55] Nevertheless, consumer protection was no priority topic for the EU when it was formed in 1957. It took 35 years before consumer protection in Europe was formally confirmed as a separate common policy.

After two devastating wars in only 50 years, European leaders faced the challenge of searching for remedies that might bring lasting peace to the continent. Understanding that the previous European model based on political union did not work well, since it often served only the dangerous ambitions of certain nations, European states decided to develop an economic dimension.[56]

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[55]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). See also *Ibid.*34 at 21 to 26.

[56]The major problem of political unions is their unstable nature, which often depends solely on relations between the political elite. Political unions may appear as easy as they disappear, since disintegration does not have any economic consequences. Conversely, economic unions are stable formations, since the political elite must take the economic consequences of disintegration into consideration.

The main goal of the *Rome Treaty Establishing the European Economic Community*[57] signed by six European countries in 1957 is economic integration between member states through the creation and good functioning of a common market. Special emphasis is put on the elimination of barriers and obstacles that may prevent the free movement of goods, people, services, and capital.[58] However, the 1957 treaty did not establish an explicit consumer protection policy. Only a few articles refer to the consumer in relation to common agricultural policy and rules on competition.[59]

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 states decided that economic integration should bring about positive changes in the everyday life of Community citizens. As a result, just three years later, the first plan of action in favor of consumers was introduced in which five fundamental consumer rights are recognized: the right to protect health and physical integrity, the right to protect economic interests, the right to seek effective redress, the right to consumer education, and the right to have interests actually represented in the decision-making process.

Nevertheless, this explicit recognition did not quickly bring about a desirable result, as the legal basis for such changes was not present in the treaty itself. Moreover, at that time it was difficult to obtain the necessary unanimity of member states

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[57]EC, *Treaty Establishing the European Economic Community*, EEC Treaty - original text (non-consolidated version) Rome, 25 March 1957, on line: Summary of European Legislation <http://europa.eu/scadplus/treaties/eec_en.htm>.
[58]*Ibid.* at Art. 3.
[59]Common agricultural policy: Art. 39 ensures that supplies reach consumers at reasonable prices and Art. 40 excludes any discrimination between producers or consumers within the Community. Rules of competition: Art. 85 prohibits any agreements between enterprises that may effect competition and Art. 86 prohibits any abusive practices by enterprises with a dominant position on the common market.

regarding issues not 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 be better protected against potential market failure. During the period between1975 and 1990, all consumer-related directives adopted at the European Community level shared a similar concern for increasing consumer information or protecting the quality of consumer consent so that he/she could play an active role in the marketplace. The following subject matters are dealt with: the labeling, presentation, and advertising of foodstuffs for sale;[60] the indication of the prices of foodstuffs and of non-food products;[61] the prohibition of misleading advertising;[62] the granting of a cooling-off period in contracts negotiated away from business premises;[63] and the approximation of the laws, regulations, and administrative provisions of the member states concerning the presentation of consumer credit agreements and the disclosure of interest rates.[64] The only non

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[60]EC, *Commission Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labeling, presentation and advertising of foodstuffs for sale to the ultimate consumer*, [1978] O. J. L 33/ 1, on line: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31979L0112:EN:HTML>.

[61]EC, *Commission Directive 79/581/EEC of 19 June 1979 on consumer protection in the indication of the prices of foodstuffs*, [1979] O. J. L 158 /19, on line: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31979L0581:EN:HTML>, EC, *Commission Directive 88/315/EEC of 7 June 1988 on consumer protection in the indication of the prices of non-food products*, [1988] *O.J. L 142/*19, on line: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31988L0314:EN:HTML>.

[62]EC, *Commission Directive 84/450/EEC of 10 September 1984 relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising*, O.J. L 250/17, on line: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31984L0450:EN:HT*ML*>.

[63]EC, *Commission Directive 85/577/EEC of 20 December 1985 to protect the consumer in respect of contracts negotiated away from business premises*,[1985] O.J. L 372/31, on line: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31985L0577:EN:HTML>.

[64]EC, *Commission Directive 87/102/EEC of 22 December 1986 on the approximation of the laws, regulations and administrative provisions of the Member States concerning consumer credit*, [1986] O.J. L 042/48, on line: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31987L0102:EN:HTML>.

information-oriented initiative is the directive concerning liability for defective products.[65]

Cassis de Dijon

One major development that speeded up the evolution of consumer protection policy in the European Community was the *Cassis de Dijon* case of February 20, 1979.[66] In this landmark case, the European Court of Justice 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.

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).

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

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[65]EC, *Commission 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*, [1985] O.J. L 210/29, on line: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31985L0374:EN:HTML>.

[66]*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, on line: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:61978J0120:EN:HTML>.

consumer protection policy will have to be sought for, namely in order to avoid distortions of competition and further market drawbacks.[67]

Maastricht and Amsterdam Treaties

The decisive step in the development of European consumer policy came with the Maastricht Treaty amending the EC treaty.[68] 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 states 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.*[69] There is an explicit requirement that the level of protection to be ensured to consumers at the level of the Community must be held 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

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[67]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) at 280 to 281.
[68]EC, *Maastricht Treaty* (1993), on line: Eurotreaties <http://www.eurotreaties.com/maastrichtec.pdf>
[69]*Ibid.* at art 129A.

to organize themselves in order to represent and defend their interests.[70]

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 does not limit the development of national consumer protection measures. In accordance with the Treaty, EC directives in the consumer field must not prevent any member state from maintaining or introducing more stringent protective measures. Third, consumer protection policy was given a broad understanding, as consumer protection requirements must be taken into account in defining and implementing all other Community policies and activities.[71]

2.2 The golden age of consumer protection in the EU

The 90s have become the golden age of consumer protection in Europe. During this decade the European Community adopted several directives on a large variety of consumer issues, namely: package travel contracts,[72] general product safety,[73] unfair terms in consumer contracts,[74] timeshares agreements,[75] comparative advertising,[76]

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[70]EC, *Amsterdam Treaty* at Art. 129A, on line: Eurotreaties <http://www.eurotreaties.com/amsterdamtreaty.pdf>.
[71]*Ibid.* at art129A.
[72]EC, *Commission Directive 90/314/EEC of 13 June 1990 on package travel, package holidays and package tours*, [1990] O.J. L 158/59, on line: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990L0314:EN:HTML>.
[73]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, on line: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0095:EN:HTML>.
[74]EC, *Commission Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contract*, [1993] O.J. L 095/29, on line: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0013:EN:HTML>.

indication of prices of products,[77] out-of-court settlement of consumer disputes,[78] injunctions for the protection of consumers' interests,[79] advertising and sponsorship of tobacco products,[80] liability for defective products,[81] sale of consumer goods and associated guarantees,[82] unfair commercial practices,[83] and consumer credit.[84]

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[75]EC, *Commission Directive 94/47/EC of the European Parliament and the Council of 26 October 1994 on the protection of purchasers in respect of certain aspects of contracts relating to the purchase of the right to use immovable properties on a timeshare basis*, [1994] O.J. L 280/83, on line: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31994L0047:EN:HTML>.

[76]EC, *Commission Directive 97/55/EC of European Parliament and of the Council of 6 October 1997 amending Directive 84/450/EEC concerning misleading advertising so as to include comparative advertising*, [1997] O.J. L 290/18, on line: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31997L0055:EN:HTML>.

[77]EC, *Commission Directive 98/6/EC of the European Parliament and of the Council of 16 February 1998 on consumer protection in the indication of the prices of products offered to consumers*, [1998] O.J. L 080/27, on line: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0006:EN:HTML>.

[78]EC, *Commission Directive 98/257/EC: Commission Recommendation of 30 March 1998 on the principles applicable to the bodies responsible for out-of-court settlement of consumer disputes (Text with EEA relevance)*, [1998] O.J. L 115/31, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998H0257:EN:HTML>.

[79]EC, *Commission Directive 98/27/EC of the European Parliament and of the Council of 19 May 1998 on injunctions for the protection of consumers' interests*, [1998] O.J. L 166/ 51, on line: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0027:EN:HTML>.

[80]EC, *Commission Directive 2003/33/EC of the European Parliament and of the Council of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products*, [2003] O.J. L 152/16, on line: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003L0033:EN:HTML>.

[81]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, on line: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0034:EN:HTML>.

[82]EC, *Commission Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees*, [1999] O.J. L 171/12, on line: EUR-Lex <http://eur-lexeuropa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0044:EN:HTML>.

[83]EC, *Commission Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market*, [2005] O.J. L 149/22, on line: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005L0029:EN:NOT>.

[84]The proposed directive on consumer credit was formally submitted to the European Parliament for its second reading at the end of 2007. Depending on progress, the proposal could be formally adopted during Spring/Summer 2008. EC, *Proposal of Commission Directive 2007/.../EC of the European Parliament and of the Council on credit agreements for consumers and repealing Council Directive*

All such achievements are not only impressive in terms of the numbers of Community acts actually adopted in the area of consumer protection, but even more importantly in terms of substance. Initiatives taken went far beyond the objective of increasing consumer information in the marketplace and had a more interventionist tone. Unfair terms are prohibited from consumer contracts, as unfair marketing practices are from the marketplace; unsafe consumer goods are prohibited; strict pre- and post-market obligations are imposed upon producers and distributors; and comprehensive market surveillance schemes are put in place.

Also during this last decade, 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,[85] e-commerce,[86] general interest services,[87] and financial services.[88]

2.3 EU institutions and consumer policy-making

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 protection policy at the EU level.

87/102/EEC, on line: European Parliament <http://www.europarl.europa.eu/meetdocs/2004_2009/documents/cls/cons_cons(2007)09948(rev2)_/cons_cons(2007)09948(rev2)_en.pdf>.

[85] *Ibid.*67 at 301 to 302.

[86] *Ibid.*67 at 302 to 303.

[87] *Ibid.*67 at 303 to 304.

[88] *Ibid.*67 at 304 to 305.

Since 1975, consumer protection plans of actions or strategies have been prepared by the European Commission and then adopted by the Council of Ministers. They 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. The Program of Action 2007 -2013 is currently in force.[89]

Within the European Commission, an administrative structure specifically in charge of consumer protection – the Consumer Policy Directorate within the Directorate General Health and Consumers – was established and has proved to be the main driving force in the area. 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 European Court of Justice has made a revolutionary movement towards a clear recognition of consumer rights. 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.[90] Experience shows that when having to decide about the compatibility of some national consumer protection measures with the Treaty free trade and internal market policy requirements, the European Court of Justice plays a

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[89]EC, *EU Consumer Policy strategy 2007-2013, Empowering consumers, enhancing their welfare, effectively protecting them,* on line: European Commission <http://ec.europa.eu/consumers/overview/cons_policy/doc/EN_99.pdf>.

[90]*Ibid.*34 at 21 to 26.

well-balanced arbitration role.[91]

The EC institutional framework also provides for consultation procedures and bodies allowing consumers to be included in the regional decision-making process.[92]

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[91]Jorge Pegado Liz, *Compatibility of national consumer protection measures with free trade rules in the EU: Proceedings of Conference on economic regional integration and consumer protection in the Americas and Europe, Montreal, 18 -19 October 2007* (Montreal: UQAM, GREDICC, 2007) at 1 to 8.

[92]For more on the criteria for representative consumer associations in the EU, see *Ibid.*79 and Jorge Pegado Liz, *EU Consumer protection law and policy: recent developments and perspectives*: *Proceedings of Conference on economic regional integration and consumer protection in the Americas and Europe, Montreal, 18 -19 October 2007* (Montreal: UQAM, GREDICC, 2007) at Art. 6.

CHAPTER III

CONSUMER PROTECTION IN THE CIS

3.1 CIS 1991-2000 development

There is a lot of speculation and myths surrounding the creation of the Commonwealth of Independent States. Nevertheless, the fact is that the creation of the CIS was dictated by the egotistical ambitions of the political elite, who were craving power.[93] The social-economic agenda that appeared in some early CIS documents was used only as camouflage to calm political opponents and the population. Indeed, creation of the CIS was not aimed at bringing about economic or social integration. 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 ties between the republics was interrupted under the pretext that it might jeopardize independence. Thus, it is crystal clear that the CIS was not designed for the economic prosperity of the population and served only the egotistical geo-political ambitions of some members. Economic agreements adopted in recent years have slightly shifted the CIS agenda toward economic union. Nevertheless, the CIS remains a political union with some elements of economic integration.

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[93] This section is based primarily on resources available on the official website of the CIS, and so some information may be incomplete or missing.

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.[94] The Charter of the Commonwealth of Independent States signed just two weeks changed little by adding only a few stipulations on interstate joint activity in the spheres of health and environmental protection.[95] As a result, each member has developed its own blueprint on how to approach consumer protection. However, after only 10 years of existence, the CIS has made some first steps toward developing comprehensive and sustainable common policy.

During the first decade, all 11 state members[96] have given attention to the issue of consumer protection. However, the urgency with which measures have been taken and the scope of their approach has varied greatly from state to state. One of the reasons why there are such big differences between the approach each state has taken toward development and implementation of consumer protection law has been the absence of agreements or guidelines that could compel or invite members to do so, following common standards.

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[94] CIS, *Соглашение о создании Содружества Независимых Государств (The Agreement on creation of the Commonwealth of Independent States)* [translated by author], on line: CIS Executive Committee <http://www.cis.minsk.by/main.aspx?uid=176>.

[95] CIS, *The Charter of the Commonwealth of Independent States* at Art. 4, on line: Russian Site, <http://www.therussiasite.org/legal/laws/CIScharter.html>.

[96] Today, the CIS comprises 11 former Soviet Republics: Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Ukraine, and Uzbekistan. Turkmenistan discontinued permanent membership as of August 26, 2005, and is now an associate member.

3.2 Sources of consumer protection law and policy in the CIS

Legal sources

On December 25, 2000, during a Moscow meeting, the members of the CIS signed 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*,[97] whereby the members of the CIS admit that such coordination is crucial for fair competition within the CIS free market, and for protection of consumer rights. In this treaty, the CIS members established legal and administrative frameworks for fair competition within the CIS and to promote consumer protection in direct and indirect ways. For example, Article 3 par. 3 forbids the provision of any false information to consumers about the nature, ways, place of production, quality, or consumer characteristics of a product. Article 3 par. 1 prohibits maintaining unreasonably high prices through use of a market monopoly or by limiting production, and Article. 3 par. 2 makes it illegal for producers to conclude agreements that restrict competition.

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.[98] Moreover, members of the CIS agreed to exchange information regarding consumer markets and companies found guilty of antitrust infractions.

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[97] Договор о проведении согласованной антимонопольной политики (Implementation of coordination regarding common practices in competition) [translated by author], the CIS Executive Committee, on line: http://www.cis.minsk.by/main.aspx?uid=1938.
[98] *Ibid.*97 at Art. 4.

The antitrust accord includes a series of provisions regarding consumer protection. It was designed as an instrument for implementation of common actions against the dishonest commercial practices of monopolies, and as a result does not include the full range of tools available to protect consumers.

On the same day, CIS members signed a second document that raised consumer protection within the union 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*[99] 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: 1) activation of trade cooperation among members of the union; 2) creation of a truly free trade zone within the CIS; 3) protection of consumers against defective products and services; 4) implementation of common consumer policy within the CIS; and 5) increasing well-being 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.

Article 1 of the Agreement offers definitions of consumer, producer, service provider, etc., and as a result provides a virtually common or regional approach to such terminology. Article 2 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 equivalent conditions of protection for citizens of each member state." In other words, the agreement is

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[99] 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], the CIS Executive Committee, on line: http://www.cis.minsk.by/main.aspx?uid=1944.

designed to push the members of the CIS toward a standard approach to consumer protection strategy that would benefit every consumer by virtue of truly universal protection within the CIS. At the same time, the agreement stipulates that unification of national consumer protection laws should only be done to the extent necessary to implement the treaty, and as a result the parties would not have any unexpected obligations.[100] The agreement guarantees protection and access to justice in member states in accordance with national law for every citizen of the CIS, and consumers are therefore privileged to be recognized as truly trans-border subjects.

The parties also agreed to cooperate in the following areas: 1) providing consumers and consumer organizations truthful and up-to-date information regarding products (services); 2) taking action against producers who manufacture defective products and preventing the export of defective products; 3) promoting fair competition and creating conditions for fair consumer choice; 4) including consumer rights education in the school curriculum; 5) involving mass media in the systematic education of the population about consumer rights; and 6) creating conditions for the free operation of consumer organizations and to involve them in the decision-making process.[101]

Basically, the agreement embraces all major points of the United Nations guidelines for consumer protection and reconfirms the rights of consumers in accordance with international law.

Under the agreement, 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. This committee conducts its work in

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[100] *Ibid.* 99 at Art. 4.
[101] *Ibid.* 99 at Art. 5.

close cooperation with designated authorities and consumer organizations from every member-state.[102]

The agreement is essentially in force since the parties have signed it; however, for some parties, which need to make the necessary legal and administrative changes, the agreement will only come into force once such changes are made and an official memorandum is sent by the member-state to the Interstate Antitrust Committee.[103]

An interesting fact is that the agreement is an open agreement and any state that shares the same goals and principles can join it.[104] Moreover, because the agreement does not specify that only CIS members can be parties to it, virtually any state even from outside the CIS could become a full member.[105]

As for consumer organisations, Article 5 of the agreement states that the parties should contribute to the formation of consumer organizations and create conditions for such organizations to take part in the process of consumer policy-making. This

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[102]*Ibid.*99 at Art. 6.
[103]*Ibid.*99 at Art. 8.
[104]The agreement was signed by all members of the CIS, except Turkmenistan.
[105]In addition to the documents mentioned above, the members of the CIS have signed additional agreement related to consumer protection: Соглашение о применении технических, медицинских, фармацевтических, санитарных, ветеринарных и фитосанитарных норм, правил и требований в отношении товаров, ввозимых в государства - участники Содружества Независимых Государств (The application of technical, medical, pharmaceutical, sanitary, veterinary, and phytosanitary norms, rules, and requirements regarding products and medication imported into the member-states of the CIS). [CIS, *Соглашение о применении технических, медицинских, фармацевтических, санитарных, ветеринарных и фитосанитарных норм, правил и требований в отношении товаров, ввозимых в государства - участники Содружества Независимых Государств (The application of technical, medical, pharmaceutical, sanitary, veterinary and phytosanitary norms, rules and requirements regarding products and medication imported into the member-states of the CIS)* [translated by author], on line: CIS Executive Committee <http://www.cis.minsk.by/main.aspx?uid=1578>.]
This agreement standardizes the certification procedure for products and medication and serves as a mechanism of prevention against the import of defective or dangerous products and medication across external borders shared by CIS members. This agreement contributes to the protection of the health and life of all consumers within the CIS free-market zone. The agreement was signed on September 28, 2001; however, Russia, Turkmenistan, and Uzbekistan abstained from signing the agreement.

process includes development of legal norms and documents related to consumer protection, elaboration of consumer redress procedures, and exchange of information.

The agreement remains silent on the crucial issue of reconciliation of national consumer protection measures with free trade rules, and no institution is in charge of arbitrating such conflicts. According to Article 10, all disputes regarding interpretation and implementation of the agreement should be solved through consultation and negotiation between interested parties.[106]

The main disadvantage of the CIS agreements is that both documents related to consumer protection are not of a binding nature, hence jeopardizing their effective implementation. Since the adoption of the treaties, there has been no further development of the CIS legal framework in the field of consumer protection.

3.3. CIS Institutions and consumer protection policy-making

The Interstate Antitrust Committee was founded on December 23, 1993, and before 2000 it was responsible only for coordination and execution of antitrust policy within the CIS. Since 2000, this institute has also provided and coordinated all necessary

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[106]The CIS does have one agreement that may be helpful in solving trade-consumer disputes: Соглашение по техническим барьерам в зоне свободной торговли (The agreement concerning technical barriers in the free-trade zone).[CIS, *Соглашение по техническим барьерам в зоне свободной торговли (The agreement concerning technical barriers in the free-trade zone)* [translated by author] , on line: CIS Executive Committee <http://www.cis.minsk.by/main.aspx?uid=1902>.] On the one hand, this document forbids the use of technical standards and norms as a mechanism of controlling movements of products inside the CIS free-trade zone. On the other hand, the agreement confirms the rights of every member-state to have standards which "protect the lives and health of people" and the environment, and also "protects consumers from false information regarding the safety, quality, and purpose of products"(Art. 3).

work regarding consumer protection policy of the CIS according to the status specified in the agreement. After the meeting held on October 13, 2004, under the auspices of the Interstate Antitrust Committee, the member-states, bearing in mind the importance of reinforcing such issues as consumer protection, decided to create a subcommittee as part of the Interstate Antitrust Committee to be responsible solely for consumer protection policy.[107]

Another CIS institute that takes part in the approximation of consumer protection policy is the Interparliamentary Assembly. Founded in 1992 as consultative body among parliaments of the member-states, this organization does a significant amount of work in harmonizing national legislation regarding consumer protection. In 1995, the Interparliamentary Assembly adopted the *Recommendation on common principles regulating consumer protection in Assembly member-states*[108] with the aim of promoting a mutual approach in developing a legal base for consumer protection by member-states. This recommendation restates all the international norms highlighted in the UN Guidelines for Consumer Protection of 1985 and serves as a blueprint for developing national consumer protection law.[109]

Following a brief review of all documents developed by the CIS, we can see that certain important steps have been made toward implementation of common consumer protection policy. However, recent events involving the use of consumer protection, by some members of the CIS, as a pretext for economic and political sanctions places a very big question mark on further progress in this field, as well as on the future of

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[107]Unfortunately we could not determine the role played by such an institute within the CIS hierarchy. The results of its work are also unknown.

[108]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 Assembly member-states.*)[translated by author], on line: CIS Executive Committee, <http://www.lawbelarus.com/world/sub02/texa3945.htm>.

[109]In general, the national consumer protection laws developed by CIS member-states have similar patterns and follow proposals prescribed in the recommendations.

the CIS as an organization. For instance, to advance certain political goals, Russia limited imports of certain products from Moldova and Georgia using the consumer protection agreement. As result, both were considering leaving the CIS. Without a doubt, in today's free-trade world, consumer protection is often a very suitable mechanism and sometimes the only possible way to prevent the import of a product. But when this is done as part of a political game, the consumer often pays a price.[110]

[110]C. J. Chivers, "A Russian 'Wine Blockade' Against Georgia and Moldova," *The New York Times* (6 April 2006), on line: New York Times <http://www.nytimes.com/2006/04/06/world/europe/06russia.html> and "Russian wine move draws protests" *BBC* (30 March 2006), on line: BBC <http://news.bbc.co.uk/2/hi/europe/4860454.stm>.

CHAPTER IV

CONCLUSIVE REMARKS

First, the EU and CIS were created for very different reasons. The European Union emerged from a clear political will to unite the European countries into a peaceful stable formation. The CIS is a surrogate product of the Soviet Union's disintegration and has served only as a mechanism of "civilized divorce." Second, the EU and CIS have different patterns of organization. The EU formation where the members have given up some political power to the central bodies resembles a federation. The CIS formation is more akin to a confederation, as the central organs have only consultative power. Third, both unions pursue different goals. The EU goal is economic-social union trough economic integration. The principal goal of the CIS is political union with elements of economic integration.

