U.S. Practices in Risk Assessment and Risk Management for Product Safety under Article 2.2 of the Agreement on Technical Barriers to Trade

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US PRACTICES IN RISK ASSESSMENT AND RISK MANAGEMENT FOR PRODUCT SAFETY UNDER ARTICLE 2.2 OF THE AGREEMENT ON TECHNICAL BARRIERS TO TRADE

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CHAPTER I
INTRODUCTION

The Uruguay Round (UR)\(^1\) revised the Agreement on Technical Barriers to Trade (TBT),\(^2\) which was first introduced in the Tokyo Round.\(^3\) The revised TBT has been applied to the GATT member countries since 1995. Article 2.2 of the TBT provides national product safety agencies with requirements for risk assessment and risk management.\(^4\) The terms used in the Article are broad and can have various interpretations: minimum requirements, common denominators of GATT member countries' practices for risk assessment and risk management. The Article also allows

\(^1\) The UR (1986-1994) had discussed especially such topics as dispute settlement procedure and principles, agriculture, intellectual properties, services, and so on. See John H. Jackson, *Legal Problems of International Relations*, at pp. 302-304 (forthcoming 1995) [hereinafter, Jackson]; on the text of agreements resulting from UR, see GATT, *The Results of the Uruguay Round of Multinational Trade Negotiation* (1994)

\(^2\) The UR also introduced the Agreement on the Application of Sanitary and Phytosanitary Measures (ASPM), which regulates the sanitary and phytosanitary aspect of all kinds of food. ASPM is the special agreement to the TBT.

\(^3\) The Tokyo Round (1973-79) was held in order to handle non-tariff barriers such as subsidies, dumpings, and the like; TBT was born as one of the agreements in this line. Id. at pp. 304-305.

\(^4\) In ASPM, Article 5. Setting safety regulations and standards is a dominant measure among risk management strategies.
vast discretion for national practices in order to make room for the differences in national practices.

However, vast discretion and broad terms cannot solve technical barriers effectively. The minimum requirements have already been criticized for failing to consider those countries whose technology in product safety is inferior to that of developed countries. Moreover, the minimum requirements can raise trade barriers in international trade between developing countries and developed countries. Developed countries can protect their industries from products competitive in price through technologically strict standards; developing countries can require the companies of the developed countries to reveal state-of-the-art technology, the pivot of their international competition. Therefore, the TBT should contain detailed provisions in order to solve this problem.

The United States is one of the developed countries with the strongest product safety measures, thanks to the consumer protection movement and advanced technology. The US has its own system of risk assessment and risk management for product safety. Since these are activities of a sovereign nation, they will not violate Article 2.2 of TBT unless these regulations and standards are more trade-restrictive than necessary to achieve safety legitimacy. Some practices of the US product safety agencies have been

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5. On technical barriers, see infra at pp. 57-61.
criticized because they consider not internationally accepted practices but their own industrial practices. Moreover, some of their methods in risk assessment and risk management are under attack for violating Article 2.2 of the TBT. If the interpretation of the Article finds the US practices in violation of the TBT, the US must change its practices in accordance with the Article. In addition, when the TBT adds detailed provisions, as I suggest that it should, US practices should also make deep and broad changes to comply with the new provisions.

This thesis will discuss the current problems of the TBT and of US practices and suggest changes. For these purposes, I will first discuss general theories on the reasons why each country has different practices and standards, the types of product safety regulations, and the characteristics of product safety regulations and standards. Then, an analysis of the US practices and Article 2.2 of the TBT will follow. Finally, possible changes will be suggested in order to address the problems.
CHAPTER II
RISK ASSESSMENT AND RISK MANAGEMENT

A. Risk in Product Safety

A risk is "a notion of observation, and not just an object to be observed."\(^6\) It can be compared to "a kind of lens through which we see the world."\(^7\) Depending on notions and methods of observation, the definition of a risk can change. In one of the definitions, a risk means "potential adverse events,"\(^8\) while safety means "freedom from danger, injury or damage."\(^9\) A risk in product safety, therefore, can be defined as potential adverse events such as danger, injury or damage from the use and storage of products.\(^10\)

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\(^7\) Id.

\(^8\) A risk can have three different definitions. It generally means "potential events whose concrete manifestation cannot be foreseen with any certainty," but narrowly means "potential adverse events" as seen above. Even more generally, it means "unspecified aberrations from a normal or average trend whether ... in the adverse direction or in both directions including favorable departures from a norm as well." Id. at 9.


\(^10\) This thesis will only deal with human injury. The definition of an injury is a level of harm or concern about harm, sufficient to result in activity cutdown for one day or more or medical examination with or without activity cutdown. Irving Scher, *Consumer Product Safety Act*, at p. 112 and 116 (1973) [hereinafter, Scher 1973].
risk is a potential event which is described in terms of probability in comparison with other risks.\textsuperscript{11}

B. Risk Assessment and Risk Management

1. Facts and Values

Risk assessment is the process of determining the probability and severity of an accident or a disease. It considers facts, and its outcome is stated mostly in statistics or comparison statements,\textsuperscript{12} based on empirical or scientific analysis.\textsuperscript{13} The assessment may be based on an assumption as well as facts.\textsuperscript{14}

Risk management, on the other hand, means control over the identified risks. It deals with social values\textsuperscript{15} and seeks to evaluate selected measures, alternatives, effects on society, costs and benefits and so on.

\textsuperscript{11} Holzheu and Wiedermann, at p. 10.


\textsuperscript{14} Even though risk assessment deals with facts, the assumption based on these facts also needs value judgment.

\textsuperscript{15} Kathryn Harrison and George Hoberg, \textit{Risk, Science and Politics}, at p. 7 (1994).
2. Characteristics

a. Risk Assessment: Technical and Scientific Uncertainty

Safety agencies have a tough task of determining regulations based on uncertain data, which stems from the attributes of science and technology. Data for risk assessment always include technical and scientific facts and assumptions such as ceteris paribus. Since variable factors can change the conclusion based on an assumption, risk assessment and risk management decisions are based on a high level of uncertainty. Health and safety agencies must make value judgements regarding the probability of harm and the degree of acceptable risk despite this uncertainty.

b. Risk Management: Value Judgement

The safety regulation on product safety is one of the social regulations that focus on social values. Safety is one of the social values; risks are the opposite side of

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16. It means "all else remaining the same." See Guralnik, p. 234.
17. Harrison and Hoberg, at p. 5; refer to organization theory and sociology.
18. The regulations can be classified into economic regulations and social regulations based on the difference of the weight between values and information. Social regulations concern the living quality of national people, examples of which are the protection of consumers of products and environmental health and safety. See Peter K. Manning, The Limits of Knowledge: The Role of
safety. The areas of risks are still too new to form a reliable and coherent model for value judgments in making regulations and standards. The terms in product safety provisions are usually so ambiguous and symbolic that their operation is often challenged surrounding the interpretation.

3. Risk Assessment and Risk Management in the Process of Making Product Safety Regulations and Standards

The process of making product safety regulations and standards comprises five stages: hazard identification, risk characterization, the survey of overall measures and their data, the decision of a measure and its details, and implementation and feedback. Risk assessment and risk management cover the entire process of making safety regulations or standards.

For example, suppose the risk assessment and the risk management of carcinogens in a consumer product. Risk assessment involves the first stages. The first stage is hazard identification. Safety agencies try to find out


21. Id. at pp. 6-7.
whether or not a certain substance causes cancer, the hazard assessed from the number of incidents, severities of injuries and so on. This information molds the assumption that a certain product is dangerous to humans. However, this identification process remains at a preliminary level. Based on this preliminary assumption, the source and the probability of potential harm will be assessed on the basis of collected data as the risk characterization.

The second stage is risk characterization. Here, the severity and the probability of cancer are estimated, based on the carcinogenic potency of substances in the product as well as the extent and the nature of human exposure to it. At this stage, a preliminary decision is made regarding the necessity for and priority of safety measures.

Risk management consists of three stages. In the first stage, a survey of overall measures is made. The safety agencies identify and compare as many safety measures and alternatives as possible. Basic information is gathered on cost, technical feasibility, impact on the society, and the possibility of alternative measures. The next stage is selecting a safety measure and determining its details. Here, an acceptable level of risk and the measures to achieve the best result are chosen. Such decisions are founded on the information from the preceding stages. The choice can be made based on intuition, political motives and existing formal criteria such as cost-benefit analysis.
of the safety agencies, or the policy and philosophy of certain influential participants. The final stage is implementation and feedback. The chosen strategy is reviewed and adjustments are made. This process helps safety agencies assess correctly the efficiency of the chosen measures and shift quickly to another strategy if the results are not satisfactory.

C. Factors that Cause Different Practices among Countries

1. Examples of Differences

The practices of risk assessment and risk management vary among countries and depend on how people in different areas perceive risks: the greater the fear of risks in an area, the stricter the safety requirements. For example, the safety regulations of the US National Highway Traffic Safety Administration (NHTSA) have a notorious reputation among developed countries in that the conformity with these regulations requires technical enhancement.\(^{22}\) Japan has more fear about risks in food than any other country.\(^{23}\) The US is one of the countries which have the greatest fear about technological products with unknown hazards.\(^{24}\) These are

\(^{22}\) OECD 1991, at p. 27; on the reasons for the notorious reputation, see infra, Chapter V, B, 1 and 2.

\(^{23}\) Aaron Wildavsky, Comparative Study of Risk Perception in Bayerishe Rück ed. Risk is a Construct, at p. 185 (1993).

\(^{24}\) Id. at p. 190.
some examples of how different notions about risks result in different risk assessment and risk management practices.

The quantitative differences in risk assessment and risk management can be shown by the relative degree of acceptability or appropriateness. For example, suppose Country A determines product X hazardous if it causes more than one casualty out of 100 consumers, whereas Country B considers X hazardous if it causes one casualty out of 1000 customers. If no trade in product X exists between those two countries, there will be no dispute over product safety measures because the decision of acceptable risk is a right of national sovereignty. However, the reality is that countries do trade with each other.

2. Basic Principles

Though different countries take different approaches to risk assessment and risk management, they operate under common principles. The first two principles stem from the free market system, the first being that a zero risk of products is not only almost impossible but also inefficient, the second, that different consumers and societies evaluate the safety of a product differently. 25

Third, risk management aimed toward manufacturers prevails over risk management toward consumers. The safety agencies survey consumer behaviors and their influence on the agencies’ total safety regulation scheme.\textsuperscript{26} Theoretically, they should take account of reasonably foreseeable consumer behaviors and set the safety program to change. However, in real practice safety regulations usually concentrate on trying to change manufacturers rather than consumers just because changing manufacturers’ practices is easier than changing consumers’ behaviors.\textsuperscript{27} Without any efforts to correct consumer behaviors, it is doubtful that safety regulations will achieve the objective of consumer safety. For example, despite the introduction of a certain type of car seat belt, the accident rate might not be reduced.

The fourth principle is that risk assessment and management are a matter of degree and attitude. As discussed earlier, “different kinds of lens” determine things to be seen.\textsuperscript{28} The lens is the society, time, and the situation. For instance, the degree of risks in nuclear power plant safety or traffic safety, is different depending on the societies.

\textsuperscript{26} Id. at p. 19.
\textsuperscript{27} Id. at p. 20.
\textsuperscript{28} Holzheu and Wiedemann, at pp. 9-10.
3. Factors in Risk Assessment

a. Hegemony between Experts and Lay people

The hegemony within safety agencies between experts and lay people may influence product safety regulations and standards since lay people and experts view risk assessment differently.²⁹ Experts regard probability and uncertainty as very important elements.³⁰ They try to exploit all the available data and perform fault-free analyses, prefer mathematical calculations and consider uncertainty with a high degree of exactness when calculating the probability of occurrences.³¹ They try to be free of the emotional element in their jobs. These experts tend to underestimate the risks of low-consequence but high-probability events.³²

On the contrary, lay people tend to overestimate the risks of high-consequence but low-probability events. Lay people base their risk perception on fear, familiarity, and the number of people exposed to the risks.³³ They are not familiar with the experts’ methods for dealing with probability and uncertainty. Therefore, depending on

²⁹. Lay people are people other than experts who specialize in scientific or technological knowledge in a relevant area.
³². Id. at p. 106.
³³. Id. at pp. 106-107.
relative power of experts and lay people within the safety agencies, the outcome of risk management will differ.

b. Methodology of Experts in Risk Assessment

The result of risk assessment in the process of making product safety regulations and standards may depend on which method is adopted among experts’ methods. Moreover, the degree of reliance on experts’ reports can make safety agencies’ risk management different.

