The Precautionary Principle and WTO Law: Divergent Views Toward the Role of Science in Assessing and Managing Risk

by Lawrence A. Kogan

Introduction—The Debate surrounding the use of science to assess and manage public risks to human health and the environment

The role of science in government assessment and management of public risks has increasingly become the subject of a heated transatlantic political debate that is likely rooted, in part, in the "deepening global economic integration"[1] and the continuing expansion and ascendancy of the EU on the world economic stage. While the contours of this debate appear bilateral in nature, however, the issues are truly international in scope, with potential legal, economic, and social ramifications for all WTO member governments and industries, including those of developing countries.[2]

The EU and the United States hold divergent views toward the usefulness of science as a tool to understand and address the uncertainties surrounding risks to human health and safety and the environment posed by the activities engaged in and the innovations produced by modern life. In both the United States and the EU, government regulators have had to address increasing public concerns about the safety of food, health and environmental hazards associated with chemical emissions, and chemical residues generated by products. More recently, regulators have had to consider growing public concern over the possible impact of climate change (global warming) on the environment and human health.[3] In many respects, public reaction to the manner in which regulators have responded (or not responded) to analogous popular concerns in the past has prompted regulators to be more sensitive to public perceptions of risks of possible harm in the future, no matter the realities. The problem is that such a practice may trigger other potential risks that may be even greater than the risks perceived.[4] It is thus arguable that the once substantive debate over the role of science in assessing and managing possible risks is gradually being controlled by policymakers.

Lawrence Kogan is admitted to practice in New York and New Jersey, and has worked with and advised international businesses for more than fifteen years. Mr. Kogan previously earned a Masters of Laws in Taxation at Georgetown University Law Center, and is currently pursuing a Masters of Arts in Diplomacy and International Relations at the John C. Whitehead School of Diplomacy and International Relations at Seton Hall University.

In the case of the United States and the EU, these disparate public views toward the role of science in risk assessment and risk management have resulted in divergent regulatory approaches. It is, furthermore, arguable, that these relative views are shaped, at least in part, by distinct underlying social, economic, and political values, reflecting different societal fears and thresholds for risk and "quality of life" notions.[5] These societal norms or cultural preferences, which have been transposed at the national and regional levels through the establishment of institutional legal frameworks (legislation and regulations) and commercial adoption of less formal technical product and safety standards, have increasingly come into conflict at the level of international trade. As reported in a recent *National Journal* article:

> *International commerce once comprised mainly of value-free economic transactions involving largely interchangeable commodities and manufactured products. Now, it increasingly involves trade in goods and services that are often laden with 'ideological content,' according to a [November 2003] European Union discussion paper, 'The Emergence of Collective Preferences in International Trade'…In other words, Americans would argue that the trade in genetically modified foods, for example, should be affected only by* the scientific facts*, whereas Europeans would argue that the whole idea of such modifications makes them queasy…*It is perceived threats to such collective preferences *that drive much of the anti-globalization movement today. Indeed, the greatest challenge facing the international trade policy community in the years ahead, predicted E.U. Trade Commissioner Pascal Lamy in a March 5 speech in Brussels, may be 'how we can organize market-opening in such a way as to uphold the varying collective preferences of different societies.'*[6]

This author posits that, in some cases, these preferences may rise to the level of trade protectionism—namely through the promulgation of disguised health and safety and environmental regulatory barriers to market access.[7]

In general, the prevailing view within Europe is to take a "better safe than sorry" or precautionary approach to managing a growing number of possible but uncertain health and environmental hazards. This regulatory mindset or philosophy, known more formally within Europe as the Precautionary Principle,[8] dismisses the need to identify an ascertainable and measurable risk of particular harm or to establish a specific causal link between suspect products, processes or substances and any damage that might ultimately result there from. Instead of focusing on specific empirical exposure data and statistical analyses, government regulators charged with addressing significant public risks (risk managers) focus *a priori* on the inherently dangerous characteristics or intrinsic properties of a general group of products and substances. These characteristics are collectively identified and set forth pursuant to carefully defined "risk profiles," which are essentially classifications of similar "risk types."[9]

Conventional risk assessment serves only a minimal function within this type of precaution-based regulatory system, given the widespread belief that risk assessment, as an empirical process, reflects only the current state of limited human scientific knowledge—it cannot account for the uncertainties surrounding most human activities. Hence, when the possibility for significant irreversible harm is great, a

lack of scientific certainty as to cause and effect, likelihood of occurrence or timing, or of actual evidence of harm, does not preclude EU regulators from taking precautionary measures to prevent the harm from materializing in the first place. It has been argued that Europe's resort to the precautionary principle reflects an institutional and cultural aversion to risk.[10] Whether or not this is true, it imposes on industry (foreign as well as domestic) a considerable legal and commercial burden of demonstrating that a product or substance is safe or harmless, which is tantamount to the imposition of a negative burden of proof or a zero risk threshold.

The EU Commission believes strongly in the need to use a precautionary approach to achieve a "*high* level of health and environmental protection."[11] Its goal has been to establish such an approach as a formal precautionary principle within an international legal framework that governs the assessment and management of global risks to the environment and human health and to establish it as a WTO treaty norm and as a norm of customary international law. According to European proponents of this philosophy, although there is "some divergence in the terminology used (principle or approach or measure) in the various international conventions and agreements [it] is of no legal significance."[12]

The EU Commission believes strongly in the need to use a precautionary approach to achieve a "high level of health and environmental protection."

Within the United States, the prevailing regulatory view, with certain limited exceptions, is to identify and evaluate health and environmental risks in an ad hoc manner[13] depending on the type of risks faced and the groups potentially affected. It is common practice to then address risks on the basis of their probability of occurrence and the likelihood that they may inflict serious actual harm. These factors are determined, in large part, from the results of an empirically driven and objective science-based risk assessment that is performed with respect to a particular product or substance (not process). The risk assessment identifies the nature and significance of the particular risks, the magnitude and severity of known and/or uncertain potential harms, the degree and certainty of human exposure to such harms and the vulnerability of the various groups (populations) so exposed.[14] Where there are profound uncertainties as to any of these factors, estimates and assumptions (safety factors)[15] are employed that incorporate an appropriate degree of precaution.

Depending on the results of the risk assessment and the judgment of risk managers, precaution may again be employed through the selection of a suitable risk management framework. Finally, certain regulatory proposals, prior to publication, are then subject to another level of review, namely an economic cost/benefit analysis (an equity-balancing test) aimed to determine whether the chosen approach "maximizes net-benefits, including potential economic, environmental, public health and safety and other advantages."[16] Under certain statutes, "the level of precaution is reflected [yet again] in the forgone economic benefit from the [substance]

or product and/or high cost of control from decisions to ban or limit its use relative to the health benefits gained."[17] The U.S. risk-based regulatory system does not recognize the existence of a formal precautionary principle.[18] Consistent with WTO jurisprudence, although the United States acknowledges that governments may lawfully employ precautionary measures under certain limited provisional conditions, it does not consider the precautionary principle to be either a WTO treaty norm or a general norm of customary international law.

The U.S. risk-based regulatory system does not recognize the existence of a formal precautionary principle.

These divergent[19] views form the basis of a political, legal, economic, and social debate toward the definition and role of science in WTO treaty law and within public international law, generally, that will have significant implications for international trade. In particular, it will determine the extent to which governments must balance their need to assess and manage public risks to human health and safety and the environment with their need to help facilitate international trade flows. This paper aims to highlight how this debate is being shaped by the evolution of the precautionary principle, a European-based social and environmental norm being promoted by the EU Commission in international fora, the debated status of the precautionary principle within public international law, and its impact on international trade.

THE NATURE AND CONTEXT OF GLOBAL HEALTH AND ENVIRONMENTAL CONCERNS

The recent discovery, this past December, of the first documented case of mad cow disease in the United States caused many people to question the safety of U.S. beef and the reliability of the U.S. beef inspection system. These concerns were largely based on what was perceived to be the inadequate response of European governments to a more pronounced "mad cow" crisis that had swept Europe during the 1980s.[20] Such thinking was understandable in light of other reports about beef safety issued by the European Commission and consumer and environmental groups. Such reports have highlighted the potential but uncertain risks posed to our endocrine systems by the synthetic hormones injected into cows to enhance growth and milk production.[21] They have also discussed the potential but uncertain risks posed to our immune systems by the antibiotics administered in cattle feed rather than therapeutically to maintain a herd's health and to enhance livestock growth.[22] There was no mention, however, that the science underlying these reports was less than conclusive or that the findings were the subject of debate within the scientific community.[23] Even if one were inclined to give up beef consumption to avoid these risks, one would still encounter different potential health risks related to other foods, such as chicken and seafood.[24]

There are also the potential but uncertain future benefits and risks to human health and the environment associated with new food processing techniques, such as genetic engineering (biotechnology).[25] These new techniques are being used to grow heartier, insect-resistant wheat, corn, soy, and produce that do not require the volume of pesticides currently in use to protect against disease and infestation. Also, the use of such techniques has resulted in more bountiful harvests that could, along with the technology, be exported abroad in the course of international commerce or as a component of international food aid administered to nations stricken by endemic food shortages. However, as the technology of agricultural biotechnology rapidly expands, concerns about its safety and effects on the surrounding environment have become commonplace in Europe and have been exaggerated by civil society to induce consumer fear. Although scientists (risk assessors) at both the USDA/FDA and the European Commission, Directorate General for Health and Consumer Safety have determined that there is no known risk to human health posed by genetically modified foods,[26] national policymakers (risk managers) from these governments have embraced different approaches toward regulating them. It is fair to conclude that, in the case of Europe, scientists, influenced by policymakers and civil society, seem to be more concerned about the uncertain risks that they have not yet identified and are unaware of than those risks which they can effectively manage.[27]

Divergent views on the definition and role of science in WTO treaty law will have significant implications for internatonal trade.

We also encounter in our daily lives risks posed by non-food items. During the past decade, numerous reports have theorized about how many of the everyday non-food products we use contain or are produced with potentially harmful chemicals from which residues may be absorbed by human tissue during usage. Such products include children's toys, computers, electrical and electronic equipment, brominated flame retardants, clothing, and cosmetics.[28] Reports have also indicated that traces of some of the more specialized chemicals that are produced or used as intermediates in industrial processes have been found in and thought to pose unknown risks to the local, regional, and global ecosystems within which rare animal and plant species reside.[29] In addition, it is alleged that when products containing toxic substances are disposed of in landfills, such substances leak into the soil and underground aquifers.[30] What is not discussed is that the scientific findings underlying these reports are less than conclusive. And, given the lack of international consensus concerning the nature and extent of such unknown risks from a scientific standpoint, national policymakers from the United States and the EU, in light of divergent public perceptions, have pursued different approaches toward assessing and managing them.