One conclusion that can be made is that in the spite of so many differences between the EU and the CIS, both of them include elements of consumer protection policy. Started as an economic union, the European Economic Community (EEC) did not have explicit consumer policy on its agenda. Only some scattered elements of consumer protection were adopted during the first three decades. This is not a big surprise, since consumer measures by nature are not "economy friendly." And only when the political will of the member states had transformed the EEC into a social-economic union, the European Community, with the mandate to *contribute to the attainment of a high level of consumer protection*,[111] did consumer protection receive a

[111] *Ibid.*68 at Art. 129A.

high level of recognition. For its part, the CIS has always been a political union, and when the members of the CIS expressed their political will, consumer policy was put on the union's priority agenda. In other words, it does not really matter what kind of historical, economic, or geo-political background the union has. Any regional formation may retain consumer policy if there is a political will to do so.

In strictly economic unions, consumer protection may exist only in an embryonic form. NAFTA, for example, a regional formation with exclusively economic goals, does not have any direct provisions for consumer protection. Only very restrictive stipulations on health may be attributed to consumer safety. One can project that, when social integration further propagates across the union, additional elements of consumer protection will be seen on the union agenda, providing the political will is there. The protection of consumer rights is mostly a political matter, as is the protection of human rights. However, in contrast with human rights, consumer rights have a direct and often negative effect on the economy, and this is why we will not see explicit consumer policy in purely economic unions. Only once social affairs are sufficiently present on the union agenda, and there is a political willingness to guarantee consumer rights, can we expect consumers to receive adequate protection.

Consumer protection policy in the EU has received greater recognition since the provision regarding consumer policy was integrated into the principal treaty. Before 1992, the range of consumer protection actions remained limited and did not embrace the full spectrum of consumer rights. Only after the leaders of the member states expressed their political will and new provisions regarding the consumer protection were incorporated into the treaty establishing the European Community did the European Commission receive *carte blanche* to develop explicit and distinctive consumer policy initiatives. Indeed, EU consumer policy has been developed

primarily since 1992, therefore confirming that only a clear legal basis will lead to active consumer protection policy.

A second conclusion is that regional consumer measures guarantee only minimum or basic protection through mechanisms that approximate the national consumer legislation of member states towards the minimum level agreed within the regional formation. Nevertheless, the member states may develop national consumer protection measures that give a consumer more protection. And this power is very much used by EU countries. For its part, the CIS does not establish a minimum threshold for consumer protection measures, since it promotes only cooperation and does not really develop strict rules for such matters. The CIS Treaty on consumer protection offers only guidelines of a non-binding nature, the implementation of which is based solely on the good will of the parties. Obviously, the EU model seems more desirable. However, the CIS model may work for regional formations where the level of interstate integration is not high enough, and members are not yet ready to sign a binding treaty.

A third conclusion is that in both the EU and CIS, consumer protection measures are held a legitimate exception from rules of free trade under certain conditions. The principle rule is that consumer measures should not interfere with, or interfere only to a minor degree, with the rules of commerce within a free trade zone. That is to say, the measures taken by an exporting member state must be equivalent to those used by the importing one, and measures taken must be proportional to the potential threat to public safety. In the EU, consumer protection measures are held by the European Court of Justice as a legitimate exception to the rules of free trade. As for the CIS, the Treaty is silent. However, base on observations, we may conclude that they are indeed applied. One need only recall the recent vine dispute between Russia and

Moldova /Georgia, when Russia used consumer protection to stop the import of products.

A final conclusion is that any regional formation has designated specific bodies responsible for consumer policy. The functions and organization of such bodies may vary and depend on the administrative structure of the union. Moreover, the EU has proficient institutional structure, with legislative, executive, and judicial branches. In contrast, the CIS has only a partial organizational structure with an executive branch. As a result, we cannot expect from the CIS the same effective and beneficial work outcome that we can observe in the EU.

PART TWO

INTERNATIONAL SOURCES OF CONSUMER PROTECTION

Brief observation shows that on the international level, there are two types of international institutions concerned with consumer-related issues. First, the institutions that form part of the UN network, such as the WTO and WHO, and second, private bodies such as the ISO.

The focus of this work will be limited to UN institutions because they more adequately reflect the policy of the international community regarding this issue, as opposed to private organizations, which reflect the position of professionals or certain limited groups of private interests. It may well be that nowadays, and because public international law is still in its infancy in the consumer protection area, the main international sources of consumer protection are private ones, i.e., quality, safety, and performance standards adopted by international standardization bodies. This certainly would be a most relevant topic for research, but it is not the subject of this work.

Despite the fact that the international community has dozens of institutions responsible for all segments of seemingly all aspects of our lives, there is no one institution within the UN network that is directly responsible for consumer protection strategy. As a result, we must identify the international documents that do have an effect, whether direct or not, on the protection of consumer interests.

As we limit our inventory to UN-linked institutions, this selection process will be made by reference to the UN Guidelines for Consumer Protection of 1985.[112] Indeed, these guidelines can be viewed as a document that incorporates the consumer protection strategy generally accepted by the international community.

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[112]Department of Economic and Social Affairs, *The UN Guidelines for Consumer Protection of 1985, as expanded in 1999*, ECOSOC, UN ECOSOCOR, 1985, the UN, on line: UN <http://www.un.org/esa/sustdev/publications/consumption_en.pdf>.

The Guidelines set out six basic principles of consumer protection:

> 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 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.[113]

International sources of consumer protection will be selected and assessed according to the UN Guidelines' six basic principles in an attempt to verify whether the international scene currently provides consumers effective tools of protection with regard to each of the proclaimed rights conferred by the UN document.[114]

This work does not pretend to be a complete or exhaustive study of all possible international sources of consumer protection law. It remains preliminary and

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[113]The UN Guidelines for Consumer Protection also include specific provisions related to developing countries and their needs, such as effective distribution of essential consumer goods and services and responsibility in areas related to consumer health, such as food, water, and pharmaceuticals. In addition to the six main principles of the UN Guidelines for Consumer Protection, the Guidelines force governments to exchange essential information regarding products that have been banned, withdrawn, or severely restricted in order to protect importing countries from such products, as well as to ensure that information about all consumer products has universal meaning. However, we will limit this study solely to the six basic principles.

[114]Part 2 of this work illustrates all steps in the evolution of the UN Guidelines, including the integration of the provisions regarding the environment and sustainable consumption into the UN Guidelines during the last amendment. Nevertheless, since such provisions relate to the environment, we will not study and evaluate the international legal sources of those issues within the scope of this work.

selective, but sufficiently documented to allow us to formulate some final observations on the status and state of international consumer protection law.[115]

[115]There is no general directory on international consumer protection law, and the documents relating to consumer protection are scattered. Apparently some sources may remain undetected. The most logical way to systemize sources of international consumer law would be to regroup them in accordance with the six basic principles of the UN Guidelines. However, many international documents pertain to more than one principle at a time. As a result, it would be impossible to organize them this way. To facilitate systematization, some documents will be regrouped by topic and some will be discussed individually. As the information on historical, political, social, and other aspects of the documents introduced in this work is often limited or absent, it will be presented only if available and relevant.

CHAPTER I.

THE UN GUIDELINES ON CONSUMER PROTECTION

Before the Guidelines for Consumer Protection were adopted, the international community had taken certain steps toward consumer recognition and protection. For example, since 1961, under the auspices of the World Health Organization (WHO) and the Food and Agriculture Organization (FAO), a normalization program has existed for food products known as the *Codex Alimentarius*,[116] as well as the International Code of Marketing of Breastmilk Substitutes,[117] adopted in 1981 by the WHO. However, prior to 1985, the international community did not recognize the full range of consumer rights. Only with the adoption of UN General Assembly Resolution 39/248 Consumer Protection[118] and the appended Guidelines for Consumer Protection on April 9, 1985,[119] were such rights proclaimed and given substance at the international level.

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[116]*Codex Alimentarius*, FAO, on line: Codex Alimentarius net <http://www.codexalimentarius.net/web/index_en.jsp>.
[117]*International Code of Marketing of Breastmilk Substitutes*, WHO, on line: WHO <http://www.who.int/nutrition/publications/code_english.pdf>.
[118]*Consumer protection (Guidelines for Consumer Protection)*, GA Res.39/248, UN GAOR, 1985, UN Doc. A/RES/39/248, on line: UN <http://www.un.org/documents/ga/res/39/a39r248.htm>.

[119]The Guidelines for Consumer Protection were amended in 1999, when new parts about sustainable consumption were added.

1.1 History of the Guidelines for Consumer Protection

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."[120] The first draft of the Guidelines for Consumer Protection was ready in 1982. A broad range of implacable parties 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," implying that transnationals are responsible for most consumption-related problems.[121] However, if some disagreements about the Guidelines were based on different ideological approaches and could find support on only one side of the Iron Curtain, others were even more antagonistic by virtue of global disagreement with the United Nations position.

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[120]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.

[121]*Ibid.* at 3.

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."[122] The capitalist bloc had a fairly similar vision in that members believed that free market economy had all necessary mechanisms of self adjustment needed to meet consumer needs and could not be regulated, especially at the international level.

Despite the many difficulties encountered during elaboration and discussion, the Guidelines for Consumer Protection were finally adopted. But even 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.

1.2 The Guidelines for Consumer Protection

Resolution 39/248 is a fairly compact document that includes four parts and spans less than three pages.[123] 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.

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[122] *Ibid.*
[123] *Ibid.* 118.

The Guidelines note that consumers are often faced with imbalanced economical terms, 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 government to facilitate production and distribution in accordance with consumer needs and desires, encourage maintenance of a high level of ethical conduct in the production and distribution of goods and services, help combat abusive business practices at the national and international levels, facilitate the creation of independent consumer groups, encourage international cooperation in consumer protection, and develop market conditions which give rise to a wide range of choices and low prices.

As we can see, 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.[124] As for business operators, the government appeals to them to follow the laws and regulations in countries where they operate. However, even though government asks them to follow international consumer protection standards, businesses are only obliged to do so when the competent state authority adopts such standards.[125]

From a positive point of view, the Guidelines possess the necessary flexibility to be universal. The Guidelines provide optimal mechanisms for 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 price tag and benefits. This is particularly important for developing countries, because the Guidelines provide the freedom needed for governments to act according to financial ability while ensuring that their actions regarding consumer protection do not exceed reasonable cost.

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

[124] *Ibid.* 118 at Art. 4.
[125] *Ibid.* 118 at Art. 5.

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 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 standards go if the competent authorities of the country of operation disagree with the international standards? They key point is that 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 standards may be higher than local ones and only local business is forced to make investments to meet new national consumer regulations.

According to the Resolution, consumer protection can be admitted as a legitimate barrier to international trade. If a government wishes to halt the import of unsafe products, the Guidelines can serve as an instrument for this purpose.

1.3 Basic principles of consumer protection

The Guidelines set out six basic principles of consumer protection:

a) *Physical safety and product security*

Even before the Guidelines became international law, the UN released several documents regarding product safety, especially for food, and in so doing underscored the importance of this issue.

The Guidelines quite fully cover all aspects of safety. Under the Guidelines, government is responsible for adopting the complete package of legislation regarding consumer safety, such as safety regulations, standards, etc. As for business operators, they must ensure that all products are safe and suitable for use when they reach consumers, even after handling and storage.

As well, businesses are responsible for providing proper, easy-to-understand instructions on using products safely. In the event an unsafe product (or a product which 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, or compensate consumers for the purchase price.

b) *Promotion and protection of consumers' financial interests*

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

Government and consumer organizations have a shared responsibility to develop relevant legislation for marketing, advertising, business practices, etc., especially with respect to one-side standard contracts which limit consumer rights and 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.

c) *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.

d) *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.

e) As for *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.[126]

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[126]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 health, such as food, water, and pharmaceuticals. 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. Finally, concerning pharmaceuticals, government should have an adequate regulatory system to ensure proper drug distribution and use in accordance with international recommendations. The final part of the Guidelines focuses on international cooperation and covers the following areas: 1) international information exchanges regarding consumer protection; 2) cooperation regarding joint action on consumer protection in such areas as education, control, testing, etc.; and 3) cooperation on distribution of essential products and services. Finally, the Guidelines force governments to exchange essential information regarding products that have been banned, withdrawn, or severely restricted in order to protect importing countries from such products, as well as to ensure that information about all consumer products has universal meaning.

1.4 The Guidelines amended

The fast-growing world economy and global concerns for environmental matters pushed the international community toward amendment of 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 would be an important step in this direction."[127]

Steps towards amending the United Nations Guidelines for Consumer Protection were made at the Conference on Environment and Development, more commonly known as 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 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 community underlined the urgency of a shift toward sustainable patterns of consumption and production.[128]

Two objectives were introduced in Agenda 21: a) to promote consumption and production patterns that reduce environmental stress and meet the basic needs of

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[127]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, on line: UN <http://www.un.org/documents/ecosoc/cn17/1998/background/ecn171998-consumer.htm>.

[128]UN Department of Economic and Social Affairs, Division for Sustainable Development, *Agenda 21*, ECOSOCOR, 1992, on line: UN <http://www.un.org/esa/sustdev/documents/agenda21/index.htm>.

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.[129] Afterward, Resolution 1995/53 of the Economical and Social Council called upon the secretary-general to develop guidelines on sustainable consumption.[130]

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.[131] 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.

The most important outcome of the Earth Summit+5 was 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

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[129] 1) all countries should strive to promote sustainable consumption patterns, and developed countries should take the lead in achieving this objective; 2) 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; 3) governments should develop a domestic framework that will encourage a shift toward sustainable patterns of consumption and production; 4) governments and industry should shift their efforts towards use of energy and resources in a financially efficient and environmentally friendly manner: a) minimize waste, b) assist individual households to make environmentally sound purchase decisions, c) encourage leadership through government purchasing, d) exercise environmentally friendly price policy, and e) educate and inform the general public about becoming conscientious consumers.

[130] *Consumer Protection*, ECOSOC Res. 1995/53, UN ECOSOCOR, 1995, on line: UN <http://www.un.org/documents/ecosoc/res/1995/eres1995-53.htm>.

[131] *Nineteenth special session, the Earth Summit+5*, GA, UN GAOR, on line: UN <http://www.un.org/esa/earthsummit/>.

undertaken should cooperate and coordinate in this regard."[132] 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."[133] 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 having tremendous impact on the environment, and it was time to match the UN Guidelines for Consumer Protection to the requirements dictated by reality.[134]

Consumers International, on request of the 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 these amendments was to shift careless patterns of consumption towards sustainable

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[132]*Programme for the Further Implementation of Agenda 21*, GA Res19/2, UN GAOR, 1997, UN Doc. A/RES/S-19/2, on line: UN<http://www.un.org/documents/ga/res/spec/aress19-2.htm>.

[133]*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, 1998, on line: UN <http://www.un.org/documents/ecosoc/cn17/1998/background/ecn171998-consumer.htm>.

[134]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.

consumption.[135] 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. [136] 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.

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.[137]

However, large sections were omitted from the amendments, for example, the 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.

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[135]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.

[136]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, on line: UN <http://www.un.org/esa/documents/ecosoc/cn17/1998/ecn171998-5.htm>.)

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

So what was finally left of the proposals in the Guidelines? 1) Government promotion of access to non-misleading information about the environmental impact of products and measures against misleading practices; 2) Cooperation between governments and organizations involved in consumer education, as well as consumer education about pollution and proper use of materials, energy, and water; 3) Collective responsibility of all parts of society to implement sustainable consumption patterns; 4) Promotion of sustainable consumption through a mix of government policies that could include regulations, economic and social instruments, etc.; 5) Government restrictions and bans on products and substances that are harmful to the environment; 6) Government promotion of the health-related benefits of sustainable consumption; 7) Government's leading role in sustainable practices; 8) Government and international research on consumer behaviour and damage to the environment; 9) Government promotion of sustainable agriculture; 10) International cooperation on sustainable consumption.

So as we can see, despite the fact that a large portion of the proposed amendments were deleted, the United Nations Guidelines for Consumer Protection nonetheless underwent major changes and became a document which better reflects reality and meets the objectives specified in Agenda 21 and the Earth Summit.

1.5. Assessing the impact of the Guidelines

Immediately following their adoption, the Guidelines found as many supporters as they did opponents. Both camps 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 may not.

But the existence of a UN-sponsored Charter of Consumer Rights can simply not be ignored by any nation that wishes to be considered civilized."[138]

Opponents warned that some provisions of the Guidelines could aggravate the situation, especially in developing countries, where, for example, the extra cost of safety measures can make products less affordable to consumers with low income.[139]

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.[140] The UN Guidelines have played an important role in providing a clear and comprehensible set of reference points.[141] They provide explicitly stated aims while allowing governments and consumers activists operating in different social, cultural, and historical contexts to build governmental structures, legal

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[138]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.
[139]Murry Weidenbaum, "The Case Against the UN Guidelines for Consumer Protection" (1987) 10 Journal of Consumer Policy 425-432.
[140]*Ibid.*120 at 6.
[141]For more on the impact of the UN Guidelines for consumer protection, see *Consumer protection. Report of the Secretary-General*, ECOSOC, UN ECOSOCOR, 1995, UN Doc.E/1995/70, on line: UN <http://www.un.org/documents/ecosoc/docs/1995/e1995-70.htm> and *Co-ordination Questions – Consumer Protection-Report of Secretary-General*, ECOSOC, UN ECOSOCOR, 1992, UN Doc.E/1992/48.

systems, and social policies that are appropriate to their own conditions.[142] 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 development of national consumer policies. The Guidelines have also been used actively by the consumer movement in its work.[143]

As for the future of the UN Guidelines for Consumer Protection, there is lots of room for improvement. First, all omissions made during the last round of amendments could be added to complete the sustainable consumption section. Second, the Guidelines do not cover every possible consumer protection problem. For instance, the Guidelines make no mention of housing or any related issues. Third, it would be practical if the Guidelines included some sanctions regarding their completion, since implementation of the provisions currently relies solely on the good will of the UN members. Nevertheless, it must be noted that when the Universal Declaration of Human Rights was adopted it was no more than a guideline, and many governments do not view it as an obligation. To date, it seems that the United Nations Guidelines for Consumer Protection have replicated the same pattern of evolution and have become a sort of universal declaration of consumer rights. And even so *de jure* the Guidelines are still not of a binding nature, *and* the international community has accepted its postulates as imperatives.

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[142]M. Andruszkiewcz, "Central and Eastern Europe: A Reference Point in Changing Times" (1995) Consumer international, n.1, at 2 to 3.
[143]*Ibid.*120 at 6 to 10.

CHAPTER II

SAFETY OF CHEMICALS

2.1. Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade adopted on 10 September 1998 by a conference of plenipotentiaries in Rotterdam, the Netherlands

For years the international community has tried to deal with the notorious practice of exporting products 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.[144] Of particular concern has been the effect of chemicals on consumer health. The Rotterdam Convention can be seen as a major international instrument with which importing nations can obtain a certain level of protection from this practice. However, the road to the Rotterdam Convention was not short. 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.

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[144]Many believe that the problem of exporting products that have been banned, severely restricted, or never approved in the country of origin is an issue only for the importing country, but this is not the case. First, such products can still put health, life, and the environment in grave danger during production and handling in the exporting country if any accident occurs. Second, resent studies show that some chemicals return in the form of residues into the country of origin in agricultural products, creating the so-called "Circle of Poison." (For more, see Paula Barrios, "The Rotterdam Convention on Hazardous Chemicals: A Meaningful Step Toward Environmental Protection?" (2004) Georgetown International Environmental Law Review, on line: Allbusiness <http://wwwallbusiness.com/legal/contracts-agreements/1153645-1.html>.)

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 states "do either explicitly or tacitly exclude exported goods from the requirement to comply with national safety regulation."[145] The principle arguments of such exclusion were that "...no country has a right to impose on others its own standards and judgments on safety matters...," as well as that an exporting country, which has higher standards, may jeopardize its competitive position on the international market.[146] 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, economical, 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 a dilemma and accept certain harmful effects because the population could be in greater danger without certain products.[147] In such circumstances, it seems unrealistic to extend the high safety standards of the industrial nations to all exported goods, but the international community also understands that certain steps must be taken to minimize the possible harmful effects of importing dangerous products.

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[145]OECD, *Safety of consumer products - Policy and legislation in OECD member countries* (Paris: OECD, 1980) at 36 to 37.

[146]David Harland, "Legal Aspects of the Export of Hazardous Products" (1985) Journal of Consumer Policy 8.

[147]For example, some south 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.

There are a few possible approaches to this matter:

1. Products that have been banned, severely restricted, or never approved in the country of origin must continue to be exported (double-standard rule);
2. The products may be exported only after the importing country receives notification of the intention to export;
3. The products may be exported only upon obtaining official permission or formal consent from the importing country;
4. No such products should be allowed to be exported.

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 exports are made.

The first concern related to the export of products that have been banned, severely restricted, or never approved in the country of origin was recognized on the international level in the 70s/80s. From 1979 to 1981, the General Assembly of the UN adopted three resolutions on the exchange of information regarding banned hazardous chemicals and unsafe pharmaceutical products.[148]

In resolution 36/166 adopted in 1981, the General Assembly of the UN urges the member states and transnational corporations to exchange information on banned

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[148] *Exchange of information on banned hazardous chemicals and unsafe pharmaceutical products*, GA Res. 34/173, UN GAOR, 1979, UN Doc. A/RES/34/173, on line: UN <http://www.un.org/documents/ga/res/34/a34res173.pdf>; *Exchange of information on banned hazardous chemicals and unsafe pharmaceutical products*, GA Res. 35/186, UN GAOR, 1980, UN Doc. A/RES/ 35/186, on line: UN <http://www.un.org/documents/ga/res/35/a35r186e.pdf>; *Exchange of information on banned hazardous chemicals and unsafe pharmaceutical products*, GA Res. 36/166, UN GAOR, 1981, UN Doc. A/RES/36/166, on line: UN < http://daccessdds.un.org/doc/RESOLUTION/GEN/NR0/407/92/IMG/NR040792.pdf?OpenElement>.

hazardous chemical and unsafe pharmaceutical products, and "to deal with this subject through appropriate means including possible legislation on the national level."[149] Just a year later, the General Assembly adopted Resolution 37/137, in which the international community first "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," second agrees that the exporting country should make full information available on those products for safe use in comprehensible language. Finally, the General Assembly requested that the Secretary-General elaborate within a year an easy-to-read and understand consolidated list of products that have been banned, severely restricted, or never approved by Government and keep updating the list on a regular basis.[150]

The first international response to Resolution 37/137 was adoption by the Food and Agriculture Organization (FAO) of *the Code of Conduct on Distribution and Use of Pesticides* in 1985,[151] the elaboration under the auspices of the United Nations Environmental Program (UNEP) of *The London Guidelines for the exchange of information on chemicals in international trade* in 1987 and the introduction of the Prior Informed Consent (PIC) procedure in both documents in 1989.[152]

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[149] *Ibid* Res. 36/166.

[150] *Protection against products harmful to health and the environment*, GA Res.37/137, UN GAOR, 1982, UN Doc. Res. 37/137, on line: UN <http://daccessdds.un.org/doc/RESOLUTION/GEN/NR0/426/15/IMG/NR042615.pdf?OpenElement>.

[151] FAO, *The Code of Conduct on Distribution and Use of Pesticides*, 1985, on line: FAO <ftp://ftp.fao.org/docrep/fao/009/a0220e/a0220e00.pdf> (The Code was updated in 1989 and revised in 2002.)

[152] Following the adoption of the Rotterdam Convention on Prior Informed Consent Procedure in 1998, the provision relating to the PIC procedure in the Code became redundant and was not included in the revised version in 2002.

