THE INTERNATIONALIZATION OF REGULATION: IMPLICATIONS FOR DEVELOPING COUNTRIES[*]

GIANDOMENICO MAJONE
Comparative Public Policy
European University Institute

From "shallow" to "deep" integration

The profound changes of the world trading system since the 1980s are reflected in the transition from "shallow" to "deeper" integration. Shallow integration is economic integration based on the removal of barriers to exchange at the border, and limited coordination of national policies. The General Agreement on Tariffs and Trade (GATT) and the International Monetary Fund were the core global institutions in the management of shallow integration. The remarkable success achieved in the 1960s and the first half of the 1970s in removing tariffs and quantitative restrictions served to underscore the significance of non-tariff barriers (NTBs) to international trade. Economists had been aware for a long time of a "principle of equivalence", according to which any trade concessions can be nullified by imposing an offsetting set of domestic policies. However, the practical significance of this principle was generally appreciated only in the late 1970s, when national governments reacted to the double threat of economic stagnation and inflation by increasing the level of protection of domestic industry by massive recourse to NTBs, in particular technical and health standards.

These developments could be observed not only in the world economy at large, but even in the European Community/European Union (EC/EU), where the abolition of internal tariffs, already achieved in the 1960s, was seriously impaired by the proliferation of national regulations and standards. It thus became clear that no institutional arrangement that oversees trade liberalization can afford to confine its rules and attention to "border" measures. Hence the emergence of issues of deeper integration on the international agenda. These issues concern "behind-the-border" policies that had previously not been subject to international scrutiny or negotiation. Instead of the older agenda of removing barriers that block exchange at the national borders, the new agenda items include conflicts over domestic regulatory regimes and perceived policy "externalities" (Kahler, 1995, p.2). In the EC/EU the turn to deeper integration was signified by the internal market program, which was supposed to achieve a fully integrated European market by 1992. In the international trading system, concerns about the impact of domestic regulations on free trade led to the Tokyo and Uruguay Rounds Agreements on technical barriers to trade; to the Agreement on the Application of Sanitary and Phytosanitary Measures, (SPS agreement), also reached in the Uruguay Round; to extending the scope and competence of the international trading rules by the inclusion of new subjects such as agriculture and intellectual property rights; finally, to the transformation, in 1995, of the GATT into the World Trade Organization (WTO).

Spontaneous regulatory convergence

Concerns about the adverse effect of different national regulations and other NTBs on free trade, usually lead to demands of harmonization. There are, however, many different types of harmonization, as is shown in the first part of this paper. A first distinction is between spontaneous harmonization achieved through "parametric adjustment" (see below), and harmonization achieved through multilateral agreements, usually with the help of formal international institutions.

A good deal of convergence of different national regulations occurs spontaneously-- through market or other social processes, such as imitation, and the independent decisions of a multitude of individuals—rather than by the deliberate efforts of policymakers and bureaucrats. In this section I review some of the most important strategies of spontaneous convergence. In the case of *unilateral harmonization* a country chooses to adapt its regulations to those of another country or group of countries. This strategy is particularly important to small countries whose economies are heavily dependent on international trade and which therefore tend to be "regulation takers". Like unilateral harmonization, *policy imitation* is an example of what Charles Lindblom calls *parametric adjustment*—a decision situation where decision-maker X adjusts his/ her decision to Y's decisions, without seeking to induce a response from Y. Policy imitation affords relief from the necessity of searching for conscious innovations which, if wrong, expose the policy-maker to severe criticism. In a complex and uncertain environment the strategy of adopting successful foreign models may be rational—provided the timing is right and the two systems are not too dissimilar.

Models emanating from economically and politically powerful countries are most likely to be imitated. The force exerted by a foreign model can be of two types: push or pull. American influence on the development of anti-trust policy in Germany and Japan at the end of World War II exemplifies the first type. On the other hand, American deregulatory policies of the 1970s, and British privatization policies of the 1980s attracted the attention of policy-makers in developed and developing countries without direct pressures, except those transmitted through the markets. In practice, policy imitation is often the resultant of both push and pull forces.

Private legislation is a special case of the pull model of policy imitation. Private legislatures are organizations—often professional bodies—that draft laws in the hope that other bodies will adopt them. They do not purport to enact legislation themselves, but they often enjoy sufficient prestige to make their recommendations attractive to legislators. In the field of international trade, private legislatures have enjoyed substantial influence by promulgating model laws that many national legislatures have enacted. The greater the success of a particular proposal, the greater the pressure individual states face to adopt them. This is an instance of the effect of network externalities: once a model takes on the character of an international standard, states or private economic actors derive benefits from conforming to it that are independent of

the intrinsic virtues of the particular rules contained in the law. *Self-regulation* may be regarded as a type of private legislation, but its special features and importance for international economic relations suggest to treat it separately.

Self-Regulation

The present drive toward international regulatory harmonization rests in part on the belief that *ex ante*, top down harmonization of product standards is a prerequisite for free and "fair" trade. In fact, *ex ante* harmonization is less essential to international economic integration than it was once thought. Recent research shows not only that an initial difference in standards need not distort trade, but that it is trade itself that leads to their (*ex post*) convergence. This is because standards concerning environmental quality, risk control, or consumer protection are positively correlated with the standard of living. Thus, as wealth grows as a result of free trade, the endogeneous demand for higher standards grows as well. It follows that, paradoxically, the *ex ante* harmonization of standards as a precondition of free trade can be counterproductive since it may prevent or limit trade, and the wealth effects it produces (Casella 1996).

Historical traditions may also militate against a full acceptance of self-regulation since there is a strong historical link between standardization and the emergence of the sovereign territorial state (Spruyt 1994). Views of standardization have changed radically, however, as a result of the development of technology and the advance of globalization. Standards are indeed public goods—in the sense that they fulfill specific functions deemed desirable by the community that shares them--but this does not mean that they must be established by government fiat. A good standard must reflect the preferences, levels of acceptable risk, resources, and technical constraints of the community of users, rather than some centrally defined vision of the "public interest". The fact that, in today's integrating world economy, the relevant community of standards users need not be territorially defined, distinguishes the contemporary from the traditional understanding of standards, in particular their nature as a special type of public goods known as "club goods" .