During the preliminary stage of hazard identification, experts use more varied and specific methods of risk assessment than do lay people. The lab test is one of them. Products which “go into human” almost always go through lab tests performed by toxicologists, food scientists, or biochemists. The toxic substance test, the bio-organization test, and the like are conducted on animals such as mice and rats. These tests may reveal such information as the exact amount of a substance, the tolerance of the human body, or the threshold of a disease.

Experts may take one of two approaches. In a qualitative approach, research is focused on at how much amount of intake a substance crosses the threshold to unsafety. In a quantitative approach, any toxic substance

34. On the meaning of products which go into human, see infra Chapter III, A, 1.
is considered dangerous regardless of its amount. The
greater the consumption, the more dangerous it is
proclaimed to be to humans. In some countries where
scientific technology can calculate the effect of a minute
amount of a toxic substance, safety agencies have chosen
the quantitative assessment approach as their primary
method. When this quantitative approach is combined with
the theory of probability, the risk assessment process may
reveal the statistical chances of individuals' contracting
a disease in proportion to the increasing consumption of
the substance.\(^35\)

The lab tests have limitations. Thirty-four substances
out of thirty-five extrinsic substances known to cause
cancer in people generate the same results in animals, but
the site of the cancer can be different. Moreover, the
extrapolation of animal tests to humans is still a
controversial issue because a substance which does not
cause cancer in animals can, in rare cases, cause cancer in
humans, as in the case of the Thalidomide disaster.\(^36\) Some
also criticized that the heavy-dose tests on a small number
of animals may undermine the credibility of animal tests
when the test results are extrapolated to humans.

\(^{35}\) Harrison and Hoberg, at p. 5.

\(^{36}\) New York University Medical Center, *Staying Healthy in a
Risky Environment*, at p. 231 (1993); Linda Cummings, *The Political
Reality of Artificial Sweeteners* in Harvey M. Sapolsky ed.
*Consuming Fear*, at p. 121 (1986).
Another method is the epidemiological study, in which the responses of the real population are researched on the products. This requires a great deal of data gathered from a large number of people over a long time. The problem here is that all the possible variables cannot be considered and that the results may vary depending on the individuals.37

c. The Progress of Science and Technology

Scientific and technological development may affect consumer attitudes toward the notion of safety. One of these changes is the reduction of a fatalistic attitude toward risks.38 This change becomes complicated when combined with other changes: the increased feeling of insecurity which results from increased reliance on other people;39 reduction of direct experience;40 a less predictable future; bulky mass media information; the

37. Cummings, at p. 121.
38. A concrete example is the way perceptions regarding bearing children and delivery have changed. We can see how fast mothers' views on the death or disability of a newborn have changed into suspecting medical or scientific incompetence from the earlier fatalistic viewpoint. See, Lübbe at pp. 26-28.
39. Modernization means more reliance on other's action and warranty. This reliance means a situation seems out of one's own control. The risk perceived of public transportation, for example, is higher than that of one's own transportation. See, id. at pp. 28-30.
40. As basic knowledge of technical and scientific matters has become more difficult for a lay person, the experience of specialists or experts has started filling the gap. However, as in hearings on certain regulations, these specialists sometimes have opinions divided enough to disturb lay people's confidence. See, id. at pp. 30-32.
decline of social control, and a high anticipation of technological social security.\textsuperscript{41} In addition, uneven scientific development among different countries produces different practices of risk assessment and risk management.\textsuperscript{42}

Progress in science and technology produces a feeling of uncertainty about the future more frequently now than ever. This uncertainty has led safety agencies to make stricter regulations. For example, as detection methods for food safety have improved, certain foods or food additives that have long been regarded as relatively safe are being challenged as unsafe. The more revelations are made, the more people feel unsafe.\textsuperscript{43}

This technological and scientific uncertainty also causes regulatory uncertainty in companies.\textsuperscript{44} For example, the Consumer Product Safety Commission (CPSC) required industries to use a flame-retardant textile, Tris. However, when it was discovered to contain a carcinogen, it was banned. The companies that invested to comply with the CPSC requirement incurred massive losses.

\textsuperscript{41} For example, the expectations for newly developed medicine have increased. See id. at pp. 36-37.


\textsuperscript{43} Cummings, at p. 119; this panic culminated in the zero risk policy on the carcinogenicity of food additives in FDCA’s Delaney Amendment.

\textsuperscript{44} Viscusi, at p. 68.
4. Factors in Risk Management

a. Different Cultures

The product safety agencies in different countries respond differently to the same risk assessment results. One of the reasons is that their national cultures influence their responses.45

In anthropology societies can be classified into hierarchical cultures, egalitarian cultures, individualistic cultures, and fatalistic cultures.46 Risk management is different in each culture. A hierarchial culture follows the rejection or absorption of risks by its decision makers; an egalitarian culture rejects or deflects risks without harming the principle of equality; an individualistic culture accepts or deflects risks in accordance with the consensus among individuals; and a fatalistic culture accepts and absorbs risks without any reservation. Though these cultures can coexist within a country, the most prevalent culture will represent the culture of the country when defining the characteristic of a country.

46. On details, see Wildvsky, at pp. 185-187.
b. Lay People and Experts

A different level of acceptable risk depends on whether lay people or the experts are dominant in the decision making process within safety agencies. According to Juregan Habermas, experts are theoretical and empirical, while lay people are practical and norms or value-oriented. Lay people try to find tolerable risks and focus on evaluation, while experts try to find quantifiable risks and statements of facts. Lay people regard appropriateness as the standard of judgment, whereas truth is the scale for the experts. The lay people in an agency try to justify the motives behind safety, while the experts try to explain the causes of accidents or phenomena.

c. Risk Communication

Risk communication refers to activities among safety agencies, industries, and citizens through the media concerning risks. In a democratic country, it aims to help the participants in risk assessment and risk management to make rational decisions based on unrestricted information.

The extent and frequency of risk communication determine what is feared and how much it is feared, and

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47. Kemp, at p. 115.
this varies among the countries. For example, the countries of former Eastern Europe were ignorant of the risks of new substances made by new technology, because they restricted risk communication believing that technical progress equaled social progress. Distortion of the risk communication process induces false information or no information, while a guarantee of participation and discussion as well as availability of the mass media enhances risk management.

d. Attitude toward Science

The attitude toward science is also very important. The degree of acceptability of scientific evidence and its role were disputed in the ban case on the use of hormonal substances in livestocks in 1987. The European Community (EC) Directive on this measure was to go into effect beginning January 1 of 1988. The US argued that hormones at a certain level were safe according to their scientific evidence and that the EC’s regulations were not necessary. The EC contested the Production and Process Methods (PPMs), expressing doubt about the scientific findings because they found miscalculations of certain chemical products. In the

49. On an example, see Wildavsky, at p. 190.
dispute resolution procedure, the US insisted on the establishment of an expert group, whereas the EC insisted on setting up a panel without the expert group. This case shows the differences between two parties on the role of science and technology and expert assistance in dispute settlement procedures.\textsuperscript{52}

e. Participation

Participation by consumers, companies or foreign companies with less developed technology changes the results of the standards and regulations. For example, restricting participation to industry members that have already attained a certain level of technology allows those members to be able to discourage other lower-price competitors. They may try to avert the new technology of foreign companies.\textsuperscript{53} Those members may ask safety agencies or private standard makers to reflect only their own manufacturing practices and technical feasibility. This situation happens when safety agencies rely solely on the expert knowledge of manufacturers.\textsuperscript{54}

\textsuperscript{52} GATT, GATT Activities 1987, at p. 80 (1988) [hereinafter, GATT 1987]. On the international dispute on the safety measure, see id. at p. 100.


\textsuperscript{54} In reality, limited participation is prevalent in some countries or safety agencies.
Consumer participation in risk management has a very important meaning in that it can check the industry's intention to drive out competitors who offer overall good quality at a reasonable price. Theoretically, consumers' taste worldwide is becoming more homogenous as product information flows quickly throughout the world. Consumer participation, therefore, may reflect an international view on the quality of products. However, the degree and effect of participation is different among the countries. Moreover, unless foreign companies are allowed to participate in the entire process of making safety regulations and standards, the standards or regulations will inevitably reflect the national culture and practices.

D. Styles of Risk Management

1. Focus on Consensus

As discussed above, the styles of risk assessment and risk management among countries vary depending on many factors. First, the adversary structure universal in

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[^56]: See Chapter III, A, 3, b.
typical democratic countries such as the US, is characterized by free information, free lobbying, and multi-polar authority. Its regulatory process is essentially adversarial among influential participants.\footnote{Hawkins and Thomas, at p. 4.} Under the adversarial system, the method of how and in favor of which participant decision makers interpret the external limits influences both the efficiency and the equity of the risk management. The second style, called the consensual structure, can be seen in the UK or the Scandinavian countries. It has such characteristics as deference to decisions made by elite groups which include experts, the industries and the unions.

The third style is the authoritative style, as in the French system. It encourages the autonomy of the technicians of the central government. Another structure is the corporate style, as in Germany. This style is less democratic than the adversary structure but decentralizes the government authorities into many participants. However, to assure coherence of policies, it has a multi-layer surveillance program and various participation programs.\footnote{Otway and Peltu, at p. 5.}

The above four styles are prototypes. The characteristics of these structures may be combined in various ways. The US has a more typically adversary structure than any other country. It pays more attention to
due process, one of the democratic principles, to solve adversarial clashes among participants.

2. Focus on Decision Makers

There are four types of decision makers in risk management, according to the OECD report. The first is the vertical model, where the central government has safety regulation authority and disperses it through the regional or branch governments by means of a command. It is generally common in the developing countries. The second one is the centralized model, in which, despite the existence of private standard makers, the regulatory activities are entirely dependent on governmental control and a relation between two sectors exists. Germany, Japan, and France follow this model. The third model is the decentralized model. Here, governmental influence is significantly diminished. Many private standard makers are organized and actively participate in the regulatory process. Canada and some parts of the US have this model. The fourth one is the horizontal standardization model that can be seen in the US. In this model regulatory authority is dispersed throughout influential groups and other decision makers. This is such a democratic process that
cooperation among the participants and the standard makers is weaker than in the third model.\textsuperscript{60}

3. **Focus on Relation between Standards and Regulations**

The relations between standards and regulations can be classified into four types. The first type is the establishment of safety specifications through regulation by the safety agencies.\textsuperscript{61} The safety agencies incorporate already existent voluntary safety standards into mandatory standards in regulations or develop specific mandatory safety standards in regulations for themselves.\textsuperscript{62} The Consumer Product Safety Commission (CPSC), for example, sometimes incorporated certain privately developed standards into regulations after amendment of the Consumer Product Safety Act (CPSA) in 1980.

The second type is the establishment of standards by independent standardization bodies, private or governmental entities. There is no legal relation between those entities and safety agencies. However, mandatory standards created by safety agencies occasionally refer to specific safety standards of these bodies. The Deutsches Institut für Normung (DIN) in Germany and the American National

\begin{flushright}
\textsuperscript{60}. OECD 1991, at pp. 24-25.
\textsuperscript{61}. Hereinafter, the safety specification means the mandatory safety standards within regulations.
\end{flushright}
Standards Institute (ANSI) and the American Society of Testing and Materials (ASTM) in the US are examples of these independent standardization entities.

The third type makes reference to standards in regulations. This style is prevalent in the United Kingdom, Germany, and France. There is an agreement on the reference between the safety agencies and the private standard makers. The safety agencies prescribe as general provisions as possible, and they support and finance activities by the private standard makers. The standards are then mandatorily enforced. This can also be seen in the US system.\textsuperscript{63}

The fourth is the voluntary approach, which concentrates on private standard makers' self-regulation. Regulators and standard makers are separated and are independent from each other. There is no relation with safety agencies, no reference to standards by regulations and no monitoring system. This is true, for example, in Sweden and Australia.\textsuperscript{64}

The US originally used a mixture of the first type, the second type and third types. After the product safety agencies' vigorous attempts to use the first type were frustrated, the second and the third types are now prevalent.\textsuperscript{65}

\textsuperscript{63} Id. at pp. 31-32.
\textsuperscript{64} Id. at p. 33.
\textsuperscript{65} See infra Chapter III, B, 2.
CHAPTER III

US PRACTICES ON RISK ASSESSMENT AND RISK MANAGEMENT FOR
PRODUCT SAFETY

A. Practices in Safety Regulations on Products

1. From FDCA to CPSA

The US history of safety regulations on consumer products may be divided into the three stages: food and drug legislation (1906-1953); legislation directed at specific hazards (1953-1972); and the birth of comprehensive laws like the CPSA. In the first stage, the Food, Drugs, and Cosmetics Act (FDCA) of 1938 concentrated on the following: for the regulations that created standards of identity and for the labeling of products; the burden of proof of product safety; and supervision over manufacturing practices. In the second stage, many laws and regulations targeted specific kinds of products or

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67. Id. at 1.02. The burden of proof lies on manufacturers.
issues: flammable fabrics,\textsuperscript{68} products containing hazardous substances like chemicals,\textsuperscript{69} children’s items,\textsuperscript{70} car accidents,\textsuperscript{71} suffocation in refrigerators,\textsuperscript{72} the control of radiation from electronic products\textsuperscript{73} and poisonous products.\textsuperscript{74}

In the third stage, product safety has been regulated under the CPSA, a general legislation, although some products are still under other laws and regulations.\textsuperscript{75} Tobacco is regulated under the FHSA and the Cigarette Labeling and Advertising Act; motor vehicles, under the NTMVSA; pesticides, under the FIFRA; aircraft and related products, under the FAA; boats and vessels, under the Federal Boat Safety Act of 1971 (FBSA); food, drugs, and cosmetics, under the FDCA; products related to the work place and working condition, under the Occupational Safety

\textsuperscript{68}. Flammable Fabrics Act of 1953 (FFA). It was amended in 1967 to include whole fabrics and give authority to the Secretary of Commerce to set standards for flammability. See Lemov at 1.04. FTC can ban fabrics worse than standard. See Lemov at 1.05.