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 pesticides 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) pesticides testing; 3) information exchange; 4) action to reduce health and environmental risks; 5) reducing health and environmental risks; 6) regulatory and technical requirements; 7) availability and use; 8) distribution and trade; 9) information exchange; 10) 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.[153] The London Guidelines include three voluntarily procedures: information exchange, export notification, and the prior informed consent (PIC) procedure.[154]

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,

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[153]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, on line: UNEP < http://www.chem.unep.ch/ethics/english/longuien.htm>.

[154]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. *Ibid.* at Art. 1.

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, etc. (Art. 8).

As for the PIC procedure, those countries which elect to participate in it 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 10 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.

The Code reiterates the postulates of the London Guidelines, e.g., the section regarding global management of the pesticides trade[155] and the part on information exchange.[156] However, when the Guidelines are aimed only at government, 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

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

[156]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.

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 are of only a voluntary nature, they cannot guarantee total eradication of notorious practices. The international community understands that only a transformation of voluntary measures into a solid and obligatory instrument would ensure effective implementation of the recommended mechanisms.

Through negations during the 90s initiated by the Joint Programme of FAQ and UNEP, 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 nations signed the *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade* (the Rotterdam Convention).[157]

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

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[157]*The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade*, 1996, on line: Rotterdam Convention <http://www.pic.int/en/ConventionText/ONU-GB.pdf>.

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. 19).[158] 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 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.[159]

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[158]The Secretariat functions are performed jointly by the Executive Director of UNEP and the Director-General of FAO.

[159]*Ibid.*157 at Art. 5 to 7, Art. 9.

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 listed 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; etc. (Annex1). 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 into Annex III, the parties must apply a PIC procedure. After receiving a DGD, which advises that a certain chemical has been listed in 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 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. A party that has decided not to import a chemical is subject to the same conditions: import of the chemical from any source as well as domestic production of the chemical for domestic use (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 DNA of the importing party by the exporter (Art. 11).

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, 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 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. 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.

Nevertheless, there are a few points that can weaken and jeopardize the convention's positive effect. First, even though the preamble to the convention takes into account the circumstances and particular requirements of developing countries and countries with economies in transition, in particular the need for technology transfer, providing financial and technical assistance, it remains silent and vague when we move further into the text. One of the basic conditions for proper operation of the convention is the ability of the importing party to have an adequate technical and administrative capacity to evaluate potential risks for its population and the environment from hazardous chemicals and make appropriate decisions. Without 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. Such an antagonistic approach to a pecuniary matter forced the removal of all proposals related to a financial mechanism from the final draft, and the current convention does not include any features 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). A crucial point for any binding system is the existence of provisions regarding compliance.[160]

How successful is the Rotterdam Convention? Even before 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.[161] Since the PIC has become a binding scheme under the Rotterdam Convention, it has shared similar success. Annex III currently lists 39 chemicals subject to the PIC procedure,[162]and 117 countries have become parties to the Convention.

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[160]*Ibid.*144 at Paula Barrios.

[161]*Ibid.*

[162]In 1998, the text of the convention was adopted with 27 chemicals in Annex III. In September 2004, the Conference of the Parties added a further set of chemicals based on work completed during the interim PIC procedure. The convention lists a total of 39 chemicals subject to the Prior Informed

Taking into account the fact that the Convention has been in force for three years, it seems quite a good start. Nevertheless, 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 particular developed nations should instead outlaw the production and export of chemicals that have been banned or severely restricted domestically.

2.2 The Stockholm Convention on Persistent Organic Pollutants 2001 and the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal 1989

The international legal system for chemicals control also comprises the instruments provided by the *Stockholm Convention on Persistent Organic Pollutants*[163] and the *Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal.*[164]

The Stockholm Convention entered into force on 17 May 2004 and more than 90 parties have joined the treaty. The convention calls for the reduction and eventual

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Consent (PIC) procedure. Among these chemicals, 24 are pesticides, 11 are industrial chemicals, and 4 are extremely hazardous pesticide formulations.

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

[164] *Basel Convention*, 1989, on line: Basel Convention <http://www.basel.int/convention/contributions/bc-index.html>.

elimination of certain chemicals known as Persistent Organic Pollutants (POPs).[165] The Convention lists 12 POPs and divides them into categories where some substances must be banned immediately and others gradually. As an exemption, some nations may use for some chemicals for a limited time in accordance with WHO recommendations and guidelines, e.g., dichloro-diphenyl-trichloroethane (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. 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.* [166]

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.

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

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[165]Persistent Organic Pollutants are powerful pesticides that serve a range of industrial purposes and pose 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. One the best known POPs is DDT. Widely used previously, it continues to be applied against mosquitoes in several countries to control malaria.

[166]UNEP, *Rio Declaration on Environment and Development*, 1992, Principle 15, on line: UNEP <http://www.unep.org/Documents.Multilingual/Default.asp?DocumentID=78&ArticleID=1163>.

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).

The Basel Convention was adopted in 1989 during a diplomatic conference held in Basel, Switzerland, 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. The key goal of the convention is 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. For practical and information purposes, all waste is divided into groups: waste to be controlled (required to be disposed of by the provision on national law, Annex 1); waste requiring special consideration (household (consumer) waste, Annex 2); and hazardous waste (Annex 8, 9).

Transport between the parties is subject to a procedure similar to the one in the Rotterdam Convention, 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.[167]

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.[168] In addition, although the parties provide financial

[167]The shipment can still take place as part of an agreement between the parties outside the convention.
[168]In 2005, total contribution was US$1,472,000. The most generous donors were: Finland, US$401,000; the Netherlands, US$105,000; the United Kingdom, US$337,000; Switzerland, US$410,000. Moreover, *Holcim Group*, one of the world's leading suppliers of cement and aggregates, contributed US$117,000. For more detailed information regarding financial aid for technical assistance, see the Basel Convention, *Trust Fund to Assist Developing Countries and other Countries*

support on a voluntary basis, most entities, especially the industrialized nations, have contributed their share.[169]

A majority of members of the international community have ratified the Basel Convention. Up to now, 170 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.[170]

One of the crucial aspects of implementation of the convention during the current decade 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.[171] So far, there are no provisions regarding the consumer role or education in the convention. However, it seems to be just a matter of time before such stipulations are added. Certain talks on this matter already have been initiated between the parties.

A few words should be said 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

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in Need of Technical Assistance (BD), on line: Basel Convention <http://www.basel.int/convention/contributions/bd-index.html>.

[169]In 2005, the total contribution was US$2,862,000. The most generous donors were: Canada, US$119,000; France, US$256,000; Germany, US$368,000; Italy, US$207,000; Spain, US$107,000; Japan, US$723.000; United Kingdom, US$260,000. For more detailed information regarding financial assistance, see the Basel Convention, *Trust Fund for the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (BC)*, on line: Basel Convention <http://www.basel.int/convention/contributions/bc-index.html>.

[170]Although the US is not a party to the convention, it provides major financial aid. In 2005, the US contributed US$135,000 in technical assistance and US$75,000 in financial assistance.

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

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 five years, under the auspices of the UN, the international community has made a few steps towards 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.[172] 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.[173] It is expected that cooperation and coordination between the conventions will intensify in the following years, especially with respect to sharing the financial and resources burden.

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[172]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), on line: AHJWG <http://ahjwg.chem.unep.ch/index.php?option=com_content&task=section&id=6&Itemid=3>.

[173]For a more detailed list of joint activities between the three conventions see *Ibid.*

2.3 The Globally Harmonized System of Classification and Labeling of Chemicals

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 protection.

The work to develop the Globally Harmonized System of Classification and Labeling of Chemicals (GHS)[174] 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 a need to develop harmonized hazard classification and labeling systems, building on ongoing work.*"[175] The first version of the GHS was adopted in December 2002 and later amended in 2004 and 2006.[176] The GHS system has been implemented in the pilot countries and is expected to be fully functional in 2008.

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[174]UNECE, *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*, on line: <http://www.unece.org/trans/danger/publi/ghs/ghs_rev01/English/01e_part1.pdf>.

[175]UN Department of Economic and Social Affairs, Division for Sustainable Development, *Agenda21*, ECOSOCOR, 1992 at Chapter 19 (*Harmonization of classification and labeling of chemicals*), on line: UN <http://www.un.org/esa/sustdev/documents/agenda21/index.htm>.

[176]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.

The Globally Harmonized System of Classification and Labeling of Chemicals (GHS) 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 classification is based on currently available scientific data, including human evidence and experts judgments, and uses only "neutral test" methods to determinate health and environment hazards.

The GHS targets the following objectives:

1. enhancing the protection of human health and the environment by providing an internationally comprehensible system for hazard communication;
2. providing a recognized framework for those countries without an existing system;
3. reducing the need for testing and evaluation of chemicals; and
4. facilitating international trade in chemicals whose hazards have been properly assessed and identified on an international basis.[177]

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 needs.

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[177] *Ibid.*174 at Chapter 1.1.

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 an effective approach in this respect.[178] The GHS introduces an assigned pictogram, signal word, and hazard statement for each hazard category of the hazard class.[179]

Since the due date for implementation the GHS is one year, parties to the treaty have time to make certain steps towards preparation of a legal, administrative, and technical basis. Today, most parties have taken actions towards development and adoption of the regulation to integrate elements of the GHS nationally.[180] The progress shown in implementation of the GHS requirements indicates that all parties

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[178]Labels based on this approach provide targeted information on identified risks but may not include certain information on chronic health effects. Eventually, once the GHS is fully functional, the competent national authority needs to establish the level of risk when labeling for chronic effects must be implemented.

[179]*Ibid.*174 at Chapter 1.4.

[180]Only recently last year the European Commission adopted the *"Proposal for a Regulation of the European Parliament and of the Council on classification, labeling, and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006"* (COM(2007) 355 final). The proposed act aligns the EU system of classification, labeling, and packaging substances and mixtures with the United Nations Globally Harmonised System (GHS). The proposal is awaiting approval by the European Parliament and the European Council. (For more, see EC, *Proposal for a Regulation of the European Parliament and of the Council on classification, labeling, and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006,GHS*, on line: European Commission <http://ec.europa.eu/enterprise/reach/ghs_en.htm>.)
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. 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. The next steps expected will be draft regulations and a regulatory process. (For more, see Health Canada, *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*, on line: Health Canada <http://www.hc-sc.gc.ca/ahc-asc/intactiv/ghs-sgh/index_e.html>.)

are taking the matter of chemical safety very seriously.[181] From this perspective, the future of the GHS looks quite bright.

2.4 A Strategic Approach to International Chemicals Management

The review of international instruments that benefit the consumer regarding chemical safety would not be complete without mentioning the UN's *Strategic Approach to International Chemicals Management* (SAICM).

Adopted by the International Conference on Chemicals Management in 2006, the SAICM is a policy framework for international action on chemical hazards. The SAICM is a response to the International Community on a challenge, sounded in 2002 during the Johannesburg World Summit on Sustainable Development, that by the year 2020, chemicals are produced and used in ways that minimize significant adverse impacts on the environment and human health.[182] The SAICM pays especial attention to the chemical safety of the vulnerable groups, such as children, pregnant women, fertile populations, etc.

The core of the SAICM consists of three documents: the Dubai Declaration,[183] the Overarching Policy Strategy,[184] and the Global Plan of Action.[185]

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[181]For more detailed information on implementation of the GHS, see *Ibid.*174.
[182]UNEP, *Strategic Approach to International Chemicals Management (SAICM)*, on line: UNEP <http://www.chem.unep.ch/saicm/>.
[183]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)*, 2006, *Dubai Declaration*, at 4 to 6, on line: <http://www.chem.unep.ch/saicm/SAICM%20texts/standalone_txt.pdf>.
[184]*The Overarching Policy Strategy*, *Ibid.* at 7 to 18.
[185]*The Global Plan of Action*, *Ibid.*183 at 19 to 24.

The Dubai Declaration expresses the commitment to SAICM by governments, civil society, and the private sector to chemicals management. *The Overarching Policy Strategy* sets out the scope of SAICM, the needs it addresses, and objectives for risk reduction, knowledge and information, governance, capacity-building, and technical cooperation and illegal international traffic, as well as underlying principles and financial and institutional arrangements. *The Global Plan of Action* sets out proposed "work areas and activities" for implementation of the Strategic Approach.

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, about the risks that the chemicals they use pose to themselves and their environment, and the pathways by which exposures occur during the period from 2006 –to 2015.[186] 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."[187]

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[186] *Ibid.*182.

[187] UNEP, *Resolution I/4, Quick Start Programme, International Conference on Chemicals Management*, on line: UNEP <http://www.chem.unep.ch/saicm/ICCM%20decision%20I.4%20QSP%20Eng.pdf>.

CHAPTER III.

BREAST-MILK SUBSTITUTES

3.1 The issue

Throughout human history, breastfeeding has been one of the most natural and universal ways of providing babies a whole necessary ration during their first months. Ancient medical writers were the first to link children's health and breastfeeding. Hippocrates, Soranus, and especially Galen emphasized in their works the importance of breastfeeding for children's health.[188] Modern science attributes many benefits to breastfeeding. In the short term, breastfed children are less susceptible to many common infant diseases and recover more rapidly from them in comparison with formula-fed children. In the long term, breastfed children not only have less chance of developing chronic illnesses and cancer, but also have greater intellectual ability.[189] Breastfeeding also brings benefits to mothers and society. Women who breastfeed their children have less chance of developing breast cancer and other breast illnesses, and they generally recover faster after childbirth. Advantages of breastfeeding for society are both financial (by eliminating the costs of milk substitutes[190] and by reducing medical expenses[191]) and environmental (by putting

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[188] Ted Greiner, "The history of breastfeeding", on line: Child Birth Solutions <http://www.childbirthsolutions.com/articles/postpartum/historybreast/index.php>.
[189]United States Breastfeeding Committee, "Benefits of Breastfeeding," on line: United States Breastfeeding Committee <http://usbreastfeeding.org/Issue-Papers/Benefits.pdf>.
[190]According to the United States Breastfeeding Committee, in the US the price of a one-year supply of breast-milk substances is as much as US$1200. At the same time, the price of supplemental nutrition for lactating women is only US$300.
[191]Breastfeeding reduces medical expenses for governments, hospitals, business, and families.

less stress on the environment, considering the amount of resources that are used for breast-milk substance production).[192]

In spite of the fact that breastfeeding has a long list of benefits and is an easy and natural way to nourish a baby, the number of breastfed babies has declined since the beginning of the last century. Nowadays, worldwide only 35% infants are exclusively breastfed during their first four months; the majority of newborns receive supplementary food too early. [193] As a result, more than 4 million children die every year as result of impropriate feeding practices.[194]

There are two major factors explaining why breastfeeding has declined. The first factor is a dramatic change in the role of women in modern society. Women, who previously devoted themselves to motherhood, have more and more become workers who often put their careers ahead of maternity. When a woman-worker becomes a mother, she has to give up breastfeeding too early because it is too overwhelming and stressful to combine work and feeding schedules.[195] The second key factor which

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[192]*Ibid.* 189.

[193]The earliest mention of artificial feeding date back to 2000 BCE. Some evidences and artifacts show that in ancient Egypt and later in Rome newborns were nourished with the help of clay feeding vessels. However, even then such practices were criticized by ancient Greek and Roman physicians, who believed that artificial feeding should not be started during the early stages of life. Similar beliefs were shared by medical practitioners in the Middle Ages. A study conducted in the 17th and 18th centuries showed an unprecedented high level of death among artificially fed infants, which ranged between 54% and 90%, compared with only 19% for breastfed infants). No wonder that Sweden introduced in the 18th century a special fine for mothers who did not breast feed. *Ibid.* 188.

[194]WHO, *Global Strategy for Infant and Young Child Feeding*, 2003, at 11, on line: <http://www.who.int/nutrition/publications/gs_infant_feeding_text_eng.pdf>.

[195]ILO Convention 183, adopted in 1952, stipulates: "A woman shall be provided with the right to one or more daily breaks or a daily reduction of hours of work to breastfeed her child. The period during which nursing breaks or the reduction of daily hours of work are allowed, their number, the duration of nursing breaks, and the procedures for the reduction of daily hours of work shall be determined by national law and practice. These breaks or the reduction of daily hours of work shall be counted as working time and remunerated accordingly"(Article 10). However, this convention was adopted by only 13 member-states. *Maternity Protection Convention*, ILO Convention C183, ILOOR, 1952, on line: <http://www.ilo.org/ilolex/cgi-lex/convde.pl?C183>; The key problem in maintaining lacto status for working women is that only a few employers provide private rooms for emptying breasts during working hours. For more, see M. Sara Rosenthal & Gillian Arsenault, "The Breastfeeding

contributes to breastfeeding decline is the introduction of relatively safe breast-milk substitutes at the beginning of the last century.

Originally, breast-milk substitutes were developed as a "medical acceptable alternative form of food supply" for children who refused breastfeeding. In 1867, German pharmacist Henri Nestlé tried his invention "*la Farine Lactée,*" a mix of bread and cow's milk, on a premature baby who refused his mother's milk and other food. The fact that the baby survived on only the new product pushed its inventor towards mass production of breast-milk substitutes. Just six years later, Henry Nestlé sold 500,000 tins annually of his *Farine Lactée* in Europe, and North and South America.[196]

In the beginning, infant formula was mostly used by medical professionals. However, after WWII, the popularity of formula feeding increased significantly among the general population in both developed and developing countries.[197] One of the key reasons why breastfeeding declined dramatically in the second part of the last century was an aggressive marketing campaign unleashed by infant formula producers.

Since new technologies for milk sterilization and preservation have made breast-milk substitutes relatively safe for consumption, international corporations, led by Nestlé, have used all possible ways to persuade mothers to give up breastfeeding.

Sourcebook", on line: WebMD, <http://www.webmd.com/content/Article/87/99614.htm?pagenumber=1>.

[196]In 1875, Henri Nestlé sold his company and name to a group of Swiss businessmen for 1,000,000 Swiss francs.

[197]Sami Shubber, *The international code of marketing of breast-milk substance. An international measure to protect and promote breast-feeding* (Hague: Kluwer Law International, 1998) at 3 to 4.

They have emphasized the similar or superior quality of infant formula compared to breast milk; have evoked mothers' concerns about whether the amount of breast milk is sufficient for nutrition; have used images of healthy-looking babies for advertising; have dressed up their personnel as nurses; have sent free supplies of formula to future mothers and to hospitals; and have used medical professionals to promote their products. Such marketing practices have worked very well. As a result, in 1967 only 25% of US mothers breastfed their children.[198]

In spite of the fact that studies conducted in the early 1900s in the US showed that children who fed with "safe" formula still have up to six times higher death rates than breastfed ones,[199] the first concerns regarding the substitution of infant formula for breastfeeding arose only in the late 1930s.[200] In the 1960s, health professionals from developing counties alarmed about unacceptable marketing practices of distribution of infant milk substances and fatal effects of such actions called it *"commerciogenic malnutrition"*.[201]During the 1970s, growing public movements[202] against notorious

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[198]Codes in Context, TNC Regulation in an Era of Dialogues and Partnerships, the Corner House, at 2 on line: http://www.thecornerhouse.org.uk/pdf/briefing/26codes.pdf.

[199]National Alliance for Breastfeeding Advocacy, "Breastfeeding timeline", at 1, on line: National Alliance for Breastfeeding Advocacy <http://www.naba-breastfeeding.org/images/Timeline.pdf>; Also *Ibid.*

[200]In 1939, pediatrician Cicely Williams voiced concerns regarding formula-related infant mortality in her famous speech "Milk and murder": *"Misguided propaganda on infant feeding should be punished as the most criminal form of sedition, and that those deaths should be regarded as murder."* (Infact Canada, "History of the campaign," on line: Infact Canada <http://www.infactcanada.ca/The%20History%20of%20the%20Campaign.pdf>.)

[201]The term *"commerciogenic malnutrition"* first was introduced by Dr. Derrick Jelliffe, director of the Caribbean Food and Nutrition Institute in Jamaica; Also *Ibid.* 198 at 2 & *Ibid.* 200 at Infact Canada.

[202]Crucial citizen action during the 1970s: 1974- the publication by the British group War on Want, *The Baby Killer,* the report on infant food marketing practices and their consequences in Africa; 1977- the start of an international consumer boycott of Nestlé; 1978-the US Senate public hearings on marketing of breast-milk substitutes in developing countries; Important moral victory was won in 1976 by the Bern-based Third World Working Group, which was sued by Nestlé for using its label in the German-language version of *The Baby Killer*, distributed in Switzerland under the title *Nestlé Kills Babies*. Although Bern Judge Jürg Sollberger ruled that the title indeed was defamatory and ordered payment of a symbolical fine, he also noted that Nestlé "must modify its publicity methods fundamentally."

practices brought this issue to the international stage and pushed the international community to take certain steps towards the development of a legal framework for the marketing of breast milk substances.[203]

3.2 The International Code of Marketing of Breast-Milk Substitutes

Facing public pressure, the UN put the issue of breast-milk substance marketing on its political agenda. The first alarming report regarding inappropriate methods of infant formula marketing was released in 1970 by the UN Protein-Calorie Advisory Group (PAG).[204] Just four years later, the World Health Organization (WHO) raised their concerns about the decline in breast-feeding and offensive marketing practices. The resolution adopted by the World Health Assembly (WHA) noted "*the general decline in breast-feeding, related to socio-cultural and environmental factors, including the mistaken idea caused by misleading sales promotions that breast-feeding is inferior to feeding with manufactured breast-milk substances*" and urged the international community to examine baby food marketing practices to develop adequate "*... remedial measures including advertisement codes and legislation ...*"[205]

During its session in May 1978, the WHA again emphasized the problem related to infant formula sales promotion and strongly advised member states to take legislative action to develop appropriate regulations.[206] Later in 1978, the WHO and UNICEF joined together to organize a meeting on infant and child feeding. The full spectrum of concerned parties (governments, NGOs, scientists, baby food producers, etc.) were

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[203]"The Formula Flap (Cont'd)" *Time magazine* (12 July 1976), on line: Time magazine <http://www.time.com/time/magazine/article/0,9171,914298,00.html>; Also *Ibid* 198 at 2.
[204]*Ibid* 200 at Infact Canada.
[205]WHA, Res. WHA27.43, Handbook of Resolutions and Decisions of the World Health Assembly and the Executive Board, Volume II, 4th ed., Geneva, 1981 at 58.
[206]WHA, Res.WHA31.47, Handbook of Resolutions and Decisions of the World Health Assembly and the Executive Board, Volume II, 4th ed. at 62.

invited to take a part in the consultations during preparation for the meeting.

The apotheosis of development of international infant and child feeding legislation came in 1979, when the Joint WHO/UNICEF Meeting on Infant and Young Child Feeding, attended by some 150 representatives of governments, recommended the adoption of "an international code of marketing of infant formula and other products used as breast milk substitutes" and asked the WHO/UNICEF "to organize the process for its preparation, with the involvement of all concerned parties, in order to reach a conclusion as soon as possible."[207]

Just three months later, the first draft of the code was ready. In spite of enormous pressure from the baby food industry and a nasty campaign unleashed by some media, after numerous consultations among parties,[208] in May 1981 the International Code of Marketing of Breast-Milk Substitutes[209] (hereinafter referred to as the "Code") was adopted at the Thirty-fourth World Health Assembly.[210]

Goals

The ultimate goal of the Code is to "contribute to the provision of safe and adequate nutrition for infants through the protection and promotion of breast-feeding and by ensuring the proper use of breast-milk substances, when these are necessary, on the

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[207]WHO/UNICEFOR, *Statement and recommendations of the joint WHO/UNICEF meeting on infant and young child feeding,* Mtg., *Geneva, 9-12 October 1979*, on line: United Nations University <http://www.unu.edu/Unupress/food/8F023e/8F023E04.htm>.