The properties of joint supply—it does not cost anything for an additional individual to enjoy the benefits of a public good, such as air quality improvements--and non-excludability—it is impossible or inefficient to exclude individuals from the enjoyment of the public good--define what the literature of public finance refers to as "pure public goods". If only the joint supply property is retained, i.e. we assume that exclusion is possible, we have "club goods" (Buchanan 1965). A voluntary association established to provide excludable public goods is a "club". If the preferences and the technologies for the provision of club goods are such that the number of clubs that can be formed in a society of given size is large, then an efficient allocation of these excludable public goods through the voluntary association of individuals into clubs is possible. With a large number of alternative clubs available, any effort to discriminate against an individual will induce her exit into a competing club, or the creation of a new one. If optimal

club sizes are large relative to the population, however, discrimination is possible and stable equilibria may not exist. With an optimal club size of two-thirds of the population, for example, only one such club can exist (Mueller 1989: 150-154). In a non-competitive situation the normative concerns expressed in the past about the delegation of powers to self-regulatory organizations (SROs)—for example, the lack of internal democracy of these bodies, where industrial interests tend to be over-represented--are understandable. But these criticisms, developed in contexts where a few SROs are given near monopoly powers, lose much of their point where many "clubs" are available. This tends to be the situation in expanding markets.

In fact, what happens to the number of standard-setting organizations as the size of the market expands, for example as a result of the merging of previously separate national markets? It has been shown (Casella 1996) that under reasonable assumptions, the number of clubs increases as the size of the market increases. Two elements determine the optimal number of clubs. One is the cost of producing the standards ("club fees"); the other, is the cost of an inappropriate standard. Notice that because a standard represents a public good, its cost is shared by the members of the corresponding club, while the cost of an inappropriate standard is borne separately by each club member. Now, as the market expands, also the number of standards expands because the increase in the variety of goods makes necessary a more finely tuned targeting of the public goods provided by the standards—product quality, safety, equipment compatibility, etc. The standards required for transactions in a more diverse market are likely to be both more sophisticated and more costly. The higher cost of the standard, because of the larger size of the club, is shared over more members, but the standard is less precisely tailored to individual needs. Hence, for a sufficiently large increase in market size the optimal number of clubs must increase.

The general implication of Casella's model is that top down harmonization is desirable only when the market is small and relatively homogeneous. In a large market, harmonization, especially technical harmonization, often is brought about not by a policy imposed from the top, but simply through the recognition of similar preferences or similar needs (for example, for producers in the same industry). This conclusion seems to be supported by empirical evidence. Thus, already some ten years ago, the OECD observed that all industrialized countries tend to converge towards a greater emphasis on self-regulation and non-mandatory standards—hence towards a greater variety of standards and standard-setting organizations. A large market like the United States is remarkable for the high decentralization of its standardization system. There are literally hundreds of organizations involved in the development of standards. The American National Standards Institute (ANSI), a private organization, coordinates private standards, approves standards as American National Standards, and represents the United States in international standards organizations. In practice, however, only about one-half of all standards developers participate in the ANSI system, and several organizations which do not participate, such as the American Society of Testing, are as well known internationally as ANSI.

International Standards Organizations

International bodies like the International Standards Organization (ISO), the Codex Alimentarius Commissions, or the European standardization bodies CEN, CENELEC and ETSI, occupy an intermediate position between the private "clubs" mentioned above, and public regulatory institutions. On the one hand, the standards produced by these international bodies are voluntary, i.e., they are not legally binding, and are generally produced by consensus of the participants. On the other hand, the influence of national governments is considerable, even if it is often exercised indirectly, i.e. through the national standardization bodies. At any rate, the importance of these international organizations is growing continuously, and no government can afford to ignore them or to be a purely passive member. For example, ISO—which we may take as a prototype of similar international organizations--is a worldwide federation of national standards bodies from 132 countries, of which 88 are full members, 35 are correspondent members, and 9 are subscriber members. The ISO achieved only modest results in its early years—it was created in 1947 from the union of two pre-existing organizations—but began to play a bigger role in the 1960s. Thus, it more than doubled the number of standards between 1968 and 1971, while the membership grew from 15 countries in 1947 to 70 in 1971. It also began in the 1970s to cooperate with several regional associations—notably with the European standards organizations—and made a particular effort to attract Japan and other Asian countries to the organization.

The technical work of ISO is highly decentralized, being carried out in a hierarchy of over 200 technical committees and subcommittees, and more than 2,000 working groups. The main cost of standardization is borne by the member organizations: member firms in national bodies supply and support the experts who comprise the various committees. Some 30,000 experts participate annually in ISO standardization: The technical work is coordinated from the ISO central secretariat in Geneva which has a full time staff of some 165. ISO standards—which cover most technical fields with the exception of the electrotechnical domain which falls under the responsibility of the International Electrotechnical Commission--are developed on the basis of consensus among the experts from the sectors which have expressed a requirement for a particular standard. Since ISO standards are voluntary, they are used only to the extent that people find them useful. In this sense, they are market-driven.

Of particular relevance to international regulation in the area of food safety--with which this paper is particularly concerned--is the Codex Alimentarius Commission (CAC), an international organization set up in 1962 under the auspices of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). The role of CAC—with a current membership of 165 member governments-- is to promote international trade in food through the adoption of standards aimed at ensuring fair trade practices and the protection of consumers' health. Initially it was felt that Codex standards—which define the identity of the product and describe the basic composition and quality factors required for international trade, especially provisions on food additives, contaminants, and hygiene requirements—were being

developed so as to assist developing countries by providing a ready made standard which they could adopt. Hence, developing countries tended to assume that, if they adopted Codex standards into their own legislation, they might gain access to the markets of the developed world. This did not happen since most Codex standards were not implemented by developed countries, which were unwilling to disrupt their long established system of controls.