Assessing and managing Health and Environmental Risks

Risk Analysis

Although empirical uncertainties remain with respect to the identification and evaluation of the various risks noted above, scientists continue to expand their knowledge and understanding of them. They do so by engaging in a formal internationally recognized multi-step process known as risk analysis.

> *[T]he development of a formal risk analysis provides a conceptual and transparent framework for evaluating the public health benefits associated with the selection of various policy options. The risk analysis paradigm includes three elements—risk assessment, risk management and risk communication—and allows regulatory officials to focus finite resources on those hazards that pose the greatest risk to public health.*[31]

In general, an objective risk assessment is first performed and scientists apply what they do know about the impact of specific products and substances on human health and the environment from actual data gathered from the field or calculated statistical extrapolations, rather than from any administrative presumption of hazard.

National policymakers then rely upon these tentative but evolving scientific assessments to devise optimal strategies that can help to manage those risks in both the short and long term. The management of risks is part science and part political decision-making. It is therefore often based on a balancing of the social, economic, and environmental costs and benefits associated with each of the alternative strategies considered and each of the constituencies potentially affected. For this reason, the process of risk management should be a participatory and transparent one that takes into account and reflects the views of multiple stakeholders.[32] However, in reality, this is not always the case.

When national or regional policymakers determine that the potential health or environmental risks posed by particular products, substances or activities necessitate action, they usually decide to develop a legal framework to manage and communicate those risks in a manner acceptable to society. The type of approach selected—formal regulation and/or informal product standardization—depends on the relative values assigned by policymakers to each of the factors noted above and each society's relative perceptions of and thresholds for risk. It also depends, in part, on how the general public responds to the regulators' communication[33] of the risk assessment findings and the strategies they have chosen to manage them. While the draft risk analysis guidelines of the Codex Alimentarius Commission state that "precaution is an inherent element of risk analysis,"[34] it is employed differently by the United States and the EU.

Both the United States and the EU, to various degrees, strive to prevent emerging health and environmental risks before they can arise. Yet, they both recognize it is not always possible to identify and quantify such risks in advance. A cause and effect relationship linking the source of a potential hazard (product, substance or activity) and the harm that it *may* later produce often cannot be established. Even "when

exposure to environmental hazards causes immediate and obvious harm, scientific uncertainty about cause and effect relationships is minimal."[35] And, in other cases where a cause and effect relationship has been tentatively established, it is sometimes difficult to estimate or predict the magnitude and severity of the consequences that might flow there from.[36] In light of these unknowables, many commentators have argued that advanced and preventive measures must be taken.

During the past ten years, the EU and its member states have formally adopted a precaution-based approach to risk analysis that focuses mostly on actions that can be taken *before* an emerging risk of perceived rather than actual magnitude and severity can be conclusively identified or quantified. Such an approach prefers not merely to address (contain, manage or eliminate) extant health and environmental risks, namely those that have already been identified or have caused noticeable and perhaps even serious harm. Reflecting a "better safe than sorry" philosophy or ethos, the approach adopted within Europe has emphasized the limitations of human knowledge and has focused on the uncertainties surrounding scientific prediction.[37]

The EU Commission has increasingly employed precaution when assessing and managing what it perceives to be possible future significant public risks, even though the draft Codex risk analysis guidelines state that "*there should be a functional separation of risk assessment and risk management*" (emphasis added).[38] This separation is intended "to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers, and to reduce any conflict of interest."[39] In the process, the EU has sought to rework the current international paradigm for risk analysis, and consequently, to redefine the prevailing U.S. and international legal framework adopted by the WTO that focuses on the role of empirical science (the "knowables") in conducting "risk assessments." At the most fundamental level, how the United States and the EU respectively view the role of science in the process of risk analysis can be understood as reflecting a core philosophical difference over whether a glass filled with water halfway is either half full or half empty (positivism vs. negativism).

Risk Assessment[40]

According to the United States Department of Agriculture, risk assessment is defined as

> *[A]* scientifically based process *of evaluating hazards and the likelihood of exposure to those hazards and then estimating the resulting public health impact. It provides a scientific framework for understanding the impact of a wide variety of variables…Risk assessments may be qualitative, semi-quantitative, or quantitative. Qualitative assessments usually identify a high, medium, or low level of risk. Semi-quantitative assessments may be used to prioritize risks in relation to one another. Quantitative assessments are often used to identify and evaluate food safety control points or estimate the benefits of various intervention strategies.* (emphasis added)[41]

In general, a risk assessment looks at several key issues. First, it considers those factors that give rise to a public health risk. Second, it considers the likelihood that

such harm will occur. Third, it considers the amount of harm (adverse health effects) that could occur. Fourth, it considers the amount of harm that can be reduced through the use of intervention strategies.[42] The final phase of a risk assessment is referred to as "risk characterization." At this stage, "all of the information gathered during the risk assessment process is integrated to show who is at greatest risk, which variables contribute most to the risk (e.g., food borne illness), and which intervention strategies would lead to the greatest reduction of risk."[43]

The USDA definition of risk assessment is similar to that articulated by the Codex Alimentarius Commission.[44] While the Codex definition of "a risk assessment requires that information be organized in specific ways, it does not [however] require any specific scientific evaluation methods."[45] Rather, the steps of risk assessment may be applied differently depending on the type of products being evaluated.

The Codex definition of risk assessment requires that uncertainties

> *having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of the* uncertainty or variability *in risk estimates may be qualitative or quantitative, but should be* quantified to the extent that is scientifically achievable*…The report of the risk assessment should indicate any…uncertainties and their impact on the risk assessment…*The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors. (emphasis added)[46]

In at least once case (e.g., chemical risk assessment), the U.S. government has determined that the type of scientific risk assessment traditionally conducted may need to be revised to take into account other factors from evolving science.

> *[I]t may be necessary to move beyond single exposure pathways or single chemical assessments and to explore the accumulation of risk…Aggregate exposure assessment involves the analysis of multiple pathways and routes of exposure such as food, drinking water, ambient and indoor air for a single agent or stressor. Cumulative risk looks at how multiple agents or stressors with a common mode of action interact to pose risk to health or the environment.*[47]

The United States Environmental Protection Agency, for example, in seeking to reduce uncertainties in the information used for environmental decision-making, has gone beyond focusing on chemical-specific impacts. It recently unveiled a proposed framework to facilitate development of methods to assess or control the effects of chemical mixtures and general stressors on human health and ecosystems,[48] taking into account chemical exposures that occur cumulatively[49] and simultaneously.[50]

The EPA's proposed framework, as well, is consistent with the Codex guidelines, which provide that

> *Risk assessments should be based on* realistic exposure scenarios, *with consideration of different situations being defined by risk assessment policy. They should include*

> *consideration of susceptible and high-risk populations groups… [C]umulative and/or combined adverse health effects should be taken into account in carrying out risk assessment, where relevant.* (emphasis added)[51]

The U.S. and Codex definition of what a science-based risk assessment entails is currently consistent with WTO law, as has been interpreted by the WTO dispute panels and the Appellate Body. The relevant WTO risk assessment jurisprudence is briefly discussed later in this paper. Notwithstanding these WTO rulings and the definition draft adopted by Codex, however, the EU Commission has found that the process of scientific risk assessment as so defined has failed to adequately address scientific uncertainties. In a report recently adopted by the Commission's Scientific Steering Committee in April 2003,[52] the Commission proposed to enlarge the scope of scientific risk assessment, with respect to new risks[53] similar to those described above, so that it takes into account quality of life considerations.[54] According to the report, quality of life considerations such as risk perception help ensure human "well being," whether or not the risks are real.[55]

The EU Commission has found that the process of scientific risk assessment as so defined has failed to adequately address scientific uncertainties.

The differences in how the United States and the EU have each defined and implemented "risk assessment" are real (i.e., it is more than just semantics), as is the likelihood that they will increasingly give rise to barriers to international trade if they are not resolved. A joint program initiated by the Organization for Economic Cooperation and Development (OECD) and the International Program on Chemical Safety (IPCS) has endeavored to resolve these differences through dialogue, with the ultimate objective of harmonizing the generic terms used in the process of chemical risk assessment. However, based on the findings of a recently released report, resolution is not likely to come easily anytime in the near future.[56]

Risk Management

> *The risk management phase involves using all of the information gathered during the [risk] assessment to evaluate policy options. Risk managers consider the results of the risk assessment in the context of other policy considerations such as cost, feasibility, and the social impact of implementing certain policies. This phase identifies, selects, and implements measures that can be applied to reduce the risk identified during the assessment.*[57]

According to the draft Codex risk analysis guidelines,

> *risk management should follow a structured approach including preliminary risk management activities,*[58] *assessment of risk management options, monitoring and review of the decision taken. [Risk management] decisions* should be based on risk assessment*, and taking into account, where appropriate, other legitimate factors*

> *relevant for the health protection of consumers and for the promotion of fair practices in food trade…* (emphasis added)[59]

As interpreted by the U.S. government, this means that, "When considering the role of precaution *in risk management*, it is appropriate for policy makers and the public to inquire about the degree of precaution embedded in the risk assessment. If precaution is taken to an extreme, it can be very harmful to technological innovation" (emphasis added).[60] In other words, "the proper degree of precaution to be *exercised in risk management* cannot be determined unless risk managers understand the degree of precaution that scientists have already embedded in the risk assessment" (emphasis added)[61] through the use of safety margins or uncertainty factors to characterize a "plausible" upper bound.[62]

By contrast, the EU Commission argues that precaution should be applied separately by risk assessors *and* by risk managers.

> Precaution should be applied both by the scientists completing the risk assessment, on the basis of science policy guidelines, and by the regulatory authorities themselves who have to draw the necessary implications. *Both risk assessors and risk managers attribute to any given time different subjective values to available scientific data, the risks, and the nature of possible adverse effects. Precaution applied by scientists in a risk assessment does not, therefore, eliminate the need for risk managers to apply precaution to the same agent, activity, or process when taking regulatory action. Risk assessors' technical precaution (when developing hypotheses, modeling and interpreting evidence and data) is, therefore, distinguishable from the risk managers' regulatory precaution (when taking normative regulatory action). This proposition is forcefully denied by the United States internationally, basically for reasons of economic competition, trade policy consideration, and general litigation and negotiation tactics.* (emphasis added)[63]

They reason that this is necessary because "one of the functions performed by the precautionary principle is to put constraints on how regulators act under uncertainty. This entails both ex ante and ex post control of measures taken to regulate risk."[64]

A key issue of contention between the United States and the EU apparently concerns the role and scope of "preliminary risk management activities" in the risk analysis process, as defined by the Codex risk analysis guidelines.[65] Among the activities included, the "establishment of a risk profile" and the "ranking of the hazard for risk assessment and risk management priority" appear to constitute the major sticking points. While the U.S. government restricts its consideration of these activities to the risk management stage only, the EU Commission considers those activities as applicable to *both* the risk assessment *and* the risk management stages.