[208]For more on the history of the development of the International Code of Marketing of Breast-Milk Substances, see *Ibid.* 197 at 3 to 45.

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

[210]118 votes in favour, 1 against (the US), 3 abstentions (Argentina, Japan, and the Republic of Korea). The US adopted the code in 1994; *Ibid.*197 & *Ibid.*209 at Introduction of the International Code of Marketing of Breast-Milk Substances.

basis of adequate information."[211]

In others words, with a view to safeguarding child health, the Code protects and supports breastfeeding and does not ban but establishes the rules of the game for the production and marketing of breast-milk substitutes for rare cases when mothers cannot breastfeed their children. The protection and support of breastfeeding is sought through educating and by informing mothers of the benefits of breastfeeding, and by eliminating the possible negative effects of advertising or other marketing techniques, which discourage mothers from breast-feeding. The marketing of breast-milk substitutes must be done through appropriate techniques and labeling, and only if the quality of the product meets applicable standards.

Products and marketing techniques concerned

The Code applies to the marketing of all products which can be used as substitutes for breast-feeding. Since marketing practices are numerous and it would be difficult to list all of them, the Code embraces all possible marketing techniques by defining marketing as "product promotion, distribution, selling, advertising, product public relations, and information services" and specifies that all "practices related thereto" are the subject of the Code.[212] As for products, the Code applies not only to breast-milk substitutes and infant formula, but to any food and beverage that is "marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast-milk."[213] In other words, were Pringles or Coca-Cola to be marketed as suitable alternatives to breast-feeding, these products would automatically become breast-milk substitutes and subjects of the Code[214]. The Code also applies to feeding bottles and teats, since such products encourage artificial

[211] *Ibid.*209 at Art. 1.
[212] *Ibid.*209at Art. 2 & 3.
[213] *Ibid.*209 at Art. 2.
[214] *Ibid.*197 at 64.

feeding.

Information and educational materials

In accordance with Article 4 of the Code, governments are responsible for the provision of information on the importance of breast-feeding to anyone involved in the field of infant nutrition, including family members.

Among other things, education and information destined to future and feeding mothers must be provided on the following subjects: the benefits and superiority of breast-feeding; maternal nutrition; the negative effect on breast-feeding of introducing partial formula-feeding; the difficulty of revising the decision not to breast-feed; where needed, the proper use of infant formula; health hazards of unnecessary or improper feeding methods; and social and financial application of the use of formula-feeding.

On government request, manufacturers can provide educational-informative material and equipment, provided such materials meet government standards and not idealize the use of breast-milk substances.

Advertising and distribution

There are special provisions in the Code regarding advertising and distribution. Article 5 states: "There should be no advertising or other form of promotion to the general public of products within the scope of this Code." It is interesting to note that the Code takes a precautionary position and bans any form of marketing not only towards mothers but also towards the general public to eliminate any possible indirect effect of marketing campaigns on mothers and to prevent the cultivation of positive

public opinion regarding bottle-feeding.[215]

The Code also bans distribution by producers or sellers, "directly or indirectly, to pregnant women, mothers or members of their families, samples of products within the scope of the Code".[216] This ban also extends to health care workers, to whom such samples should not be provided and who "should not give samples of infant formula to pregnant women, mothers of infants and young children, or members of their families." Nevertheless, health workers can obtain baby-food samples "when necessary for the purpose of professional evaluation or research at the institutional level."[217]

Despite the fact that the Code bans any marketing practices including special displays, discount coupons, premiums, special sales, loss leaders and tie-in sales, as well as distribution of any gifts of articles or utensils which may promote the use of breast-milk substitutes or bottle feeding, it does not restrict "the establishment of pricing policies and practices intended to provide products at lower prices on a long-term basis."[218]

The Code establishes special rules for persons employed by manufacturers and distributors. First, marketing personnel should not seek any contact with future mothers or mothers of infants. Second, the Code restricts sales practices by employers aimed at increasing sales, for example, if the salary of sales personnel is based on the volume of sales or quotas. Finally, marketing personnel cannot act as tutors for pregnant women or mothers of infants; conversely, they can perform other functions within the health system.[219]

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[215]For more, see *Ibid.*197 at 103 to 119.
[216]*Ibid.*209 at Art. 5.2.
[217]*Ibid.*209 at Art. 7.4.
[218]*Ibid.*209 at Art. 5.3 & 5.4.
[219]*Ibid.*209 at Art. 5.5 & 8.1 to 8.3.

Labeling

Since labeling is sometimes the only available source of crucial information for the consumer, a substantial part of the Code is dedicated to this matter.

First, the Code states that labels have to provide necessary information about appropriate use of the product.

Information has to be easily readable, in appropriate language, and include the following points: the word "Important Notice;" a statement of the superiority of breast-feeding; a statement that the product should only be used on the advice of a health worker; instruction for appropriate preparation; and a warning against the health hazards of inappropriate preparation.

The Code bans the use of any images of children or text, including "humanized" or similar terms, which may idealize the use of formula. At the same time, labels may have some pictograms for illustrating the use of the product. Second, products which do not meet all the requirements of an infant formula, but which can be modified to do so, e.g., sweetened condensed milk, must carry a warning that such products are not suitable for child nourishment. Finally, labels must include: ingredients used; composition of the product; required storage conditions; and expiration date, taking into account the climatic and storage conditions of the country concerned.[220]

Health care system role

In accordance with the Code, the health care system and health workers play a key role in the promotion and protection of breast-feeding. The health authority in member states must disseminate guidelines and crucial information regarding the

[220] *Ibid.*209 at Art. 9.

benefits of breast-feeding and health hazards of bottle-feeding to health workers, who have to pass on such information and techniques to pregnant women and mothers of infants.[221] Health care system facilities should not be used for the promotion of artificial feeding by any means; nevertheless, such facilities can be used to provide to health workers new information received from manufacturers or distributors.[222]

The Code bans the use of any personnel in the health system who are provided and remunerated by manufacturers or distributors. Moreover, health workers and members of their families are prohibited from receiving any financial or material compensation from manufacturers or distributors. Any contributions made by manufacturers or distributors to health workers, e.g., study tours, research grants, etc., must be disclosed.[223] Health workers should be the only personal to instruct mothers and family members on appropriate bottle-feeding techniques.[224] Health workers should not distribute any samples of infant formula; nevertheless, low-price formula supply for infants can be provided through the health system when necessary but only on a long-term basis.[225]

Quality

In accordance with Article 10 of the Code, "the quality of the infant formula is an essential element for the protection of the health of the infant and therefore, it should be of highly recognized standards." All products covered by the Code should meet the Codex Alimentarius Commission (CAC) standards.[226]

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[221] *Ibid.*209 at Art. 6.1.
[222] *Ibid.*209 at Art. 6.2 & 6.3 &7.2.
[223] *Ibid.*209 at Art. 6.4 & 7.3.
[224] *Ibid.*209 at Art. 6.5.
[225] *Ibid.*209 at Art. 6.6 & 6.7 & 7.4.
[226] For more on the Codex Alimentarius Commission standards, see part 2.6 of this work.

To protect the integrity of children's health, the CAC has adopted two documents regarding infant formula: the *Codex Code of Hygienic Practice for Foods for Infants standards* (CCHPFI) in 1979[227] and *the Codex Standards for Infant Formula* (CSIF) in 1981.[228]

The CCHPFI standards cover: hygienic requirements in production and harvesting areas,[229] design and facilities of the establishment,[230] hygienic requirements for the establishment,[231] personal hygiene and health requirements,[232] hygienic processing requirements,[233] and end-product specifications.[234] As for the CSIF standards, they apply to infant formula as a substitute for human milk in meeting the normal nutritional requirements of infants. The CSIF includes provisions regarding: essential composition (vitamins, minerals, protein, fat, etc.), quality factors (consistency, particle size, purity requirements, etc.), maximum level of food additives, contaminants (pesticide residue, hormones, antibiotics, etc.), hygiene, packaging, degree of container filling, labeling, methods of analysis, and sampling.

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[227]Codex Alimentarius Commission, *Codex Code of Hygienic Practice for Foods for Infants standards*, on line: Codex Alimentarius Commission <http://www.codexalimentarius.net/download/standards/297/CXP_021e.pdf;jsessionid=35973AC7BDB51F57978B05755482C9FF>.

[228]Codex Alimentarius Commission, *Codex Standards for Infant Formula*, on line: Codex Alimentarius Commission <http://www.codexalimentarius.net/download/standards/288/CXS_072e.pdf>.

[229]Include requirement for environmental hygiene in areas from which raw materials are derived, harvesting and production, storage on the place of production and harvesting, transportation and etc.

[230]Include requirement for location, roadways, buildings and facilities, sanitary facilities such as water supply or waste disposal, equipment and utensils and etc.

[231]Include requirement for maintenance, cleaning and disinfection, storage and disposal of waste, pest control, storage of hazardous substances and etc.

[232]Include requirement for hygiene training, medical examination, communicable diseases, personal cleanliness and etc.

[233]Include requirement for raw material requirements in the establishment, prevention of cross-contamination, processing, packaging, storage and transport of the End-Product, sampling and laboratory control procedures and etc.

[234]Include requirement for pesticide residues, food additives, microbiological specifications and etc.

Implementation and monitoring

The last part of the Code includes provisions about its implementation and monitoring.

The Code calls upon government to set up a legal framework suitable for national conditions, if needed with the help of the UN network, and provides a highly flexible means of implementation through legislation, regulation, and other suitable measures. Adopted national policies and measures must be publicly stated and applied on the same basis to all parties involved in production and marketing of the infant food. Independently of any other measures taken, the manufacturers and distributors have to abide by the provisions of the Code, and should inform their personnel of their responsibilities under it.[235]

The monitoring of Code application is very important, since only through monitoring can progress be measured in achieving the goals of the Code. Governments are responsible for the implementation of this part of the Code. The infant food producers and distributors, NGOs, professionals, and consumer groups should collaborate with governments to this end. Manufacturers and distributors themselves have to conduct monitoring of their marketing practices according to the principles and aim of the Code. For their part, NGOs, professional groups, institutions, and individuals concerned should note violations and report them to the manufacturers and distributors as well as to an appropriate state authority. To record and measure the progress of implementation, member states shall submit information on action taken annually to the WHO, and the latter must submit a summary report every even year.[236]

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[235] *Ibid.*209 at Art. 11.1 & 11.3 & 11.5.
[236] *Ibid.*209 at Art.11.2 to 11.4 & 11.6 &11.7.

3.3. Related WHA resolutions

Since 1981 numerous resolutions clarifying and amplifying the Code have been produced by the WHA on a regular basis.[237]

In general, all resolutions reconfirm concerns about and the importance of three matters: the exclusive breast-feeding of infants until the age of six months, Code implementation, and the need to eradicate notorious marketing practices of infant formula.

Nevertheless, some resolutions go beyond the usual pattern and address a particular problem related to breast-feeding marketing practices and quality of infant formula.[238]

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[237]WHA, Res. WHA 35.26 (1982), on line: International Baby Food Action Network (IBFAN) <http://www.ibfan.org/english/resource/who/whares3332.html>;WHA, Res. WHA 37.30 (1984), on line: IBFAN <http://www.ibfan.org/english/resource/who/whares3730.html>; WHA Res. WHA 39.28 (1986), on line: IBFAN http://www.ibfan.org/english/resource/who/whares3928.html>; WHA, Res. WHA 41.11 (1988), on line: IBFAN <http://www.ibfan.org/english/resource/who/whares4111.html>; WHA Res. WHA 43.3 (1990), on line: IBFAN <http://www.ibfan.org/english/resource/who/whares433.html>; WHA, Res. WHA 45.34 (1992), on line: IBFAN <http://www.ibfan.org/english/resource/who/whares4534.html>; WHA, *Infant and young child nutrition*, Res. WHA 47.5 (1994), on line: IBFAN <http://www.ibfan.org/english/resource/who/whares475.html>; WHA, *Infant and young child nutrition*, Res. WHA 49.15 (1996), on line: IBFAN <http://www.ibfan.org/english/resource/who/whares4915.html>; WHA, *Infant and young child nutrition*, Res. WHA 54.2 (1998), on line: INFAN <http://www.ibfan.org/english/resource/who/whares542.html>; WHA *Infant and young child nutrition*, Res WHA 55.25 (2002), on line: IBFAN, <http://www.ibfan.org/english/resource/who/whares5525.html>; WHA *Infant and young child nutrition* Res. WHA 58.32 (2005), on line: IBFAN <http://www.ibfan.org/english/resource/who/whares5832.html>.

[238]Since the resolutions where adopted by the WHA, they focus primarily on health issues such as malnutrition in children, hunger, etc. However, we will review only those parts that pertain to consumer protection.

WHA Resolution 39.28[239] addresses the issue of so-called "follow-up milks." Since the marketing of breast-milk substitutes has been restricted by the Code, the infant food industry came out with "follow-up formulas," marketed as "complements" to breast milk (in contrast to infant formulas, which are marketed as breast-milk substitutes).[240] Resolution 39.28 directs the attention of members states to the fact that the "practice being introduced in some countries of providing to infants specially formulated milks (so-called "follow- up milks) is not necessary." and WHA Resolution 49.15 subsequently urged Member States to take measures "to ensure that complementary foods are not marketed for or used in ways that undermine exclusive and sustained breast-feeding."

Another concern recognized by Resolution 39.28 as well by resolutions 43.3 and 45.34 is that free or low-cost supplies of infant formula are available in hospitals and maternities.[241] Resolution 45.34 urges member states to take measures "aimed at ending the donation or low-sale of supplies of breastmilk substances to health-care facilities providing maternity services."[242] Nevertheless, Resolution 47.5 subsequently allowed donations of breast-milk substitutes provided that: infants have to be fed by formula because of health or socioeconomic circumstances; the supply is continued for as long as the infants concerned need it; and the supply is not used as a sales inducement.[243]

Finally, Resolution 58.32 addresses quality of infant formula,[244] more specifically the problem of contamination of formula with microorganisms, which have been a cause

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[239] *Ibid.*237 at Res. WHA 39.28.
[240] Ted Greiner, "The Dangers of Follow-up Formulas", on line: GeoCities <http://www.geocities.com/HotSprings/Spa/3156/follow.htm>.
[241] *Ibid.*237, at Res. WHA 43.3 & WHA 45.34.
[242] *Ibid.*237 at Res. WHA 45.34.
[243] *Ibid.*237 at Res. WHA 47.5.
[244] *Ibid.*237 at Res. WHA 58.32.

of infection and illness, including several cases of death amongst infants.[245] The resolution underlines the importance of informing the general public of the potential risk of contamination of powdered milk infant formula with dangerous and deadly microorganisms. The resolution urges member states to take measures to minimize health hazards from powdered infant formula and calls on the international community to develop production guidelines to reduce the level of contamination of infant formula with microorganisms.

3.4 Assessing Code implementation

Although the Code was adopted more than 25 years ago and many of the member states have introduced some measures on the national level,[246] there is overwhelming evidence of Code violations, since only a few states have implemented it in a legally binding instrument.[247]

According to a report published by the International Baby Food Action Network

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[245]Between 1998 and 2002, at least three formula-fed infants died in Belgium from *Enterobacter Sakazakii,* a very resistant bacteria that can live in powdered milk. In some cases, the cause of death was not released to the general public nor even to the families. Studies conducted in 2002 by the US Food and Drug Administration (FDA) found that 14% of infant food tins were contaminated with *Enterobacter Sakazaki* and suggested not using infant formula in neo-natal units. (Office of Nutritional Products, Labeling and Dietary Supplements, FDA, *Health Professionals Letter on Enterobacter sakazakii Infections Associated With Use of Powdered (Dry) Infant Formulas in Neonatal Intensive Care Units*,2002, on line: FDA <http://www.cfsan.fda.gov/%7Edms/inf-ltr3.html>.) In recent years, in the EU there have been several recalls of infant food as result of contamination with microorganisms including *Enterobacter Sakazakii* and *Salmonella*. (For more, see IBFAN, "How safe are infant formulas? The death of a one-week old formula-fed baby in Belgium", on line: IBFAN <http://www.ibfan.org/english/news/press/press10may02.html>.)

[246]According the *Report of the Director-General of the WHO on Infant and Young Child Nutrition (progress and evaluation report; and status of implementation of the International Code of Marketing of the Breast-Milk Substitutes)* more then 160 Members States and territories have adopted national measures to implement the Code. WHA, *Report of the Director-General of the WHO on Infant and Young Child Nutrition (progress and evaluation report; and status of implementation of the International Code of Marketing of the Breast-Milk Substitutes)* WHA, Doc. WHA47/1994/REC/1, Annex 1, at 63 et seq.

[247]*Ibid.*197 at 232.

(IBFAN),[248] only 35 countries, all of them developing ones, have integrated all provisions of the Code into national legislation in the form of a law. In 44 states, including the member-states of the EU, many provisions of the Code have been adopted as binding legislation. Sixty-four states have adopted only a few provisions of the Code as regulations or have introduced voluntary measures such as guidelines.[249] However, more then 50 states, including the US, not only have done very little or made no progress towards Code implementation but have even sabotaged implementation of the Code by different countries.[250] In these circumstances, it is no wonder why numerous violations of the Code can be spotted everywhere.

The report *Breaking the Rules, Stretching the Rules,* authored by IBFAN, records a long list of violations collected during a 14-country survey of 16 transnational baby food companies and 13 manufacturers of bottles and teats.[251] Since the survey was

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[248]IBFAN, "A survey of measures taken by governments to implement provisions of the International Code of the Marketing of the Breastmilk Substitutes" (2001), on line: IBFAN <http://www.ibfan.org/site2005/abm/paginas/articles/arch_art/298-11.pdf>.

[249]In January 2007, the Canadian Food Inspection Agency (CFIA) released *the Letter to Industry: Requirements Related to Nutrition Information and Health Claims for Infant Formula,* where the CFIA and Health Canada "strongly urge the infant industry to support and implement the principles" of the Code. The Letter clarifies specific moments regarding the labeling and advertising of the infant formula. However some provisions of the Code are only recommended for implementation, e.g. the Letter only recommends companies don't use the picture infant on formula containers. Other stipulations just violate provision of the Code, e.g. if the article 5.1 of the Code states that "there should be no advertising … to the general public", the Letter requests that all advertising for infant formula should comply with provisions of the Letter. (Canadian Food Inspection Agency, *Letter to Industry: Requirements Related to Nutrition Information and Nutrition and Health Claims for Infant Formula* (8 January 2007), on line: Canadian Food Inspection Agency <http://www.inspection.gc.ca/english/fssa/labeti/inform/20070112e.shtml>)

[250]Guatemala was the first nation in successful reducing infant mortality rates, after passing a law based on the Code in 1983. However US infant food producer *Gerber* has refused to remove its "Gerber Baby" from its packaging since it is the logo used by the company from 1928 and the code violates international trademark protections. In 1995, under threat of a WTO challenge by the U.S. State Department, Guatemala was forced to change its law to allow labeling that violates the Code. (See more WTO, "Baby-Food Trademark Controversy", on line: WTO <http://www.speakeasy.org/~peterc/wtow/wto-cont.htm#baby>)

[251]IBFAN, "Breaking the Rules, Stretching the Rules, Evidence of Violation of the International Code of Marketing of the Breast-Milk Substitutes and subsequent Resolutions" (2001), on line: IBFAN <http://www.ibfan.org/english/codewatch/btr01/MAIN-en.HTM>.

conducted in a limited number of countries, only a limited number of violations have been documented and included in the report. IBFAN projects that the true scale of violations exceeds imagination. Basically, the report records violations of any provision of the Code.

Health care facilities have been used by companies as preferred locations for reaching mothers through distribution of promotional materials, from booklets and leaflets on infant feeding to free formula samples and numerous gifts with company branding or product logos. Most of the companies have continued to supply the full spectrum of baby food products to health care facilities on a free-of-charge basis, often using the technique of not collecting payment against invoices.

Almost all companies distribute free samples of infant formula among health workers, who pass them on to mothers or often resell them on the market for profit. Moreover, the report notes notorious practices whereby companies provide healthcare workers with endless gifts and funding for travel or research, in order to keep them loyal. Various booklets, leaflets, and magazines distributed to mothers through retail chains, mail, Internet, and health care facilities appearing to support breastfeeding often include incorrect information and images to encourage formula feeding. In addition, recruiting for *Baby Clubs* has become one of the easiest ways of making contact with mothers directly to provide them free formula samples, discount coupons, gifts, etc.

Not even a single company fully meets the labeling requirements of the Code. Violations such as using of images that idealize the use of artificial feeding, comparisons of formula to breast milk, labeling in foreign languages, etc. have been part of everyday marketing practices. Overall, the infant food industry has recently

diversified their product offerings with the addition of new brands of complementary food, which have been promoted for use as early as the first week.

In conclusion, more then 25 years ago the Code introduced minimal requirements for infant formula marketing. Nevertheless, even today infants and mothers around the globe are still facing notorious marketing practices of breast-milk substitutes by the infant food industry that spends billions of dollars to promote their products.[252] In spite of international efforts to protect breastfeeding, the most beneficial and natural way of nourishing infants, many states are still putting business ahead of child health. Only the adoption of all provisions of the Code in form of the law by all member states could force international corporations to implement the Code requirements globally.

[252]The Nestlé advertising budget is nearly $8 billion annually, four times the budget of the WHO. (Someshwar Singh, "Baby food manufacturer accused of violation of the WHO Code," on line: Third World Network <http://www.twnside.org.sg/title/baby.htm>.)

CHAPTER IV.

PHARMACEUTICALS

Medicines are an essential element of the public 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. Nevertheless, poor quality, unsafe and ineffective medicines, and misuse of drugs can sometimes be even more dangerous or mortal than an illness itself. This is why the international community has taken numerous steps to make sure that only high quality, safe, and effective medicines pass to the consumer, who is properly informed on how to use them correctly.

Nowadays, globalization of pharmaceutical production, commerce, and trade has reached an excessive level. Thus, only the development and implementation of international norms and standards for medicines can provide the consumer adequate protection. The 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."[253]

Up to now, the WHO has developed numerous norms, standards, and guidelines regarding quality, safety, and efficacy of pharmaceuticals and other medical

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[253]WHO, *Norms, standards and guidance for pharmaceuticals*, on line: WHO <http://www.who.int/medicines/areas/quality_safety/quality_assurance/norms_standards/en/index.html>.

products.[254] Most of these acts only indirectly benefit consumer protection. Nevertheless, some of them include provisions directly linked to consumer protection topics, and only those are reviewed hereunder by us.

4.1 The Consolidated List of Pharmaceuticals

The first international instrument that benefits consumer protection is *The Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or Not Approved by Governments (Pharmaceuticals),*[255] (The Consolidated List of Pharmaceuticals).[256]

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 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*[257] 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

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[254]For list of the *WHO publication on medicines* see, on line: WHO <http://www.who.int/medicines/publications/en/>.

[255]UN Office for ECOSOC Support and Coordination, *The Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or Not Approved by Governments (Pharmaceuticals)*, on line: UN <http://www.un.org/esa/coordination/CL12.pdf>.

[256]On history of the Consolidated List of banned hazardous chemical and unsafe pharmaceutical products see Part. 2.2.1.