The situation has changed, however. The CAC is playing in increasingly important role in international trade since 1995, the year in which the World Trade Organization (WTO) was established. Under WTO agreements (to be discussed in greater detail below) national measures which are based on international food standards, are presumed to comply with WTO principles. The close connection between WTO rules and Codex (and other international) standards implies that the latter are now important also to developed countries. Thus, Codex standards have been invoked in several trade disputes between the United States and the European Community/ European Union (EC/EU). The following recent (2002) example is particularly interesting for the present discussion because it shows how a Codex standard helped protect the economic interest of a developing country—in this case, Peru—against a restrictive EC regulation.

The dispute, known as the *Sardine* case, involved an EC regulation reserving the name "sardine" to certain fish species (sardine pilchardus, to be found in the Mediterranean) to the exclusion of others (such as the Peruvian sardinops sagax), thus precluding Peru from marketing its sardines under the name "sardines" in the territory of the EC. The WTO Panel's finding that the European regulation violated Article 2.4 of the Agreement on Technical Barriers to Trade (TBT) is interesting because the Panel considered a Codex standard on sardines, adopted in 1978, as a "relevant international standard". This standard laid down common marketing standards for preserved sardines and it covered twenty sardine species, including both pilchardus and Sardinops sagax. The fact that the Codex recognized both species as "sardines" meant that also the Peruvian product should be allowed to be marketed in Europe under that name. The WTO Panel found that the EC had not used the Codex standard as a basis for its own regulation. In other words, the EC regulation was not conform to the international standard since it had not taken the later as "the principal constituent or fundamental principle" of its technical standard. The EC appealed against this point of law, arguing that "using a standard as a basis for a technical regulation" simply means that there must be a "rational relationship" between the technical regulation and the standard. This was the case for the EC regulation since it used part of the international standard as a basis for the regulation. The Panel did not accept this argument, saying that "something cannot be considered a "basis" for something else if the two are contradictory". The EC regulation contradicted the Codex standard because it prohibited the use of the label "sardine" for species other than pilchardus, while the Codex standard allowed Sardinops sagax to be marketed under the label "sardines". Thus, it could not be maintained that the European regulation took the international standard as a basis.

It should be noted, however, that there are many instances of EC regulations that are based on Codex standards or incorporate its guidelines. Such standards are even appealed to in

cases before the European Court of Justice. For instance, the Court has used reports of the Codex Commission to clarify the meaning of the terms "hazard" and "scientific risk assessment". It also referred to Codex standards to determine the characteristic features of yogurt in a case on the labeling of foodstuffs, and in deciding whether a food additive presented a risk to public health or met a real need. Reference has also been made to Codex standards on the limits for lead and cadmium in certain foodstuffs.

Varieties of regulatory harmonization

As the above discussion shows, a good deal of regulatory harmonization today is achieved by reference to international standards. It is important to realize, however, that the term "harmonization" can apply to any aspect or stage of the regulatory process, not just to the final outcome, i.e., a specific standard or regulation. Generally speaking, the purpose of harmonization, as the term is used in the present context, is to make the regulatory requirements or public policies of different jurisdictions more similar, if not identical. Regulatory regimes, and the political and institutional systems in which they are embedded, can differ in numerous aspects. Hence, several broad types of harmonization may be usefully distinguished (Leebron, 1996). First, specific rules or standards that prescribe the desired characteristics of the outputs of production processes, institutions, or transactions could be harmonized. For example, emission limits for polluting factories located in different countries may be made more similar . We may call this "output harmonization" since the goal is to reduce pre-existing differences in certain characteristics of the relevant outputs or outcomes. Second, international regulatory harmonization may relate to certain governmental policy objectives—for example, the central banks of the G-7 countries attempt to keep inflation within agreed limits—or to general policy principles such as the "polluter pays" and the precautionary principles.

Finally, harmonization of institutional structures, procedures or methodologies is often sought. Thus, some of the provisions of the North American Free Trade Agreement (NAFTA; the reference here is to the NAFTA "side agreement" on the environment) require that certain procedures for enforcement of domestic laws, including appellate review, be harmonized. Procedural harmonization often serves to reinforce other types of harmonization. If the aim is to harmonize decisional outcomes, both substantive criteria and decisional processes are implicated. Rules, policies, and principles will generally not be truly harmonized unless the procedures and institutions for implementing them are made more similarly effective, and doing so may mean making them more similar (Leebron, 1996, p.46). This, incidentally, is the reason why harmonization, for example in the environmental field, fails to produce identical, or at least very similar, results across the European Union. European measures are typically implemented by national administrations, but the EU is not competent to harmonize national administrative procedures and processes. The problem has been recognized for some time, and certain directives attempt to harmonize not only national laws and policy objectives, but also the institutional

design of the "competent authorities" at national level (e.g., with respect to their independence in the case of telecommunications). The power of the EU in this area is, however, quite limited.

There are situations where procedural harmonization is not meant to reinforce other types of harmonization, but is the only type which is politically, economically, or technically feasible. Thus, in the case of the NAFTA environmental side-agreement it would have been impossible to impose on Mexico the same environmental standards used in Canada or the United States. Hence, Article 3 of the agreement recognizes "the right of each Party to establish its own levels of domestic environmental protection…", while Article 5 requires that "each Party shall effectively enforce its environmental laws and regulations through appropriate government action…"; and Article 6 requires that "interested persons" be able to request a Party's regulatory authorities to investigate possible violations of *domestic* environmental laws and regulations.

An important example of procedural harmonization is provided by the already mentioned WTO Agreement on Sanitary and Phytosanitary (SPS) Measures. Harmonization is discussed in Article 3, which states, in part, that: a) In order to harmonize SPS measures on as wide a basis as possible, member states shall base their measures on international standards, guidelines or recommendations, where they exist; b) SPS measures that conform to international standards shall be deemed to be necessary to protect human, animal or plant life or health; c) Member states may, however, introduce or maintain SPS measures which result in a higher level of protection than would be achieved by measures based on the relevant international standards, provided there is "scientific justification" for the stricter measures; d) Member states are required to "play a full part, within the limits of their resources, in the relevant international organizations and their subsidiary bodies", such as the Codex Alimentarius Commission.