Many within the EU debate the role served by classical risk analysis as well as the limited usefulness of current risk assessment procedures in directing regulatory decision-making. Such advocates have questioned these conventions on several grounds. First, they question "whether technical risk estimates [really] represent 'objective' probabilities of harm or reflect only conventions of an elite group of professional risk assessors that may claim no more degree of validity or universality

than competing estimates of stakeholder groups or the lay public."[66] Second, they question the role of the public in determining thresholds for risk. "Since it is the people…that are affected by the potential harm of technologies or other risk-inducing activities," these advocates argue that "it should be the [public's] prerogative to determine the level of risk that [its members] judge tolerable for themselves and their community."[67] In other words, they propose that individual consumer/citizen risk perceptions (fear factor) should be considered as integral to the process of evaluating *and* managing risks.

Third, these advocates question the manner in which the professional risk community has traditionally assessed scientific uncertainty. They claim that this term "implies a portfolio of different aspects [or components] that are often neglected or amalgamated in risk analysis"[68] but which should, as a matter of prudence, be analytically distinguished. In this regard, one EU legal commentator has defined scientific uncertainty to exist "when there is no adequate theoretical or empirical basis for assigning possibilities to a possible set of outcomes."[69] He notes further that, "In the strict sense, even if there is relatively high confidence about the possible set of outcomes, there is no basis to confidently assign probabilities to these outcomes."[70] In his estimation, "uncertainty… [may arise] due to the novelty of the substance or activity concerned or because of complexity or variability in its context."[71]

Many within the EU debate the role served by classical risk analysis as well as the limited usefulness of current risk assessment procedures in directing regulatory decision-making.

Fourth, those calling for a new risk analysis paradigm question the conventional methods or frameworks chosen to address uncertainties and manage risks. In a world facing more risks and uncertainties than any one society can handle at the same time,[72] these proponents complain that current "risk reduction policies have been designed [only] in proportion to the severity of the potential effects [and that] [s]everity has been operationalized [merely] as a linear combination of magnitude of harm and probability of occurrence."[73] They refer to this approach as a "risk-based" management strategy because it "relies on numerical assessments of probabilities and potential damages."[74] Considering the different types of uncertainties, they recommend new management strategies that make "the social system more adaptive to surprises, and at the same time, allow only those human activities or interventions that can be managed even in extreme situations (regardless of the probability of such extremes to occur)."[75] They refer to this type of approach as a precaution-based management strategy, "implying the prudent handling of uncertain or highly vulnerable situations."[76]

Fifth, advocates of a new risk analysis paradigm question how better to incorporate fair and open procedures for promoting public deliberation of common and divergent public values and preferences into *both* the risk assessment *and* risk

management processes.[77] While the United States and the EU agree that such a procedure is indispensable to managing public risks, however, the EU does not wish for such an open and inclusive process to vest industry with the ability to work against precaution. This concern may relate to what Brussels perceives as the U.S. business lobby's successful exploitation of the U.S. Administrative Procedures Act (APA), which generally provides stakeholders and the public with the opportunity to comment prior to the government's adoption of a federal regulation.[78] Many EU regulators believe that U.S. industry has skillfully utilized the APA process to ensure that U.S. regulators conduct an economic cost-benefit analysis,[79] which serves to protect U.S. industry interests against the possible adoption of stringent economically significant precaution-based regulations.[80,81] According to one EU legal commentator, "[c]ost-benefit analysis and other influences can lead to undue delays in precautionary action and further losses."[82]

The Precautionary Approach/Precautionary Principle As a New International Legal and Regulatory Standard

Proponents of the precaution-based management strategy or precautionary approach who have sought to establish a more formal precautionary principle[83] find fault with the public policy of quantifiable risk embraced within the United States.[84] They explain that the concept of "risk is actuarial in spirit" and the ability to insure oneself against a particular kind of risk is acutely dependent upon the availability of relevant actuarial data.[85] When extended to "environmental decision-making, the concept of risk retains the connotation of something that can be defined and quantified, and hence managed."[86] The problem, as proponents see it, however, is

> *that the language of risk [simplifies] most human-environment interactions as harmless or positively beneficial. Risk is thought to be the exception, not the rule, in human engagements with nature. [It is believed that risk] is something that one can guard against without upsetting underlying philosophies of development, consumption or resource use.*[87]

To the contrary, these advocates emphasize how a precautionary approach/precautionary principle "requires a different kind of science."[88] Unlike the concept of risk, it displays a greater sensitivity to scientific uncertainty,[89] human ignorance,[90] and public perceptions.[91] This approach requires that policymakers take preventive action in all cases to avoid significant possible harm to the environment and human health, even in the absence of any causal link or proof of likelihood of occurrence. In other words, it imposes a broad, affirmative, forward-looking, legally binding "duty of care" upon policymakers not to permit, and upon individual economic actors not to engage in, activities currently that may potentially trigger unascertainable but serious risks of harm in the future.[92] According to at least one commentator, this amounts to a "duty of positive obligation that would require decision-makers to be fully informed about the possible consequences of environmental change" (emphasis added).[93]

As explained by another commentator,

> *The principle states in brief that damage to the environment should be avoided in advance,* implementing a *duty of care* on the part of policymakers. *As with risk, the principle emphasizes prevention rather than cure.* But precaution seems to urge something more than mere prevention. It demands heightened caution in the face of uncertainty, to the point of favoring inaction when the consequences of action are too unclear. *And unlike risk, which invites calculated action, precaution implies a greater need for judgment and, where necessary, restraint.* (emphasis added)[94]

In essence, "a *precautionary approach asks how much harm can be avoided rather than asking how much is acceptable.*"[95] Other commentators view the concept of precaution as going beyond science.

> *[Precaution] is not simply the prevention of manifest or predicted results that have been scientifically proven. Rather,* the precautionary principle goes beyond the notion of prevention *in the sense that it insists that policymakers move to anticipate problems before they arise or before scientific proof of harm is established.* (emphasis added)[96]

This has been interpreted to mean that an economic actor would be deemed to have not satisfied its duty of care "even if best practice and appropriate regulatory rules [were] followed."[97] Although European industry had, for a time, persuaded regulators in many Community member states to allow a "strategy of 'best available techniques *not entailing excessive costs*' (BATNEEC)…[this] cost justification element [has] steadily [been] restricted. If the technology is available, or can be developed in a reasonable time, [the current prevailing view is that] it should be deployed."[98, 99]

Furthermore, the precautionary principle shifts the regulatory burden of proof, consisting of both the burden of producing evidence and the burden of persuasion,[100] from the government concerned about the possible occurrence of a serious harm to the manufacturer or operator whose activity may potentially give rise to it. "Precaution means, in effect…that one is guilty until proven innocent when tampering with the environment in manifestly risky ways."[101] In other words,

> *the many industrial and technological products, substances or processes (additives, contaminants,medicinal products, veterinary drugs and growth promoters, GMOs, etc.)…[that require regulatory pre-approval before gaining access to EU markets]…are generally deemed to be dangerous unless and until the interested manufacturer carriers out the necessary scientific work and demonstrates to the satisfaction of the authorities [their] safety or lack of harm [harmlessness].*[102]

In addition, the standard of proof imposed by regulators in regard to such products or substances under European Commission law requires the manufacturer to "demonstrate safety 'adequately or sufficiently,' which is comparable to the 'proof beyond reasonable doubt' standard applied in common law jurisdictions,"[103] such as the United States, in *criminal* cases.

In the event certain industry actors fail to satisfy this affirmative duty of care—to exercise due diligence—*and* that failure subsequently causes significant damage

to the environment, that actor can be subject under the new EU polluter's pay principle[104] liability directive to strict legal liability for such environmental damage.[105] "Businesses primarily affected are those involved in traditionally polluting activities, such as plants releasing heavy metals into water or into the air, installations producing dangerous chemicals, landfill sites, and incineration plants."[106]

The new paradigm envisioned by the EU Commission and other proponents of the precautionary principle has been developed into a legal policy framework. That framework is intended to serve as a general model of precautionary risk regulation and to provide guidance to European policymakers seeking to implement the precautionary principle.

> *[T]he thematic network PrecauPri [is] aimed at devising a policy framework for the application of the Precautionary Principle which provides guidance to European policymakers with respect to European and international risk governance. In a fruitful cooperation of social scientists specialized in risk and uncertainty issues, natural scientists specialized in chemical risks, and a legal scholar with special expertise in risk regulation the project team developed* a general model for the implementation of precaution in European risk regulation. *The model is understood as a strategic response to the most prominent challenge of risk reduction and management for the protection of human health and the environment which accompanies the European integration process."* (emphasis in original)[107]

Among the milestones this project claims to have achieved, "it defines the precautionary principle as a general principle employed in the [pre-risk assessment] screening of threats for properties of seriousness or uncertainty in order to determine their subsequent treatment in regulatory appraisal and management."[108] In addition, it "identifies Precautionary Appraisal as a specific approach to appraisal, adopted in cases where screening has identified a lack of scientific certainty."[109] Furthermore, it defines and concretizes scientific uncertainty as one of four key challenges dealing with contemporary threats; the other major issues are identified as seriousness, complexity and socio-political ambiguity."[110]

The seriousness with which the EU Commission and environmental groups view their efforts to establish the precautionary principle as an absolute international legal standard in multiple fora, notwithstanding the objections of other WTO member governments, should be neither underestimated nor doubted. In fact, a leading precautionary principle advocate, who also serves as a part-time adviser to the Commission, has recently set forth Europe's thinking on this matter.