\textsuperscript{69}. Federal Hazardous Substances Act of 1960 (FHSA), Federal Insecticide, Fungicide and Rodenticide Act of 1959 (FIFRA), FDCA, and Federal Caustic Poison Act of 1927 (FCPA). See Lemov at 1.05. FHSA was amended to give the Secretary of Health, Education and Welfare (HEW) the power to ban household goods and toys containing certain chemical substances.

\textsuperscript{70}. Child Protection and Toy Safety Act of 1969 (CPTSA). See Lemov at 1.05. It gives the HEW the power to recall or remove banned substance from children’s goods.

\textsuperscript{71}. National Traffic and Motor Vehicle Safety Act of 1966 (NTMVSA). It introduces a special agency called the National Highway Traffic Safety Administration (NHTSA)

\textsuperscript{72}. Refrigerator Safety Act of 1956 (RSA)

\textsuperscript{73}. Radiation Control for Health and Safety Act of 1968 (RCHSA)

\textsuperscript{74}. Poison Prevention Packaging Act of 1970 (PPPA)

\textsuperscript{75}. Lemov, at 4.05, 4.07 note 2 and 3 and 4.08.
and Health Act (OHSA); radioactive products, under the Atomic Energy Act (AEA); and radiation from electronic products, under the Public Health Service Act (PHSA).  

Among the numerous laws and regulations that have been introduced since the first stage, the CPSA is still a typical comprehensive regulation scheme, and therefore, the analysis of the CPSA can be analogous to that of other special legislation. Meanwhile, the FDCA is not comprehensive but can be regarded as a general regulatory scheme on food, drugs and cosmetics, categories that are very broad in kinds and make up a great portion of the consumer market. Therefore, the analysis of these products will also be worthwhile in understanding similar styles of legislation in the US. In this section of the thesis, the practices of the CPSA and FDCA will be discussed in reference to the aforementioned five stages.

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76. CPSA Section 31.

77. Howard Abbott, Product Liability, at pp. 23-24 (1978); The amount of consideration concerning safety is different depending on products and can broadly be divided into two groups of products, "products which go into" human and "products which go onto" human. The former, such as food, cosmetics and drugs, need "a full scale safety program" because they directly affect the human body inside, whereas the latter, such as household products, household appliances, and so-called consumer products do not. The latter group has exception. Transportation vehicles have a strict safety program. As a further example, Abbott enumerates comparisons between meat and an aftershave lotion and shows how biologically active face cream has more risk than a cream cracker. Within the same group, the degree of risk varies depending on the inheritant attribute of products and human activities; for example, an electric carpentry machine is more dangerous than an electric cleaning machine.
2. Risk Assessment Stage

Hazard identification can be achieved by research before or after the sale of products. Pre-sale research consists of lab experiments and tests on a sample population. The lab experiments test contaminants or additives of the products, e.g., residual pesticides on agricultural products and additives in food. Post-sale research collects data mainly from the epidemiological studies that survey the results from the use of products by actual consumers.

The products to be consumed by human bodies, i.e., food and drugs, are tested in the laboratory before they go on the market, and the FDA is responsible for judging the safety of food and drugs. The safety of other products is judged based on voluntary research by the manufacturers. The risk information obtained through post-sale research, e.g., statistics on injuries during the use of products, may prompt the safety agencies to start regulating those products. Transportation vehicles, however, are somewhat different. The NHTSA requires that some safety tests, such as of the crashworthiness of cars, be done before the vehicles are sold to consumers.

78. Research after sale also can be done in the final stage, the implementation stage. See supra II, B, 3.
The data for risk assessment typically come from four important sources: 79 expert knowledge, information accumulated by standardization bodies and regulation agencies, 80 accident surveillance schemes or similar plans, and information from consumers such as comparative test results and consumer complaints. 81

Risk assessment in the labs requires expert knowledge. 82 The data from lab experiments can be described in two ways, quantitatively and qualitatively. The threshold approach to hazard is a qualitative method, whereas the linear approach to hazard is quantitative. The quantitative method, taking into account progress in scientific methodology, is considered the most important method in the US. 83 However, neither quantitative nor qualitative data explain chronic problems or attendant circumstances, and, as a result, may mislead the decision maker. 84

79. Data for risk management also come from same sources.
80. The rapid-exchange system of information on dangerous products in the EC is an example.
81. Id. at pp. 33-34. On information from consumers, see infra at pp. 42-43.
82. The US’s scientific and technological conclusions are another expert knowledge which is almost automatically honored in other countries, especially regarding products containing toxic chemicals.
83. While the US, in most cases, does not use the qualitative method any more, other developed countries such as Canada and the UK, in many cases still stress the threshold approach. See Kathryn Harrison and George Hoberg, Risk, Science and Politics, pp. 171-173 (1994).
84. Otway and Peltu, at p. 6.
Let us consider some risk assessment practices in the US, for example. As an accident surveillance scheme, the famous National Electronic Injury Surveillance System (NEISS) has been used in the US since mid-1972, after unification of the Food Drug Administration (FDA)'s National Injury Surveillance System and the National Commission on Product Safety's Hospital Emergency Room Injury Reporting System. The NEISS supplies information related to injuries from more than 1,000 product groups, information on consumers, and related background information. The information comes from the hospital emergency rooms. Then the results are extrapolated to the national average.

The surveillance schemes investigate two kinds of accidents, deaths and injuries from products. The US uses the Medical Examiner and Coroner's Alert System (MECAP) and the death certificate data base supplied by the CSPC. The death certificate data base has details on deaths related to products. In cases of injury, the US has a data-collecting system centering on hospital records, which may

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85. OECD 1991, at p. 42, note 14, 15. In the EC, a home accident surveillance system is the counterpart of the US system.
86. These product groups are selected as representative.
87. Viscusi, at p. 49.
88. According to the OECD Report, other OECD member countries than Sweden, Holland, the United States and the United Kingdom have weak death data on the products and the process of death, or may not commonly use even weak data.
include data from interviews with the victims. In the CPSA, the Commission maintains the Injury Information Clearinghouse to gather statistical and epidemiological information on injury and death as well as economic loss or health impairment. The National Commission on Product Safety (NCPS) describes injury and death data not only in terms of the total number of incidents but also in terms of the total cost to society. The NCPS's report deals with sixteen consumer products that, unreasonably, were not safe.

The CSPC's priorities are based on the following: data on the frequency and severity of injuries; the causes of injuries and their amenability to policy influences; the unforeseen nature of the risk; the vulnerability of the population at risk; the probability of exposure to the hazard; and analysis of chronic illnesses, future injuries and costs and benefits. The necessity for safety regulation should become clear in the preliminary stage of risk assessment. People select a specific product, unconsciously or consciously, after comparing quality including safety features, price and other special purposes, such as the speed thrill of a motor cycle.

Under a perfect market, individuals' demands on quality,

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90. CPSA Section 5 (a).
91. Lemov, at 1.09.
92. Id.
93. Viscusi, at p. 43.
94. Id. at p. 1.
price and special purpose may meet the manufacturers' calculation of consumers' demands at the equilibrium.\footnote{Id. at p. 2.}

However, the necessity for intervention by safety agencies arises if the safety of a product is below the consumers' demands or the government-recommended standard.

3. Risk Management Stage

a. Survey of Overall Measures and Their Data

1) Rule Making\footnote{The CPSA's procedure has modified that of the Administrative Procedure Act (APA) and is different depending on measures; standards and bans follow Section 7-9; disclosure of information, Section 6; recall, Section 15; rule making on inspection and record keeping, Section 16. The FHSA and FFA have their own procedure modifying APA procedure.} and Adjudication

Risk management in US government agencies has two facets: rule making and adjudication. Rule making means "the promulgation of generally applicable requirements or standards governing future conduct," while adjudication means determination of "the legal consequences of past events in a particular controversy between specific parties."\footnote{Stephen G. Breyer and Richard B. Stewart, Administrative Law and Regulatory Policy, at p. 398-399 (1979) [hereinafter, Breyer and Stewart]. Breyer and Stewart think this distinction somewhat absurd because each may share some of the others' characteristics. On the definition of rule, see Breyer and Stewart, at p. 407; adjudication here is a remnant of the definition of rule making as administrative activity.} Therefore, mandatory standards, regulations,
and statutes are part of rule making; on the other hand, bans, recalls and cancellations of admission of import are part of the adjudication facet of risk management.

The procedures for rule making and adjudication are different. Rule making, generally, follows the notice-and-comment procedure, while adjudication adopts a trial-like proceeding. The former process requires more commitment of time and energy than the latter. Their characteristics are also different. The former, rule making, targets the future, while adjudication attempts to mend the past. The scope of judicial review is also different. Rule making prefers consistency and uniformity to the individuality of adjudication and is clearer and more publicized. The former usually allows participation by the interested. Selection between them as policy measures depends on many considerations.\textsuperscript{98}

Rule making can be divided into notice-and-comment rulemaking and on-the-record rulemaking; in other words, informal rule making and the formal rule making. These require differing degrees of substantial evidence depending on the decisions to be made. Informal rule making is satisfied with any information or sources of knowledge.\textsuperscript{99}

Hybrid rule making, between informal rule making and formal rule making,\textsuperscript{100} was created so that it can use

\textsuperscript{98} Id. at p. 404.
\textsuperscript{99} Id. at p. 480.
\textsuperscript{100} Id. at p. 501.
documents in a hearing procedure. It is a trial style without the parties' presence, oral testimony, or cross examination.\textsuperscript{101} Hybrid rule making has merits such as the clarification of goals as well as impact evaluation of a broad range of alternatives.\textsuperscript{102}

2) Specific Measures

The measures utilized by product safety agencies may be mandatory or voluntary. Voluntary standards and voluntary rating systems are obviously some examples of voluntary measures,\textsuperscript{103} whereas the mandatory measures may take the form of mandatory standards-setting such as pre-market clearance and approval before sale, the hazard-reporting duty of the manufacturer, certification requirements, continuous inspection, regulation of the end products and PPMs, product ban or recall, the blacklisting of manufacturers who do not meet standards, red-tagging to shut down a piece of dangerous equipment, fines including criminal charges, injunctions and cease orders to eliminate

\textsuperscript{101} This is one of EPA's rule making methods. See id. at pp. 509-510. In Appalachian Power Co. v. Ruckelshaus, 477 F. 2d. 495 (4th Cir. 1973), certain types of technical issues require limited cross examination. See, id. p. 511.

\textsuperscript{102} Id. at p. 8.

\textsuperscript{103} As a voluntary industry rating system for product safety may work as a tactic to get competitive low-quality product makers out of competition, regulations are often introduced for the protection of such companies and out of deference to consumers' freedom of choice. These voluntary measures will be discussed in another section.
unsafe practices of a manufacturer, and the like. These measures exist within the statutes or regulations, in part or in all, under different names, in different countries. These mandatory measures may then be classified into preparatory actions, regulatory actions, corrective actions, and monitoring actions, depending on the time of application.

The CPSA's risk management techniques include mandatory standards, bans, recalls, imminent procedures, penalties and so forth. The mandatory standards and bans are issued based on the unreasonable risk involved, while recalls are based on the existence of substantial hazard.