This article is noteworthy in several respects. First, nothing substantive is said about the level of the international standards, not even of a qualitative nature. By way of comparison, the NAFTA Agreement on Environmental Cooperation stipulates that "each Party shall ensure that its laws and regulations provide for high levels of environmental protection and shall strive to continue to improve those laws and regulations". At the same time, the Agreement recognizes "the right of each Party to establish its own levels of domestic environmental protection". Thus, at least according to a widely accepted interpretation, a member of NAFTA is permitted to set its own levels of protection, as long as those levels are "high" by some more or less objective standard (cp. also Article 95(3) of the Treaty on the European Union, according to which "The Commission, in its proposals…concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection…").

By contrast, the approach of the WTO SPS Agreement is purely procedural, as shown also by the requirement that the member states play an active role in the activities of the international standardization bodies. Also the requirement that a country provide "scientific justification" if it wishes to adopt a higher level of protection than what is provided by international standards, goes in the same procedural direction. Given the uncertainty surrounding the scientific basis of risk regulation, "scientific justification" can only mean that the relevant

arguments should satisfy generally accepted rules of scientific methodology—an important point we elaborate in the following pages.

Regulatory science and free trade

Increasingly, science is playing a significant role in the regulation of international trade. In particular, the SPS Agreement introduces a new science-based regime for disciplining health regulations which may affect international trade in agricultural products and foodstuffs. Annex A to the Agreement defines a sanitary or phytosanitary measure as any measure applied to protect animal or plant life or health from a variety of risks, including "risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs".

Article 2(2) of the Agreement states, *inter alia*, that members of WTO shall ensure that any SPS measure "is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5". Article 5 deals with risk assessment as a method for determining the appropriate level of health protection. Risk assessment is the standard by which SPS measures are to be judged as necessary and justified. In other words, for such measures to be necessary, based on scientific principles and not maintained without sufficient scientific evidence, they must be supported by a risk assessment conducted according to the criteria, and taking into account the factors, mentioned in Article 5. As interpreted by the WTO Appellate Body in the beef hormones case, this article says that there must be a rational relationship between the SPS measure and the risk assessment.

The exception provided by Article 5(7) applies to cases where relevant scientific evidence is insufficient, in which case a member state may *provisionally* adopt a measure "on the basis of available pertinent information… Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly *within a reasonable period of time*" (emphasis added). Article 5(7) is the only reference to a precautionary approach in the entire Agreement. I come back to this approach in a later section, after briefly discussing some of the conceptual and technical complexities surrounding the notions of "scientific justification" and "risk assessment" as they apply to regulatory measures.

The process of standard setting is at the core of risk regulation. If we understand the extent of scientific uncertainty in standard setting, we are in a good position to appreciate the problems of regulatory science. Extrapolation is a key element in the establishment of environmental and health standards, hence a good part of the uncertainty inherent in standard setting originates in various types of extrapolation processes. There is, first, the problem of extrapolating from animal experiments. A major issue in regulatory science is the determination of the animal species that best predicts the response in humans. There is little hope that one species could provide the broad range of predictive potential needed to assess the responses of a highly heterogeneous human population to different types of toxic substances. The heterogeneity

of human populations leaves the public authorities with an almost impossible regulatory task. In an effort to find a way out of this dilemma, scientists have developed several mathematical models expressing the probability of a lifetime response, P, as a function of dosage D: $P = f(D)$. This is the dose-response function. Different choices of f lead to different models.

Regardless of the choice of model, however, one has always to extrapolate from data points at high doses (the type of data provided by animal experiments) to the low levels relevant to the regulation of risk to humans. However, the same data points are compatible with a variety of extrapolating functions (Calabrese, 1978). Thus, under a threshold (non-linear) dose-response model it would be possible to establish a "virtually safe" level of exposure, at the numerical value of the threshold, even though high doses produce adverse health effects. Instead, if one uses a linear dose-response relationship, adverse health effects are predicted at every level of exposure, so that there is no obvious point at which a reasonable standard could be set.

It may be argued – as do many advocates of the precautionary principle – that if there is no firm scientific basis for choosing among different dose-response models, then one should prefer the safest or most conservative procedure. One problem with the conservatism argument is that it is not clear where one should stop. A no-threshold model is more conservative than one that admits the existence of thresholds for adverse health effects. But within the large class of no-threshold models many degrees of conservatism are possible. Again, in designing a toxicological experiment one could use the most sensitive species, the most sensitive strain within the species, and so on down to the level of the most sensitive animal. In short, it is difficult to be conservative in a consistent manner unless one is prepared to propose a zero-risk approach to regulation. This, in a nutshell, is the main conceptual problem with the precautionary principle.

Now, extrapolating from the high doses shown to cause harm in animal experiments or in epidemiological studies, to the much lower exposures normally faced by humans is the essence of quantitative risk assessments. From what has been said above it follows that uncertainty is a pervasive characteristic of regulatory risk assessments. But the technique has been accepted and continues to be used because there are no better alternatives. Thus the United States Supreme Court in *AFL-CIO v. American Petroleum Institute* (448 U.S. 607 (1980)) – the landmark benzene case – not only confirmed the legitimacy of quantitative risk assessment; it effectively made reliance on the methodology obligatory for all American agencies engaged in health regulation. In most subsequent disputes over regulatory decisions to protect human health, the question has not been whether a risk assessment was required but whether the assessment offered by the agency was plausible (Mashaw *et al.*, 1998, pp. 823-825). This historical background may explain U.S. advocacy of science-based risk assessment at the international level, as well as that country's opposition to the precautionary principle advocated by the EU. Today the methodology of risk assessment is used by regulators in all developed and in many developing countries. Moreover, as mentioned above, risk assessment is the standard by which trade-restricting health regulations are evaluated as being necessary and justified. As such, it plays a crucial role in the debate about the application of the precautionary principle at the international level.