[257]Everyone can automatically receive the electronic version of every new issue of the WHO Pharmaceuticals Newsletter after subscription on the WHO website. See more *WHO Pharmaceuticals Newsletter*, on line: WHO <http://www.who.int/medicines/publications/newsletter/en/index.html>.

information to the general public and to consumer groups about hazardous drugs that are severely restricted and banned in some countries but still on market in others.[258]

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 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 two international conventions,[259] 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

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[258] *Ibid.* 255 at 4 to 6

[259] UN Office on Drugs and Crime, *The Single Convention on Narcotic Drugs*, 1961, on line: 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, on line: UN Office on Drugs and Crime <http://www.unodc.org/unodc/en/bulletin/bulletin_1971-01-01_3_page002.html>,
UN Office on Drugs and Crime, *The United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances*, 1988, on line: UN Office on Drugs and Crime <http://www.unodc.org/pdf/convention_1988_en.pdf>.

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.

The first part is divided into two sections: monocomponent products, and combination and group products. To facilitate use, whenever possible, all pharmaceuticals products are arranged in alphabetical order according to International Non-Proprietary Names (INN)[260] and include other scientific and common names and the date when regulation came into force.[261] 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.[262]

4.2 The WHO Guidelines for Drug Donations

During disasters or wars, many human lives have been saved only because of donations of drugs. This is why every year the value of drug donations reaches up to US$300 million.[263] However, donation without assessment of emergency medical needs and without guidance can cause more problems than help. Unfortunately, there

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[260]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 Nonproprietary Names (INN), also know as generic names, a unique name that is globally recognized and is public property. See more: WHO, *The International Nonproprietary Names*, on line: WHO <http://www.who.int/medicines/services/inn/en/>.

[261]*Ibid.*255 at 6 & 7.

[262]*Ibid.*255 at 7; Annex 2 includes an example of how the Consolidated List of Pharmaceuticals is organized. The first page represents legislative or regulatory actions on the pharmaceutical Thalidomide. The second page shows cross-references on scientific-trade names for the same medicine.

[263]WHO, Department of Essential Drugs and Medicines Policy, *First-year experiences with the interagency guidelines for drug donations*, 2000, on line: WHO <http://whqlibdoc.who.int/hq/2000/WHO_EDM_PAR_2000.1.pdf>.

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.[264]

To improve the quality of drug donations, in 1996 the WHO in cooperation with major international agencies active in humanitarian relief[265], elaborated *The WHO Guidelines for Drug Donations (the WHO Guidelines).*[266]

The WHO Guidelines identify the following problems related to drug donations. Donated drugs are often not relevant for the emergency situation or unknown to local health professionals. Many donated drugs are unsorted, without proper labels. The quality of the drugs can be below the standards of the donor country. The donor agency sometime ignores local regulations on drugs. Drugs can be donated in the wrong quantities. High declared customs value and the price of logistics can make some drugs too expensive for local drug budgets. Of all the problems listed above, two (labeling and quality) can be identified as related directly to consumer protection.

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's/patient's health and life. Moreover, some donated drugs are labeled only with unregistered local trade names and don't

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[264]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. For more examples of problems with drug donation, see *infra* note 266 *at Annex: Examples of problem with drug donation* at 15 & 16.

[265]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.

[266]WHO, *WHO Guidelines for Drug Donations*, 1996 at 1 to 3, on line: WHO <http://www.euro.who.int/document/EHA/PAR_Donate_Guidelines.pdf>.

have an INN or generic name on the labels. Such situations can confuse health professionals and may be fatal for consumers/patients. To avoid problems related to improper labeling, The WHO Guidelines specify that *"all drugs should be labeled in a language that is easily understood by health professionals in the recipient country; the label on each individual container should at least contain the International Nonproprietary Name (INN) or generic name, batch number, dosage form, strength, name of manufacturer, quantity in the container, storage conditions, and expiry date."*[267]

The WHO Guidelines specify three problems related to the quality of donated drugs. First, there are double standards for donated drugs, when drugs of unacceptable quality in donor countries are donated to other countries. The WHO Guidelines stipulate that *"all donated drugs should be obtained from a reliable source and comply with quality standards in both donor and recipient country."*[268] Second, a quality related problem is a practice whereby unused drugs or drug samples are returned to the pharmacy by patient/health workers for safe disposal are used for donations. In view of the fact that in most countries returned drugs cannot be reissued to other patients, since their quality cannot be guaranteed, the WHO Guidelines prohibit using such drugs for donations.[269] Finally, the WHO Guidelines address the problem of shelf-life of donated drugs. Since in many recipient countries, and especially under emergency situations, drug distribution can take a significant amount of time, short-dated drugs can expire before they reach the consumer/patient. As a general rule, the Guidelines suggest that "*after arrival in the recipient country all donated drugs should have a remaining shelf-life of at least one year.*"[270]

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[267] *Ibid.* 266 at Art. 7 *Presentation, packaging, labeling* at 9 & 10.
[268] *Ibid.*266 at Art. 4 *Quality assurance and shelf-life* at 8.
[269] *Ibid.*266 at Art. 5 *Quality assurance and shelf-life* at 8.
[270] *Ibid.*266 at Art. 6 *Quality assurance and shelf-life* at 8 & 9.

Even though 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.*"[271] The future of the WHO Guidelines looks quite optimistic, because even five years after the adoption of the WHO Guidelines many international humanitarian organizations have noticed improvement in donation practices, especially in the case of drug shelf-life and labeling.[272]

4.3 Good Manufacturing Practices for pharmaceutical products and Certification Scheme

The quality of the pharmaceuticals products circulating on the market has always been a priority for the international community. As the quality of pharmaceuticals depends highly on proper production protocol, the WHO has elaborated a few documents regarding the manufacturing of medicines.

The first document regarding the production of medicines, *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 part of the Scheme. In 1975, after revision, the WHA adopted both the GMP[273] and the Scheme.[274]

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[271] *Ibid.*266 at Art. 5 *Practical benefits as a result of the Guidelines* at 21.
[272] *Ibid.*266 at 21 & 22.
[273] In 1992 the GMP was revised a second time.

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. All these considerations indirectly benefit consumer safety, and some provisions such as product recall or proper labeling have an even more direct impact.

One of the key principals of the manufacturing of medicines is the concept of quality assurance,[275] "*a wide-ranging concept covering all matters that individually or collectively influence the quality of a product*".[276] 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*".[277] Good manufacturing practices are a part of a quality assurance concept with an aim to diminish potential risks[278] inherent to any pharmaceutical production.[279]

Among other things related to product quality, good manufacturing practices call for proper labeling and a product recall scheme.

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[274]WHO, *Good Manufacturing Practices for Pharmaceutical Products: Main Principles*, 1975, on line: WHO <http://whqlibdoc.who.int/publications/2004/9241546190_part1.pdf>.
[275]The quality assurance concept incorporates not only production but also product design and development.
[276]*Ibid.*274 at Art.1.1 at 16.
[277]*Ibid.*274 at Art. 1.3 at 17.
[278]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.
[279]*Ibid.*274 at Art. 2.1 at 17.

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; (g) and the name and address of the manufacturer or the company or the person responsible for marketing the product. Labels must be clear and unambiguous[280] and quality is subject to self-inspection procedures.[281]

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.*"[282] The manufacturer has to appoint an authorized person responsible for the implementation of recalls and support him/her with "*sufficient staff to handle all aspects of the recalls with the appropriate degree of urgency.*"[283] As well, the manufacturer must develop written instructions for its personal concerning how to handle and monitor recalls, and keep records on action taken.[284] Finally, the manufacturer must inform national authorities promptly "*of any intention to recall the product because it is, or is suspected of being, defective.*"[285] From time to time, the product recall procedure must be examined and reevaluated.[286]

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[280] *Ibid.* 274 at Art. 15.11 at 41.
[281] *Ibid.* 274 at Art. 8.2 at 24.
[282] *Ibid.* 274 at Art. 6.1 at 20.
[283] *Ibid.* 274 at Art. 6.2 at 20.
[284] *Ibid.* 274 at Art. 6.3 & 6.4 & 6.6 &6.7 at 20 & 21.
[285] *Ibid.* 274 at Art. 6.5 at 21.
[286] *Ibid.* 274 at Art. 6.8 at 21.

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.[287]

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.[288]

To participate in the scheme, any member state should have: an effective national 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.[289]

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[287]WHO, *Guidelines on the implementation of the WHO certification scheme on the quality of pharmaceutical products moving in international commerce*, on line: WHO <http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/guidelines/en/index.html>.
[288]*Ibid.*287 at Art. 1.3.
[289]*Ibid.*287 at Art. 2.4.

At the request of the importing country, the exporting country must submit three different types of certificates: the Certificate of a Pharmaceutical Product[290] (used if a product is subject to licensing for import and sale),[291] the Statement of Licensing Status[292] (used to confirm license status of a particular product in the exporting country),[293] and the Batch Certificate[294] (used only exceptionally for vaccines, sera and some other biological products).[295] In the case of any quality defect in an exported product, a certifying authority must institute an enquiry.[296] 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.[297]

4.4 The Guidelines for Appropriate Use of Herbal Medicines

For millenniums, herbal medicines have played an important role in primary health care in many places around the globe. Nowadays, herbal medicines are still the only

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[290]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.

[291]*Ibid.*287 at Art. 3.5 & 3.6.

[292] Importing agents use the Statement of Licensing Status to facilitate the screening and preparation of information for an international tender.

[293]*Ibid.*287 at Art. 3.13.

[294]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.

[295]*Ibid.*287 at Art. 3.14.

[296]*Ibid.*287 at Art. 5.1.

[297]FIP/IFPMA, *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, on line: FIP <http://www.fip.nl/www2/uploads/database_file.php?id=237&table_id=>.

affordable remedy for a majority of the world's population in developing countries. [298] 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, more and more governments are considering establishing comprehensive policies on the appropriate use of herbal medicines.[299]

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.[300] In addition, since many herbs originate from unverified sources, they can be contaminated. Thus, only an adequate and effective system of quality control and appropriate treatment protocols can help to avoid dangerous consequences.

The WHO has always supported the use of herbal medicines. During the 70s and 80s, the WHA adopted numerous resolutions on medicinal plant management, inventory, safe preparation, cultivation, etc.[301] However, with the growing popularity of herbal medicines worldwide, many member states asked for assistance in developing a legal framework for 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,*"[302] and later in 1997, the WHO Regional Office for the Western Pacific Region prepared a set of *Guidelines for the appropriate use of herbal*

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[298] For example, in China medicinal plants and their products had a 33.1% share of the pharmaceutical market in 1995, infra note 303 at Art. 1.1.
[299] *Infra* note 303 at Art.1.3.
[300] *Infra* note 303 at Art.1.3.
[301] Resolutions on traditional medicine (Res. WHA29.72, Res. WHA30.49, Res. WHA40.33), resolutions on medicinal plants (Res. WHA31.33, Res. WHA41.19).
[302] WHA, *Traditional medicine and modern health care,* Res WHA42.43., on line: INFOMED, <http://whqpauling.who.int/sd/cgi-bin/om_isapi.dll?hitsperheading=on&infobase=wha&record>.

medicines (the Guidelines AUHM).[303]

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.[304] The two last objectives should be reviewed in the scope of this work since they directly relate to consumer protection.

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.[305] To ensure the quality of herbal medicine services and thus protect the public, the state should establish a regulatory framework and a certification scheme for practitioners.[306] 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

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[303]WHO, *Guidelines for Appropriate Use of Herbal Medicines*, 1997, on line: WHO <http://www.who.int/medicinedocs/library.fcgi?e=d-01dedmweb--000-1-0--010---4----0--0-10l--1en-5000-0--50-about-01en-5000-01131-0011N%40%2f2%5bmSa9ee80c740000000043e740be-0utfZz-8-0-0---01001-001-110utfZz-8-0-0&a=d&c=edmweb&cl=CL2.1.2&d=Jh2945e>.
[304]*Ibid.*303 at Art. 2.2.
[305]*Ibid.*303 at Art. 5.7.
[306]*Ibid.*303 at Art.6.

and quality control in accordance with the provisions of both[307] the GMP and the *Good manufacturing practices: supplementary guidelines for the manufacture of herbal medicinal products.*[308] To ensure that only good quality herbal medical products reach international markets, the Guidelines AUNM suggest following the principles of the scheme.[309]

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 following information: name of product; the name and quantity of active ingredients; dosage form; directions for use, including indications, dosage, mode of administration, duration of use, age group limitations, and use during pregnancy and lactation; warning statements and relevant contraindications, adverse effects, if any, and overdose information when relevant; batch number; expiry date; storage conditions; name and address of manufacturers and/or importers; and registration or notification (listing) number.[310]

Regarding advertisements and other promotional activities addressed to health personnel and the public, the Guidelines AUHM request that such activities be fully consistent with the accepted product information, and some advertising claims can be subject to restrictions.[311]

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[307] *Ibid.*303 at Art. 7.1 & 7.2.
[308] WHO, *Good manufacturing practices: supplementary guidelines for the manufacture of herbal medicinal products*, 2005, on line: WHO <http://www.who.int/medicines/services/expertcommittees/pharmprep/QAS04_050Rev3_GMPHerbal_Final_Sept05.pdf>.
[309] *Ibid.*303 at Art. 7.4.
[310] *Ibid.*303 at Art. 8.5.
[311] *Ibid.*303 at Art. 8.7.

4.5 Medical Products and the Internet: a Guide to find reliable information

In recent years, sales of medical products over the Internet have increased substantially. 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.[312]

Nevertheless, consumers who buy medical products over the Internet are at risk of suffering adverse events, some of which may 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 ingredients; adverse or no effect from medical products that are expired, contaminated, poor quality, etc.[313]

Although most Internet pharmacies conduct honest and reliable businesses and provide genuine medical products to the consumer, there are numerous pseudo e-

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[312] "*Because it provides easy access to controlled drugs, the Internet is becoming an important route for trafficking by on-line 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.*" (International Narcotics Control Board (INCB), *INCB Targets Illicit Sales of Drugs on Internet Pharmacies International Experts to Meet in Vienna to Discuss Solutions*, 2004, on line: INCB <http://www.incb.org/incb/en/press_release_2004-10-18_1.html>).

[313] *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), 2004, on line: FDA <http://www.fda.gov/ola/2004/internetdrugs0318.html>.

pharmacies that don't play by the rules. Such e-businesses use aggressive marketing techniques to sell poor quality or counterfeit medical products.[314]

There are a few weapons in the WHO arsenal to battle such practices, for example the *Guidelines to fight counterfeit drugs*[315] or the *Guidelines on Inspection of drug distribution channels.*[316] 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 can diminish wide-scale consumer abuse, the WHO has developed a guide for consumer shopping on the Internet.

In May 1998, the Fifty-first WHA adopted a resolution whereby the international community expressed concerns about the effects of advertising, promotion, and 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.[317] A year later, the WHO released *Medical Products and the Internet: a Guide to find reliable information* [318] 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.[319] The guidelines offer practical and easy-to-follow information on what the consumer has to do when buying medical product s over the Internet.

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[314]Such marketing can employ low prices, aggressive advertising, website designs similar to genuine e-pharmacies, etc.
[315]WHO, *Guidelines to fight counterfeit drugs.*
[316]WHO, *Guidelines on Inspection of drug distribution channels .*
[317]WHA, *Cross-border advertising, promotion and sale of medical products using the Internet*, Res. WHA51.9 (1998), on line: WHO <http://ftp.who.int/gb/archive/pdf_files/WHA51/ear9.pdf>.
[318]WHO, *Medical Products and the Internet: a Guide to find reliable information,* on line: WHO <.http://www.who.int/medicinedocs/en/d/Js2277e.1#Js2277e.1>.
[319]*Ibid.*318 at *Introduction.*

Although the Internet is a valuable source of information on a wide range of health topics, and when used properly, it allows quick and easy access to such information from numerous on-line databases, it is often difficult for users to determine whether such information posted on the Net is reliable, complete, and up to date.[320] 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.[321] 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.[322]

When using the Internet, consumers must keep the following considerations in mind. The information may not be truthful,[323] and identically named products may contain different ingredients in different countries; therefore, the consumer should use only the INN to identify the pharmaceutical's composition.[324]

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[320] *Ibid.*318 at Art.1.

[321] 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 trails; 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.

[322] *Ibid.*318 at Art. 2.

[323] 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.

[324] 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. *Ibid.*318 at Art.3.

There are many reasons why buying medical products from another country may risk consumers' health and waste consumers' money. The guidelines list at least ten.[325] Consumers should consider most of them before buying medical products overseas.[326]

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.[327]

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

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[325]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 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 for personal medical information and may not keep it confidential.

[326]*Ibid.*318 at Art. 4.

[327]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. *Ibid.*318 at Art. 5.

information. For example, Health Canada's *Buying Drugs over the Internet* includes only a few provisions of the WHO Guidelines.[328] It would be more useful if the business selling medical products on line were obliged to provide to consumers information on the WHO Guidelines on its Web site 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. It remains as important as ever to arm the consumer with truly vital and universal information on how to buy medical products over the Internet.

4.6 The WHO Programme for International Drug Monitoring

The WHO Programme for International Drug Monitoring (the Program) was established in 1968, after the Thalidomide disaster.[329] 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.

Regulatory agencies, healthcare professionals, researchers, the pharmaceutical industry, and other interested stakeholders use the UMC resources as an essential

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[328]Health Canada, *Buying Drugs over the Internet*, on line: Health Canada <http://www.hc-sc.gc.ca/iyh-vsv/alt_formats/cmcd-dcmc/pdf/buying_drugs_internet_e.pdf>.

[329]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 in overdosage. 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).

global database on adverse drug reactions.[330]

Today, 83 countries take part in the Program,[331] and another 20 countries participate as associate members.[332]

4.7 Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine

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.[333] However, as a result of different cultural traditions, local CAM practitioners and consumers may often be unfamiliar with the proper and adequate use of techniques and therapeutic products of CAM. As the use of traditional or alternative medicines increases, so do reports of adverse reactions.[334]

Faced with this challenge, in 2003 the WHO adopted a resolution that urges the international community "*to provide reliable information on traditional medicine and*

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[330]Presently, the UMC database contains over 3.7 million case reports.

[331]Canada has been a member of Program since 1968.

[332]For more information on *The WHO Programme for International Drug Monitoring* and the Uppsala Monitoring Centre, see *Uppsala Monitoring Centre*, on line: WHO < http://www.who-umc.org/>.

[333]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. WHO, *New WHO guidelines to promote proper use of alternative medicines*, 2004, on line: WHO <http://www.who.int/mediacentre/news/releases/2004/pr44/en/>.

[334]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. *Ibid.* at *New WHO guidelines to promote proper use of alternative medicines.*

complementary and alternative medicine to consumers and providers in order to promote their sound use."[335] 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."*[336]

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).

With the primary goal of assisting member states in developing context-specific and reliable consumer information on proper 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 to develop the consumer information on promoting proper use of CAM.[337]

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,[338] 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

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[335]WHA, *Traditional Medicine*, Res. WHA56.31 (2003) on line: WHO <http://www.who.int/gb/ebwha/pdf_files/WHA56/ea56r31.pdf>.
[336]*Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine,* Foreword, the WHO, on line: <http://www.who.int/medicinedocs/collect/edmweb/index/assoc/s7149e/s7149e.pdf>.
[337]*Ibid.*336 at *Preface.*
[338]Countries with an *integrative* health system: China, the Republic of Korea, and Vietnam.

CAM. The second type, an *inclusive* healthcare system, recognizes CAM but does not included it in all aspects of healthcare.[339] 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 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.[340]

Although proper 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 proper use of CAM, such as quality control of herbal medicines, development of reliable treatment guidelines, training and qualified practice for CAM practitioners, organization of TM/CAM practitioners, etc.[341]

Three sets of information tools are suggested:

Development of Consumer Information

Even though public consumer information on CAM cannot compensate for poor 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

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[339]Countries with an *inclusive* health system: Canada, Germany, India, United States, Ukraine, etc.
[340]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 well-being? 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? *Ibid.*336 at Art. 1.3.
[341]*Ibid.*336 at Art. 1.4.

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.*"[342] Moreover, in accordance with the Guidelines to develop adequate consumer information on CAM use, national authorities should take the local type of healthcare system into account.[343]

General Principles and Activities for Ensuring Reliable CAM Information

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.[344] In order to reach as many CAM consumers as possible, consumer information has to be acceptable, understandable, and in plain and simple language.[345] Education programs on CAM use may be included in school

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[342]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. *Ibid.*336 at Art 2.1.

[343]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 African and Asian 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. *Ibid.*336 at Art. 2.2 & 2.3.

[344]*Ibid.*336 at Art. 3.1.

[345]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 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

curricula. It would be also useful to introduce pertinent regulations for CAM and put into place adequate surveillance systems.[346]

Topics to consider when developing consumer information promoting proper use of CAM

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.[347]

In conclusion, the guidelines provide simple, easy-to-follow tips on issues to look out 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.

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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.

[346]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. *Ibid.*336 at Art. 3.2 & 3.3.

[347]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. *Ibid.*336 at Art 4.1 & 4.4.

CHAPTER V

DRINKING WATER

Water is an essential nutrient for all known forms of life. For humans, water is the second most important life-depending constituent after oxygen. As much as 70% of the human body consists of water,[348] and the average adult must replace at least 2,7 liters of water it loses each day through perspiration, the kidney/bladder system, bowel movements, and the respiratory system.[349] Since water is the most consumed product, access to safe drinking water is crucial for consumer health. Bad quality, untreated water can be life threatening if contaminated with deadly bacteria and viruses.

The international community has always expressed its concern about the quality of potable water. The Director-General of the WHO has testified: *"Water (……) is one of the primary drivers of public health. (.....) which means that once we can secure access to clean water (....) for all people, irrespective of the difference in their living conditions, a huge battle against all kinds of diseases will be won."*[350]

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[348]Department of Environment Quality, "The Human Body-Water Relationship", on line: Michigan Government <http://www.deq.state.mi.us/documents/deq-wb-wws-HumanWaterReqs.pdf>.
[349]WHO, *Rolling Revision of the WHO Guidelines for Drinking-Water Quality*, 2004, at 9, on line: WHO <http://www.who.int/water_sanitation_health/dwq/nutwaterrequir.pdf>.
[350]WHO, *Information Products: Water, Sanitation and Health*, 2004, at 4, on line: WHO <http://www.who.int/water_sanitation_health/en/Watercatalogue2004.pdf>.

To ensure potable water safety and protect consumer health, the WHO has developed *The Guidelines for Drinking-water Quality*, (the Guidelines DQ),[351] a document that,[352] first, is "*intended to support the development and implementation of risk management strategies that will ensure the safety of drinking-water supplies through the control of hazardous constituents of water,*" and second, describes *"reasonable minimum requirements of safe practice to protect the health of consumers and/or derive numerical "guideline values" for constituents of water or indicators of water quality.*"[353]

The DQ guidelines address a wide range of issues related to water quality, such as microbial aspects; disinfection; chemical aspects; radiological aspects; acceptability aspects; surveillance and quality control; the role of public health and local authorities, water vendors, individual consumers; etc.

The guidelines define safe drinking-water as water that does not represent any significant risk to health over a lifetime of consumption. Moreover, the guidelines *"provide a scientific point of departure for national authorities to develop drinking-water regulations and standards appropriate for the national situation."*[354]

Although the DQ guidelines are primarily intended for water and health regulators, and the major part of the document is comprised with rather technical content, it may be also used by many others as a source of information on water quality, health, and effective management approaches.[355] In some instances, the guidelines directly

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[351]WHO, *Guidelines for Drinking-water Quality*, 2006, on line: WHO, <http://www.who.int/water_sanitation_health/dwq/gdwq0506.pdf>.
[352]In 1983–1984 and in 1993–1997, the WHO published the first and second editions of the *Guidelines for Drinking-water Quality,* which were revised in 1998, 1999, and 2002.
[353]*Ibid.351* at *Introduction* at 1.
[354]*Ibid.*351 at *Introduction* at 2.
[355]*Ibid.*351 at *Preface* at xvii.

address consumer-related issues.