The mandatory standards consist of requirements "expressed in term of performance" whenever feasible and the manifestation by warnings or instructions or by any requirements "reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product." These requirements are identical to the voluntary

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104. The range of discretion on the same measure by regulators is also different depending on countries. The most frequently used measure against dangerous products in most countries is the ban of use of the product in question. The second and third are limitation of the quantity of dangerous substances in products at issue and labeling or packaging requirements, if a product is indispensable and there are no other practical methods. Both of these are mandatory standards or certification requirements. Regarding the ban, each country has a negative substance list where specific toxic substances are prohibited; however, the range varies somewhat. See, OECD 1974, at pp. 7-8.


106. CPSA Section 7 (a) and 8. Hereinafter, "mandatory standards" is used with the same meaning as "specification."

107. CPSA Section 15.
standards' requirements. The CPSC can ban any hazardous products which do not meet the mandatory standards, or when the condition is such that "no feasible standards [can] protect the public from the unreasonable risk," e.g., injury from products.

The requirement for a recall is a violation of existing safety rules or a product defect that creates "a substantial risk of injury to the consumer." A recall is used in order to shorten the time required in making the standards from more than a year to a mere several weeks. A recall requires manufacturers to provide notification of replacement, repairs or refund. The prerequisites of a ban, "unreasonable risk" and "appropriateness," have the possibility of arbitrary interpretation, as do those of a recall, e.g., "a substantial product hazard," unless they have clear criteria.

The first action by the CPSC in a ban is to file a complaint and a motion for an injunction in court so as to seize the dangerous products. A civil penalty or criminal penalty may be imposed on those who violate the

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108. CPSA Section 7 (b) (1).
110. CPSA Section 8.
111. Viscusi, at p. 63.
112. CPSA Section 15(c).
113. CPSA Section 15(d).
114. CPSA Section 12(a).
115. CPSA section 20.
116. CPSA section 21.
CPSA's provisions, e.g., the manufacturer, the distributor, the retailer or the importer whose products do not conform to the safety standards.\textsuperscript{117} When the CPSC finds that imported products, before their entrance into the US territory, violate safety requirements, the CPSC can refuse their admission.\textsuperscript{118} Some may argue that this refusal of admission is a fatal measure to exporters and related industries, in contrast with the situation that domestic industry can repair or notice or replace the products in violation of the same requirement. However, because only the MFN treatment of the GATT, not the national treatment, is applied before the products' entry into the country, such discriminatory treatment of imported products is still legal under the TBT.

Recalls and voluntary standards are more frequently issued than mandatory standards. The reasons are not only that the courts have unfriendly attitudes toward mandatory standards for fear that the courts as well as the safety agencies would have to share responsibilities for injuries or deaths that might happen after they authorize mandatory standards, but that Congress has also criticized the practices of making mandatory standards and cut the budgets of safety agencies for political gain.\textsuperscript{119} As a result, the function of making specifications of product safety is

\textsuperscript{117} CPSA Section 19.  
\textsuperscript{118} CPSA section 17.  
\textsuperscript{119} Lemov at 3.12, note 6 and 3.13, 3-19.
nowadays in the hands of private standard makers, and the safety agencies just monitor their efficiency with such mandatory measures as recalls or bans.\footnote{On standards, see supra Chapter II, D, 3.}

3) **Dangerous Products: General Control or Specific Control**

The risk management method for chemical substances and products may be general control or specific control. General control decides the safety of finished or end products using criteria such as the reasonableness, acceptableness, and substantiality of the risks. Whether a product is safe or not is determined through those criteria. General control preserves the freedom for manufacturers to be innovative because they can adopt any technology to obtain the acceptable level of safety and get the agency's approval. The disadvantages in this system are the possibility of procrastination of approval and the uncertainty of approval. The criteria and the procedures of approval are normally published beforehand to foreign manufacturers.

Specific control may take the form of publishing which substances are permitted and, even if substances are permitted, the maximum quantity of those substances. This style of control does not deal with final products. The problem here is that it can sometimes discourage the
innovation of the manufacturers. On the other hand, exporting countries need not worry about the time required for the approval and the unpredictability of approval as in the case of general control. Moreover, specific control can be easily harmonized on an international level, while general control allows various practices in individual countries over a wide range.\textsuperscript{121} Specific control is commonly used for food, drugs, agricultural products, cosmetics and pesticides, while general control is used for most household products.\textsuperscript{122}

b. Decision on a Measure and its Details

1) Common Requirements

The criteria for the decision on acceptable risk in the CPSA’s measures\textsuperscript{123} are “unreasonable risk” of products and “substantial risk” of a defect.\textsuperscript{124} These criteria bear on such factors as the pattern of the defect, the number of defective products, the severity of risk and the cost and benefit analysis.\textsuperscript{125} As can be seen from these terms, the

\textsuperscript{121}. OECD 1974, at pp. 35-36.
\textsuperscript{122}. Id. at p. 38. On the definition of cosmetics and household products, see id. at pp. 42-44.
\textsuperscript{123}. Scher 1973, at p. 30.
\textsuperscript{124}. CPSA Section 15.
\textsuperscript{125}. Scher 1973, at p. 57. Other laws also have similar terms: in FDA, “substantial risk,” and in OSHA, “significant risk.”
bridge between risk assessment and risk management rests on such vague words as "substantial" and "unreasonable."

Measures under the CPSA should be issued in the public interest but also to minimize adverse effects on competition.\textsuperscript{126} For this purpose, cost-benefit analysis was introduced in the 1981 Amendments to the CSPA. This analysis is vulnerable, however, to the influence of safety agencies' philosophies, objects and motives.\textsuperscript{127}

The CPSC prepares the data to describe the potential benefits and costs of the chosen measures, even those costs and benefits that cannot be quantified in monetary terms. For example, in the case of lead poisoning, there has been some criticism that the CPSC simply calculated the costs in cents per gallon without considering many intangible factors such as the lead level in children's blood, the relation of lead exposure levels to individual health, and the overall expense of such harmful effects on health.\textsuperscript{128} The critics say that the CSPC should have considered whether the ban on the paint containing lead would give consumers greater health benefits than total costs.\textsuperscript{129}

The CPSC is not expected to perform the cost-benefit analysis as a strict requirement but rather as a flexible

\textsuperscript{126} Id.

\textsuperscript{127} OECD 1987, at p. 15. For example, the US is thought to have more parentalism when drafting regulations than Canada, focusing on excessive protection of the consumer.

\textsuperscript{128} Id. at p. 44.

\textsuperscript{129} Id. Another example is a lawn mower specification case.
mandate.\textsuperscript{130} While agencies under the Office of Management and Budget (OMB) mostly consider and perform cost-benefit analysis as the most important element in decision, independent agencies like the CPSC just refer cost-benefit analysis to unreasonable risk judgment as a supplement.\textsuperscript{131}

Adjudication must not be used if a standard would "adequately protect the public from the unreasonable risk of injury."\textsuperscript{132} The requirements in the adjudication process are judged based on the findings on such issues as the degree and nature of the risk of injury, the approximate number of consumer products subject to the rule, and the indispensability to the public of that particular product.

2) Participation

One of the most important elements that can bring about different results in risk management is who participates in the regulatory process, e.g., consumers, industries, employees, mass media, etc.\textsuperscript{133} Participation by consumers is one of the most important factors.\textsuperscript{134} Consider

\begin{itemize}
  \item \textsuperscript{130} Id. at p. 43. The other agencies are strictly supervised by OMB.
  \item \textsuperscript{131} Viscusi, at p. 44.
  \item \textsuperscript{132} Id. at p. 42.
  \item \textsuperscript{133} Cummings, at pp. 130-136.
  \item \textsuperscript{134} Foreign industries's participation is rare though very influential. For example, five OECD member countries adopted statutes on cosmetics safety that introduced a private trade association to create voluntary standards and provide surveillance. Among them, only the UK and the US gave foreign exporters the chance to participate in making regulations. See
\end{itemize}
this example. When the FDA announced the proposal of a ban of saccharin because of its carcinogenicity, the diabetes association appealed and mobilized the mass media focusing on what those with juvenile diabetes and those employed in related industries would suffer from the ban. This mobilization was dramatic because people personalized the possible agonies which would result from the FDA's decision. Industries that used saccharin also attacked the FDA report, which warned of the possibility of cancer if an average adult consumed 800 cans of diet soda a day, and appealed that there was no substitute for saccharin. The frustrated FDA gave up the idea of a ban on saccharin.

In order to prevent undue influence from industries, the CPSC prohibits its staff and employees from having any relations with them.¹³⁵ For example, they do not have the voting right to decide voluntary standard proposed by the private standardization bodies.¹³⁶

3) Decision Cases

An excellent example of the attitude of the product safety agencies toward scientific evidence can be seen in the carcinogen standard and the ban on aspartame and cymalate as food additives. At first, aspartame was

¹³⁵ Lemov at 3.11. CPSA Section 4(c).
¹³⁶ Lemov at 3.11, 3-17, note 8.
petitioned in 1973 to the FDA for sale as an ingredient in dry foods, powdered beverages and tabletop sweeteners. The FDA approved it on the condition that a warning be attached for people who have phenylketonuria. However, before it went on sale, formal opposition was publicized that it was especially harmful to children and pregnant women, possibly causing brain tumors or mental retardation. The FDA suspended its use in 1975 for further study and created Board of Inquiry to review the reports from fifteen safety studies.

The FDA subsequently permitted the use of aspartame in dry foods with a warning label in 1980, under the condition that the manufacturers voluntarily monitor the product and notify the FDA of any possibility of harm. This decision was made contrary to two scientific reports: one by Richard Wurtman, a specialist in neuroendocrine regulation, and the other by the Center for Science in the Public Interest, which warned that it may cause chemical changes in the brain when combined with carbohydrates. The FDA also approved its use in soft drinks and wet foods.

Saccharin and aspartame survived the battle, though they are regarded as more dangerous than cyclamate among scientists. Their survival demonstrates that adjuciations
are often issued without inconsistency in value judgment on the scientific report.\textsuperscript{137}

In 1958 the FDA listed cyclamate, another artificial sweetener, in the Generally Recognized As Safe list (GRAS list) after it analyzed comments of the scientists on safety questionnaires. The FDA did not perform any tests on it because there were no indications of harm in the reports of the scientists. It was then sold in great amounts in the wake of the fitness fad. However, subsequent reports of possible harm as well as the aggressive lobbying and advertisement of the sugar industry prompted the FDA to initiate animal experiments. After cancer symptoms were discovered in the lab animals, the FDA banned cyclamate.\textsuperscript{138}

In this instance the FDA made its decision following these negative reports instead of those positive reports that pointed out that saccharin and other additives in processed foods were more harmful than cyclamate. When the FDA assessed the risk of cyclamate and decided measures and acceptable risk, it carried out experiments on cyclamate and did not carry out experiments on its substitute, saccharin.\textsuperscript{139} Many subsequent reports after the ban supported the relative safety of cyclamate, but whether or not cyclamate is a carcinogen to human bodies is still

\textsuperscript{137} In Canada there is no restriction on the sale of cyclamate, but saccharin was banned, contrary to the decision of the US. See Cummings, at p. 139.

\textsuperscript{138} Cummings, at pp. 123-127.

\textsuperscript{139} Id. at p. 130.
uncertain. Nonetheless, the public and the beverage companies now show lukewarm attitudes toward the banned cyclamate,\textsuperscript{140} and most beverage companies have discontinued cyclamate in their products.\textsuperscript{141}

Whether a substance is a carcinogen is based on Delaney’s zero-risk cancer standard, which states that “no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or by animal.” However, the Delaney Amendment has been criticized on account of inaccuracy and inefficiency. The critics argue that extrapolation from animal experiments to humans can possibly contain errors, and that the zero-tolerance policy is unnecessarily rigid and prohibits the possible significance of other product features and freedom of choice.\textsuperscript{142}

\textsuperscript{140} Id. at p. 128.
\textsuperscript{141} Id. at p. 129.
\textsuperscript{142} Id. at pp. 133-134.
B. Safety Standards on Products

1. Regulation and Standard

The regulation makers and the standard makers are largely different from three perspectives. Firstly, from an economic prospective, the former usually overestimates the benefits and underestimates the costs, while the latter usually overestimates costs and underestimates benefits. Secondly, in the regulatory philosophy perspective, the regulation makers have the view that manufacturers should follow enhanced technological standards. They have a more paternalistic tendency to protect consumers from harmful products than the standard makers. The standard makers, on the other hand, try to understand industrial situations, assuming that buyers are clever enough to judge the products for themselves. Standards are based on the technology feasible to the industry and are protective of managerial discretion. They tend to put the practices and the technical and economical feasibility of industry in the foremost position, while the regulation makers try to consider a variety of opinions from participants. Regulation makers set early deadlines for compliance, while

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143. On examples of product safety standards, see Bass at p. 94, table 5-1.
standard makers are careful in the adoption of unproven and new technology. These differences result from the fact that standard makers are concerned about product liability more often than regulation makers. Such concern dictates that standard makers avoid addressing issues of consumer misuse and embracing new technologies. Regulations are usually made by lawyers, while standards are set by engineers.