The precautionary principle and the WTO

The precautionary "principle" is an idea (perhaps a state of mind) rather than a clearly defined concept, much less a guide to consistent decision-making under uncertainty. Not surprisingly, an authoritative and generally accepted definition is nowhere to be found. The principle is of German origin (*Vorsorge Prinzip*), and has been used in that country since the 1980s in order to justify a number of important developments in environmental law. However, an eminent legal expert has distinguished no less than eleven different meanings assigned to the precautionary principle within German policy discourse.

The German approach was taken up by other policy elites in Europe, including those which drafted the EC's *Fourth Environmental Action Program*, who sought to develop an approach to environmental policy that was preventive rather than reactive. In the EC Treaty the principle appears only in the Title on environment. Article 174 EC (ex Article 130(r)) provides that Community environmental policy "shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at the source and that the polluter should pay". No definition of the precautionary principle is provided in this article or anywhere else in the Treaty.

As mentioned above, there is an indirect reference to a precautionary approach (again undefined) in Article 5(7) of the WTO SPS Agreement. WTO member states are allowed to take measures unsupported by a risk assessment when the relevant scientific evidence is insufficient, but only provisionally. Perhaps the best known statement of the precautionary "approach" (suggesting something more flexible and less binding that a "principle") is provided by Principle 15 of the Declaration of the 1992 UN Conference on Environment and Development (Rio Declaration):

> In order to protect the environment, the precautionary approach shall be widely used by States according to their capabilities. Where there are threats of serious and irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

Since the precautionary principle lends itself to a wide range of interpretations, it would be instructive to see how the European Court of Justice (ECJ) and the Court of First Instance have dealt with it. A detailed discussion of relevant cases is of course beyond the scope of the present paper, but a general inference from major decisions appears to be that in cases of scientific uncertainty, member states have considerable discretion in deciding to err on the side of caution. They must however provide some evidence of scientific uncertainty. They must adduce evidence of a specific, concrete risk and not merely of potential risks based on a general precautionary approach. Thus in the famous *German Beer* case (Case 178/84 [1987]),--where the German government wanted to prohibit the sale of any beer not brewed according to German standards--

the ECJ refused to allow a ban on additives in beer, based on a generic principle of prevention. The national authorities must come up with more specific scientific evidence than a mere reference to the potential risks posed by the ingestion of additives in general.

As already mentioned, the EU is currently engaged in a major effort to have the precautionary principle adopted as a "key tenet" of Community policy a "full-fledged and general principle" of international law (European Commission, 2000). While some progress has been made in the field of international environmental law, the EU's commitment to, and application of, the principle has been repeatedly questioned or opposed by the WTO, by the United States, and by many other developed and developing countries. Thus, the proposals on the precautionary principle presented by the EU to the Codex Alimentarius Committee on General Principles in April 2000 were opposed by the U.S. and many other third countries, which fear that the principle may be too easily misused for protectionist purposes. Such fears are fed by episodes like the proposed aflatoxin standards, to be discussed in the next section, and the beef hormones dispute which for years has opposed the EU to some of its major trading partners. The European Commission argued that the precautionary principle applies across the whole of the SPS Agreement as a general principle of international law. The WTO's Appellate Body specifically rejected this argument and stated that the principle must receive authoritative formulation before it can be raised to the status sought for it by the EU. The same body also observed that a precautionary approach has not been written into Article 5(7) of the SPS Agreement as a ground for justifying measures that are otherwise inconsistent with the obligations of the WTO set out in particular provisions of the Agreement.

Food safety, the precautionary principle, and the cost of non-harmonization

As mentioned above, the European Commission would like to interpret the entire SPS Agreement in the light of the precautionary principle, in order to be able to conclude that the EU is free to adopt the level of safety that it deems appropriate, regardless of the objections other countries may raise. However, the search of higher and higher levels of safety leads to promulgate standards so stringent that the regulatory action ultimately imposes high costs without achieving significant additional safety benefits. Perhaps we should not be too concerned if such costs were felt only by exporters in rich countries like the United States and Canada, and by affluent European consumers. But what if the cost is borne by some of the poorest countries in the world?

The EU and all its member states are deeply committed to assist, financially and otherwise, developing countries, especially African ones. However, World Bank economists have estimated the impact on some of the poorest African countries of new and very strict standards for aflatoxins proposed by the Commission in 1997 in the name of the precautionary principle. Aflatoxins are a group of related toxic compounds that contaminate certain foods and have been associated with acute liver carcinogens in humans. Aflatoxin B1 is the most common and toxic of

these compounds. It is generally present in corn and corn products, groundnuts and groundnuts products, and tree nuts. The proposed standards are significantly more stringent than those adopted by the U.S., Canada, and Australia, and also stricter than the international standards established by the Codex Commission. Countries such as Brazil, Bolivia, India, Mexico, Uruguay, Australia, Argentina and Pakistan, in opposing the European measures, requested detailed risk assessments from the European Union used in setting the new standards. As a consequence of consultations with the trading partners about these concerns, the European Commission relaxed the proposed aflatoxin standard for cereals, dried foods, and nuts. Even after this relaxation, aflatoxin standards for products intended for direct human consumption, remain quite stringent: 4 parts per billion (ppb), and 2ppb for B1, against an overall Codex standard of approximately 9 ppb.

Using trade and regulatory survey data for the member states of the EU and nine African countries between 1989 and 1998, the World Bank economists estimate that the new standards would decrease African exports of cereals, dried fruits and nuts to the EU by 64 percent, relative to regulation set at the international standards (Otsuki *et al.*, 2000).The total loss of export revenue for the nine African countries is estimated to be US$ 400 million under EU standards, compared to a gain of US$670 million if standards were adopted according to Codex guidelines. Are the costs imposed on some of the poorest countries in the world justified by the health benefits for EU citizens? According to studies conducted by the Joint FAO/WHO Expert Committee on Food Additives, the Community standard of 2 ppb for B1 aflatoxin would reduce deaths from liver cancer by 1.4 deaths per billion, i.e. by less than one death per year in the EU. For the purpose of this calculation the Community standard is compared to a standard that follows the international (Codex) guideline of 9 ppb. Since about 33,000 people die from liver cancer every year in the EU, one can see that the health gain produced by the precautionary standard is indeed minuscule.