> *The EU is attempting to establish a radical new approach to science and technology based on the principle of sustainable development and global stewardship of the Earth's environment…The precautionary principle is designed to allow government authorities to respond preemptively, as well as after damage is inflicted, with a lower threshold of scientific certainty than has been the rule of thumb in the past. 'Scientific Certainty' has been tempered by the notion of 'reasonable grounds for concern.' The precautionary principle gives government the flexibility to respond to events in real time, so that potential adverse impacts can be forestalled or reduced while the suspected*

> *causes of harm are being evaluated. At the heart of the precautionary principle is a radical divergence in the way Europe has come to perceive risks compared to the U.S. In Europe, intellectuals are increasingly debating the question of the great shift from a risk-taking age to a risk-prevention era…The EU hopes that by integrating the precautionary principle into international treaties and multilateral agreements, it will become the unchallenged standard by which governments oversee and regulate science and technology.*[111]

According to these advocates, "[the] precautionary principle is deeply at odds with the traditional Enlightenment idea about science."[112] That model entails risk taking and is enshrined within the WTO agreements and within the principles established by international bodies such as the Codex Alimentarius.

Historical Origins of the Precautionary Principle and its evolution in international environmental law

The origins of the precautionary principle can be traced back to the German *vorsorgeprinzip*, which means literally "forecaring principle" or simply "care." It is one of five fundamental principles recognized in German law as constituting the basis for environmental policy.[113] It is related to the German clean air environmental policies of the 1970s that called for *vorsorge* or prior care, foresight, and forward planning to prevent harmful effects of pollution.[114] The German *vorsorgeprinzip* introduced

> *a distinction between human activity with dangers of catastrophic consequences (nuclear apocalypse was then high on the list) and which must be prevented at all costs (Gefahrenvorsorge) and human activity with potentially harmful consequences (Risikovorsorge), in which case, preventive measures should be investigated and taken in case of sufficiently high risk of sufficient harm.*[115]

In other words,

> *[A] difference [was] made between human behavior which causes* dangers *on the one hand or risks on the other hand. When dangers are at stake, the government is to prevent these by all means (Gefahrenvorsorge). If there is only a risk of effects occurring, the possibilities of risk prevention have to be investigated and if the risk is high enough, preventive measures can be ordered (Risikovorsorge).* (emphasis added)[116]

Germany introduced the concept of precaution at the international level during a series of conferences on the protection of the North Sea held at Bremen (1984), London (1987), the Hague (1990) and Esbjerg (1995).[117] By the second of such conferences, the term precautionary approach appeared as a decision approach that may require "*action to control inputs of the 'most harmful substances (...) even before a causal link has been established by absolutely clear scientific evidence.' "*[118] By 1990, this same approach was referred to as the precautionary principle." And by the fourth conference, the Esbjerg Declaration was adopted, recommending that the precautionary principle also be applied where fisheries management policies are concerned.[119]

The most widely recognized expression of the precautionary principle is contained in Principle 15 of the Rio Declaration on Environment and Development, as adopted at the United Nations Conference on the Environment and Development (otherwise known as the Earth Summit) convened in Rio de Janeiro during 1992.

It provides that

> *in order to protect the environment, the precautionary approach shall be widely applied by all States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.*[120]

Some commentators and governments have interpreted this to mean that a precautionary approach is called for even if there is no guarantee that adoption of a given measure would prevent serious environmental harm. They believe that

> *scientific certainty often comes too late to design effective legal and policy responses for preventing potential environmental threats. Most environmental issues involve complex analyses of scientific, technical, and economic factors. [There is] rarely anything approximating perfect knowledge when lawmakers are asked to make decisions whether to respond to a specific threat.*[121]

Plainly stated, although we may lack scientific certainty about the magnitude or nature of an environmental threat, we should err on the side of caution.

European legal authorities argue that the precautionary principle has become a norm in regional environmental law within the EU.

According to some commentators, the U.S. government recognized the legal difference between the concepts precautionary approach and precautionary principle early on and endeavored at the Earth Summit to forge a compromise between them. The then and current prevalent U.S. view is that the lack of clear scientific evidence of a causal relationship between human behavior and the greenhouse effect does not justify taking expensive measures.[122]

Today, European legal authorities argue that the precautionary principle has become a norm in regional environmental law within the EU. This is reflected within a document entitled *Communication on the Precautionary Principle* prepared by the European Commission.[123] The precautionary principle, for example, has received European endorsement in various treaties, including the Maastricht Treaty forming the EU[124] and the 1992 United Nations Economic Commission on Europe Helsinki Convention on the protection and use of transboundary watercourses and international lakes.[125] At least one commentator has noted that the definition of the precautionary principle employed by the Helsinki Convention is broader in scope than that employed by the Rio Declaration, "as it does not limit itself to serious or irreversible damage."[126]

The precautionary principle was incorporated into an international action plan at the 1996 international conference "Codifying Rio Principles in National Legislation." At the conference, a formal declaration was crafted—known as "The Hague Declaration on Principles of Environmental Law"—which included the precautionary principle as one of the Rio Declaration principles that needed to be incorporated into national and international legal systems.[127]

> *An explicit way to reflect the principles as such in law is through codification of the principles themselves…The substantive principles which are to be incorporated both into national law systems and policies, include but are not limited to the following principles…the* precautionary principle *(Principle 15)…Individual states bear the main responsibility for the incorporation of the principles into their own national legal systems, bearing in mind their own legal, cultural and political structure. However, regional cooperation is strongly encouraged.* (emphasis added)[128]

The precautionary principle/precautionary approach, furthermore, is directly or indirectly referenced in at least six multilateral environmental agreements.

1. The United Nations Framework Convention on Climate Change and the Kyoto Protocol. This convention is to be implemented by the Kyoto Protocol, which has not yet entered into force. The Kyoto Protocol states in its preamble that it is to be "guided by Article 3 of the Convention."[129] Article 3.3 of the Convention provides that "the Parties should take *precautionary measures* to anticipate, prevent or minimize the causes of climate change and mitigate its adverse effects" (emphasis added).[130]

2. The Cartagena Protocol on Biosafety and the United Nations Convention on Biological Diversity. Perhaps, the broadest and most detailed expression of the precautionary principle is contained within the Cartagena Protocol on Biosafety,[131] which is intended to implement Article 8(g)of the Convention on Biological Diversity.[132] The Protocol recently entered into force during September 2003. The Protocol refers to the *precautionary approach* within several of its provisions. The Preamble states: "Reaffirming the *precautionary approach* contained in Principle 15 of the Rio Declaration on Environment and Development…"[133] Article 1 states, "In accordance with the *precautionary approach* contained in Principle 15 of the Rio Declaration…"[134]

Article 10(6) speaks to the issues of inadequate knowledge and causation that are emphasized by the German *vorsorgeprinzip*. It states that

> *Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question…in order to minimize such potential adverse effects.*[135]

3. The Stockholm Convention on Persistent Organic Pollutants (POPs). The POPs Treaty, which will enter into force on May 17, 2004,[136] contains various references to

precaution. Its Preamble states, "…Acknowledging that *precaution* underlies the concerns of all Parties and is embedded within this Convention…"[137] Article 1, setting forth the Convention's objective, provides, "mindful of the *precautionary approach* as set forth in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Convention is to protect human health and the environment from persistent organic pollutants."[138]

Article 8, entitled, "Listing of Chemicals in Annexes A, B and C" provides generally that "…the Conference of the Parties, taking due account of the recommendations of the Committee, including any scientific uncertainty, shall decide in a *precautionary manner* whether to list the chemical and specify its related control measures…"[139]

4. The Rotterdam Convention on Prior Informed Consent Procedure. The Rotterdam Convention on Prior Informed Consent for Certain Hazardous Chemicals and Pesticides in International Trade (the 'PIC Procedure') entered into force on February 24, 2004.[140] It requires Treaty Parties to exchange

> *scientific, technical, economic and legal information concerning the chemicals [covered by] the Convention… [particularly]… information on domestic regulatory actions that substantially restrict one or more uses of [such] chemicals…[and]…on* precautionary measures*, including hazard classification, the nature of the risk and the relevant safety advice."*[141] *Export notifications shall contain…information on* precautionary measures *to reduce exposure to and emission of the chemical…* (emphasis added)[142]

5. The Montreal Protocol on Substances that Deplete the Ozone Layer. The Montreal Protocol implements the Vienna Convention for the Protection of the Ozone Layer. The Preamble states,

> *Determined to protect the ozone layer by taking* precautionary measures *to control equitably total global emissions of substances that deplete it, with the ultimate objective of their elimination on the basis of developments in scientific knowledge… taking into account technical and economic considerations… Noting the* precautionary measures *for controlling emissions of certain chloroflourocarbons (CFCs) that have already been taken at national and regional levels…* (emphasis added)[143]

6. The United Nations Convention on International Trade in Endangered Species. It has also been argued by certain governments, primarily the EU and its member states, that the precautionary principle is enshrined within The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). CITES regulates the protection of over 30,000 plant and animal species depending on their biological status and the impact that international trade may have upon them. This argument is based on a resolution adopted outside of the text of the Convention by the Conference Of the Parties (COP) at its 9th meeting during November 1994. Although only a guidance document, the resolution is intended to provide a process for determining the status of species to be included within either of the Convention's Appendices. Consistent with the Kyoto and Montreal Protocols, the POPs Treaty

and the PIC Procedure, the resolution's language refers to the *precautionary measures* that must be taken. In this case, the precautionary measures referred to are those that determine, based on "sufficient available data," which species satisfy the Convention's criteria in order to be listed within either of the Appendices.[144]

The Relationship between International Environmental Law and International Trade Law—The WTO Agreements Do Not Generally Permit the Application of The Precautionary Principle

At the November 2001 Ministerial meeting that launched the Doha Round of Trade Negotiations, it was acknowledged that

> *[The WTO rules] do not prevent [members] from taking measures for the protection of human, animal or plant life or health, or of the environment at the levels they consider appropriate, subject [however] to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, and are otherwise in accordance with the provisions of the WTO Agreements.*[145]

In the spirit of multilateral cooperation it was agreed that trade and environmental issues would be formally discussed as part of the current round of negotiations. The stated objectives were to negotiate and clarify the relationship between WTO rules and existing trade obligations specified within multilateral environmental agreements and to set up procedures for regular information exchanges between MEA secretariats and the relevant WTO committees.[146]

In addition, the Preamble to the WTO Agreements states "the WTO is intended to promote the optimal use of the world's resources in accordance with the object of sustainable development, seeking to both protect and preserve the environment and to enhance the means for doing so."[147]

There are at least two WTO Agreements, however, that were specifically designed to prevent countries from enacting technical regulations and/or standards that constitute unnecessary obstacles to trade. Technical regulations and standards relating to food and plant-based products are covered by the Sanitary and Phytosanitary (SPS) Agreement. All other non-food and non-plant-related technical regulations and standards are covered by the Technical Barriers to Trade (TBT) Agreement. Measures that cannot be classified as either a technical regulation or a standard are otherwise covered by the provisions of the GATT.[148] The SPS and TBT Agreements generally recognize that standards and regulations can be utilized as disguised non-tariff barriers to trade. They generally premise national (or regional) regulatory action upon relevant international science-based standards formulated through consensus by widely recognized international standards bodies, or in their absence, upon substantially equivalent national science-based standards developed by other WTO members.