Thirdly, from an evolutionary perspective, while the standard makers have a prospective view, regulation makers have a retrospective one. Regulation makers usually intervene after a crisis, or a major disaster, while standards are usually set in order to avoid such disasters. Most countries adopt either or both of them as a risk management strategy. Nonetheless, the degree of dependence on either may be different.

The CPSC tried to set mandatory standards but was frustrated by the unfriendly attitudes of courts and the Congress. As a result, it has occasionally turned to private standards. Meanwhile, the European Community (EC) is more dependent on standards than the US. The EC has the directives on general safety and standards; relevant laws of the member states are subject to these directives. Most product safety standards in the EC are made by the private

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145. Id. at pp. 17-20.
146. This different degree may influence on foreign exporters with different severity of trade pressure.
standardization bodies, such as the European Committee for 
Standardization (CEN) and the European Committee for 
Electro-Technical Standardization (CENLEC).\textsuperscript{147} Contrary to 
the developed countries, the developing countries have few 
private institutions that are able to get safety standards 
due to a lack of money finance and experts. Most 
institutions are usually monopolized by their government, 
and standards are also rare. Therefore, the voluntariness 
of standards is really weak in most developing countries.

2. Conditions

The CPSC can set mandatory standards under the CPSA if 
voluntary standards are not complied with or if the 
compliance with such voluntary standards would not 
eliminate or adequately reduce the risk of injury.\textsuperscript{148} The 
issue here is how the CPSC interprets the above conditions,

\textsuperscript{147} The European Committee for Standardization(CEN) and the 
European Committee for Electro-Technical Standardization(CENELEC) 
are private associations whose members are the eighteen national 
standardization bodies. However, CEN and CENELEC’s drafted 
standards are publicized to members of ISO/IEC, which then make 
comments on them. The areas not covered by the European 
standardization scheme are under national standard-making 
or industrial federations can initiate the standardization project. 
Proposed standards are usually decided by consensus. Then, 
national member organizations start to modify the standards. 
European standardization usually starts from the initiation of 
ISO/IEC, whose representative national member organizations are 
British Standards Institution(BSI), Deutsches Institut für 
Normung(DIN), American National Standards Institute(ANSI) and 
Association Francaise de Normalisation(AFNOR). See GATT, Trade 
Policy Review: European Communities 1991, at p. 122, 123 and 125 

\textsuperscript{148} CPSA Section 7 (a).
because only the CPSC can determine the existence of one of those situations as a pre-judiciary decision.

The CPSC’s interpretation was in the beginning favorable toward mandatory standards. The CPSC’s vigorous attempts to create mandatory standards were, however, frustrated by the court’s denial of the agency’s ambitious regulation scheme and budget reduction by Congress.\footnote{149} As a result, the CPSC started resorting to recalls and bans.\footnote{150} Eventually, the CPSC seems to have concluded that it should only set comprehensive general safety specifications or general provisions and entrust the details to private standards, while monitoring the private standard makers’ activities and regularly performing inspections and surveys over their operations.

3. Characteristics

Despite their voluntariness, a good number of standards have turned out to be economic mandates against manufacturers, sellers, or distributors, because they recognize that they will be out of competition unless they follow those standards. This power of standards is demonstrated in the showdown between the UL standards and the CPSC standards on a woodstove. Product liability

\footnote{149} Lemov, at 3.09.\footnote{150} OECD 1991, at p. 12.
insurance and the local building code require wood stoves to follow the UL safety standards rather than CPSC's specifications. Without the UL marks, the premium is higher, and the product cannot be used as material for buildings.\textsuperscript{151}

Furthermore, recent trends see voluntary standards being more utilized than mandatory standards of government agencies on the international level.\textsuperscript{152} The reason is attributable to the limited capacity of the safety agencies. As a compromise, product safety agencies prescribe general product safety regulations and laws and entrust the power to make specific standards to non-governmental bodies, controlling their compliance with a ban or a recall.\textsuperscript{153}

There are three points to consider in judging the standards.\textsuperscript{154} The first is the general nature of products, i.e., their performance or characteristics. Therefore, a standard can be either a performance standard or a characteristic standard. Compliance with a performance standard can be judged by a performance attribute test, such as a flammability test of clothing materials. Most standards are claimed to be performance standards, but many

\textsuperscript{151} Cheit, at p. 95.
\textsuperscript{152} The other two of three distinctive trends nowadays are the regionalization of standards and mutual recognition instead of harmonization. See, OECD 1991, at p. 11.
\textsuperscript{153} OECD 1991, at p. 12.
\textsuperscript{154} These three considerations are also true of mandatory standards.
of these are, in fact, characteristic standards because some performance standards derived from one feasible design for compliance. The second consideration is the scope and level of protection intended by the standards. The standards do not mean only one level of standard for one product. Depending on different degrees of safety features, different measures can be taken. The third consideration is applicability. It costs less for new products to comply with strict standards than for existing products. Strict regulation is therefore rational for new products. The costs of compliance should be embodied in similar products with the same ratio as much as possible.\textsuperscript{155}

4. US Practices

a. Types of Voluntary Standard Makers

According to the National Bureau of Standards, 420 nongovernmental standard organizations compiled 32,000 standards, of which health and safety standards take up the largest part. The private standard makers may be trade associations, professional societies, general membership

\textsuperscript{155}. Viscusi, at pp. 24-26.
organizations, and third party certifiers. These four groups regard due process and consensus as very important.\textsuperscript{156}

The trade associations, such as the American Petroleum Institute, make few product safety standards. They are driven by their closed structure and homogeneous members for their interests. Professional societies and general membership organizations have more diverse members than the trade associations, but the general membership organizations have a broader range of members and are more related to public safety. Examples of these are the Society of Automotive Engineers and the American Society of Agricultural Engineers; examples of the professional societies are the American Society for Testing and Materials (ASTM) and the National Fire Protection Association (NEPA), which have various members including competitors. Most standards the general membership organizations have drafted deal with public safety including product safety. The general membership organizations have arranged their budget by means of sales of their publications and standards. Third party certifiers test the product in the light of standards and make their own standards. For example, Underwriters Laboratories (UL), the National Sanitation Foundation, which certifies

\textsuperscript{156} Chait. at pp. 21-23. Consensus here does not mean the consensus in Chapter II, D, 1. Consensus here means less than animosity and more than majority.
restaurant equipment, and the International Association of Plumbing and Mechanical Officials are some of examples.\footnote{157}{\textit{Id.} at pp. 23-25.}

b. Their Practices

All private standard makers do not slant toward the industry's interest. Other organizations than trade associations are often asked to set standards independently in order to serve the clients of the trade organizations.\footnote{158}{\textit{Id.} at pp. 11-14.} The procedure for making private standards is often similar to that for mandatory standards in terms of such features as the notice-and-comment procedure and the guarantee of interest groups' participation. For example, the Board of Standards Review, which reviews appeals from the standards of the ANSI and ASTM, allows consumers to participate in making standards. Some private standard makers insist on their professionalism and impartiality, and not all standard makers are controlled by determining industrial interests. Nonetheless, their efforts still fall short of those of mandatory standard makers.\footnote{159}{\textit{Id.} at pp. 14-17.}

The private standard makers in most OECD countries utilize consumer participation. For example, the ANSI has the Consumer Interest Council to incorporate consumers' attitudes toward products in their standard-making
process.\textsuperscript{160} The International Organization of Standards (ISO) also utilizes consumer participation in a similar way.

c. Specific Standard Makers

ANSI can be called a coordinator and certifier of overall national voluntary standards, although it does not make standards but only approves standards proposed by other standard makers. 900 standards of ANSI's 8,500 certified standards are under the category of "safety and health" and consist of procedural and substantive standards. The members of ANSI are industry representatives and standard makers including governmental product safety agencies.\textsuperscript{161}

Other important private standard makers are the American Gas Association (AGA) which approves standards for gas appliances, and the American Society of Mechanical Engineers (ASME) whose Boiler and Pressure Vessel Code is incorporated into law in the US and Canada.\textsuperscript{162} Also, the ASTM's F-15 Committee has developed product safety standards for such items as high chairs, cigarette lighters and bathtub grab bars.\textsuperscript{163} In local or provincial building

\textsuperscript{160} OECD 1991, at p. 35.

\textsuperscript{161} Id. at p. 26.

\textsuperscript{162} The Supreme Court decided that this code is anti-competitive in 1983. Id. at p. 27, note 8.

\textsuperscript{163} The relation between ASTM and ANSI broke up and the former no longer files standards for approval to the latter. Id. at p. 27.
codes, references have been made to the codes drafted by
the International Conference of Building Officials (ICBO),
the Southern Building Code Congress International (SBCCI),
the Building Officials and Code Administrators
International (BOCA), and the Council of American Building
Code Officials (CABO).\footnote{164} The NEPA's National Electric Code
and Life Safe Code are also frequently referred to by other
laws.\footnote{165} Furthermore, the UL has safety standards on
microwave ovens, fire extinguishers, and so forth.\footnote{166}

If a private company's purchasing power is great due
to its large size, its standards in purchasing heavily
influence the suppliers of those products. Retailers
generally quote the private safety standards. For example,
J.C. Penny, a huge retailer, incorporates private safety
standards into its purchase orders.\footnote{167}

\footnote{164} Despite domination like the above, local building codes
are still broad depending on the region, the type of construction
and the standards of the insurance industry. In addition, those
building codes usually quote standards drafted by other types of
standard makers. For examples, many UL standards are incorporated
into local building codes. Gas utilities can be installed only
when complying with safety standard of American Gas Association
(AGA). \textit{Id.} at p. 28.

\footnote{165} \textit{Id.}

\footnote{166} \textit{Id.}

\footnote{167} \textit{Id.} at p. 9.
CHAPTER IV
THE ANALYSIS OF ARTICLE 2.2 OF THE TBT

A. History

1. From GATT XX (b) to TBT

Before the TBT, the rules of international risk assessment and risk management of product safety were provided by GATT. The relevant provisions in GATT provided that a GATT member state may issue “measures ... necessary to protect human, animal or plant life or health,” unless those measures are “a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade”\(^{168}\) and discriminate against foreign goods outside of a Contracting Country compared with domestic goods.\(^{169}\) GATT also required that those measures “pertaining to requirements, restrictions or prohibitions on imports ... or affecting their sale, distribution ... insurance, [or] warehousing inspection” should be published.\(^{170}\)

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\(^{168}\). GATT Article XX body and Article I.
\(^{169}\). GATT Article III.
\(^{170}\). GATT Article X.
Article XX(b) is a representative provision on the national risk assessment and risk management of product safety, and this provision has been called the mother provision of the TBT. However, since Article XX(b) has been shown to impose limits on national sovereignty over health and safety legitimacy, some protectionistic countries have tried to interpret their sovereignty very broadly in regards to all areas of the NTBs.\textsuperscript{171} This protectionism has become a wake-up call to the free-trade believers.

Despite the urgent need for an international agreement on technical barriers, due to diversity and complication it took twelve years to conclude the NTBs.\textsuperscript{172} After the decision in the Tokyo Round to develop health and safety regulations, the TBT was adopted on April 12, 1979 and entered into effect on January 1, 1980.\textsuperscript{173} They decided that "the only way to remove NTBs was to write new and clearer rules defining what governments could and could not do with

\textsuperscript{171} Houtte, at p. 130, note 9.

\textsuperscript{172} OECD 1991, at pp. 17-18; within the OECD region the matters on safety regulations and standards make up 5 or 10 percent of all technical barriers. Most of them are related to electrical appliances. Despite the ratio, they have significant effects. On difficulty of measuring the effect of NTBs, see Jackson, at p. 364. Oliver Long thinks that it is almost impossible to measure. The agreements on NTBs are agreements on subsidies and countervailing duties, customs valuation, anti-dumping, import licensing procedures and government procurement. See, Oliver Long, Law and its Limitations in the GATT Multilateral Trade System, at p. 25 and 28 (1985). The cost in EC due to differences in health and safety standards and regulations amounts to 60 billion dollars annually. See Houtte, at p. 129, note 4.

\textsuperscript{173} There are thirty-nine member states as of 1990.
various non-tariff policy instruments." The TBT embodied the new enforcement system that has been discussed.