In a recent new study, Wilson and Otsuki (2003) extend the above analysis by estimating the effect of aflatoxin standards in 15 importing (of which 4 developing) countries on exports from 31 (21 developing) countries. They estimate that world exports would rise by an impressive US$38.8 billion if an international (Codex) standard were adopted, compared to the current divergent national standards in place. On the other hand, world exports are estimated to decrease by US$3.1 billion if the world adopted the EU standard (i.e., 2 ppb) compared to current national standards. Thus, harmonization of this food safety standard at a level more stringent than one suggested by international standards can severely limit developing countries exports. The authors conclude that an initiative to encourage the adoption of international standards, along with mechanisms to directly assist developing countries in raising standards to international levels, merits serious consideration.

The precautionary principle and the logic of decision-making under uncertainty

This section is devoted to a methodological critique of the principle of precaution. The critique is based on some key notions of modern (subjective) probability and utility theory that are summarized in the Appendix. As I have repeatedly suggested, the precautionary principle is seriously flawed as an aid to rational decision-making under uncertainty. Although lack of precise definitions makes it difficult to develop a formal critique, the following considerations may help to grasp the principle's main theoretical shortcomings.

To begin with, recall that risk is a compound measure (more precisely, a product) of the probability of harm and its severity. Now, according to the fundamental theorem of decision theory, the only consistent rule for decision-making under uncertainty is to choose the alternative which minimizes the expected loss (or maximizes the expected utility). Consider a situation where there are various possible events (or "states of nature") E_1, E_2, …, E_n, with probabilities p_1, p_2, …, p_n, alternative actions A_1, A_2, …, A_m, and losses l_{ij} for each combination of alternative A_i and event E_j, i = 1, 2, …, m; j = 1, 2, …, n. The optimal decision consists in choosing the alternative which minimizes the expected loss, i.e., the sum of the products of the losses by the corresponding probabilities (formally: the alternative which minimizes $S_j\, p_j l_{ij}$).

Any good textbook on decision theory (e.g., Lindley, 1971) provides the proof that any other decision rule – and in particular any rule which does not use both the losses and the corresponding probabilities – can lead to inconsistent decisions. One such decision rule is the minimax principle, which in some respects is quite similar to the precautionary principle. The minimax approach to decision-making under uncertainty uses losses but not probabilities, either denying the existence of the latter, or claiming that the method is to be used when they are unknown (here is an important similarity with the precautionary principle). This approach makes sense in special situations – zero-sum games where the uncertainty is "strategic", i.e. part of the strategy of a rational opponent – but not in the general case, as may be seen from the following examples. Consider first the decision problem described in Table 1, where the entries indicate losses, e.g. extra deaths due to exposure to a toxic substance:

	E_1 (p_1)	E_2 (p_2)
A_1	10	0
A_2	1	1

TABLE 1

Following the minimax rule, for each row (i.e., alternative) we select the maximum loss (10 for A_1 and 1 for A_2), and choose that alternative having the minimum of these values. This is A_2 with value 1. Hence the minimax rule says: always choose A_2. The principle of expected loss

would assign probabilities p_1 and p_2 to the uncertain events and choose A_2 if $1 < 10 p_1$, i.e. $p_1 > 1/10$, otherwise A_1 should be selected. To see which of the two rules is more reasonable, suppose that p_1 is quite small (say, $p_1 = 0.01$ or 0.001) so that $10 p_1$ is much less than 1. The minimax rule would still choose A_2, even though it is almost sure that no extra deaths would occur under A_1.

The result is even more striking in Table 2, where only the loss corresponding to the pair (A_1, E_1) has been changed:

	E_1 (p_1)	E_2 (p_2)
A_1	1.1	0
A_2	1	1

TABLE 2

The minimax rule would still choose A_2, even though the expected loss for A_1 is much smaller for all values of p_1 less than, say, 0.8. In short, the problem with the minimax rule is that it does not take account of all the information available to the decision-maker. The advantage of the expected-loss rule is that it takes account of both losses and probabilities.

As noted above, one defense of the minimax is that it is to be used when probabilities are unknown (and perhaps unknowable). This argument is strongly reminiscent of the distinction made by the American economist Frank Knight in the 1920s between "risk" (when the events are uncertain, but their probabilities are known) and "uncertainty" (where the probabilities are unknown). Knight attached great theoretical importance to this distinction, but modern analysis no longer views the two classes of events as different in kind. Probabilities may be known more or less precisely, they may be more or less "subjective", but there are some logical difficulties involved in giving meaning to the statement that the probabilities are unknown. If we insist that we are "completely ignorant" as to which of the events E_1, …, E_n will occur, it is hard to escape the conclusion that all the events are equally likely to occur. But this implies that the probabilities are in fact known, and that $P(E_i) = 1/n$ for all i: the well-known uniform distribution!

The point of this digression on decision theory is to identify with more precision than would otherwise be possible the logical problems raised by the application of the precautionary principle. Like the minimax principle, the principle of precaution tends to focus the attention of regulators on some particular events and corresponding losses, rather than on the entire range of possibilities. As a consequence, regulators will base their determinations on worst cases, rather

than on the weighted average of all potential losses, i.e. on the expected overall loss. The most serious conceptual flaw, however, is the artificial distinction between situations where scientific information is sufficient to permit a formal risk assessment, and those where "scientific information is insufficient, inconclusive or uncertain". In reality, these are two points on a knowledge-ignorance continuum rather than two qualitatively distinct situations. The same logic which leads to the rejection of Knight's distinction between risk and uncertainty, applies also here. As we saw, by its very nature regulatory science deals with uncertainties. For example, for most toxic substances it is still unknown whether the relevant model for standard setting is a threshold or a linear one. Most scientists favor the latter model, but this only complicates the regulator's problem, since it is unclear where a standard should be set above the zero level. Moreover, the continuous progress of science and technology produces increasingly precise measurements of toxicity (e.g., parts per billion) so that the search of safety becomes ever more elusive.