Authorities must pay special attention to the Issue of aesthetical acceptability of water. In assessing the quality of drinking-water, consumers relay mostly on taste, odor, and general appearance of water. In some cases, the consumer may avoid aesthetically unacceptable, because of bad taste and/or odor, but otherwise safe drinking water in favor of more pleasant but potentially unsafe sources. As a result, consumer health can be put in danger. Drinking-water provided to consumers should not only be safe, but also acceptable in appearance, taste, and odor. The guidelines affirm that water should be free of taste and odor that would be objectionable to the majority of consumers.[356]

Affordability and accessibility of drinking water for consumers is another important issue. The high cost of water may force households to use alternative sources of water of poorer quality that represent a greater risk to health. Furthermore, high costs of water may reduce the volumes of water used by households, which in turn may influence hygiene practices and increase risks of disease transmission. The DQ guidelines suggest that authorities provide an availability of at least 20 liters of affordable drinking water per person per day within one kilometer of the user's dwelling.[357]

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[356] *Ibid.351* at Art. 10 at 210.
[357] *Ibid.*351 at Art 5.3.2 & 5.3.3 at 91 & 92.

CHAPTER VI

FOOD SAFETY

6.1 WHO documents and International Food Safety Authority Network

Health problems caused by unsafe food have been known since ancient times and still remain a key public health concern, since more than 200 diseases are transmitted through food.[358] Nowadays, in spite of all the new advanced techniques of food production, logistics, and major government efforts in this field, the occurrence of food-borne disease remains a significant health issue in both developed and developing countries.[359]

According to the WHO, each year 1.8 million people die because of contaminated food or water.[360]

Understanding the importance of consumer and food-handler education on food safety, the WHO has come out with a few documents related to this matter.

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[358]Since *the Codex Alemintarius* covers most international standards and regulations on food safety, this section only reviews documents on food safety developed by the WHO.
[359]P.S. Mead, "Food-Related Illness and Death in the United States" (1999) 5 Emerging Infectious Diseases, Vol 5.
[360]WHO, "Food safety," on line: WHO <http://www.who.int/foodsafety/en/>.

The *Five Keys to Safer Food Poster*[361] provides easy-to-follow tips on safe food handling,[362] and the *Five Keys to Safer Food Manual*[363] suggests ways to communicate the message. The manual also provides tips on how to adapt the training program for different target groups (e.g., professional food handlers, consumers, children, and women).

The core messages of the poster are: (1) keep clean; (2) separate raw and cooked; (3) cook thoroughly; (4) keep food at safe temperatures; and (5) use safe water and raw materials. The poster has been translated into more than 40 languages and is being used to spread the WHO's food hygiene message throughout the world.[364]

The manual is divided into two sections. Section one provides background material that identifies a problem and provides useful information on microorganisms and the symptoms of food-borne disease.[365] Section two elaborates the core food safety information provided in the WHO Five Keys to Safer Food poster and suggests how to communicate these messages.[366] The WHO, in collaboration with national and international organizations, NGOs, public health institutions, consumers associations, local communities, industries, and academia, actively promotes the adaptation of the

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[361]WHO, *Five Keys to Safer Food Poster*, 2001, on line: WHO <http://www.who.int/foodsafety/publications/consumer/5keys/en/index.html>.

[362]The poster was devised by the WHO in the early 90s to replace the *Ten Golden Rules for Safe Food Preparation* handbook, when it became obvious that something simpler and more generally applicable was needed. In 2001, the WHO introduced the *Five Keys to Safer Food* poster that incorporates all the messages of the *Ten Golden Rules for Safe Food Preparation* under simpler headings that are more easily remembered.

[363]WHO, *Five Keys to Safer Food Manual,* 2006, on line: WHO <http://www.who.int/foodsafety/publications/consumer/manual_keys.pdf>.

[364]*Ibid.*363 at 4.

[365]*Ibid.*363 at 7 to11.

[366]The manual also includes evaluation forms. For the organizer and/or trainer, the manual includes forms which evaluate the demographics of the audience, the suitability of the adaptation process, and whether or not the training session achieved its goal. Forms for the participants evaluate food safety knowledge, and the attitude and behavior of the participants. Participants should complete the form before and after the training. *Ibid.*363 at 12 to 26.

Five Keys food hygiene protocol at the local level through educational projects.[367]

Food Safety Measures for Eggs and Foods Containing Eggs is an educational brochure for consumers as well as professional foodhandlers outlining safe procedures to follow when handling and preparing eggs and food containing eggs.[368]

20 Questions on Genetically Modified (GM) Food answers the most common consumer questions on GM food and assists the consumer in better understanding the health and environmental risks related to GM food.[369]

Ensuring Food Safety in the Aftermath of Natural Disasters provides guidelines for officials on how to ensure food safety in case of natural disasters and includes guidance for the development of simple messages to consumers involved in food preparation in disaster areas.[370]

The *Guide on Safe Food for Travelers, How to Avoid Illness Caused by Unsafe Food and Drink and What to do if you get Diarrhea,* helps travelers to avoid illnesses caused by unsafe food and drink by giving practical advice and basic hints on how to eat safely, and what to do in case of diarrhea.[371]

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[367]WHO, "Implementation of the five keys", on line: WHO <http://www.who.int/foodsafety/consumer/5keys/en/index1.html>.
[368]WHO, *Food Safety Measures for Eggs and Foods Containing Eggs*, on line: WHO <http://www.who.int/foodsafety/publications/consumer/eggs/en/index.html>.
[369]WHO, *20 Questions on Genetically Modified (GM) Food*, on line: WHO <http://www.who.int/foodsafety/publications/biotech/20questions/en/index.html>.
[370]WHO, *Ensuring Food Safety in the Aftermath of Natural Disasters, Consumer education and information*, at Art. 2, on line: WHO <http://www.searo.who.int/LinkFiles/List_of_Guidelines_for_Health_Emergency_FSAdvice-tsunami.pdf>.
[371]WHO, *Guide on Safe Food for Travelers, How to Avoid Illness Caused by Unsafe Food and Drink and What to do if you get Diarrhea*, 1997, on line: WHO <http://www.who.int/foodsafety/publications/consumer/travellers/en/index.html>; For a full list of publications on consumer education, see: *Consumer education publications*, on line: WHO <http://www.who.int/foodsafety/publications/consumer/en/index.html>.

Apart from providing food chain actors and consumers with relevant information, the WHO is also keen to make the enforcement of food laws throughout the world more effective and uniform.

The *International Food Safety Authorities Network* (INFOSAN)[372] was established in March 2004 "to promote the exchange of food safety information and to improve collaboration among safety authorities at the national and international levels."[373] With the main goal of preventing the international spreading of contaminated food through the food chain,[374] the INFOSAN complements and supports the *WHO Global Outbreak Alert and Response Network* (GOARN).[375] Under INFOSAN, each member state should institute two bodies nationally. First, INFOSAN Focal Points are the national officials appointed to serve as liaison between their counterpoints and the INFOSAN global network. INFOSAN Focal Points officials must receive data on food safety from INFOSAN and disseminate it to government and health officials, the food industry, NGOs, and other interested stakeholders.[376] Second, INFOSAN Emergency Contact Points are the national officials responsible for communicating with INFOSAN in the event of a food safety emergency, and for coordinating action on the national level.[377] In September 2007, 163 member states designated an

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[372]*International Food Safety Authorities Network*, on line: WHO <http://www.who.int/foodsafety/fs_management/infosan_1206_en.pdf>.

[373]INFOSAN is established by both the WHO and FAO.

[374]The food chain includes the following elements: production, processing, transportation, storage, and consumption.

[375]GOARN is a technical collaboration of existing institutions and networks for the rapid identification, confirmation, and response to outbreaks of international importance. Using technical and operational resources from scientific institutions in member states, the UN, and NGOs, GOARN contributes to global health security by combating the international spread of outbreaks, ensuring that appropriate technical assistance reaches affected states rapidly, and contributing to long-term epidemic preparedness and capacity building. See more *GOARN,* on line: WHO <http://www.who.int/csr/outbreaknetwork/en/>.

[376]WHO, *International Food Safety Authorities (INFOSAN) Users Guide*, 2006, at Art. 4, at 2, on line: WHO <http://www.who.int/foodsafety/publications/fs_management/INFOSAN_User_Guide_Final.pdf>.

[377]*Ibid.* at Art. 5 at 4.

INFOSAN Emergency Contact and INFOSAN Focal Points.

6.2 The Food and Agriculture Organization of the United Nations and the Codex Alimentarius Commission

The first codex of food commodity standards, *Codex Alimentarius Austriacus,* was developed between 1897 and 1911 in the Austro-Hungarian Empire.[378] Although lacking legal force, this codex was used as a reference tool by the courts.[379] In the 1940s, when new and more sensitive analytical tools became available and consumers received precise information about the nature of food and potential hazardous problems related to it, public concern regarding the safety of food grew. With the appearance of well-organized and informed worldwide consumer groups, the pressure on national and international governance to protect consumers from poor-quality and hazardous food intensified.[380] As a response, the International Community established the international food safety network, with the key instrument being the *Codex Alimentarius.*

In 1945, in Quebec City, Canada, the first session of The Food and Agriculture Organization Conference established *The Food and Agriculture Organization* (FAO).[381] The FAO is the main agency within the United Nations specializing in all

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[378] Since ancient times, state authorities have tried to protect the consumer from dishonest practices in food production and sale. Ancient Egypt, Athens, and Rome had certain rules for sale, labeling, and food quality control. Later, in the Middle Ages, some European counties introduced laws concerning the quality of certain food products. In the second half of the nineteenth century, the first general food laws were adopted and elements of the basic food control system were put in place. During the same period, scientific tools were used for the first time to test food quality and safety. FAO, "Understanding the Codex Alimentarius", at 5 & 6, on line: FAO <ftp://ftp.fao.org/codex/Publications/understanding/Understanding_EN.pdf>.

[379] *Ibid.* at 6 & 7.

[380] *Ibid.* 378 at 8.

[381] FAO, "A short history of FAO", on line: FAO <http://www.fao.org/UNFAO/about/history_en.html>.

aspects of food quality and safety, and in all stages of food production, from harvesting and storage to processing and distribution. With the principal goal "*to make sure people have regular access to enough high-quality food to lead active, healthy lives,*"[382] the FAO has protected the interests of consumers around the globe for more then 60 years.

Within the FAO network, consumer protection has been segmented as an independent matter and attributed to the *FAO Nutrition and Consumer Protection Division* within the *Agriculture and Consumer Protection Department.*[383] Among others, the principal aims of the *FAO Nutrition and Consumer Protection Division* are promoting food safety and quality, and focusing on consumer protection and fair practices in food trade. To achieve these goals, the FAO promotes the establishment and operation of national regulatory frameworks compatible with international requirements. It provides technical advice to ensure food quality and safety throughout the food chain to all interested parties, provides scientific assessments of food safety, including the assessment of food additives, chemical and microbiological contaminants, naturally occurring toxicants, etc.[384]

The primary universal instrument that helps the FAO to achieve its objectives is the Codex Alimentarius.

The Codex Alimentarius Commission was created in 1963 by the FAO and WHO to develop food standards, guidelines, and related texts, such as codes of practice under the Joint FAO/WHO Food Standards Programme.[385] The main purposes of this Program are: protecting the health of consumers and ensuring fair practices in the

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[382]FAO, *FAO's mandate*, on line: FAO <http://www.fao.org/UNFAO/about/mandate_en.html>.
[383]FAO, *Agriculture and Consumer Protection Department*, on line: FAO <http://www.fao.org/ag/>.
[384]FAO, *Food Safety and Quality*, on line: FAO <http://www.fao.org/ag/agn/index_en.stm>.
[385]FAO, *Codex Alimentarius*, on line: Codex Alimentarius net <http://www.codexalimentarius.net/web/index_en.jsp>.

food trade; promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations; determining priorities and initiating and guiding the preparation of draft standards through and with the aid of appropriate organizations; finalizing elaborated standards and publishing them in a Codex Alimentarius either as regional or world wide standards, together with international standards already finalized by other international governmental and non-governmental organizations, wherever practicable; and amending published standards, as appropriate, in light of developments.[386]

Membership in the Commission is open to all member nations and associate members of the FAO and the WHO that are interested in the international food standards.[387] Moreover, any member nation that is not a member of the Commission but has a special interest in the work of the Commission may attend sessions of the Commission and of its subsidiary bodies as observers.[388]

Today, more than 160 countries are members of the Codex Alimentarius Commission (CAC).[389] The Executive Committee of the Commission is formed by adequate representation of the various geographical areas of the world and acts as the executive body of the Commission between sessions.[390] When necessary for the accomplishment of its work in the finalization of draft standards and when funds are available, the Commission may establish two types of subsidiary bodies: Codex Committees for the preparation of draft standards for submission to the Commission, when intended for worldwide use; or Coordinating Committees for regions or groups

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[386]FAO, *Statutes of the Codex Alimentarius Commission*, *Codex Alimentarius Commission - 16th Procedural Manual, Codex Alimentarius,* 2006, at Art. 1 at 3, on line: FAO <ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_16e.pdf>.
[387]*Ibid.*386 at Art. 2 at 3.
[388]A member nation that is not a member of the Commission may submit memoranda and participate in discussions boes does not have voting rights; *Ibid.*386 at Art.3 at 3.
[389]Codex Alimentarius, *Membership of the Commission*, on line: Codex Alimentarius <http://www.codexalimentarius.net/web/members.jsp?lang=EN>.
[390]*Ibid.*386 at Art. 6 at 4.

of countries that exercise general coordination in the preparation of standards relating to such regions or groups of countries.[391] To date, the Commission has established: codex committees on *general subjects* such as food hygiene, food additives and contaminants, food labeling, etc.; codex committees on *commodities* such as processed fruits and vegetables, milk and milk products, natural mineral waters, fish and fishery products, etc. In addition, to accelerate development of standards and guidelines on certain subjects, for a fixed period of time, the CAC has formed the Codex ad hoc Intergovernmental Task Force.[392]

The Commission has also set up six FAO/WHO coordinating committees for Africa, Asia, Europe, Latin America, the Near East, and North America.[393]

International non-governmental organizations (INGOs) may take part in the work of the Commission, albeit only with the status of observer and always without the right to vote.[394] To be eligible for observer status, an INGO should have a consultative status in the FAO or the WHO, or must be an INGO that has covered a part or all of the Commission's field of activity for the previous three years, that has a permanent

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[391]FAO, *Rules of Procedure of the Codex Alimentarius Commission, Rule XI, Codex Alimentarius Commission - 16th Procedural Manual*, 2006, at 14, on line: FAO <ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_16e.pdf>.

[392] To date, the Commission has established a few ad hoc intergovernmental task forces: Task Force on Animal Feeding, 1999-2004; Task Force on Foods Derived from Biotechnology, 1999-2003 and 2005-2009; Task Force on Fruit and Vegetable Juices, 1999-2005; etc.

[393]Geographically, the committees are scattered around the world. Canada hosts two committees: *Codex Committee on Food Labeling* and *Codex Committee on Vegetable Proteins*; For a complete list of subsidiary bodies, see: *Subsidiary bodies of the Codex Alimentarius Commission*, *Ibid.*386 at 124-160.

[394]The reason the CAC collaborates with INGOs is: to secure expert information, advice, and assistance; to enable organizations that represent important sections of public opinion to express the views of their members; and to play an appropriate role in ensuring the harmonizing of intersectoral interests among the various sectoral bodies concerned in a country, regional, or global setting. FAO, *Principles Concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission,Codex Alimentarius Commission - 16th Procedural Manual*, 2006, at Art. 1 at 34 on line: FAO <ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_16e.pdf>.

directing body and secretariat, and that it or its members carry out activities in at least three countries.[395] INGOs that meet such criteria may obtain observer status that grants them certain privileges and obligations.[396]

Since 1965, consumer organizations have participated in the work of the Commission as observers.[397] In recent years, there has been some dialogue regarding the involvement of consumer organizations in the decision-making process. Nevertheless, although the Commission agreed to continue working in close cooperation with consumer representatives, the latter still do not have the right to vote.[398]

All decisions made by the CAC are solely based on scientific evidence. The CAC does not conduct scientific examinations and relies on the opinions of scientific experts of the FAO and the WHO[399] who are independent of the CAC and its subsidiary bodies. Nevertheless, the meetings of the expert bodies normally take the advice of the CAC into account.[400]

With the ultimate goal of establishing sound internationally agreed-upon guidelines for national food control systems, the CAC pursues six objectives: promoting a sound regulatory framework; promoting the widest and most consistent application of

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[395] *Ibid.*386 at Art. 3 at 34 & 35.

[396] INGOs with observer status are entitled to send an observer (without the right to vote) to sessions of the Commission and specified subsidiary bodies; to participate in discussions; to receive from the secretaries of the subsidiary bodies, in advance of the session, all working documents and discussion papers; to circulate their views in writing, without abridgement; etc. For a full list of privileges and obligations, see *Ibid.*386 at Art. 5 at 36 &37.

[397] In the spite of their status, consumer organizations have had a very significant impact on standards in many areas, including the safety of genetically engineered food, infant formula, mercury in fish, pesticide residue, etc. For more, see Consumer International "Codex," on line: Consumer International <http://www.consumersinternational.org/Templates/Internal.asp?NodeID=94643&int1stParentNodeID=89651&int2ndParentNodeID=89689>.

[398] *Ibid.*378 at 28.

[399] Joint FAO/WHO Expert Committees on Food Additives, the Joint FAO/WHO Meetings on Pesticide Residues and the Joint FAO/WHO Expert Meeting on Microbiological Risk Assessments.

[400] FAO, *Codex Alimentarius Commission Strategic Framework 2003-2007*, at 4, on line: <http://www.fao.org/DOCREP/004/Y2361e/y2361e00.htm>.

scientific principles and risk analysis; promoting linkages between the Codex and other multilateral regulatory instruments and conventions; enhancing capacity to respond effectively and expeditiously to new issues, concerns, and developments in the food sector; promoting maximum membership and participation; and promoting maximum application of Codex standards.[401]

To date, the Codex Alimentarius contains hundreds of standards, recommended codes, and guidelines. Only a few of them are referred to below.

a) Commodity standards

There are more than 200 international standards on commodities. They cover a wide spectrum of food products, from common cheese and chocolate to exotic gari and carambola.[402]

Content of the commodity standards may vary and depends on the type of product in question. Nevertheless, in general, commodity standards follow a similar pattern, and the examination of one will give a general idea of the entire system. Even if some data included in commodity standards appears too technical, overall information provided is quite simple to follow and comprehend.

One illustration thereof is the *Codex Standard for Chocolate and Chocolate Products* (CSCCP).

The *Scope* of the standard provides information on the product to which the standard applies. For example, the CSCCP applies to chocolate and chocolate products prepared from cocoa and cocoa materials with sugars and may contain sweeteners,

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[401] *Ibid.* at 5 to 11.
[402] There are a few regional standards on commodities.

milk products, flavoring substances, and other food ingredients, and intended for human consumption.[403]

The second part, *Description and Essential Composition Factors,* is divided into two sections. The first section describes the various chocolate types and their composition.[404] For every type, the standard provides data on composition.[405]

The second section describes forms of chocolate. This section includes three forms: *Chocolate Vermicelli and Chocolate Flakes, Filled Chocolate,* and *Chocolate or Praline.* For each form the codex gives a physical description as well as composition.[406]

The third part of the standard sets up rules about *food additives* which may be contained in chocolate, such as *acidity regulators, emulsifiers, flavoring agents, sweeteners, glazing agents, antioxidants, colorants, bulking agents, and processing aids.* For some additives, the standard prescribes maximum levels.[407]

The fourth part includes some provisions regarding hygiene and prescribes that products should be prepared and handled in accordance with the appropriate sections

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[403]Codex Alimentarius, *Codex Standard for Chocolate and Chocolate Products* (1981) CODEX STAN 87-1981, Rev. 1, 2003, Art. 1, on line: Codex Alimentarius <http://www.codexalimentarius.net/web/standard_list.do?lang=en>.

[404]There are six types of chocolate: *Chocolate, Sweet Chocolate, Couverture Chocolate, Milk Chocolate, Family Milk Chocolate, Milk Chocolate Couverture;* and four types of chocolate products: *White Chocolate, Gianduja Chocolate, Gianduja Milk Chocolate, Chocolate para mesa.*

[405]For example, *chocolate* shall contain, on a dry matter basis, not less than 35% total cocoa solids, of which not less than 18% shall be cocoa butter and not less than 14% fat-free cocoa solids. For *Sweet Chocolate,* the content of total cocoa solids shall be not less than 30%, of which at least 18% shall be cocoa butter and at least 12% fat-free cocoa solids.

[406] A *Chocolate* or *Praline* designates a product in a single mouthful size, where the amount of the chocolate component shall not be less than 25% of the total weight of the product. The product shall consist of either filled chocolate or a single or combination of the chocolates. This part as well includes a *Summary Table of Compositional Requirements*, which integrates all information of the section and presents it in easy-to-follow form. *Ibid.*403 at Art. 2.

[407]*Ibid.*403, Art. 3.

of the *Recommended International Code of Practice – General Principles of Food Hygiene* and other relevant Codex texts, such as *Codes of Hygienic Practice and Codes of Practice*. Moreover, the products should comply with any microbiological criteria established in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods.*[408]

The fifth part specifies requirements for labeling. In addition to the requirements of the *Codex General Standard for the Labeling of Prepackaged Foods,*[409] the following information has to be provided to consumer: the name of the product as prescribed in Part Two; and ingredients, those of which that are especially aromatic and characterize the product should form part of the name of the product (e.g., Mocha Chocolate). A label should have a declaration of the minimum cocoa content.[410]

The final section contents provisions regarding methods of analysis and sampling.[411]

b) *Recommended codes and guidelines*

Other groups of standards cover questions of labeling, contaminants and toxins in food, general methods of analysis for food additives and pesticide residues, etc. Recommended codes of practice and guidelines cover questions of hygiene, processing, handling, marketing, storage, transportation, inspection, maximum residue limits for certain substances, etc.

Most of them, such as the *Guidelines for the Use of Non-Meat Protein Products in Processed Meat and Poultry Products, Recommended International Code of Practice*

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[408]*Ibid.*403, Art. 4.
[409]Infra note 413.
[410]Except for *White Chocolate; Ibid.*403 at Art. 5.
[411]*Ibid.*403 at Art. 6.

for the Packaging and Transport of Tropical Fresh Fruit and Vegetable, have very specific technical content related to food production, handling, and distribution.

All this regulatory armada benefits the consumer greatly by enhancing the quality of food. Nevertheless, some codes and guidelines have a higher level of pertinence to consumer protection. These mainly concern food labeling.