In the event international or substantially equivalent national standards do not exist, the SPS Agreement requires governments to conduct an objective risk analysis that must include a science-based risk assessment of a particular product or substance in light of a specifically identified and ascertainable risk in order to justify their regulatory actions.[149]

> *Theoretical uncertainty should* not *be assessed. The existence of unknown and uncertain elements does* not *justify a departure from the risk assessment requirement. In addition, the risk to be evaluated in a risk assessment under SPS Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist—the actual potential adverse effects on human health in the real world where people live and work and die…If a measure is not based on a 'risk assessment,' it can be presumed* not *to be based either on 'scientific principles' or to be maintained* without *'sufficient scientific evidence.'* (emphasis added)[150]

Likewise, the TBT Agreement requires national (or regional) legislatures and/or administrative agencies to base their regulatory actions upon relevant objective performance-oriented standards developed by recognized international standards bodies.[151]

The TBT Agreement requires that WTO member states shall ensure that national and/or regional technical regulations and standards (voluntary and mandatory) are not prepared, adopted or applied with a view to create unnecessary obstacles to international trade.[152] In the context of technical regulations, this requirement means that any new regulatory requirements imposed shall not be more trade-restrictive than necessary to fulfill a legitimate state objective, taking into account the risks non-fulfillment would create.[153] In other words, health and environment-related measures must always be proportional to the objectives sought and they must always reflect the least trade restrictive alternative available.[154] Examples of legitimate state objectives include the protection of human health and safety, animal and plant life or health and the environment.[155] When assessing such risks, WTO members shall consider of relevance "…inter alia available *scientific and technical information* or intended end-uses of products."[156]

Similarly, the SPS Agreement requires WTO members "when establishing or maintaining sanitary or phytosanitary protection, to ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of…protection, taking into account technical and economic feasibility."[157] And they must ensure that any SPS measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles, and is not maintained without sufficient scientific evidence, *except* as provided in Art. 5.7.[158]

SPS Article 5.7 is the only WTO provision that has been interpreted as providing WTO Members with the right to apply the precautionary principle. It generally permits WTO Members to take precautionary measures when they do not possess sufficient evidence of a product's safety. WTO Members, however, must satisfy certain tests to invoke this provisional safeguard.

> *WTO case law has determined that a WTO Member must demonstrate that: 1) The provision is imposed in respect of a situation where relevant scientific evidence is insufficient; 2) The provision is adopted on the basis of available pertinent information; 3) The Member affirmatively seeks to obtain the additional information necessary for a more objective assessment of risk; AND 4) The Member reviews the measure within* a reasonable period of time… *Whenever one or more of these four conditions is not met, the measure will be found to be inconsistent with the SPS Agreement.* (emphasis added)[159]

Even if a WTO member is able to satisfy these requirements, it must be remembered that the safeguard provided by Article 5.7 has been considered by the WTO Appellate Body in the *EC Hormones*[160] case to be only *a limited, permissible application of the precautionary principle*. "The precautionary principle (other than as that expressed in Article 5.7 on provisional measures) does not override the obligation to base SPS measures on a risk assessment."[161]

The Appellate Body, in this case, ruled against the EU. It held that the EU measures banning the use of six growth-promoting hormones, which effectively blocked U.S. hormone-injected beef product exports, lacked a scientific justification. In other words, such measures were not based on scientific evidence of a health risk and no scientific risk assessment had been performed. Because the EU has continued to maintain the ban in opposition to the 1998 WTO ruling, the United States has continued to impose 100 percent retaliatory tariffs on $116 million of EU agricultural products (as has Canada) from mostly France, Germany, Italy, and Denmark, countries deemed the biggest supporters of the ban.

Health and environment-related measures must always be proportional to the objectives sought and they must always reflect the least trade restrictive alternative available.

In December 2002, the EU permanently banned the use of oestradiol-17-B, a growth- promoting hormone widely used in the United States, which was determined by the U.S. Food and Drug Administration to pose no health risk to consumers. The EU has since presented the results of new studies that it says are based on scientific evidence showing that the six hormones pose a significant risk to public health.[162] The U.S. and Canadian governments have continued to reject these results as not presenting any new scientific evidence to support the EU ban. During October 2003, the EU reported that it had amended its ban,[163] "in a way that should satisfy both the complainants (the United States and Canada) and the WTO,"[164] and that therefore, "the United States and Canada should lift their trade sanctions against the EU."[165] The EU has refused to lift its amended ban, insisting that it "was now fully backed up by scientific evidence proving the risks and dangers of the hormones that are widely used in North American beef production."[166] EU Commission Pascal Lamy even hinted that "the EU would have to seek another WTO ruling in the case."[167]

The Implications of the Precautionary principle for International Trade

The implications of the precautionary principle for international trade are extremely significant. The debate in which the EU and the United States are engaged in focuses on whether a WTO member's use of the precautionary principle can be consistent with its WTO obligations. That debate has focused, in particular, on concerns about the impact (arguably a "chilling effect") that such a principle could have on the marketability of future and emerging technologies developed in the United States and their potential use throughout the world. However, the economic and social advancement of developing countries is also arguably at stake.[168] Apparently, the United States and a number of developing countries are concerned that some WTO members may employ the precautionary principle surreptitiously, under the guise of health and environmental protection, in order to protect ailing or lagging domestic industries.

One need only look at the EU's moratorium and proposed regulations on genetically modified foods (GMOs) to see how the application by government policymakers of the precautionary principle can affect international trade. Since 1998, at least seven EU member states have imposed a de facto moratorium, the effect of which has been to block EU market access to all exports of GMO products that originated from the United States. GMO exports from Canada, Mexico, and Argentina, which are also producers of GMOs, have also been blocked by the moratorium.[169] In fact, the negative EU attitude towards GMOs generally has encouraged a global anti-GMO movement and jeopardized the establishment of GMO research and development programs and the domestic sale of GMO products within Brazil and many African and Asian developing countries.[170] Although the EU signaled to the United States during 2003 that it was prepared to lift the moratorium, which it technically did on May 19, 2004,[171] the U.S. government has insisted that the complaint it had filed against the moratorium at the WTO last year[172] would go forward.[173] "The approval of a single product is not evidence that applications are moving routinely through the approval process in an objective, predictable manner based on science and EU law rather than political factors."[174]

In addition, the United States has adopted such a tough negotiating position because the EU had previously conditioned the lifting of the GMO moratorium upon the enactment of regional traceability and labeling regulations. According to the Commission, the labeling rules, in particular, were meant to afford European consumers the choice of whether or not to buy the GMO corn. The rules would "provide consumers with the information they need to make up their own mind…The labeling rules would require that "[a]ny frozen or canned biotech corn sold in stores would have to be labeled as such under 'state of the art' rules that took effect last month."[175] They will also require retailers to place labels on displays and in advertising used in connection with such products. The EU's GMO regulations, which are to be harmonized throughout the EU, are also based on the precautionary principle.[176]

They are intended to implement EU member state obligations assumed under the Cartagena Protocol on Biosafety that recently came into force during September 2003.[177] Other than the Biosafety Protocol, there are no consensus-based international standards upon which the EU relied. The regulations will apply to all food and feed products intended for human and animal consumption that contain, consist of (except for adventitious amounts) or are produced from (even if there are no detectable traces of) GMOs. The EU has imposed these measures even though the EU Commissioner for Health and Consumer Safety has said that, "we have various prestigious scientific institutions that have said that GM foods do not cause any harm to consumers. There is no evidence that this food is any more unsafe than conventional foods."[178]

The United States has argued that these measures violate the WTO Agreements for several reasons.[179] One of the main U.S. objections to the moratorium has been that it was not based on an objective scientific risk assessment identifying an ascertainable risk of harm to human health or safety. A major U.S. objection to the labeling regulations has been that they discriminate against otherwise "like" products on the basis of process and production methods rather than on the basis of product characteristics, performance criteria or end-uses. Furthermore, the United States has alleged that these requirements violate the sovereignty of other WTO members by dictating the methods by which their food industries should manufacture and process their products. Moreover, the United States has argued that other less burdensome and trade-restrictive measures could have been selected.

The United States and a number of developing countries are concerned that some WTO members may employ the precautionary principle, under the guise of health and environmental protection, in order to protect ailing or lagging domestic industries.

Another prime example of how the precautionary principle has been applied by WTO members is the proposed EU regulation on chemical substances known as the Registration, Evaluation and Authorization of Chemicals (REACH).[180] As in the case of GMOs, the EU-proposed regulation is not premised on any consensus-based international standard or equivalent national standard. However, unlike in the case of the EU GMO legislation, there is no multilateral environmental agreement, and hence, no international legal obligation that the EU REACH regulation is implementing.

The proposed REACH regulation imposes on foreign exporters a broad legal duty of care satisfaction that requires adherence to an extensive and rigorous substance authorization process. That process places the burden of proving the safety or harmlessness of substances and products upon manufacturers/exporters. It obliges them to prepare detailed information dossiers and to meet rigorous testing

requirements as a condition precedent to granting market access to high volume chemical substances and to certain finished products containing them, with some exceptions. In addition, the regulations require technical information sharing by all producers, intermediaries, and distributors along a product's vertical supply chain as well as product labeling for consumer use.[181]

According to the EU, "the aims of the proposed regulation…are to increase the protection of human health and the environment [within the EU region] from exposure to chemicals while at the same time to maintain and enhance the competitiveness and innovative capability of the EU chemicals industry."[182] However, a review of the regulation will reveal that it is truly *global in scope*, affecting practically all industry sectors and corresponding supply chains. A revision to the proposed REACH regulation was issued during October 2003, and is currently before the Parliament for a final reading.[183] Yet, a review of the public comments received from entities and governments of other WTO members, especially those of Asian and Latin American developing countries, reveals that they consider REACH not only as a threat to their social and economic progress, but also as a disguised technical barrier to trade.[184]

A review of the REACH regulation will reveal that it is truly global in scope, affecting practically all industry sectors and corresponding supply chains.