In short, regulatory problems are not solved but only complicated by appealing to different logics of decision-making, according to the available level of information. Especially in risk regulation, the normal state of affairs is neither scientific certainty nor complete ignorance. For this reason a sensible principle of decision-making is one that uses all the available information, weighted according to its reliability, instead of privileging some particular hypothetical risk.

The prescriptions of decision theory break down only in one case, namely when losses (or utilities) are unbounded. In such a case it is clearly impossible to calculate expected values. An example of potential unbounded loss is the threat of serious and irreversible damage – the situation envisaged by Principle 15 of the Rio Declaration mentioned above. In this and similar situations, the precautionary principle may be a useful tool of risk management. But to acknowledge such possibilities is to recognize that the principle has a legitimate but quite limited role in risk management.

Conclusions

Today developing countries are more fully integrated into the GATT/WTO system than ever before. This is as it should be. For such countries a "rule-oriented" trade diplomacy is greatly preferable to a power-oriented diplomacy. In other words, settlement of international disputes with reference to rules to which both parties have previously agreed is better than settlement by negotiation with (more or less implicit) reference to the relative power status of the parties. In the latter case, a developing country would hesitate to challenge a major country on which its trade depends. In the case of reference to agreed rules, the negotiators would argue about the application of the relevant rule, knowing that an unsettled dispute would ultimately be resolved by impartial third-party judgments—such as those provided by the WTO dispute-settlement procedures—based on the agreed system of rules. Thus, the negotiators would be negotiating

with reference to their respective predictions as to the outcome of those judgments, and not with reference to potential retaliations or actions by the more powerful country (Jackson 1999).

Neither the mere existence of rules, nor mere membership in international regulatory bodies are sufficient, however. It is in the interest especially of developing countries to be active members in order to be able to influence the formulation and application of international rules. The experience of the European Union shows that small countries, such as Denmark and the Netherlands--3 and 5 votes, respectively, against the 29 votes of each of the four largest members of the EU--can have an influence on rule-making at European level which is out of proportion to their political power. What such countries lack in terms of power they make up, in areas of particular interest to them, by innovative policy ideas and the demonstrated capacity to translate those ideas into practice. As I have argued in the preceding pages, science is going to play an increasingly important role in the international regulation of risk and the harmonization of technical barriers to trade. Thus, the possibility of influencing the formulation of international rules presupposes a stock of available scientific talent. For many developing countries this is not today a problem. The problem, rather, may be to have a sufficient number of able people trained in "regulatory science". Regulatory science differs from the more traditional variety in several important respects. First, unlike his or her colleagues in academia and research laboratories, the regulatory scientist generally cannot afford to postpone a decision simply because the evidence is insufficient. In this he/she is similar to the judge, who cannot refuse to decide a case because the facts are uncertain. The risk regulator always decides under conditions of great uncertainty and, hence, must be familiar not only with the relevant branch of science—chemistry, toxicology, microbiology, nuclear physics, and so on—but also with the basic logic of decision-making under uncertainty. In particular, knowledge of the elements of decision theory is necessary in order to perform risk analysis, which is required by WTO rules in case a country wishes to depart from international standards of food safety. This heavy reliance on the principles of decision-making under uncertainty is a second importance difference from the traditional scientist, who may be concerned with probabilities, but not, usually, with the optimization of the consequences of his conclusions.

As indicated in the text, and in somewhat greater detail in the Appendix, the modern theory of decision-making under uncertainty cannot guarantee the substantive correctness of a given regulatory decision—no theory can do this—but it ensures that the decision is internally coherent. This means that by following this methodology one is sure that all factors that go into the decision process are clearly identified, and especially that they are put together in a consistent way. It is not sufficiently appreciated that this sort of "procedural rationality" is important not only for technical reasons (for example, for producing a risk assessment that satisfies WTO criteria), but, also politically , being a necessary condition of public accountability. Precisely because regulatory decisions of the type discussed here, are ultimately based on subjective evaluations of risk, it is essential that the regulator be in a position to explain and justify each step in the decision process to political leaders and to the public at large.

Independence is the other side of accountability. The regulator cannot be held responsible for his or her decisions unless he/she is given the necessary resources, and protection from undue political interference. This is of course a problem for the political leaders rather than for the regulators. It is up to the political leaders to design regulatory institutions capable of providing a good accountability framework as well as adequate protection of the regulator's political independence. The design of independent and accountable regulatory institutions is a topic deserving a separate treatment, but its importance should at least be acknowledged here. On the other hand, the regulator must be aware that she is not operating in a political vacuum. Especially when the life and health of the citizens are concerned, science, technology or economics may not provide the only relevant criteria for decision making. When basic values have to be traded-off (at the margin), the ultimate responsibility must be political. However, the decision to override the opinion of the expert regulator must follow a well defined and generally known procedure. The procedure should entail a political cost high enough to discourage unjustified interference with the regulator's decision. Specification of the conditions and methods for overruling agency decisions by the political authorities is a neglected but very important aspect of institutional design.

APPENDIX

Modern decision theory prescribes to maximize expected utility, but it is important to understand that this decision rule has procedural, not substantive, significance. It does not guarantee the best possible outcome, but "only" that the decision will be coherent, in the sense that the various probability and utility assessments are mutually consistent. As discussed below, however, this is an important result, also in practical terms. Here I can do no more than sketch the general argument, starting with the key assumption of the theory: that there is only one form of uncertainty and that all uncertainties can be compared. This assumption does away with all old-fashioned and theoretically untenable distinctions such as that between statistical and non-statistical events, or Frank Knight's (1971) distinction between risk and uncertainty. By saying that there is only one kind of uncertainty, and that therefore all uncertainties can be compared, it is meant that if E and F are any two uncertain events then either E is more likely than F, F is more likely than E, or E and F are equally likely. Moreover, if G is a third uncertain event, and if E is more likely than F, and F is more likely than G, then E is more likely than G. The first requirement expresses the *comparability* of any two events; the second expresses a *consistency* in this comparison.