General standards for food labeling

Nowadays, more and more imported food products occupy our store shelves. Such products may often confuse the consumer because of their new or exotic nature. Others seem to be familiar foods but may be produced differently and contain dissimilar ingredients. It may be just a minor frustration for the consumer if such products are of a different quality than local products; however, products may threaten the consumer health if they contain unexpected or foreign products and the consumer has hypersensitivity to them. In this situation, only a proper label may help the consumer to avoid confusion and adverse reactions. Since the label is often the only source of reliable information on content and features of the food product, it is important as ever to have a global approach to this matter. Taking into account that proper labeling is a key mechanism of consumer protection, the CAC has done a significant amount of work in this field. There are quite a few standards for labeling that follow a fairly similar pattern, and a brief look at one of them may sketch an idea of their general content.[412]

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[412]*General Standard for the Labeling of Prepackaged Foods; Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods; Guidelines on Nutrition Labeling; Standard for Labeling of and Claims for Foods for Special Medical Purposes; Standard for Labeling of and Claims for Prepackaged Foods for Special Dietary Use; General Standard for the Labeling of Food Additives when sold as such.* For a list of standards regarding labeling, see Codex Alimentarius, *Current Official Standards*, on line: Codex Alimentarius <http://www.codexalimentarius.net/web/standard_list.do?lang=en>.

General Standard for the Labeling of Prepackaged Foods

The General Standard for the Labeling of Prepackaged Foods[413] (Standard for Labeling) applies to the labeling of all prepackaged foods to be offered as such to the consumer or for catering purposes.[414]

Part two of the standard includes definitions and terms.[415] The general principles set up two basic rules. First, prepackaged food shall not be described or presented on any label in a manner that is false, misleading and deceptive, or is likely to create an erroneous impression regarding its character in any respect. And second, prepackaged food shall not be described or presented on any label by words, pictorial or other means which refer to or are suggestive either directly or indirectly of any other product with which such food might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.[416]

The section entitled *Mandatory Labeling of Prepackaged Foods* describes what kind of information should appear on the label of prepackaged foods. For example, the specific and not the generic name of the food should appear on the label and should indicate the true nature of the food. Except for single ingredient foods, a list of ingredients should be declared on the label where ingredients are listed in descending

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[413]Codex Alimentarius, *General Standard for the Labelling of Prepackaged Foods* (1985) CODEX STAN 1-1985 (Rev. 1-1991), on line: Codex Alimentarius <http://www.codexalimentarius.net/web/standard_list.do?lang=en>.

[414]*Ibid.*413 at Art. 1 at 1.

[415]For example, in accordance with the standard, "*Consumer*" means a person or a family purchasing and receiving food in order to meet their personal needs, and "*Food*" means any substance, whether processed, semi-processed, or raw, that is intended for human consumption, and includes drinks, chewing gum, and any substance that has been used in the manufacturing, preparation, or treatment of "food." Excluding cosmetics or tobacco or substances used only as drugs. *Ibid.* 432 at Art. 2 at 1 & 2.

[416]*Ibid.*413 at Art. 3 at 2.

order of ingoing weight.[417] The Code sets up specific rules for food additives.[418] The net contents shall be declared in the metric system: for liquid foods, by volume; for solid foods, by weight; for semi-solid or viscous foods, either by weight or volume.[419] The label should also include: name and address of the manufacturer, packer, distributor, importer, exporter, and vendor, as well the country of origin, the producing factory, and the lot number.

The Standard sets up requirements for date marking and storage instructions.[420] If the product requires any special storage conditions, they should be declared on the label. To ensure correct usage of the food, the label should provide instructions for use.[421]

The *Additional Mandatory Requirements* section specifies that when the labeling of a food places special emphasis on the presence or low content of an ingredient, the percentage of the ingredient should be declared. Moreover, the label for food that has been treated with ionizing radiation should carry a written statement and international

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[417]Certain foods and ingredients known to cause hypersensitivity, such as cereals containing gluten, eggs, fish, milk, etc., should always be declared. If water or food ingredients obtained through biotechnology are ingredients of the product, they should appear on the label. Except for ingredients known to cause hypersensitivity, for some ingredients, if it would be more informative, the class name may be used. For example, any types of sucrose may be listed as "sugar," or any herbs or parts of herbs, if they do not exceed 2% by weight either singly or in combination in the food, may be listed as "herbs" or "mixed herbs."

[418]For food additives falling in the respective classes and appearing in the lists of food additives permitted for use in foods generally, the class titles should be used together with the specific name or recognized numerical identification as required by national legislation. There are 23 classes of food additives listed in the standard: *Sweeteners, Preservatives, Emulsifiers, Antioxidants, Bulking Agents, Acidity Regulators,* etc. See the list of food additive classes: *Ibid.*413 at Art. 4 at 4 & 5.

[419]Food packed in a liquid medium should carry a declaration in the metric system of the drained weight of the food.

[420]For a product with a minimum durability of less than three months, the label should indicate the day and the month, and for a product with a minimum durability of more than three months, the month and the year for such products. The date should be declared by the words: "Best before ..." where the day is indicated and "Best before end .." in other cases. The day, month, and year shall be declared in decrypted numerical sequence, except that the month may be indicated by letters in those countries where such use will not confuse the consumer. Nevertheless, for some products such as fresh fruits and vegetables, wines, vinegar, solid sugars, chewing gum, etc., an expiration date may not be required. The full list includes nine groups of products.

[421]*Ibid.*413at Art. 4 at 2 to 6.

food irradiation symbol.[422]

In accordance with *Exemptions Form Mandatory Labeling Requirements*, if the largest surface area of the package is less than 10 cm^2, with the exception of spices and herbs, some requirements for labeling may be omitted.[423]

As for *Optional Labeling,* any additional information displayed on the label should not mislead the consumer in any way and as well should not conflict with the mandatory requirements of the standard.[424] In conclusion, the standard specifies certain requirements for the presentation of mandatory information.[425]

Guidelines on Nutrition Labeling

The purpose of these guidelines is to ensure that nutrition labeling is effective: in providing the consumer with information about a food so that a well considered choice of food can be made; in providing a means for conveying information of the nutrient content of a food product on the label; in encouraging the use of sound nutrition principles in the formulation of foods which would benefit public health; in providing the opportunity to include supplementary nutrition information on the label.[426]

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[422]*Ibid.*413 at Art. 5 at 6 & 7.
[423]*Ibid.*413 at Art. 6 at 7.
[424]*Ibid.*413 at Art. 7 at 7.
[425]First, the label should not become separated from the container. Second, the statement presented on the label should be clear, prominent, indelible, and readily legible by the consumer under normal conditions of purchase and use. Finally, if the language on the original label is not acceptable to the consumer for whom it is intended, a supplementary label containing the mandatory information in the required language accurately reflecting the original label may be used instead of relabeling. *Ibid.*413 at Art. 8 at 7.
[426]Codex Alimentarius, *Guidelines on Nutrition Labelling* (1985) CAC/GL 2-1985, *Purpose of guidelines* on line: Codex Alimentarius <http://www.codexalimentarius.net/web/standard_list.do?lang=en>.

In accordance with the guidelines, *Nutrition labeling* is a description intended to inform the consumer of the nutritional properties of the food. Nutrition labeling consists of two components: the nutrient declaration and the supplementary nutrition information.[427] The guidelines set up requirements for the nutrient declaration on energy value, protein, vitamins, etc.[428] To increase the consumer's understanding of the nutritional value of their food and to assist them in interpreting the nutrient declaration, supplementary nutrition information may be added.[429] Such information on labels should be accompanied by consumer education programs to increase consumer understanding and use of the information.[430]

Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods

Production of organic food is a fast-growing billion-dollar business. Although this segment of the food industry will not dominate the market in the short term, nevertheless, it provides the consumer not only a healthy choice, but it also shows ways the international community may shift the consumption and production pattern towards a sustainable one. Organic food, so popular in developed countries, often is produced by farmers in developing countries where different standards to certifying food as organic may apply. As a result, the international harmonization of production

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[427] If the nutrient declaration is used, the mandatory declaration requires: energy value; the amounts of protein, available carbohydrates and fat; the amount of any other nutrient for which a nutrition or health claim is made; and the amount of any other nutrient considered to be relevant for maintaining a good nutritional status. In addition to the mandatory declaration, vitamins and minerals for which recommended intakes have been established and/or which are of nutritional importance in the country concerned should also be declared. *Ibid.*426, Art. 2, 3, p.2, 3.

[428] Information on energy value and amounts of protein, carbohydrates, and fat in the food should be expressed respectively in kJ and kcal and in g per 100 g or per 100 ml. Information on vitamins and minerals should be expressed in metric units and/or as a percentage of the Nutrient Reference Value per 100 g or per 100 ml. If the package contains only a single serving portion, information may be expressed per package.

[429] *Supplementary nutrition information* should be optional and should only be given in addition to, and not in place of, the nutrient declaration.

[430] *Ibid.*426, Art. 4, p.5.

and handling protocols for this segment of the food industry is important as ever.

From the point of view of facilitating trade and preventing misleading claims, the Codex Alimentarius Commission adopted the *Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods* in 1999.[431] Among other things, the principal aim of these guidelines is to protect consumers against deception and fraud in the marketplace and unsubstantiated product claims.[432]

In accordance with the guidelines, there are four conditions when labeling and claims of a product may refer to organic production methods. First, when such indications show clearly that they relate to a method of agricultural production. Second, when the product was produced or imported in accordance with the requirements of these guidelines. Third, when the product was produced or imported by an operator who is subject to inspection measures set out in the guidelines. Fourth, when the labeling refers to the name and/or code number of the officially recognized inspection or certification body to which the operator who has carried out the production or the most recent processing operation is subject.[433]

As we can see the standards of the Codex Alimentarius contain fairly technical content. Nevertheless, they are quite easy to read and understand even for consumers with basic education. As a result, such standards may be used as references by all interested parties: governments, industry, consumer organizations,

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[431]Codex Alimentarius, *Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods* (1999) GL 32 – 1999, on line: Codex Alimentarius <http://www.codexalimentarius.net/web/standard_list.do?lang=en>.

[432]This document sets out the principles of organic production for all stages of the food chain, from cultivation and processing to transportation and marketing. The guidelines include provisions regarding the concept of organic production, descriptions and definitions, labeling and claims, rules of production, and preparation, inspection, and certification systems and import control. The guidelines apply to unprocessed plants and plant products, livestock and livestock products, and processed agricultural crop and livestock product, if they carry, or are intended to carry, descriptive labeling referring to organic production. *Ibid.* at *Foreword*, at 1 & at Art. 1 at 4.

[433]*Ibid.*431 at Art. 3 at 8 to 11.

and consumers. In contrast to the standards developed by industry or ISO, the Codex Alimentarius standards are accessible on line and free to use. However, since they are only soft law, they may be overlooked by industry or governments. Conversely, consumer organizations and consumers may always use them as a handbook when questions or disputes about food quality or safety arise.

CHAPTER VII

INTERNATIONAL CARRIAGE

7.1 Convention for the Unification of Certain Rules for International Carriage by Air (Montreal Convention 1999)

As early as 1929, the Convention for the Unification of Certain Rules Relating to International Carriage by Air was signed at Warsaw.[434]

It is a unique document in many ways. First, this international convention was the first to admit that users' interests had to be protected, long before the international community had recognized consumer rights. Second, some provisions of the convention address subjects that can hardly ever be found in international sources of consumer protection law. Finally it has binding nature.

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[434]The Warsaw Convention applies to all international carriage of persons, luggage, or goods performed by aircraft for reward or free of charge. The convention applies equally to a carriage performed by a sole air carrier or by several successive air carriers. This work will not discuss that part of the convention related to international cargo operations, and it will exclusively focus on consumer-related provisions regarding terms for passenger and luggage tickets and liability of carrier; *Convention for the Unification of Certain Rules Relating to International Carriage by Air, Signed at Warsaw on 12 October 1929 (Warsaw Convention)*, on line: Faculty of Law, the University of Oslo <http://www.jus.uio.no/lm/air.carriage.warsaw.convention.1929/portrait.pdf>.

Passenger ticket

In accordance with Article 3 of the Warsaw Convention, to carry passengers the carrier must deliver a passenger ticket that includes the following information: the place and date of issue; the place of departure and of destination; the agreed stopping places; the name and address of the carrier or carriers; and a statement that the carriage is subject to the rules relating to liability established by the Convention. The absence or loss of the passenger ticket does not affect the existence or the validity of the contract of carriage.[435]

Luggage ticket

For the carriage of luggage, except hand luggage, the carrier must deliver a luggage ticket in duplicate, one part for the passenger and another part for the carrier.[436] The absence or loss of the luggage ticket does not affect the existence or the validity of the contract of carriage.[437]

Liability of the carrier

The carrier is liable for damage sustained in the event of the death or any injury suffered by a passenger, if the damage is caused by an accident that takes place on board the aircraft or during embarking/disembarking.[438] The carrier is also liable for

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[435] *Ibid.*434 at Art. 3 at 1 & 2.
[436] The luggage ticket shall include the following information: the place and date of issue; the place of departure and of destination; the name and address of the carrier or carriers; the number of the passenger ticket; a statement that delivery of the luggage will be made to the bearer of the luggage ticket; the number and weight of the packages; the amount of the value declared; a statement that carriage is subject to the rules relating to liability established by the Warsaw Convention.
[437] *Ibid.*434 at Art. 4 at 2 & 3.
[438] *Ibid.*434 at Art. 17 at 6.

damage caused by delay in the carriage of passengers by air.[439] The liability of the carrier for each passenger is limited to the sum of 125,000 francs (approximately US$10,000), if the carrier and the passenger do not agree to a higher limit of liability.[440] Any provision tending to relieve the carrier of liability or to fix a lower limit shall be null and void, but the nullity of any such provision does not involve the nullity of the whole contract.[441]

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,[442] and if the carrier proves that the damage was caused by or contributed to by the negligence of the injured person.[443]

Similar rules apply to luggage. Here, the carrier's liability is limited to 250 francs per kilogram, if the carrier and passenger do not agree to a higher value and a special declaration of the value is not delivered. The liability of the carrier for carry-on luggage is limited to 5,000 francs per passenger.[444]

As for an action for damages, the plaintiff or his/her legal representative[445] may file it within two years[446] either before the court having jurisdiction where the carrier is ordinarily resident, or has Its principal place of business, or the place the contract

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[439]The convention does not establish limits of liability in case of delay. *Ibid.*434 at Art. 19 at 7.
[440]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.
[441]*Ibid.*434 at Art. 23 at 7.
[442]*Ibid.* 455 at Art. 20 at 7.
[443]In the second case, the courts may exonerate the carrier wholly or partly from its liability; *Ibid.*434 at Art. 21 at 7.
[444]*Ibid.*434 at Art. 22 at 7.
[445]*Ibid.*434 at Art. 27 at 8 & 9.
[446]*Ibid.*434 at Art. 29 at 9.

was made, or before the court having jurisdiction at the place of destination.[447]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 $US20,000). Nevertheless, the protocol did not change the liability limit of the carrier for luggage and carry-on luggage.[448]

During the 70s, the international community undertook some efforts to amend the Warsaw Convention. The Guatemala Protocol in 1971 introduced some new provisions on airline liability for passenger claims that were later integrated into the Montreal Protocol 3 (1975). However, neither instrument has come into force.[449]

The large-scale development of air transport and use thereof by consumers does call for further amendments to the Warsaw Convention. Nowadays, more and more travelers fly to overseas destinations. In 2006 alone, more than 655 million air passengers were bound for international destinations.[450]

A revolutionary step in the evolution of rules of international carriage by air has become the *Convention for the Unification of Certain Rules for International Carriage by Air,* signed at Montreal on 28 May 1999 (Montreal Convention).[451]

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[447]*Ibid.*434 at Art. 28 at 9.
[448]*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)*, at Art. XI, on line: McGill <http://www.mcgill.ca/files/iasl/hague1955.pdf>.
[449]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.
[450]IATA, "Fact Sheet: IATA - International Air Transport Association," on line: IATA <http://www.iata.org/pressroom/facts_figures/fact_sheets/iata.htm>.
[451]*Convention for the Unification of Certain Rules for International Carriage by Air Signed at Montreal on 28 May 1999*, on line: McGill <http://www.mcgill.ca/files/iasl/montreal1999.pdf>.

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.[452] While maintaining the core provisions of the Warsaw Convention, the Montreal Convention modified and clarified certain stipulations, in particular regarding liability of the carrier.

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.*"[453]

As for rules regarding passenger and baggage carriage documents, the convention has made only minor alterations.[454] The Montreal Convention did, however, introduce important changes 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 able 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[455] (SDR) for each passenger in case of death or injury of passengers.[456] Under the 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

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[452]Today, 80 countries are parties to the convention, see ICAO, on line: ICAO <http://www.icao.int>.
[453]*Ibid.*451 at *Preamble.*
[454]*Ibid.*451 at Art. 3.
[455]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 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. On 15 October 2007 1SDR= 1.55 USD. For more on SDR, see on line: IMF <http://www.imf.org/external/>.

[456]*Ibid.*451 at Art. 21.1.

was solely due to the negligence or other wrongful act or omission of a third party.[457]

The document also specifies a limit of compensation in case of a delay, when the liability of the carrier for each passenger is limited to 4,150 SDR.[458] In the carriage of baggage, the liability of the carrier is limited to 1,000 SDR[459] unless the carrier and the passenger had agreed a higher sum.[460]

In addition, the court may award the plaintiff, in accordance with national law, partial or whole legal expenses.[461] 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.[462]

The convention has also introduced 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) or the contracting carrier (who only makes a contract of carriage).[463]

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[457]*Ibid.*451 at Art. 21.2.
[458]Approximately US$6,250; *Ibid.*451 at Art. 22.
[459]Approximately US$1,500
[460]The carrier is not liable if the damage resulted from the nature of the baggage; *Ibid.*451 at Art. 22; In accordance with Article 24, the limits of liability shall be reviewed at five-year intervals.
[461]*Ibid.*451 at Art. 22.
[462]*Ibid.*451 at Art. 28.
[463]*Ibid.*451 at Art. 45.

7.2 Athens Convention relating to the Carriage of Passengers and their Luggage by Sea, 1974

The time when most long-distance international travel was accomplished by ship is long over, since air traveling has become widely accessible to the general population. Nevertheless, the problem of maritime passenger protection remains current, as in recent years the cruise industry has showed an unprecedented rate of growth. The US alone has reported *2,100%* growth in this sector over the last 35 years, with 12 million passengers having taken a cruise vacation in 2006 versus only 500,000 in 1970.[464]

Statistics also show that more and more maritime passengers have become victims of crime or fatal circumstances. In 2006, worldwide 17 people fell overboard or went missing from cruise ships and hundreds more reported being victims of crime.[465] This is why the presence of international instruments, under which the passenger and/or his family may seek protection in case of accidental death of or injury to a passenger and the loss of or damage to his luggage, is important as ever.

Since 1974, the *Athens Convention relating to the Carriage of Passengers and their Luggage by Sea* (Athens Convention) [466] has been the only instrument on the international stage establishing a regime of liability for damage suffered by passengers carried on a seagoing vessel.[467] The convention applies to any

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[464]Cruise Lines International Association, "Profile of the U.S. Cruise Industry", on line: Cruise Lines International Association <http://www.cruising.org/press/sourcebook2007/profile_cruise_industry.cfm>.

[465]"Cruise industry's dark waters" *Walt Disney World News* (24 January 2007), on line: <http://www.wdwinfo.com/news/article_00964.htm>.

[466]*Athens Convention relating to the Carriage of Passengers and their Luggage by Sea*, 1974, Art. 2, on line: Admiralty and Maritime Law Guide <http://www.admiraltylawguide.com/conven/passengers1974.html>.

[467]The convention consolidated and harmonized two earlier Brussels conventions (1961,1967) dealing with passengers and luggage.

international carriage if: the ship is registered in a state party to the convention, or the contact of carriage is made in a state party to the convention, or the place of departure or destination is in a state party to the convention. The convention covers passengers and their luggage[468] 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.[469]

In accordance with Article 3.1, *"the carrier[470] 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[471] 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."* If the national law of member states has not fixed a higher limit of liability for its carriers, the convention limits the liability of the carrier for the death of or personal injury to a passenger to 700,000 francs.[472]

As for the loss of or damage to luggage, the convention limits the carrier's liability, depending on whether the loss or damage occurred in respect of cabin luggage,[473] of a vehicle and/or luggage carried in or on it,[474] or in respect of other luggage.[475]

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[468]Luggage includes: articles, vehicles, and live animals. *Ibid.*466 at Art. 1.5.
[469]*Ibid.*466 at Art. 1.8.
[470]The carrier remains liable even though all or part of the carriage has been entrusted to a performing carrier. *Ibid.*466 at Art. 4.
[471]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. *Ibid.*466 at Art. 5.
[472]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. *Ibid.*466 at Art. 7 & 9.
[473]12,500 francs per passenger.
[474]50,000 francs per vehicle.
[475]18,000 francs per passenger. *Ibid.*466 at Art. 8; Generally, within the scope of this convention any actions for damages may be taken within two years. *Ibid.*466 at Art. 16.

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.[476] However, in most cases the burden of proving that the incident was due to the fault or neglect of the carrier, lies with the claimant.[477] 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 void the contract of carriage.[478]

Some 32 countries are currently party to the Athens Convention, and they represent 40% of the world tonnage.[479]

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*[480] has made the unit of account the Special Drawing Right (SDR).[481]

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[476]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. *Ibid.*466 at Art. 17.1.

[477]*Ibid.*466 at Art. 3.2 & 3.3; The carrier may be released wholly or partly from its liability by court if it proves that the death of or personal injury to a passenger or the loss of or damage to his/her luggage was caused or contributed to by the fault or neglect of the passenger. *Ibid.*466 at Art. 6.

[478]*Ibid.*466 at Art. 18.

[479]International Maritime Organization (IMO), *Summary of Conventions (as at 30 September 2007)*, on line: IMO <http://www.imo.org/Conventions/mainframe.asp?topic_id=247>.

[480]*Protocol to the Athens Convention relating to the Carriage of Passengers and their Luggage by Sea of 13 December 1974*, on line: Admiralty and Maritime Law Guide <http://www.admiraltylawguide.com/conven/protopassengers1976.html>; The Protocol 1974 has 25 contracting states, which represent 40% of world tonnage. *Ibid.*479.

[481]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. The liability of the carrier for the loss of or damage to cabin luggage is 833 SDR (about US$1,250) per passenger. The liability of the carrier for the loss of or damage to vehicles including all luggage carried in or on the vehicle shall in no case exceed 3,333SDR (about US$5,000) of account per vehicle, per carriage. *Ibid.*480 at Art. 2.

In recent years, 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*[482] (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).[483]

The Protocol of 2002 to amend the Athens Convention relating to the Carriage of Passengers and their Luggage by Sea, 1974 (the Protocol 2002), introduced a few new features in the convention.[484] 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.[485]

Similar to the Montreal Convention, 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-major* 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

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[482]*Protocol of 1990 to amend the Athens Convention relating to the Carriage of Passengers and their Luggage by Sea, 1974,* on line: Admiralty and Maritime Law Guide <http://www.admiraltylawguide.com/conven/protopassengers1990.html>.

[483]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. *Ibid.* at Art. 2.

[484]*The Protocol of 2002 to amend the Athens Convention relating to the Carriage of Passengers and their Luggage by Sea, 1974,* , on line: European Maritime Safety Agency (EMSA) <http://emsa.europa.eu/Docs/legis/athens_convention_2002.pdf>.