2. The Revised TBT on Risk Assessment and Risk Management of TBT

The revised TBT incorporates new provisions on risk assessment and risk management into the existing TBT. Its Preamble states that health and safety measures can be set "at the levels a country considers appropriate." This notion of national discretion in risk management raises the possibility of a controversy over its meaning. The second sentence in Article 2.2 was therefore inserted in order to address the issue of the relationship between free trade and national sovereignty: risk assessment and risk management should be "... not more trade restrictive than necessary to fulfil a protection of human health or safety taking account of risks."

Article 1.5 of the revised TBT transfers to the ASPM the newly introduced regulation on sanitary and phytosanitary measures on the products to be consumed by human bodies. The ASPM is a special Agreement to TBT, which was proposed during the UR. Under the Negotiating Structure

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175. The provision on risk assessment and risk management is Article 1.1 in the previous TBT and in the current TBT, the Preamble and Article 2.2.
and Plan of the UR prepared by the Group of Negotiations on Goods (GNG), the Group of Negotiations on Services (GNS) and the Trade Negotiations Committee (TNC) set three negotiable plans in agriculture.

The principle of "minimizing the adverse effects that sanitary and phytosanitary regulations and barriers can have on trade in agriculture," *inter alia,* was the first plan.176 Then, in the mid-term review of the Trade Negotiations Committee, the prototype of the ASPM was drafted.177 The trade negotiators agreed on four main areas of agriculture, one of which was the ASPM.178 Since the "oil seed dispute" between the US and the EC,179 these four areas were packed into one package which required all or zero approval.

B. Application

The TBT is mandatorily applied to all GATT member states, unless they abandon membership of the new GATT through Article-XXI procedure in GATT.180 This is a great departure from the previous TBT, which was only applicable

178. Hudec, at pp. 183-4, 188; other areas are "market access," "domestic support" and "export subsidies."
179. *Id.* at p. 186.
180. GATT Article 15.2.
to the members of the TBT itself. The TBT applies to all products in international trade except those regulated by sanitary and phytosanitary measures.\textsuperscript{181} The technical regulations and standards in Article 2.2 of TBT are applicable to both the characteristics and the process and production methods (PPMs) of the product.\textsuperscript{182} The TBT treats standards differently from regulations. The standards are not bound by such requirements as "not more trade restrictive than necessary to fulfill," the strict existence of legitimacy, and risk assessment.\textsuperscript{183}

According to the definition of product safety regulations and standards in the TBT, judiciary decisions on product safety are not taken into consideration.\textsuperscript{184} However, in countries like the US, where judiciary decisions are very influential in the risk management mechanism, court decisions on product safety are usually reflected in the safety regulations.


\textsuperscript{182} Annex I, Article 1 of TBT. See 30 I.L.M. 1594 (1991); the product safety regulation and standard is one of the technical regulations and standards. Recently, developing countries have felt that many safety regulations in developed countries will be more related to PPMs; for example, in the legislation of the Marine Mammal Protection Act (MMPA) in Tuna Dolphin case. The introduction of PPMs is likely to create more trade battles.

\textsuperscript{183} TBT Article 5, Annex 3: Code of Good Practice.

\textsuperscript{184} TBT Annex 1.
C. Requirements

1. General Requirements

A general requirement throughout the TBT is that the technical regulations and standards should not be an unnecessary trade obstacle. For example, in order to prevent regulations from becoming an unnecessary trade obstacle, a country should discontinue certain regulations when the circumstances or objectives which prompted them no longer exist, or when new circumstances or objectives require less trade restrictive measures.185

There must be a reasonable time period between the publication or announcement of a new technical regulation and its implementation so that other countries can respond and cope with the change.186 Countries issuing adjudications should also notify alleged violators and give them a chance to respond or explain, as is the case in the CPSA.187

The safety agencies of an importing country may require exporters to disclose certain trade secrets, e.g., methods of production. However, if the disclosure of a trade secret is required in a country where no protection is guaranteed against other competitors, it will discourage

185. TBT Article 2. 3.
186. TBT Article 2. 12.
187. CPSA Section 15.
exporters from trading with that country;\textsuperscript{188} therefore, such
practice would become a trade obstacle.\textsuperscript{189} In some cases,
some developing countries intentionally impose higher
standards than their domestic standards or require
disclosure of technologies in order to acquire advanced
foreign technology from the more advanced exporting
countries.

If a regulation gives de facto competitive
disadvantage to an exporter when compared with the domestic
industry in the importing country, it can become an
unnecessary trade obstacle. Suppose that company X in
England cannot get product liability insurance necessary to
export to the US at a reasonable cost. It would have a
disadvantage in penetrating the US market because of the
increased cost. The higher premium on export products
results from the safety standards of the US, whose
technology and practices are different from those of the
exporter.

Moreover, consider the difficulty for exporting
countries in acquiring certifications from private or
governmental safety institutions. Their products may fall
short of the expectations of consumers. The independent

\textsuperscript{188} The Freedom of Information Act (FOIA) and the CPSA in the
US protect trade secrets. This can be a touchstone for other

\textsuperscript{189} Breyer and Stewart, at p. 1060. In the US under the
Freedom of Information Act (FOIA), trade secrets and commercial
information and information not allowed to be disclosed according
to other laws are exemptions to disclosure [5 U.S.C. Section 552
(b)(3),(4)].
importers and related entities would worry about susceptibility to liability to the injured consumers or even criminal charges.\textsuperscript{190} Therefore, the exporters may face, \textit{de facto}, a rejection or stringent requests by the importers. Then the practices of an importing country that requires higher standards than the exporting country become a \textit{de facto} trade obstacle.

The clause that regulations should "not be prepared, adopted and applied with a view to or with the effect ..." in the scope covers the entire stages of risk assessment and risk management for product safety.\textsuperscript{191} Then, during the entire stages, the activities of safety agencies should not be an unnecessary obstacle requirement.

2. Specific Requirements

\textbf{a. Free Trade's Superiority to Safety Legitimacy}

The free trade principle appears to have more weight than safety legitimacy, according to the clause "not more trade restrictive than necessary to fulfill a legitimate objective." Therefore, it is difficult to apply here Daniel E. Esty's theory that the US Supreme Court's balance

\textsuperscript{190} Abbott, at p. 20. Exporting companies that have exclusive distribution contracts or equivalent subsidiaries are in a much more comfortable situation.

\textsuperscript{191} Daniel C. Esty, \textit{Greening the GATT}, at pp. 113-130 (1994).
test between interstate trade and environmental protection can be applied to the relation between the international trade and environmental protection. The environmentalists in the US would argue that environmental legitimacy is more important than free trade.

b. Necessity

The meaning of the clause, "necessary to fulfil a legitimate goal," is that regulations should be the last resort for product safety. Analogous to the Tuna Dolphin cases, a regulation which does not meet the necessity requirement is a violation of the principles in GATT and Article 2.2 of TBT.

The decision in Tuna Dolphin I describes the necessity of a measure in this way: "it has exhausted all options reasonably available to it to pursue its dolphin protection objectives through measures consistent with the (GATT)." Tuna Dolphin II described necessity in more detail:

Contracting party cannot justify a measure inconsistent with another GATT provision as necessary in terms of Article XX (d) if an alternative measure which it could reasonably be expected to employ and which is not inconsistent with other GATT provisions is available to it. By the same token, in cases where a measure consistent with other GATT provisions

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192. The interpretation follows cases such as Tuna-Dolphin I, Tuna Dolphin II, CAFE and the Gas Guzzler Tax case.
193. On the same opinion, see Houtte, at p. 134; however, he thought that "necessary" in GATT XX means at least larger legitimate purpose than restrictive trade effects.
194. BISD 3d (1955), at p. 189 et seq.
is not reasonably available, a contracting party is bound to use, among the measures reasonably available to it, that which entails the least degree of inconsistency with other GATT provisions.¹⁹⁶

This decision illustrates a narrow interpretation of necessity to maintain the international free trade. It shows a strict interpretation of the necessity of safety protection to a degree that the importance of the safety regulations should "take precedence over the requirements of free movement of goods."¹⁹⁷ Even though the TBT does not provide an exact definition of necessity, the interpretation of GATT Article XX can be applied.

c. Discretion over Appropriateness

According to the Preamble to the TBT, Article 2.2 allows a member country to decide "the levels it considers appropriate" on such issues as the degree of the risks to be protected, the measures for protection of human safety, and the nexus between risks and measures. The decision of the appropriate level is left up to the national government. The vagueness in this provision is one of the greatest failures of the TBT, since the lack of exact criteria allows a country to evade international regulation. The TBT should provide specific provisions on what appropriateness means and how to estimate it.

d. Risk Assessment

Article 2.2 explains how to utilize available scientific and technical information, related processing technology, and intended end uses of products in assessing risks. This provision, however, is too broad and leaves room for wide differences in its interpretation.

The first problem is determining the availability of scientific and technical information. Often the parties in a dispute must agree on the source of available information. For example, in the case of Thailand's restrictions on the importation of cigarettes from the US, both parties agreed to use the scientific evidence from the World Health Organization (WHO) as available information.\footnote{\textit{GATT, GATT Activities 1990}, at p. 59 (1990) [hereinafter, GATT 1990].} Without such agreement, it is difficult to define availability. Moreover, if safety test reports contradict each other, which report or theory should be adopted is a difficult question. The dispute settlement panel sometimes decides to set up an expert group for the decision on the availability and selection of scientific and technological theories.

The second problem is that Article 2.2 does not sufficiently describe the methodology of risk assessment and risk management. The TBT should classify the
differences among the member states in terms of the method and process of their risk assessment and risk management and then should decide on a uniform method and its principles.

D. Special Considerations

1. Harmonization of Standards or Specifications

a. A Harmonized Safety Standard, ISO 9000 and the Requirements in Article 2.2

The TBT encourages its member states to use international standards or relevant parts of them as bases for their national technical regulations while taking into consideration their unique national situations. For this purpose, the TBT gives an advantage to a party that adopts international standards by allowing the presumption of no violation (thus lower burden) in dispute settlement procedures. Therefore, if a country follows the

199. Specification means mandatory standards. Here, "standards" may be used as either specification or standard.

200. Houtte, at p. 129, note 3; the justification for harmonization comes from the experience that differences of regulations and standards cause a lack of scale economies, high distribution and production costs, and higher research expense because goods made in compliance with one country cannot be sold in other country.

201. TBT Article 2.4.
international standards, it does not have to demonstrate compliance with the requirements in Article 2.2.

The ISO/IEC standards are an example of the internationally harmonized standards. The International Organization of Standards (ISO) was established in 1946 and sets safety standards; the International Electro-Technical Commission (IEC), an affiliation of the ISO, was established in 1906 and specializes in electronic matters.\(^{202}\)

Some sectors in international trade which use the ISO standards for quality management standards include the electronic, computer, aerospace, transportation, and nuclear engineering industries, and the pharmaceutical and health care sectors.\(^{203}\) The ISO has many PPM standards for regulating product quality management. One of these PPMs is the famous ISO 9000 series, which includes quality control in the safety of products as well as in the work place.

The ISO/IEC standards are often incorporated into national safety standards. Japan, for example, adopted fifteen additional standards since early 1990 that are compatible with those of the IEC on household electrical

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\(^{202}\) McGovern, at pp. 55-56; other organizations working on standardization are the United Nations Economic Commission for Europe (UNECE) in 1947 and the OECD in 1960. Id. at 230; its success in this area is the Agreement concerning the Absorption of Uniform Conditions of Approval and Reciprocal Recognition of Approval for Motor Vehicle Equipment and Parts, and the International Convention on the Harmonization of Frontier Controls of Goods, which also contains control of compliance with standards.

goods and, additionally amended 117 existing standards to conform with IEC requirements.\textsuperscript{204} Also, the US adopted ISO 9000 under a different name, the ANSI/ASQC Q 900-1 series,\textsuperscript{205} which operates as a voluntary standards system.

b. International Harmonization of Methodologies

Harmonized international standards are described in general terms of performance standards, and their interpretations may vary depending on national legal theories and practices. Therefore, the differences in national theories and practices of safety standards cannot be ignored. Moreover, since national standards are more flexible than international standards in coping with changes in technology and consumer expectations, their existence is important even under a harmonized system of international standards. Considering the impossibility and undesirability of making universal international safety standards and regulations for all products, the practice of "harmonization based on well-equipped information" was proposed as second best.\textsuperscript{206}

\textsuperscript{204} GATT, Trade Policy Review: Japan, at p. 92 (1992) [hereinafter, GATT Japan]. Japan approved the use of food additives that are recognized as scientifically safe by the Codex standards.