Indeed, U.S. objections to these proposed regulations have focused on the lack of a scientific risk assessment for all of the 30,000 or so chemicals subject to the regulation. Such a risk assessment would have identified which chemicals pose the most immediate and serious risks to human health and the environment. In addition, the United States has generally argued that the regulations impose a disproportionately expensive and onerously time-consuming administrative burden on foreign (U.S.) companies, especially small and medium-sized enterprises, which comprise much of the global chemical industry. Furthermore, the United States has argued that the regulation is extra-territorial in nature and discriminates against exports of otherwise like finished products based on how they are produced rather than on how they perform or are used. Moreover, the United States and other WTO members have argued that the EU could have selected a less burdensome and trade-restrictive alternative to protect legitimate state interests.[185]

The precautionary principle has also been applied within the EU to define the notions of life cycle management and take back that underlie the EU Green Paper on Integrated Product Policy (IPP). The IPP reflects an extension of the concepts of producer responsibility and product stewardship that have been integrated into the EU Directive on End-of-Life Vehicles (ELV), the Directive on Waste from Electrical and Electronic Equipment (WEEE), the Directive on Restrictions on the Use of Hazardous Substances (RoHS), and the Proposed Framework Directive on Eco-

Design for Energy-using Products (EuP).[186] Each of these directives imposes upon industry the affirmative duty to design products from inception with the goal of not harming the environment.

The problem with these initiatives is that they reflect the formalization of precaution into an absolute principle (i.e., as an international standard), the objective of which is to eliminate almost all risk from everyday economic life, which simply is not possible. To the extent that Europe's application of the precautionary principle, which minimizes the importance of classical risk assessment, impairs humankind's ability to innovate in the short and long term, it is clearly not desirable.

Applying The Precautionary Principle in WTO Dispute Resolution

According to the WTO Appellate Body in the *EC-Hormones* case:

> *the [precautionary] principle is regarded by some as having crystallized into a general principle of customary international environmental law. Whether it has been widely accepted by Members as a principle of general or customary international law appears less clear…We note that…the precautionary principle, at least outside the field of international environmental law, still awaits authoritative formulation.*[187]

Consequently, if a WTO member relies on an interpretation of the precautionary principle that is broader than that called for by SPS Article 5.7, it will likely be operating beyond the bounds of WTO treaty law. In such instance, it will need to establish that the precautionary principle is a principle of customary international law and that such law should be substantively applied or otherwise considered by a WTO panel to resolve a WTO dispute.

To establish the precautionary principle as a norm of customary international law, it must be shown that the texts of the SPS and TBT Agreements reflect the intent and obligation of WTO members to adopt the precautionary principle as a WTO treaty norm.

In general, international customary law consists of the regular practices and rules that member states follow. These practices and rules become rules of international law when they satisfy two conditions. First, member state practice must demonstrate that states engage in acts consistently within their borders and with other member states, as reflected by court decisions, legislation, and diplomatic practice. Second, state practice must rise to the level of *opinio juris*. In other words, state practice must demonstrate that such acts are accepted as law. Something more than actual practice based on morality, habit or convenience is needed—states must be acting out of obligation; they must be acting because they believe that they must follow a rule.[188]

Therefore, in order to establish the precautionary principle as a norm of customary international law, it must be shown that the texts of the SPS and TBT Agreements (as multilateral treaties) reflect the intent and obligation of WTO members to adopt the precautionary principle as a WTO treaty norm. Alternatively, it must be demonstrated that WTO members' understanding of the WTO treaty texts has evolved enough to accommodate the precautionary principle, *and* that WTO members have actually adopted the precautionary principle as a matter of state regulatory and/or standards practice and custom in other fora (e.g., pursuant to the terms of a multilateral environmental treaty or as a matter of public international law).[189]

Even if a member state, through its multiple practices, was able to establish the precautionary principle as a norm of customary international law (i.e., as a non-WTO treaty norm), its ability to incorporate that norm within the SPS and TBT Agreements remains uncertain. There continues to be significant disagreement about the relationship between WTO law and non-WTO sources of international law that is not likely to be resolved in the immediate future. The issue, in a nutshell, is if WTO dispute resolution panels, when resolving WTO claims, are permitted to apply other sources of law than WTO substantive law. One school of thought argues that notwithstanding the fact that the WTO is a part of a much broader system of public international law, "[t]he WTO legal system [by its specific terms] does not countenance the possibility of directly applicable norms…norms that apply by their own terms, rather than by virtue of their incorporation by reference in the WTO legal system…from outside the WTO system."[190] Another school of thought argues that "both the WTO treaty and WTO dispute settlement are integral parts of public international law at large. They are not 'closed' or 'self-contained' regimes: they were created in the wider context of general international law, as well as other treaties…and continue to exist in that context."[191] Consequently, it is argued that a WTO tribunal may take them into account when deciding a WTO dispute.

Conclusion

The role of science in government assessment and management of public health and environmental risks has increasingly become the subject of a heated transatlantic political debate. Numerous concerns have arisen during the past fifteen years regarding food safety, chemicals management, waste disposal, industrial pollutants and climate change. The EU and the United States hold divergent views toward the usefulness of science as a tool to understand and address the uncertainties surrounding these risks, and their relationship to the activities engaged in and the innovations produced by modern economic life. Although the contours of this debate appear bilateral in nature, the issues being discussed are international in scope. Consequently, their resolution is likely to have a profound legal, social, and economic impact on all WTO member governments and industries, including those of developing countries.

The prevailing view within Europe is to take a "better safe than sorry" or precautionary approach to assessing and managing a growing number of possible

but uncertain health and environmental hazards. According to this view, conventional scientific risk assessment should serve only a minimal function. There is a widespread belief that risk assessment, as an empirical process, reflects only the current state of limited human scientific knowledge—it cannot account for the uncertainties surrounding most human activities. As a result, it is argued that risk managers should focus instead on evaluating and addressing systemic hazards posed by products' inherently dangerous characteristics categorized into risk profiles. Accordingly, where the possibility for significant irreversible harm is great, a lack of scientific certainty as to cause and effect, likelihood of occurrence or timing, or of actual evidence of harm, regulators should not be precluded from taking precautionary measures to prevent the harm from materializing in the first place. EU regulators argue that their aversion to risk is necessary to ensure a high level of health and environmental protection, even if it imposes a considerable legal, economic, and social burden on industry (foreign as well as domestic) and developing country governments.

The issue is if WTO dispute resolution panels, when resolving WTO claims, are permitted to apply other sources of law than WTO substantive law.

The prevailing U.S. regulatory view and practice, with certain limited exceptions, is to identify and evaluate health and environmental risks on a case-by-case basis, depending on their probability of occurrence and the likelihood that they may inflict serious actual harm. This is accomplished by means of an empirically driven and objective "science-based" risk assessment that is performed with respect to a particular product or substance (not process). The risk assessment identifies the nature and significance of the particular risk, the magnitude and severity of known and/or uncertain potential harm, the degree and certainty of human exposure to such harm, and the vulnerability of the various groups so exposed. Where there are profound uncertainties as to any of these factors, estimates and assumptions (safety factors) are employed that incorporate an appropriate degree of precaution. Additional margins of safety are also employed, if necessary, at the risk management stage through the selection of suitable frameworks. In most cases, health and environmental regulations are then subject to an economic cost/benefit analysis to determine whether the chosen approach "maximizes net social, economic and environmental benefits."

The EU believes that it is necessary to establish its precautionary approach as a formal *precautionary principle,* to be incorporated within an international legal framework that governs the assessment and management of global public risks to human health and the environment. The history and evolution of the precautionary approach/ precautionary principle reflects that it is derived from German notions of prevention and precaution and that its use was subsequently expanded throughout Europe following the creation of the EU to address a growing number of regional environmental concerns. The precautionary approachprecautionary principle was

also introduced at the Rio Summit on Sustainable Development and memorialized within a number of international declarations. And it was incorporated within several multilateral environmental treaties, few of which, however, have been in force for more than a year and implemented by treaty parties.

The legal and academic debate in which the EU and United States are engaged in focuses largely on the relationship between these declarations and international environmental treaties and the WTO agreements. The EU and like-minded advocates have argued that the precautionary principle has risen to the level of a customary international legal norm, as expressed within such treaties and declarations and that it has been ruled a provisional WTO treaty norm. Accordingly, a WTO tribunal must substantively consider the precautionary principle when deciding a WTO dispute. To the contrary, the United States acknowledges that the WTO has narrowly ruled that governments may lawfully employ precautionary measures under certain limited provisional conditions, as set forth within the SPS Agreement. It does not, however, recognize the existence of *a* formal precautionary principle either as a substantive WTO treaty norm or a customary international legal norm. Consequently, the US and like-minded advocates have argued that a WTO tribunal may not consider it when deciding a WTO dispute.

A cynic might argue that, stripped to its essence, this debate is primarily about global economic competition. At one level, the EU and United States seek to determine the extent to which they may each legally impose domestic (or regional) health and safety and environmental legislation, having extra-territorial effects without seriously impeding or otherwise distorting international trade flows. This determination is intended to ensure market access for their respective goods and services. At a seemingly more fundamental ideological and political level, however, they each endeavor to define the role of "sound science" through the imposition of cultural preferences in making this determination. Unfortunately, it seems that what each may have forgotten in this global struggle to secure the commanding heights is the social and economic welfare of the developing members of the WTO.

Notes

[1] See: Bruce Stokes, "New Trade Barriers: National Preferences," *National Journal,* April 24, 2004.

[2] See: Lawrence Kogan, " 'Enlightened' Environmentalism or Disguised Protectionism? Assessing the Impact of EU Precaution-based Standards on Developing Countries," for the National Foreign Trade Council (April 2004), available online at http://www.nftc.org/default/white%20paper/riskreg3study404_2_Final.pdf.

[3] A growing number of reports have alleged that carbon dioxide and methane have accumulated in concentrations high enough to trap heat within the global upper atmosphere. In addition, these reports argue that such greenhouse gases *could* potentially raise the Earth's surface temperature enough to cause noticeable climate change; this *could* result in raised sea levels and threaten coastline communities or adversely affect sensitive ecosystems and geographies, thereby placing irreplaceable natural resources at risk. As a result, there are concerns about how climate change precipitated by these emissions *could* potentially affect global agriculture and the water supplies necessary to sustain it, given the possibility that higher global temperatures *could* promote the conversion of arable land into deserts. While forest cover provides a primary and natural source of absorption (as a natural sink) for these greenhouse gases, environmentalists argue that this natural resource, a rich source of biodiversity, is being depleted by economic activities such as timber concessions and illegal logging. Although science has yet to identify

conclusively the extent of natural causes of global warming or the precise impacts of global warming, it has increasingly pointed to a relationship between anthropomorphic activity, increased greenhouse gas concentrations and 'real' global warming. See: "U.S. Climate Action Report 2002," Federal Register Notice, Vol. 66, No. 221, pp. 57456-57 (Nov. 14, 2001) [FR Doc. 01-28736]; "Third National Communication of the United States of America under the United Nations Framework Convention on Climate Change, Chapter 6: Impacts and Adaptation; Appendix D, Climate Change Science: An Analysis of Some Key Questions," available online at http://www.epa.gov/globalwarming/publications/car/.