[485]The limit of the compulsory insurance must not be less than 250,000 SDR (about US$375,000) per passenger on each distinct occasion. *Ibid.* at Art. 5 & 7.

fault or neglect of the carrier. [486] Nevertheless, the burden of proving the fault or neglect of the carrier as well as the burden of proving that the incident which caused the loss occurred in the course of the carriage lies with the claimant.[487] Finally, the protocol established new limits of liability[488] for loss of or damage to cabin luggage[489] and vehicles.[490]

Regrettably, neither the 1990 Protocol nor the 2002 Protocol have entered into force. The 1990 Protocol has been ratified by only six parties[491] and later was superseded by the 2002 Protocol 2002,[492] and only four parties[493] have thus far expressed their consent to be bound by the 2002 Protocol.[494]

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[486]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. *Ibid.*484 at Art. 4.
[487]*Ibid.*484 at Art. 4.
[488]*Ibid.*484 at Art. 8.
[489]2,250 SDR (about US$3,375) per passenger, per carriage.
[490]12,700 SDR (about US$19,000) per vehicle, per carriage.
[491]10 parties required.
[492]*Ibid.*479.
[493]10 parties required.
[494]*Ibid.*479.

CHAPTER VIII

WORLD TRADE ORGANIZATION

From the beginning, the principal goal of WTO has been the liberalization of international trade by lowering trade barriers between nations. Consumer protection has never been a priority of the WTO agenda. And it is not surprising, since measures taken to protect consumers often build such barriers. To understand the nature and content of the potential impact of WTO rules on consumer interests, one has to look at this issue through the prism of trade-related problems.

One of the key problems for international trade is state protectionism. The concern that some nations may use consumer protection measures as a pretext to limit imports and to give national producers unfair advantage has always existed. It is why even the WTO has introduced some provisions related to consumer protection in its treaties.

There are two WTO agreements that indirectly relate to consumer protection.

First, *the Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement)[495] recognizes governments' right to take sanitary and phytosanitary measures but only to the extent necessary to protect human, animal, or plant life or health. Measures taken should be based on scientific principles and not be maintained without sufficient scientific evidence. As well, they should not arbitrarily or unjustifiably discriminate between members where identical or similar conditions

[495]WTO, *Agreement on the Application of Sanitary and Phytosanitary Measures*, on line: WTO <http://www.wto.org/english/docs_e/legal_e/15sps_01_e.htm>.

prevail. In addition, sanitary and phytosanitary measures should not be applied in a manner that would constitute a disguised restriction on international trade[496] and should be based on an assessment, as appropriate to the circumstances, of the risks to human, animal, or plant life or health. 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, *the Agreement on Technical Barriers to Trade* (TBT Agreement)[497] seeks to ensure that regulations, standards, testing, and certification procedures do not create unnecessary obstacles to trade. Under this agreement, governments should harmonize technical regulations on as wide a basis as possible. The agreement also recognizes countries' rights to adopt the standards for human, animal, or plant life or health, for the protection of the environment.[498]

Even if the ultimate aim of WTO agreements is a facilitation of international trade, both documents could benefit consumer protection. In spite of a long list of stipulations, the STS 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. Moreover, the provision regarding precautionary measures may be a panacea for consumer-related trade problems, making the agreement a Pandora's box for international commerce. One need only recall the endless US-EU hormone-treated beef and GMO disputes.[499]

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[496]*Ibid.*495 at Art. 2.
[497]WTO, *Agreement on Technical Barriers to Trade,* on line: WTO <http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm>.
[498]Ibid. at *Preamble.*

[499]WTO, *European Communities — Measures Affecting the Approval and Marketing of Biotech Products,* dispute: DS293, 2006, on line: WTO

As for the TBT Agreement, it also benefits consumer protection in three ways. First, the treaty forces governments to adopt international standards and as result provides consumer a minimum internationally recognizable level of protection. Second, if circumstances require it, under the agreement the authorities may establish national standards to protect consumer health, life, or other interests. Third, as such national standards will themselves create barriers to trade, an incentive will exist for more approximation of consumer protection standards at the international level.

The last benefit of the WTO agreements is promotion of international standards developed by other institutions of the UN network, e.g., the standards developed by the Codex Alimentarius Commission. The TBT Agreement asks members to play a full role in the preparation by appropriate international standardizing bodies of international standards for products for which they either have adopted, or expect to adopt, technical regulations.[500] From its part, the SPS Agreement calls on countries to base their sanitary or phytosanitary measures on international standards, guidelines, or recommendations.[501]

Just one brief note about the *Agreement on Trade-Related Aspects of Intellectual Property Rights*.[502] Among others things, this agreement includes one provision related to consumers. In respect of geographical indications, the agreement specifies that all parties must provide the means to prevent the use of any indication which misleads the consumer as to the origin of goods, and any use which would constitute

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<http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds293_e.htm>; United States Department of Agriculture (USDA), "The U.S. - EU Hormone Dispute", 1999, on line: USDA <http://ffas.usda.gov/itp/Policy/hormone1.html>.

[500] *Ibid.*497, Art. 2.

[501] *Ibid.*495, Art. 3.

[502] WTO, *Agreement on Trade-Related Aspects of Intellectual Property Rights,* on line: WTO <http://www.wto.org/english/docs_e/legal_e/27-trips.pdf>.

an act of unfair competition.[503] A higher level of protection is provided for geographical indications for wines and spirits, which are protected even where there is no danger of the public being misled as to the true origin.[504]

[503] *Ibid.* at Art. 22.
[504] *Ibid.*502 at Art. 23. See also WTO, *Summary of the Final Act of the Uruguay Round*, on line: WTO <http://www.wto.org/english/docs_e/legal_e/ursum_e.htm#nAgreement>.

CHAPTER IX

CONCLUSION

These conclusions are an attempt to answer the question whether and how far the documents selected and presented in the above chapters contribute to the creation of an international law for consumer protection in line with the UN Guidelines for consumer protection adopted in 1985 and amended in 1999. To facilitate this evaluation, all data presented in the previous chapters has been systemized in the following table.

Table 1.

	Protection of consumers from hazards to their health and safety	Promotion and protection of the economic interests of consumers	Access by consumers to adequate information	Consumer education	Availability of effective consumer redress	Freedom to form consumer organizations, and the opportunity for such organizations to present their views and the decision-making processes
Chemicals						
1. **The Rotterdam Convention**	5	0	2	1	0	0
2. The Code of Conduct on Distribution and Use of Pesticides	5	0	4	2	0	0
3. The London Guidelines for the exchange of information on chemicals in international trade	5	0	2	1	0	0
4. **The Stockholm Convention**	5	0	1	1	0	0
5. **The Basel Convention**	5	0	2	3	0	0
6. Globally Harmonized System of Classification and Labeling of Chemicals	5	0	5	4	0	0
7. The Strategic Approach to International Chemicals Management	5	0	4	4	0	0
Breast-milk substances						
8. The International Code of Marketing of Breast-Milk Substances	5	2	5	5	0	0
9. The Codex Code of Hygienic Practice for Foods for Infants standards	5	0	0	0	0	0
10. The Codex Standards for Infant Formula	5	0	4	1	0	0
Pharmaceuticals						
11. The Consolidated List of Pharmaceuticals	5	0	5	3	0	0
12. The WHO Guidelines for Drug Donations	5	0	4	0	0	0
13. Guidelines on the implementation of the WHO certification scheme on the quality of pharmaceutical products moving in international commerce	5	0	2	0	0	0
14. Good Manufacturing Practices for pharmaceutical products: main principles	4	0	3	0	0	0
15. Medical Products and the Internet: a Guide to find reliable information	5	3	5	5	0	0
16. The WHO Program for International Drug Monitoring	5	0	1	0	0	0
Alternative Medicine						
17. The Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine	4	0	5	5	0	0
18. Guidelines for Appropriate Use of Herbal Medicines						
Drinking-water						
19. The Guidelines for Drinking-water Quality	5	2	5	3	0	0
Food						
20. Five Keys to Safer Food Poster/Manual	5	0	5	5	0	0
21. Food Safety Measures for Eggs and Foods Containing Eggs	5	0	5	5	0	0
22. 20 Questions on Genetically Modified (GM) Food	3	0	5	5	0	0
23. Ensuring Food Safety in the Aftermath of Natural Disasters	3	0	5	5	0	0
24. The Guide on Safe Food for Travelers, How to Avoid Illness Caused by Unsafe Food and Drink and What to do if you get Diarrhea	3	0	5	5	0	0
25. The International Food Safety Authorities Network	5	0	1	0	0	0
26. The Codex Alimentarius	5	2	5	2	0	3
Passengers						
27. **The Montreal Convection**	0	5	5	2	5	0
28. **The Athens Convention**	0	5	2	1	5	0
International trade						
29. **The Agreement on the Application of Sanitary and Phytosanitary Measures**	4	0	0	0	0	0
30. **The Agreement on Technical Barriers to Trade**	3	2	0	0	0	0
31. **The Agreement on Trade-Related Aspects of Intellectual Property Rights**	1	1	3	0	0	0
Level of recognition: absolute numbers /% 155/100%	126/81%	22/14%	100/64%	68/44%	10/7%	3/2%

The vertical columns presents the six fundamental rights of consumers stated in the UN Guidelines, while the horizontal lines present all the international documents and initiatives discussed within the scope of this work.

The documents that are binding in nature are marked in **bold**.

To quantify the level of pertinence of the documents in relation to each consumer right proclaimed by the UN, a five-point scale is used. The highest level of pertinence, 5, has been attributed to documents where the basic right has been presented explicitly. The lowest level of pertinence was attributed to documents where the basic right is of collateral nature. For example, if consumer education is not a part of document policy, but at the same time the information is presented in way that an *active* consumer could use it for self-education, then the document received a 1. If such information has been designed for consumer use, the consumer education in the document has been rated as 2. If information may be received by consumers on a regular basis in the form of mail or pamphlets, the consumer education in the document has been rated as 3.

To make the data easy to read, the bottom line of the table presents the sum/ percentage of the level of pertinence for each fundamental consumer right.

We are aware that this grading system is based on empirical work and reflects our own interpretation of the documents.

The systematization of the international sources of consumer protection selected for this work gives a clear picture of existing trends. First, it reveals the sectors for which the international community cares most. These sectors relate more to products than services (with the exception of international carriage of passengers). And among

consumer products, the following ones receive the most attention: chemicals, breast-milk substances, pharmaceuticals, alternative medicine, drinking water, and food.

Second, the table demonstrates that only 8 of 31 (26%) documents are binding in nature.

Finally, the table vividly illustrates the level of recognition each basic consumer right has actually received. According to the table, *protection of consumers from hazards to their health and safety* has received the maximum level of recognition. All sources, except two, include some provisions regarding safety measures. The level of recognition of the first basic consumer right is as high as 81%. The second most recognizable right is *access by consumers to adequate information.* Only three documents do not include any provisions regarding this matter. The level of recognition here is 64%. The third right that received some level of recognition is *consumer education.* However, nine documents are silent on this matter and eight are only mildly pertinent, for a total of 44%. The next two rights, *promotion and protection of the economic interests of consumer* and *availability of effective consumer redress,* have low levels of recognition, i.e., 14% and 7%, respectively. Eight documents with the lowest level of pertinence[505] provide protection of consumers' economic interests, and only two documents, both of maximum pertinence, refer to effective consumer redress. Finally, only one source partly recognizes the right of *freedom to form consumer organizations, and the opportunity for such organizations to present their views and the decision-making processes.* As a result, this right has received only 2% recognition.

[505]Two sources are of maximum pertinence.

Political, social, and economic considerations may explain why two consumer rights, *protection of consumers from hazards to their health and safety* and *access by consumers to adequate information,* have received the highest levels of recognition.

The matter of health and safety is so natural and fundamental to human well-being that all levels of governance in any society take this issue very seriously. No politician would dare to deny fundamental human/consumer rights to health and safety. Since this right is of dogmatic nature, the international community may easily persuade its members to develop, adopt, and implement documents regarding this issue. No wonder that health and safety is the only legal exception from the WTO free trade rules. 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 worldwide 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.

The same pressure exists for producers. Marketing a product that is found to be unsafe can destroy the image of a company and could also result in the payment of huge damages in a product liability case. Moreover, safety is a crucial condition for building consumer confidence in the opening of borders. At the same time, measures to protect consumer health and safety exist on the national and regional levels, and many of them have been adopted by the majority of honest producers as part of a national/regional program. As a result, the implementation of international obligations on product safety does not place major financial burden on industry. Finally, incentives are taken at the international level for the sake of consumer health and safety, to help secure product exports through harmonization of safety standards and techniques.

The philosophy that informed consumers can protect themselves better then uninformed ones has predominated in recent decades as an acceptable and inexpensive alternative to other consumer protection measures. Indeed, the execution of this consumer right does require either significant financial injections or major administrative resources. The only problem remains that information passing to consumers may vary dramatically not only from country to country, but also from region to region, and even between different social groups. For example, information that may be useful to an educated urban consumer may appear useless or confusing to an uneducated consumer from a rural area. This is why it is not always so easy to develop an internationally acceptable information-dissemination formula that can be applied globally. Finally, the implementation of this fundamental right does not interact in any degree with the rules of free trade. The majority of manufacturers provide consumer information under national or regional law, and implementation of international norms would require only minor corrections. At the same time, manufacturers that provide consumer information under international requirements may found themselves in a beneficial position when their products are marketed internationally.

In conclusion, there is a clear link between level of recognition of fundamental consumer rights and their interconnection with international trade. *Protection of consumers from hazards to their health and safety* is the right that has received the highest level of recognition because it can negatively impact free trade. Since this right is an exception to free trade rules, the international community, through harmonization of rules and techniques, prevents any possible distortions of free markets that could result from implementation of this right. For its part, *access by consumers to adequate information* is neutral in score and does not pose any problem to international trade, nor does it impose any economic obligations, in contrast to other fundamental consumer rights.

PART TREE

CONCLUSIVE REMARKS

International consumer protection law is an emerging field and has developed to some extent in a few areas. Major achievements have been made regarding consumer safety and consumer information. Also encouraging is the fact that several international instruments have been adopted on a broad spectrum of topics, from chemicals and drugs to food and water. Furthermore, some of these instruments are binding in nature and have received overwhelming support from the international community. However, UN institutions have shown little or almost no interest in developing international works in other areas of consumer protection, such as protecting the economic interests of consumers, consumer education, consumer representation, and consumer redress.

This two-fold approach seems to indicate what the future holds for international consumer protection law. It is overwhelmingly clear that it would be very naïve to think that we will see in the near future international consumer law that embraces all six rights. But the question remains: Should we have universal consumer law? A different model would seem more pragmatic. A model in which international and regional levels of public governance share jurisdiction looks more attractive and realistic.

There are two major factors that prevent the development of universal consumer law. First, the work leading up to the UN Guidelines and the International Code of Marketing of Breast-Milk Substitutes shows how painful it can be to develop international instruments that directly interfere with economies and free-market rules. The ideology of free markets and globalization has predominated the decision-making process at the international level for the last 40 years. To garner support from individual states, initiatives taken by UN institutions must be free market-friendly or at least neutral. Since some postulates of consumer protection are not overly responsive to economy, we cannot expect much development in this area.

Second, the antagonism that exists between member states because of cultural, socio-economic, or other differences can be hindrance to further development of consumer protection law. For example, food-related requirements may vary dramatically from one country to another or from one region to another, depending on many factors. Food that may be totally acceptable in one region may be considered unsafe or even immoral in others.[506] As a result, it is not always possible to deliver one unique document on food safety that can satisfy all members of the international community at once. The same is true of consumer education, consumer information, ways and forms of consumer representation, and consumer redress systems. Abstract norms aimed at protecting the economic interests of consumers, such as unfair contract terms, unfair trade practices, and usury credit terms, leave ample room for interpretation and flexibility. Consumer law is much more fragmented than universal.

The situation is somewhat different at the regional level. Effective, complete, and often binding instruments regarding consumer protection have been adopted by a number of regional systems across the globe. Fragmentation is admitted–and actually encouraged–but within the limits of a legal system that is highly harmonized.[507] This leads one to believe that the states should concentrate their efforts on developing consumer law at the regional level, and specifically in areas that have not yet received much attention from the UN network. Such an approach would also be relevant in cases where all 192 members are incapable of reaching a consensus because of overly antagonistic views resulting from different economic or social levels of development.

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[506]In some Asian countries for example, dog meat is widely accepted by the population as an everyday ration. In the western world, however, it is not only considered immoral, but one can also face jail time if found to be involved in any way with this kind of "food."

[507]For more on the fragmentation of consumer law within the European Union, see : Thierry Bourgoignie, "Vers un droit européen de la consommation: unifié, harmonise, codifié ou fragmenté ?", (2005) 46 Les Cahiers de Droit 153, on line: Université Laval <http://www.fd.ulaval.ca/cahiers/docprotege/46-1-2-p.pdf>.

Since it may be expected that members of regional systems have similar or at least very close economic-social agendas, it is easier for them to find common ground on many issues, including development of common consumer protection instruments. Moreover, in some regionally integrated areas, such as the CIS and the EC, membership requires that the regional *Acquis* be introduced and actually put into force. Also, common markets and open-border policies will call for law approximation and at least some regional consumer law.

As a result of such an approximation process, regional consumer protection law seems a more likely step towards defining international standards for consumer protection.

At the international level, the UN should continue to develop a strong legal basis for consumer safety and consumer information measures, while increasing the focus of member states on other consumer rights. On issues where the international community has reached a consensus, the UN should adopt binding mechanisms. The success with conventions on chemical safety indicates that the international community can develop strong instruments on issues of universal concern. In view of recent developments in international consumer markets, the next logical step in this direction would be the development of conventions on food and consumer product safety.

On more controversial issues, the UN network will continue to promote guidelines, recommendations, or other soft-law instruments. Experience has shown that voluntary instruments such as the UN Guidelines for Consumer Protection do play a decisive role in the development and approximation of national consumer protection techniques, hence making compromise-based solutions more likely.

Major efforts should be put into the development of the UN consumer protection institutional network. In this respect, the Codex Alimentarius institutional model looks most attractive. It is this author's view that the UN should put into place new institutions at both the international and regional levels.

First, at the international level, one specific body should be declared responsible for stating general policy strategies towards consumer protection and developing guiding consumer protection principles, as well as working on new sources of consumer protection in consumer-related fields where consensus among the international community does exist or can be found. The UN Consumer Protection Program (UNCPP) should be introduced as a division of the UN Economic and Social Development Department, preferably with the same status as the UN Environmental Program.

Second, regional subcommittees of the UNCPP should be put into place. Each subcommittee would be in charge of a certain region or maybe even a particular group of consumers with shared social, economic, or cultural features. Regional subcommittees would concentrate their work on two spheres of interest: first, pursuing the development of a framework for basic consumer rights that have been overlooked by the international level of governance, and second, building the legal basis for initiatives on other relevant issues, taking into account specific regional needs.

Also, similarly to the Codex Alimentarius, subcommittees could be established for specific matters, primarily to promote work in areas where the international community has not made enough progress or when answers are urgently required from the international community.

The suggested institutional system for international and regional consumer protection could be introduced as a symbiotic arrangement of existing and newly created offices of the UN network. Where practical to share administrative and financial resources, consumer protection centers of operations could be launched as integrated facilities of pertinent UN networks. For example, the Rotterdam Convention or the Codex Alimentarius Commission institutions could be used as competent offices for consumer issues related to chemical and food safety. In other cases, new offices should be established.

Also, a step that would encourage and promote further development of international consumer protection law would be the selection by the UN International Law Commission of consumer protection as a relevant topic on its agenda. This would be perceived as a clear confirmation of the fact that consumer protection is at a sufficiently advanced stage of development in all states to permit progressive development and codification, and also that coordination or approximation is actually needed on the international scene. For consumer protection to be selected as a priority topic for the International Law Commission, only one requirement seems to be missing, i.e., the existence of doctrinal works in this field.[508] Although modest and preliminary, it is hoped that this work may be seen as a first brick in the foundation of the doctrine of international consumer protection law.

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[508] *Yearbook of the International Law Commission, 1997,* vol. II (Part Two), para. 238, on line: http://untreaty.un.org/ilc/publications/yearbooks/Ybkvolumes(e)/ILC_1997_v2_p2_e.pdf. See *Yearbook of the International Law Commission,1998,* vol. II (Part Two), para. 553.

ANNEX 1

GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS)

The following hazard symbols are the standard symbols which should be used in the GHS. With the exception of the new symbol which will be used for certain health hazards, the exclamation mark and the fish and tree, they are part of the standard symbol set used in the UN recommendations on the Transport of Dangerous Goods, Model Regulations.

Flame	Flame over circle	Exploding bomb
		
Corrosion	Gas cylinder	Skull and crossbones
		
Exclamation mark	Environment	Health Hazard
		

ANNEX 2

PHARMACEUTICALS (MONOCOMPONENT PRODUCTS)

Product Name Thalidomide

C.A.S. number 50-35-1

Scientific and common names, and synonyms

? -(N-PHTHALIMIDO)GLUTARIMIDE
ALPHA-(N-PHTHALIMIDO)GLUTARIMIDE
N-(2,6-DIOXO-3-PIPERIDYL)PHTHALIMIDE
1H-ISOINDOLE-1,3(2H)-DIONE, 2-(2,6-DIOXO-3-PIPERIDINYL)-

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
BEL	1963	Pharmaceutical preparations containing thalidomide were prohibited in 1963. In 1983 they were reintroduced for limited use in special circumstances.
FIN	1963	Prohibited due to its well-known teratogenic effects.
IDN	1963	Prohibited for importation, production, sale and distribution by the Ministry of Health.
CAN	Jul 1984	Total ban under S.15 of the Food and Drugs Act has been revoked. Thalidomide is now available on a limited basis, upon specific authorization for emergency purposes only.
BRA	4 Jul 1994	The Ministry of Health has issued an Order prohibiting the prescription of thalidomide for women of childbearing age. This action has been taken in consideration of the risks of teratogenic effects of thalidomide associated with indiscriminate use of the product. (Reference: (BRASVS) Secretaria de Vigilancia Sanitaria, Portaria 63, , 04 July 1994)
BRA	04 Jul 1994	The Ministry of Health has issued an Order prohibiting the prescription of thalidomide for women of childbearing age. This action has been taken in consideration of the risks of teratogenic effects of thalidomide associated with indiscriminate use of the product (Reference: (BRACVS) Centro de Vigilancia Sanitaria, 63, . 04 July 1994)
ARG	Jul 1996	The Ministry of Health and Social Affairs has restricted the use of thalidomide to ensure that it is not accessible to pregnant women. (Reference: (ARGANM) Communication, , . 19 July 1996)
DNK		Prohibited for import, production, sale and distribution by the Ministry of Health
IND		Prohibited for import due to the lack of substantial evidence of safety and/or efficacy, except for specially authorized use in leprosy patients in leprosy hospitals excluding women patients of childbearing age.
NZL		This product is a controlled drug and is available on a very restricted basis.
SGP		Banned for importation.
VEN		Not approved for use and/or sale.

WHO Comment Notwithstanding the highly potent teratogenic action of thalidomide, this drug retains a place in the treatment of reactional lepromatous leprosy and several serious dermatological conditions refractory to other treatment. In many countries, the competent authorities have granted exemption from licensing requirements to enable doctors to obtain limited supplies of thalidomide under strictly controlled circumstances for use in named patients. Arrangements have also been made by some national drug regulatory authorities for thalidomide to be used in institutions concerned with the treatment of leprosy.

PHARMACEUTICALS (TRADE NAMES)

Product Name Thalidomide

C.A.S. number 50-35-1

Trade and brand names

Algosediv	Asidon	Bonbrain
Contergan	Distaval	E-217
Funed	Glupan	Glutanon
Hippuzon	Imidan	Isomin
Kevadon	Kevadone	Nerufatin
Neurosedyn	Pangul	Pantosedive
Pro-ban	Quetimid	Sanodormin
Sedalis	Sedoval Shinaito	
Shinnibrol	Sleepan Slipro	
Softenil	Softenon	Talimol
Tlargan	Yodomin	

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