\textsuperscript{206} OECD 1991, at pp. 63-64.
Harmonization of methodologies in making regulations and standards can be applied to fill the gap where uniform regulations are not desirable. In trying to reach an agreement on methodology, the EC proposed a code of good practices that can regulate any standard organizations. This code took the practices of the ISO and the Codex as a model. However, it was rejected because the majority in the EC at that time preferred to follow the scheme drafted by the TBT and ASPM.\(^{207}\)

However, the ISO/IEC cannot guarantee international harmonization of safety regulations and standards, despite the existence of the International Information Network (ISONET)\(^{208}\) and the Council Committee on Consumer Policy (COPOLCO).\(^{209}\) Therefore, the Technical Advisory Group (TAG) in the ISO and the Advisory Committee on Safety (ACOS) in the IEC, and the International Federation for the Application of standards (IFAN), were organized in order to assist in drafting the general guidelines for the standards.\(^{210}\)

In achieving harmonization of national practices, the harmonization of classification systems is most important because differing product-coding systems can become a


\(^{208}\) The ISONET accumulates information on regulations and standards of member countries.

\(^{209}\) The COPOLCO guarantees participation by consumers in the ISO's process of making standards.

hindrance when comparing products among countries.\textsuperscript{211} For example, after Canada changed its coding system for certain products after having used the same classification system as the US, it became difficult to compare those products between the two countries.\textsuperscript{212}

Also, the method of calculating the severity of and expenses for injuries arising out of the use of the product must be harmonized among countries in order to provide fair compensation to the injured consumers. Furthermore, all relevant information and data must be disclosed for inspection by an international organization.

2. Mutual Recognition

The GATT principle of mutual recognition or equivalency should also apply to the TBT, even though the TBT does specifically recognize each country's regulations. This is because some provisions in GATT encourage the member countries to try to enhance their mutual interest and the free trade principle.\textsuperscript{213} Article 5 of the ASPM also adopts the equivalency principle, saying that if some products comply with Country A's regulations whose

\textsuperscript{211} OECD 1987, at p. 11.
\textsuperscript{212} Id. at p. 14.
\textsuperscript{213} Long, at p. 11; on a related article, see supra Chapter IV, C, 1.
objectives and effects are equivalent to those of Country B's, A and B should recognize each other's regulations.\textsuperscript{214}

However, the US is likely to oppose the above interpretation. The US environmentalists have already argued against the equivalency principle in the ASPM, declaring that the adoption of the ASPM would undermine the national sovereignty of the US in regulating the safety of imported products.\textsuperscript{215}

The interpretation of key words such as "equivalent, similar, and identical" is problematic, since these terms can mean different things to different countries. To prevent conflicts at least among EC states, the EC clarifies "mutual recognition" in that "products which are legally produced or marketed in at least one [EC] member state are entitled to free circulation throughout the EC irrespective of their origin."\textsuperscript{216} The Non-EC countries could have mutual recognition agreements with the EC or with each other, or must pass through the standardization body within the EC, which is called "a notified body" or "accredited registrar."\textsuperscript{217}

\begin{footnotesize}
\textsuperscript{214}. ASPM Article 5.
\textsuperscript{217}. Id. at p. 125.
\end{footnotesize}
After recognizing the importance of acknowledging third party certificates, the EC established the EN 45000 series to qualify testing labs and registers. The third party agencies examine compliance with ISO 9000 and give or refuse a passing mark.\footnote{218}

3. Local Regulations and Specifications\footnote{219}

The central government of a member state has the duty of ensuring that its local governments and non-government bodies comply with Article 2.2 of the TBT.\footnote{220} The preemption theory has been utilized in the US in the pursuit of the uniformity of risk assessment and risk management. For example, in the CPSA no state or political subdivision of the state can make any regulation or retain already made regulations whenever there are CPSA standards in effect, unless local regulations are the same as or higher than the requirements under federal standards.\footnote{221} The CPSA sometimes respects the regulations and standards of the state or political subdivions of states if they provide higher protection for consumers and do not put undue burden on interstate commerce. In determining whether they are

\footnote{218. Rabbitt, at p. 33 and 35.}
\footnote{219. The EC is regarded as the central government and other countries are the local government according to the TBT. See McGovern, at p. 236.}
\footnote{220. TBT Article 3.1 and 4-5.}
\footnote{221. CPSA Section 26 (a), (b).}
unduly burdensome, data on technical and economic feasibility are considered.\textsuperscript{222}

The application of the preemption theory varies among regulations. For example, in contrast with the above example of the CPSA, preemption in the FHSA applies only to labeling, leaving the rest to the control of state laws and regulations.\textsuperscript{223} If regulations of the local government or non-government body adopt higher standards than those of the federal government, it is not necessary to notify other countries.\textsuperscript{224} Therefore, higher standards set by the local governments will make it difficult for foreign industries to recognize and to follow those standards.\textsuperscript{225} For instance, California has higher standards for automobile emission control and the cigarette ignition resistance of upholstery. New York also has tougher regulation standards for building materials, which require the fire toxicity of all materials to be inspected. These non-uniform higher standards are burdensome to exporting countries.\textsuperscript{226}

\textsuperscript{222} CPSA Section 26 (c).
\textsuperscript{223} Scher 1973, at p. 82.
\textsuperscript{224} TBT Article 3. 2. OECD 1991, at p. 27.
\textsuperscript{225} CPSA Section 26 (c).
\textsuperscript{226} OECD 1991, at p. 27.
4. Regulations or Standards in and toward Developing Countries

The idea of special treatment and technical assistance for developing countries has been deeply rooted in the GATT system since the Tokyo Round. Article XVIII speaks of "governmental assistance to economic development," and Articles XXXVI and XXXVII give special status to developing countries under the non-reciprocity principle. This preferential treatment of developing countries is also embodied in the TBT and the ASPM in the form of technical assistance and technology transfer. However, there are not yet comprehensive norms in this area, and such provisions will not be effective without imposing certain legal duties on the developed countries.

Moreover, most national safety regulations or standards do not have special treatment clauses for developing countries. The developed countries should take into consideration the developing countries' situations when making safety regulations and standards. They should also try to tolerate developing countries' regulations or standards.

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227. Long, at pp. 89-94.
229. On the origin of the special treatment, see McGovern at pp. 271-272.
5. Disputes

A violation of Article 2.2 of the TBT resulting in an "injury" can be brought before the Dispute Settlement Body (DSB) of the GATT. A violation of the previously existing safety regulations, if it also violates Article 2.2 of the TBT, may also be brought before the DSB.

Under the TBT, the individual victims of a safety regulation violation cannot bring an action against another government in a domestic court or the DSB of the GATT, while the injured individual companies or other legal entities in EC Directive may do so. Central governments as well as local governments can petition, according to Article XXIII, after consultation and negotiation. Depending on national legislation, a foreign company may be allowed to file a petition. The CPSA provides that the petitions are to be filed in a specified US court of appeals or to the CPSC.

The burden of proof of an Article 2.2 violation is on the country whose safety regulations are claimed to have been violated. However, if the regulations or the

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231. GATT XXIII and Understanding on Rules and Procedures Governing the Settlement of Disputes.
232. TBT Article 15. 2.
233. Houtte, at pp. 129-130.
234. EC Single European Act Article 30-36, 69, 170. Article 170 is for the regional commission’s right to petition.
235. CPSA Section 11(a) and 10.
standards in question are in line with internationally harmonized standards, the burden of proof will then be transferred to the country that has allegedly violated the regulations at issue.

The issues in the disputes mostly arise out of differences in interpretation of the TBT provisions. Take one such example. Korean food sanitation regulations have been attacked by the US since 1990. One issue has been the shelf life of processed foods. The US representatives claim 180 days on shelf is safe, while the Korean representatives claim less than 30 days is safe. This dispute has been under negotiation before the dispute panel of the GATT.

CHAPTER V
EVALUATION

A. Evaluation of the TBT

1. The Evaluation Standard, the New Approach of the EC

The European Community (EC) is more politically and economically, homogeneous than the TBT or GATT, and its members are historically and socially more interrelated with one another than the members of GATT. Because of similar cultures and common backgrounds, EC organizations have operated more harmoniously than those of any other international communities. Although the TBT or GATT cannot be expected to duplicate the EC experience, we may gain insights from the EC's systematic approach to risk assessment and risk management.

The EC's legal provisions are similar to those of GATT. Each member country has the right to set its own health and safety regulations or standards.\(^\text{238}\) To solve the problem of varying safety standards and regulations among the member states, Articles 30 and 36 of the European Union

\(^{238}\) EU Treaty Article 36.
(EU) Treaty provided that health and safety regulations and standards should not have the effect of quantitative restriction, arbitrary discrimination, disguised restriction, or hindrance, direct or indirect, to intra-community trade.\(^{239}\) Also, according to the Court of Justice, safety regulations and standards should satisfy the necessity requirement of human health and safety.\(^{240}\) This requirement of necessity has broader meaning than in GATT.\(^{241}\)

The EC has tried three approaches to deal with the differing safety standards and regulations among member countries.\(^{242}\) The first approach is called the "New Approach."\(^{243}\) Under the New Approach, the Council Directives prescribe essential requirements which are then supplemented by the national product safety agencies' voluntary standards. The second approach is the traditional approach, in which the Council Directive itself provides detailed standards for harmonization. The EC at first used the traditional approach to all products, until the Court of Justice in Cassiss de Dijon case strongly endorsed national sovereignty based on the principle of safety legitimacy. Consequently, the EC adopted the New Approach in the EEC Council Resolution on Technical Harmonization of Standards in 1985. See id. at p. 40.

\(^{239}\) Houtte, at p. 132, note 17.
\(^{240}\) Id. note 19.
\(^{241}\) Jackson, at p. 414.
\(^{242}\) OECD 1991, at pp. 40-42.
\(^{243}\) The New Approach was named for the EEC Council Resolution on the Technical Harmonization of Standards in 1985. See id. at p. 40.
Standards in 1985. The third approach takes national standards and regulations as the primary text for product standards, and the EC is simply notified of these as the reference for the other member countries.

2. The Characteristics of the New Approach

The New Approach is a systematic start to solving the problem of different safety regulations and standards among countries. Above all, the recent General Product Safety Directive is a comprehensive and relatively detailed program that can be a guide to the revised TBT. Therefore, a look at the characteristics of the New Approach may be helpful.

The New Approach is initiated only when national product safety requirements conflict with those of other member countries and impede free trade. If a product coming into the EC is classified as a "regulated product," related to health, safety, and environmental protection, it should meet the European standard, the EN 29000 standard, which is a voluntary standard identical to the ISO 9000

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244. Id. at p. 40.
Therefore, exporters who plan to market their products in the EC should get a certification of EN 29000 standard compliance in advance.

The following private organizations set the EN standards: the CEN for non-electrical product standards, the CENELEC for electrical product standards, and the ETSI for telecommunication standards. These standards are derived from the details of the Directives on the product safety, and they have already been approved by the EC.\(^{249}\)

Since the New Approach is to become effective in the future, the Council Directives of 1991 have not yet gone into effect, even though they have already been approved.\(^{250}\) Therefore, the detailed standards under the traditional approach are still in force as long as the Directives following the traditional approach are effective.

As long as the EC has set harmonized standards for a product, national regulations of a member state on that product cannot take effect, unless that member state notifies the Commission of its plan to make the regulation in advance. The Commission then decides whether a member state needs to have separate health and safety regulations different from the harmonized EC standards and whether

\(^{248}\) Rabbitt, at p. 36; children’s toys, the computer terminals and food Packaging are examples. Rabbitt, at pp. 31-33; one hot issue is software for operating systems because, if it has a defect, it may cause the human injury or death during operation.

\(^{249}\) GATT EC 1991, at p. 123.

\(^{250}\) Id.
those standards are reasonable. However, even the regulations endorsed by the Commission may be subject to annulment by the Court of Justice.\textsuperscript{251}

Furthermore, any private individual can challenge, in a national court, a national regulation or standard of a member country which violates EU Treaty Articles 30-36. The national court then requests the Court of Justice to make a preliminary ruling on whether the regulation at issue violates the Treaty and the Directives. The national court then predicates its own decision on the decision of the Court of Justice. The EC Commission and member countries can also request the Court of Justice to declare a member state's national regulation a violation of the Treaty.\textsuperscript{252}

Finally, it should also be noted that a defendant whose products are certified under the ISO standard or the EC standard has an advantage in defending a product liability lawsuit because his products are presumed to have been produced under a defect-free production process and are therefore safe.\textsuperscript{253}

\textsuperscript{251} EU Treaty Article 100A, 100B, and 100.
\textsuperscript{252} EU Treaty Article 169 and 170.
\textsuperscript{253} Rabbitt, at pp. 35-36.
3. The TBT in Terms of the General Product Safety Directive

As in the EC's General Product Safety Directive, the TBT should contain more details on risk assessment and risk management, such as the harmonized methodologies infra and clear definitions of general terms. For example, while the TBT does not provide a definition of safety, the EC Directive has full definitions which are helpful in hazard identification and risk characterization. The EC Directive also clearly defines the producer and distributors, which reduces the conflicts surrounding the interpretation of those words. Further, the TBT should clearly enumerate such considerations as characteristics of products, technical feasibility, and so on that are necessary in risk assessment.