The comparability and consistency requirements are then used to define the probability of any uncertain event E. This can be done in several, equivalent, ways. For example, the probability of E can be obtained by comparing it with the probability of a point falling at random

within a set S contained in the unit square. Because S is a subset of the unit square, its area is a probability, i.e., it is a number between 0 and 1, which satisfies all the rules of the probability calculus. Now, consistent comparability implies a unique value for the uncertainty of E, i.e., the probability of S (its area), is judged to be as likely as the uncertain event E, in the sense that a prize awarded on the basis of E occurring could be replaced by an equal prize dependent on a random point falling within S. The interested reader can find the details in any good textbook on decision theory, such as the one by Dennis Lindley (1971, pp.18-26). In addition to a numerical measure of probabilities, we need a numerical measure for the consequences of our decisions. We proceed as follows.

Let c_{ij} be the consequence if we choose alternative A_i and event E_j occurs, i=1, 2,…n; j=1, 2,…m. Note that the consequences may be qualitative as well as quantitative. Denote by c and C two consequences such that all possible consequences in the decision problem are better than c and less desirable than C (it can be shown that the precise choice of c and C does not matter, as long as the condition of inclusion is satisfied; thus, we could choose as c the worst possible outcome in the payoff table, and C as the best outcome). Now take any consequence c_{ij} and fix on that. Consider a set S of area u in the unit square (the reason for using "u" will be clear in a moment; also, keep in mind that the area of S is a probability). Suppose that if a random point falls in S, consequence C will occur, while c will occur if the random point falls elsewhere in the unit square. In other words, C occurs with probability u and c with probability 1-u. We proceed to compare c_{ij} with a "lottery" in which you receive C with probability u and c with probability 1-u. Thus, if u=1, "C with probability u" is better than (or at least as good as) c_{ij}, while if u=0 then "C with probability u" is worse than c_{ij} . Furthermore, the greater the value of u the more desirable the chance consequence "C with probability u" becomes.

Using again the principle of consistent comparisons it can be shown that there exists a unique value of u such that the two consequences, c_{ij} and "C with probability u", are equally desirable in that you would not mind which of the two occurred. The argument consists in changing the value of u, any increase making the "lottery" more desirable, any decrease, less desirable, until "C with probability u" is as desirable as c_{ij}. We indicate this value with u and call it the *utility* of c_{ij}: $u_{ij}=u(c_{ij})$. We repeat the process for each of the possible consequences in the payoff table, replacing each consequence by its utility. The crucial point to remember is that all these utilities are probabilities and hence obey the rules of the probability calculus.

The final step consists in calculating the (expected) utility of each of the alternatives: u (A_1), $u(A_2)$,…$u(A_n)$. Using the basic rules of probability, it is easy to show that $u(A_i)$ is simply the average (more precisely, the "expected") value of the utilities of all the consequences corresponding to A_i :$u(A_i)=u(c_{i1})p_1+u(c_{i2})p_2+…u(c_{im})p_m$. A moment's reflection will show that the expected utility of A_i is simply the probability of obtaining C, when this particular alternative

is chosen. It follows that the best alternative is the one with the highest utility, being the one which maximizes the probability of getting C. This is the principle of maximization of expected utility, the major result of decision theory. Note, that this principle, or decision rule, has nothing to do with the notion of an indefinite repetition of the same decision, as in some interpretations of expected gain in repeated games of chance. The principle follows directly from the rules of probability and hence can be applied to any decision situation, whether repetitive or unique.

The discussion so far may be summarized as follows. A decision problem can be expressed as a list of alternatives and a list of possible events. On the assumption of consistent comparison of events and of consequences, probabilities can be assigned to events, and utilities to consequences. Each alternative can also be assigned a utility, calculated as the expected value of the corresponding consequences. The best alternative is the one with the highest utility. A few more comments on the general approach follow.

First, the consistency argument is essentially one that hinges on how separate assessments —probabilities of events, utilities of individual consequences and of alternatives—are going to fit together and make a consistent whole. Second, as already noted, the rule of maximization of expected utility does not guarantee better actual results than other decision rules--including decisions made in purely intuitive fashion. It *does,* however, guarantee consistency in decision-making, and no other known decision rule can claim the same. Third, consistency is important not only logically but also practically: it facilitates communication among experts, between experts and policy makers, and with the general public; by showing how to break down the whole decision problem into separate but coherent components, it also facilitates accountability; moreover, it can be shown that the method facilitates the consistent updating of one's beliefs in light of new information. The type of decision analysis sketched here may even facilitate risk taking. Thus, if managers are evaluated exclusively on outcomes, they will naturally be reluctant to engage themselves in very risky undertakings. A more sophisticated method of evaluation, which in addition to results also includes the quality of the decision process, can reduce the cost of failure by distinguishing between foresight and outcomes due to chance.

One final point. Any decision under uncertainty, even one which does make explicit use of probabilities, in fact implies at least a partial probability assessment. There is nothing mysterious in this statement, which is only a straightforward application of a line of reasoning frequently used in elementary game theory and in other applications. Suppose a decision maker has to choose between two alternatives with the consequences indicated below:

	E_1	E_2
A_1	10	1
A_2	3	2

Without attempting to estimate the probabilities of the uncertain events E_1 and E_2, but only taking the consequences in the payoff table into account, she chooses alternative A_2. This choice suggests that our decision maker is very risk-averse. In fact, she has used the maximin decision rule, as defined in a previous section. Although the maximin rule does not use probabilities, the choice of A_2 indicates that the decision was taken *as if* the probability of E_1 was less than 1/8. In fact, letting p be the unknown probability of E_1, hence 1-p the probability of E_2, the expected values of the two alternatives are:

$$M(A_1)= 10p+(1-p)=9p+1$$

$$M(A_2)= 3p+2(1-p)=p+2$$

Thus, our decision maker is indifferent between the two alternatives if 9p+1=p+2, i. e., if p=1/8. Any value less than 1/8 makes A_2 preferable to A_1. Since A_2 was chosen we infer that the decision maker implicitly assumed that the probability of E_1 is less than 1/8, q. e. d.

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[*] To be presented at the International Conference on "Innovation and Change in Regulation and Competition", 13-15 October 2003, Mandaluyong City, Metro Manila, Philippines