[4] In the terminology of risk regulation, this phenomenon is referred to as a 'risk-risk scenario.' "Policy-makers face a serious dilemma. If they design policies according to the risk perceptions of lay people, they actually may tolerate more real sacrifices in terms of lives lost or human suffering than necessary. If they follow only the advice of the professional experts, they may lose public support or even sympathy." See: Ortwin Renn, "Risks and Society," Presentation made at the Directorate General, Health and Consumer Protection, International Conference: "Risk Analysis and Its Role in the European Union," Brussels (July 18-19, 2000), available online at http://europa.eu.int/comm/food/risk/session1_1_en.pdf, http://www.konsumentsamverkan.se/evenemang/brysselriskprogram.html.

[5] According to Theofanis Christoforou, Legal Adviser, to the European Commission, "There are many reasons and factors that explain the current divergence in the regulatory approach of the two systems. They range from social, economic, legal, scientific, cultural, ethical, tradition, political, and regulatory policy choices. They all interact and play an important role, although the relevance of one or the other of these factors may be different depending on the circumstances of each case. Two factors, however, appear to play a predominant role: the European's desire to achieve and maintain a high level of health and environmental protection, on the one hand, and the Americans' greater reliance on economic cost-benefit and market-oriented values, on the other. The application of precaution has also played a role in addressing the *European's risk adversity*. *Discussing the precautionary principle, therefore, helps underscore the fundamentally divergent understandings in the two systems of what science is and its role in risk assessment and risk regulation*…[This may help explain]…the constant claim by the United States that many European regulatory measures lack scientific basis and constitute disguised protectionism (e.g., meat hormones, recombinant bovine somatropin [rBST], GMOs, etc.) (emphasis added). Theofanis Chrisotoforou, "The Precautionary Principle in European Community Law and Science," Chap. 16, Joel A. Tickner, ed., in *Precaution: Environmental Science and Preventive Public Policy*, p. 245.

[6] "…[A]s tariffs and other border barriers melt away, trade disputes are increasingly driven by the incompatibility of societal preferences. Current international fights over hormones in beef, for example, or animal-welfare rules…are not generated just by old-fashioned protectionism. They reflect national differences in tastes and proclivities—the economic choices made by citizens in disparate societies." Bruce Stokes, "New Trade Barriers: National Preferences," p. 1. See, also: Samuel Loewenberg, "The Chemical Industry's European Reaction," *National Journal*, July 12, 2003. "This article quoted EU Environment Commissioner Margot Wallstrom as saying during a April 2003 trip to Washington, "I was told this week that the environment is not a 'door opener' in Washington…It clearly is a 'door opener' in Europe." The article's author noted that "the conflict over the [proposed EU] chemicals legislation ['REACH'] goes deeper than the usual arguments over dollars and cents. The root cause is the EU's use of the precautionary principle." Id., p. 2263.

[7] See: Lawrence Kogan, "Unscientific 'Precaution': Europe's Campaign to Erect New Foreign Trade Barriers," for the National Foreign Trade Council, Washington Legal Foundation Critical Legal Issues Working Paper Series No. 118 (Sept. 2003), available online at http://www.wlf.org/upload/kogan.pdf. "The most recent of three workshops previously organized during 2002 by the German Marshall Fund's US-European Biotechnology Initiative to discuss US and EU views toward biotechnology explains a great deal about EU reliance upon the precautionary principle. An interpretative summary of this dialogue prepared by a European is very revealing. "As one European said, 'There is a difference in what we want our countries to look like, not only with food but will all that goes with it.'…This 'way of life' statement echoed similar thoughts…one European said, 'GM food has evolved, not out of one or two big events such as growth hormones or 'mad cow' disease, but for many reasons that traverse the interdisciplinary spectrum of politics, science, economics, culture and social ethics.' " Id., p. 4, fn 11, citing Peter Pringle, "The US-European Biotechnology Initiative, Workshop 3: Segregation, Traceability and Labeling of GM Crops—An Interpretative Summary of a Transatlantic Conversation About Biotechnology and Agriculture," The German Marshall Fund of the United States (April 29, 2002). "…[T]he EU and the US are striving to define WTO law so that it best reflects their respective national/regional interests…[Arguably] [t]he EU's application of the precautionary principle…aims to preserve long-held European social and political values (i.e., the European 'way of life') rather than protect against known and

identifiable health and environmental hazards…" Id., pp. 65–66.

[8] See: Commission of the European Communities, "Communication from the Commission on the Precautionary Principle" COM (2000) (Feb. 2, 2000) (the 'Communication'). Following its issuance by the European Commission, this Communication "was distributed to international organizations as well as the European Parliament and Council. The objective was to contribute to the international debate about how regulatory officials should make risk-related decisions when faced with scientific uncertainty about suspected hazards." John Graham and Susan Hsia, "Europe's Precautionary Principle: Promise and Pitfalls," pp. 371–372. John Graham has observed how the Commission, within its Communication, has artfully situated the precautionary principle as "part of an orderly process of risk analysis, including objective scientific evaluation, risk assessment, risk management and risk communication." John Graham and Susan Hsia, "Europe's Precautionary Principle: Promise and Pitfalls," p. 386. Notwithstanding this observation, however, it is arguable that the precautionary principle *employed* by the EU Commission is not the same precautionary principle *articulated* by the Commission in its Communication.

[9] See: Ortwin Renn and Andreas Klinke, "A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based and Discourse-Based Strategies," (Fall 2002). "Our main thesis in this paper will be to offer a new *classification of risk types* and management strategies that promise scientific accuracy, a reflection of social diversity, and political feasibility…[While]…a huge number of risk classes can be deducted theoretically…*risks with one or several extreme qualities need special attention*…[O]ur exercise produced six different risk clusters…In order to evaluate risks and set risk reduction priorities we propose a procedure *assigning risk potentials to one of the six risk prototypes* of the classification…The essential objective of *the proposed risk classification* is to derive effective, efficient and politically and legally feasible strategies and measures for risk reduction and mitigation." (emphasis added). Id., pp.3, 17, 21 and 25. In the case of chemical substances, for example, the EU Commission has argued in support of its proposed chemicals regulation known as 'REACH' (Registration, Evaluation Authorization of Chemicals) that "there is a general lack of knowledge about the properties and the uses of existing substances. The risk assessment process is slow and resource-intensive and does not allow the system to work efficiently and effectively." "Strategy for a Future Chemicals Policy" ('the EU Chemicals White Paper'), COM (2001) 88 Final, at p. 6. One U.S. law firm has sized this up as follows: "The White Paper proposes that the most stringent data collection and regulatory review requirements, namely those for 'authorization' of chemicals giving rise to 'very high concern'—will be triggered for all chemicals with certain characteristics. Substances 'with certain [assessed] hazardous properties' such as category 1 and 2 carcinogens, mutagens or reprotoxins and persistent organic pollutants, will only be authorized for specific uses for which they are demonstrated to be 'safe.' " Legal Opinion of Crowell & Moring, examining certain international trade aspects of the proposal contained in the 'White Paper,' 'Strategy for a Future Chemicals Policy' (Nov. 7, 2002), at p. 6, cited in Lawrence Kogan, "Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science," for the National Foreign Trade Council, at pp. 88–89, fns 400–402, available online at: http://www.nftc.org/default/white%20paper/TR2%20final.pdf.

[10] It is the opinion of at least one commentator that such risk aversion is likely due to the "[s]harp demographic differences [between the US and the EU]…European electorates are aging much faster than America's, making Europeans generally more risk-averse." Rachel Thompson, "Transatlantic Business in an Era of Crisis and Change," available online at http://www.apcouk.com/pc/news_content.asp?ID=43.

[11] According to John Graham, the Commission's failure to set forth a definition of either the precautionary principle or the 'high' level of protection it engenders implies that these concepts may "be understood by way of cultural familiarity." Thus it would seem that risk managers could easily manipulate their use of the precautionary principle to reflect public preferences and sentiments. John Graham and Susan Hsia, "Europe's Precautionary Principle: Promise and Pitfalls," p. 380.

[12] Theofanis Christoforou, "The Precautionary Principle in European Community Law and Science," at p. 243. See, also: P. Sandin, "Dimensions of the Precautionary Principle, Human and Ecological Risk Assessment," 5(5), 889–907, identifying "19 formulations of the [precautionary] principle in different international treaties and academic writings," cited in John Graham and Susan Hsia, "Europe's Precautionary Principle: Promise and Pitfalls," p. 379. According to John Graham, "Although there are some shared aspects to these formulations, it is also apparent that these formulations have important differences…[In particular, there are] two rather different definitions, the more modest one agreed by international negotiators as the Rio convention, and a more aggressive one, the Wingspread Statement, agreed to by a selected group of scientists and activists. Note for example, the word 'cost-effective' appears in the Rio [Convention] version but not in the Wingspread version. Rio says uncertainty does not justify inaction while Wingspread suggests that uncertainty requires action. Note further that the Rio definition is a restraint on policy dialogue while the Wingspread version establishes conditions that require policy restrictions. Wingspread covers all 'threats' of harm while Rio covers only those threats that are 'serious'

or 'irreversible.' " Id., pp. 379–380.

[13] "Even within US environmental law, which does not contain explicit references to the precautionary principle, there are important elements of precaution in specific environmental statutes and important judicial decisions [citing Reserve Mining Co. v. US EPA (Dist. Ct. 1976) and Ethyl Corp. v. US EPA (Ct. App. 1976)]…Yet, there are also some aspects of US law (e.g., the regulation of existing chemicals under the Toxic Substances Control Act) that have been interpreted by EPA and the courts in a non-precautionary manner (Wagner, 2000). John Graham and Susan Hsia, "Europe's Precautionary Principle: Promise and Pitfalls," pp. 374–375.