Risk assessment and risk management in the EC are triggered by a violation by manufacturers of either a general duty or a specific duty. A general duty is the duty of due care, and a specific duty may be the duty to supply safe products, the duty to provide all necessary

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255. Of course, because the Directive is part of the New Approach plan, the features of the New Approach are true of this Directive.
258. Directive Article 2 (d), (e).
259. Id.
information, or the duty to take all possible measures. Each EC member state is responsible for adopting and implementing suitable measures for risk management within that state, and for setting up competent safety agencies for rule making and adjudication. It is internationally important that these domestic duties ensure exportation of safe products.

The TBT should also guarantee the protection of information filed with the TBT Committee and safety agencies because disclosure of information can be an unnecessary trade obstacle, as explained earlier. Also, the TBT should describe available measures for risk management. While allowing the member countries to take appropriate measures, the EC Directive describes what is appropriate in the following specific measures: the competent monitoring system, the request for all necessary information, the inspection of samples or production processes, the efficient warning system, risk communication for all possible persons, sale permission after the absolute safety check, recall and destruction, and emergency standards. Although these measures may differ among countries, the conditions and effects of as many measures or groups of measures as possible need to be harmonized to avert conflicts.

The relationship between harmonized standards and national standards should be clearly described in order to facilitate mutual recognition. In the EC Directive, if there is no EC regulation, national regulations or standards are to be complied with. If there are no national mandatory or voluntary standards, the EC standards or the standards of other member countries may be used for recognition of a safe product. The EC Directive also recognizes standards of a non-member country if they are acknowledged by a member country.\textsuperscript{263}

4. The TBT in terms of National Practices

The Code of Practice of the TBT should include general principles regarding the collection methods and the kind of data required for hazard identification. The decision on the necessity and priority of risk management plays an important part in product safety and must be predicated on hazard identification and whether product safety agencies have regulated the safety of a product. In reality, however, even developed countries like the US and several OECD countries have often decided to regulate products only

\textsuperscript{263}. Directive Article 4.
on the basis of such meager information as a medical report.\textsuperscript{264}

Uniform product classifications should be established in the TBT to enable the TBT Committee to compare the risk assessment and risk management of member countries. Differences in product classification systems have been an obstacle in judging whether the risk assessment and risk management of a country are an unnecessary trade barrier compared with those of other countries.\textsuperscript{265} The need for a uniform classification system is analogous to the need for a uniform tariff schedule.

The data on risk assessment and risk management should be described in a consistent manner in order for the Committee to understand them.\textsuperscript{266} The data should be described in a mathematical, statistical statement as much as possible, since a mathematical, statistical statement can help clarify the cost and probability of accidents and the severity of injuries.\textsuperscript{267} Relative numbers instead of absolute numbers, e.g., ratio, weight, and rank, should be employed because absolute numbers will always differ among countries and mean different things. For example,

\begin{itemize}
  \item \textsuperscript{264} OECD 1987, at pp. 12-14; the OECD once recommended a uniform system with identifiable groups of injuries and priorities among them as the minimum element in the Report on Data Collecting System in 1978. However, this recommendation is not yet achieved by member countries.
  \item \textsuperscript{265} Id. at p. 11.
  \item \textsuperscript{266} This new approach has been worked out in OECD. See \textit{id.} at p. 12.
  \item \textsuperscript{267} Id. at p. 13.
\end{itemize}
compensation for the loss of a human life is different in each country depending on the economic and political situation as well as the society's view on the worth of a human life. The US legal system is peculiar in its practice of awarding punitive damages, though it is similar to European civil law countries in other aspects like compensation of hospital expense and loss of income. However, because priorities among conflicting values, the probability and severity of injuries, and relative values are very similar among countries, the data on risk assessment should be described in relative numbers in order to compare practices more accurately.

B. Evaluation of the US Product Safety Regulation and Standard Systems

1. General Criticism of US Practices²⁶⁸

The product safety laws and regulations in the US lack coherence in comparison to the systematic organization in the EC's New Approach. The same key words in different statutes have different meanings, and value judgments are often inconsistent depending on the responsible agencies and organizations and the time of the decision. For

example, OSHA’s interpretation of the key term "unreasonable risk" is more sympathetic toward the industry than the CPSA's interpretation of the same term.\textsuperscript{269}

The US imposes adjudication measures for simple procedural violations more frequently than the EC.\textsuperscript{270} For instance, the CPSC often heavily penalizes manufacturers who fail to comply with procedural provisions that are irrelevant to the general duty of product safety required by the CPSA. It may deny importation of certain products for not having kept appropriate records, or for failing to file a proper notification.

Further, a skeptical attitude toward technology and scientific discovery in the judicial and administrative bodies discourages a foreign company with state-of-art technology from entering the US market. They often confer unreasonably strict liability decisions on the new technology without giving it due credit. This attitude is clearly evidenced in product liability cases where astronomical amounts of punitive damages are often imposed on the producers of products whose safety has not yet been proven.\textsuperscript{271}

\textsuperscript{269}. Id. at p. 180.


\textsuperscript{271}. Murray Mackay, \textit{Liability, Safety, and Innovation in the Automotive Industry} in Peer W. Huber and Robert E. Litan eds. \textit{Liability Maze}, at p. 210 (1991); on court system, see Id. at pp. 200-202. Another example is the adjustable seat belt anchorage in the 1980s. European companies worried about possible suits based
For these reasons, some new technologies that have huge advantages in fiercely competitive markets like Japan or the EC are not introduced in the US until later. A radar-controlled proximity braking system, for example, has not been introduced in cars heading for the US because European and Japanese manufacturers worried about possible liability suits for design defects and about NHTSA adjudications. In a case involving one such advanced technology, the Audi automobile company was sued for the safety of Audi 5000's unintended acceleration system. Although this new technology had no technical problems in the NHTSA report, the relentless blast by the media and massive litigations by consumers, both of which are salient cultural features in the US, caused serious financial trouble for Audi.272

2. Criticism on Risk Management in the US: Centering on Decision Making

The US system also has a few risk-management problems.273 First of all, there are few specialists and engineers participating in risk assessment and risk

on the defective design, inadequate warnings, lack of possibly astronomical punitive damage awards; see Id. at p. 214. On the child seat belt, see id. at p. 217. Even though the imported product follows safety regulations and standards, the court does not guarantee the winning of the suit. That is, no preemption is applied to the adoption of the safety feature.

272. Id. at pp. 210-211.
273. Cheit, at pp. 203-205 and 207.
management. Most participants are lawyers with little technical knowledge or comprehension of the subject matter. As a result, many provisions of the regulations unnecessarily emphasize meticulous procedural issues.

In addition, public regulations are not usually revised in accordance with a change of situation.\textsuperscript{274} Even when the current technology reveals a safety problem in a certain product, or when new tests show conflicting results, necessary changes in the safety measures are often delayed by the saturated bureaucracy and complicated procedures.\textsuperscript{275}

Furthermore, the US takes account of only its own technical level. For instance, the NHTSA established the standards for automobile crashworthiness,\textsuperscript{276} FMVSS 100s and 200s, reflecting US manufacturing practices.\textsuperscript{277} In drafting the recent FMVSS 214 standard, the side-impact standard, they again considered only whether that standard was technologically and economically feasible in the US and ignored any international feasibility.\textsuperscript{278}

As for the CPSC, three important weaknesses are apparent in regards to acceptable risk and appropriate

\begin{footnotes}
\item[274] Id. at pp. 203-204.
\item[275] Id. at pp. 204.
\item[276] The NHTSA has been operating since 1968.
\item[277] These standards technologically require manufacturers to enhance their ability. They influence those who target the US car market such as EC and Japan. These standards have so changed the concepts of manufacturers that passing the test of those standards has become one of most primary goals.
\item[278] Mackay, at pp. 202-206.
\end{footnotes}
measures. First, its regulation uses very general and broad terms, raising the possibility of arbitrary interpretations. Second, it often insufficiently considers the trade-off between the cost and the benefit of complying with the regulations. Third, it concentrates too little on the rule making process and too much on aspects of the adjudication process such as the ban and the recall, perhaps in an attempt to elude attacks from the court on the formal rule making procedure.\textsuperscript{279} In the matchbook standard, for instance, the CPSC failed to establish the necessity of regulation. It did not adequately analyze the accident generation process, accident patterns or accident statistics; it failed to consider available measures and alternatives and to compare exact costs and benefits.\textsuperscript{280} In another case involving a gas-fired space heater, the CPSC made the false assumption that a price increase of five percent would not affect consumer demand, and randomly calculated possible reduction in injury without exact data.\textsuperscript{281}

\textsuperscript{279} Viscusi, at p. ix-x.

\textsuperscript{280} Mackay, at p. 92; in making the matchbook standard, the CPSC did not pay attention to other elements capable of lighting a fire.

\textsuperscript{281} Id. at p. 98.
3. Criticism of US Practices of Making Standards

The US private standard makers have been criticized for being too heavily influenced by industry groups and not ensuring participation by all interest groups. This criticism may not be entirely correct but has some merit. For example, when the UL issued safety standards for the solid-fuel-type room heater, it consulted with the stove manufacturers and trade associations but not consumer groups. The UL 1482 standard, the codification of the generally accepted business practices among relevant industries at that time, received support from the industry.\textsuperscript{282} Only afterwards did the UL pursue a canvass process for the obvious purpose of gaining consensus of the Board of Standards Review under the ANSI and elicit comments from parties interested in developing woodstove standards.\textsuperscript{283} When standard makers rely too heavily on industry groups, they tend to base their decisions on shaky theories or information supplied by the manufacturers, who have an obvious interest in one direction or another. The performance clauses of US 1482, for example, are criticized for being founded not on scientific theories but rather on guesswork, despite the claim that it was based on "sound

\textsuperscript{282} On this example, see Cheit, at pp. 94-102.

\textsuperscript{283} ANSI does not have a technical staff and information collection system. It relies on the voluntary cooperation of standard writers. See Cheit at p. 98.
engineering principles, research, records of tests and
field experience ... and information obtained from
manufacturers, users and others having special experience
including educated guesses and concessions to the
practicalities of product testing."\textsuperscript{284}

\textsuperscript{284} Cheit, at pp. 102-104; the specific example of such
guesswork is the temperature of the exposed surface.
CHAPTER VI
CONCLUSION

Since the TBT is applicable to all GATT member states, it will often be used in deciding whether certain national safety regulations or standards are unnecessarily trade-restrictive. It is doubtful, however, that Article 2.2 will be very helpful because it allows very broad discretion of individual countries over the methodology of risk assessment and risk management. The TBT should be amended to include exclusive provisions on product safety because the Code of Good Practice in the Annex of the TBT provides meager guidance. Detailed agreements as to the definitions of certain terms like general duty, availability of safety measures, and methodologies of safety regulations, etc., are necessary. The new provisions should focus on methodological issues because the harmonization of methodologies, along with the mutual recognition of methodologies, is one of the best ways to resolve conflicts arising out of different safety regimes.

Harmonization of product classification systems in each country is the most important element in this endeavor. Harmonized classification systems will make it
easier to compare and evaluate national safety regulations under Article 2.2, and therefore the TBT Committee's harmonization efforts should start with classification systems.

Also, rules of participation in the decision-making process should be established in detail. Especially, the TBT should ensure that consumers are allowed to participate in the process of determining regulations and standards. Consumers choose products to maximize their satisfaction and are well aware of acceptable risks. Moreover, since their tastes and needs are becoming more internationally homogeneous and product information is more readily available than ever, their views on product safety are assimilated enough to create similar safety standards for the product. Open communication regarding product risks should also be encouraged between consumers and the product risk sources. Furthermore, foreign industry representatives should also participate in making national safety regulations and standards. They should participate before the standardization decisions are made.

The US risk assessment and risk management system should make certain changes. Instead of using manufacturers's current manufacturing practices as their yardstick, the regulatory agencies and private standard makers should utilize more input by other interested groups than the manufacturers. Current use of adjudication should
be more coherent throughout the various safety agencies and legal sources.
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