[14] As explained by John Graham, "The Bush Administration believes that science should have a strong role in setting risk-management priorities. Even in the relatively simple case of health risks, sound science is critical. First, there is the hazard question: What is the degree of certainty that any hazard exists?…Second, if the hazard exists, a probability assessment is required to distinguish a significant risk from a negligible one…Third, the number of people exposed to a hazard needs to be considered because population exposures contribute to the public health significance of the hazard. Fourth, the severity of the health effect is relevant…Although these basic scientific questions have been framed for health risks, it is feasible to frame a related set of questions for other types of risks, such as threats to natural resources and global ecology." John Graham, "The Role of Precaution in Risk Assessment and Management: An American's View," pp. 2–4.

[15] John Graham has noted that, "When analysts assess risks, they may introduce conservative assumptions or safety factors into the analysis to account for unknowns. These protective practices may be intended to establish an upper bound on the true but unknown risk. In the US, the technical community is now trying to bring more valid data into the risk assessment process." John Graham, "The Role of Precaution in Risk Assessment and Management: An American's View," remarks prepared for the January 11-12, 2002 conference on *The Europe, Precaution and Risk Management: A Comparative Case Study Analysis of the Management of Risk in a Complex World*, pp. 1–2, available online at http://www.useu.be/RiskManagement/Jan1102GrahamUSRiskManagementPrecPrin.html.

[16] See: "Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities," Office of Management and Budget, Office of Information and Regulatory Affairs (OIRA), Part I, Report to Congress on the Costs and Benefits of Federal Regulations, Chapter III, "U.S. Approaches to Management of Emerging Risks," pp. 51–62, p. 58.

[17] "Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities," p. 58. "Thus the Federal Regulatory framework of the United States is designed to be a responsive, consultative, science-based system, operating synergistically within multiple layers of checks and balances involving social norms, market forces, liability law, voluntary standards, and Federal, State and local regulation with executive, legislative and judicial oversight." Id., p. 53.

[18] "…[T]he US government supports precautionary approaches to risk management but we do not recognize any universal precautionary principle. We consider it to be a mythical concept, perhaps like a unicorn." John Graham, "The Role of Precaution in Risk Assessment and Management: An American's View," p. 2.

[19] See: "Margot Wallstrom, "The EU and US Approaches to Environment Policy: Are We Converging or Diverging?" Speech delivered at the European Institute (April 25, 2002), available online at http://www.eurunion.org/news/speeches/2002/020425Eimw.htm.

[20] "On December 23, 2003, the U.S. Department of Agriculture (USDA) announced a presumptive diagnosis of bovine spongiform encephalopathy (BSE, or "mad cow" disease) in an adult Holstein cow from Washington State. The diagnosis was confirmed by an international reference laboratory in Weybridge, England, on December 25. Preliminary trace-back based on an ear-tag identification number suggests that the BSE-infected cow was imported into the United States from Canada in August 2001… Since 1996, *evidence has been increasing for a causal relationship between ongoing outbreaks in Europe of a disease in cattle, called bovine spongiform encephalopathy (BSE, or "mad cow disease"), and a disease in humans, called variant Creutzfeldt-Jakob disease (vCJD)*. Both disorders are invariably fatal brain diseases with unusually long incubation periods measured in years, and are caused by an unconventional transmissible agent" (emphasis added). See: CDC National Center for Infectious Diseases, BSE and CJD Information and Resources, available online at http://www.cdc.gov/ncidod/diseases /cjd/cjd.htm. "Dr. Kenneth Petersen, an Agriculture Department veterinarian said the meat was safe. 'The recalled meat represents essentially zero risk to consumers'…He stressed, though, that the parts most likely to carry the infection—the brain, spinal cord and lower intestine—were removed before the meat from the infected

cow was cut and processed for human consumption …[and were apparently used for animal feed.]…[Petersen] said investigators have now determined that some of the meat from the cow slaughtered Dec. 9 went to Alaska, Hawaii, Idaho, Montana and Guam. Earlier, officials had said most of the meat went to Washington and Oregon, with lesser amounts to California and Nevada, for distribution to consumers. *Although federal officials maintain the food supply is safe, they have recalled as a precaution* an estimated 10,000 pounds of meat from the infected cow and from 19 other cows all slaughtered Dec. 9 at Vern's Moses Lake Meat Co., in Moses Lake, Washington…In Britain, 143 people died of [mad cow disease] after an outbreak of mad cow in the 1980s. Despite assurances that meat is safe, Japan, the top importer of American beef, and more than two dozen countries have blocked U.S. beef imports… U.S. beef industry officials estimated this week that they've lost 90 percent of their export market" (emphasis added). "Meat 'Safe'; Recall Widened," CBS/AP (Dec. 28, 2003), available online at http://www.cbsnews.com/stories/2003/12/23/national/main590039.shtml. The facts reveal that the cow diagnosed as BSE-infected was a 'downer' (i.e., nonambulatory disabled) dairy cow that was too sick or injured to stand or walk unassisted. "In the United States, the feeding of rendered cattle products to other cattle has been prohibited since 1997, and the importation of cattle and cattle products from countries with BSE or considered to be at high risk for BSE has been prohibited since 1989…On December 30, USDA announced additional safeguards to further minimize the risk for human exposure to BSE in the United States. Beginning immediately, FSIS has prohibited the use of 'downer' cattle for food for human consumption. Through its emergency rule-making powers, FSIS will take additional actions that will become effective on their publication." See: "Bovine Spongiform Encephalopathy in a Dairy Cow—Washington State, 2003," MMWR, January 9, 2004 / 52(53); 1280-1285, available online at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5253a2.htm. "The United States has formally notified its trading partners that U.S. beef is safe to eat, a principal step toward negotiations to lift bans they imposed because of mad cow disease:… summarizing what it has done to protect beef safety and search for other cases of mad cow…'*This information demonstrates that any remaining trade restrictions against U.S. beef and beef products can be lifted without compromising safety*'…said Ron DeHaven…the Agriculture Department's chief veterinarian." See: "U.S. Pressures Partners Over Beef Ban—USDA Insists Meat is Safe, Urges Resumption of Trade," The Associated Press (March 26, 2004), available online at http://msnbc.msn.com/id/4611358/.

[21] Since 1988, the EU has implemented a total ban to use any hormone growth promoters in livestock production. The EU has argued that six hormones—oestradiol-17-beta, progesterone, testerone, zeranol, trenbolone, and melengestrol acetate—may potentially cause cancer in humans. In the United States, to the contrary, use of five of these hormones is legally permitted (17 beta-estradiol, testoterone, progesterone, trenbolone and zeranol).

[22] Since 1997, the EU has banned five animal growth-promoting antibiotics administered in cattle feed on the basis of the precautionary principle. They include avoparcin, bacitracin, spiramycin, tylosin, and virginiamycin. Instead it has advocated therapeutic administration of antibiotics to individual heads of cattle to treat specific infections. During July 2003, the European Parliament and Council adopted a new regulation that "will strengthen the EU's rules on the safety of animal feed and complete the EU ban on the use of antibiotics as growth promoters…Banning the use of antibiotics as growth promoters in feed is also vital to efforts to combat anti-microbial resistance. The Regulation will come into force later this year…" See: "Council and Parliament Prohibit Antibiotics as Growth Promoters: Commissioner Byrne Welcomes Adoption of Regulation on Feed Additives," EU Institutions Press Releases, IP/03/1058 (July 22, 2003). During October 2003, "the US Food and Drug Administration (FDA) announced a new review procedure designed to curb the use of animal antibiotics that may pose a risk to human health…Many countries, researchers and some in Congress have argued that the practice aggravates the problem of antibiotic-resistant bacteria and the practice should be halted…The European Union has stopped the use of many animal antibiotics for growth promotion…*U.S. law forces [the agency] to look at products individually.* '*We think it is far better to look at the real risk…instead of just disallowing a category of uses,*' said Lester Crawford, deputy FDA commissioner…In its reviews, the agency will assess several different factors in deciding the risks to humans. One will be the likelihood that the drug could promote resistant bacteria in the animals that take it. The second major factor is the likelihood that humans would ingest the resistant bacteria. The third would weigh the chances that the exposure of people to the bacteria would have an effect on human health…" (emphasis added). See: Anna Wilde Mathews, "FDA Announces Policy Designed To Curb Animal-Antibiotics Use," *Wall Street Journal*, Oct. 24, 2003, p. A6.

[23] A discussion relating to how the United States continues to dispute 'scientific' data produced by the EU in support of its beef hormones ban is set forth in a later section of this paper. Several European studies have been prepared on this subject. See: Rainer W. Stephany, "Hormones in Meat: Different Approaches

in the EU and in the USA," National Institute of Public Health and the Environment, The Netherlands, APMIS 109 (Suppl. 103): S357-64 (2001), wherein the author explains that "the differences in approach and attitude towards the 'hormone problem' in the different parts of the world in the last decade resulted in conflicts between the EU and amongst others the USA." Id., p. 357.

See: Rainer W. Stephany, "Hormone Residue Testing: An Update in Research and Approaches," National Institute of Public Health and the Environment, The Netherlands (Oct. 2001); R.W. Stephany, "Hormones in Meat? Are Only Natural!" Laboratory for Residue Analysis (ARO), National Institute of Public Health and the Environment (RIVM), the Netherlands, wherein, the author concludes that, "…[T]here is no such thing as hormone-free meat and…the meat of animals which have been treated with anabolics in an expert and controlled manner contains hardly any more hormones than are found naturally. *Under these conditions there is no risk to the consumer*" (emphasis added). According to two recent scientific reports, the EU ban on growth-promoting antibiotics in animal feed may have given rise to a 'risk/risk scenario' wherein there is now more risk posed to human health and animal welfare because of threat of increased antibiotic resistance than before the bans were instituted.

See: Mark Casell, Christian Friis, Enric Marco, et al., "The European Ban on Growth-Promoting Antibiotics and Emerging Consequences for Human and Animal Health," *Journal of Antimicrobial Chemotherapy* (July 2003) 52, pp. 159–161. "Experience in Sweden had already shown that the bans might have adverse consequences for animal health and welfare, and economic consequences [from reduced animal production] for farmers. There were also suggestions that human health is unlikely to benefit and that it might even be adversely affected…The driving forces behind these bans were consumer and political opinion, and a scientific concern that resistance in selected animals might be transmitted to humans to the detriment of their health…The efforts and expenditure involved in the imposition of the ban would have been better spent on achieving rational antibiotic use in humans and animals, and on much greater efforts to understand the complex epidemiology of resistant pathogens and resistance genes, as well as adequate risk assessments of both the ban, the *'precaution,'* in parallel with the 'threat,' i.e., the continued use of growth promoters" (emphasis added). Id., pp. 159 and 160–61.

See: Ian Phillips, Mark Casewell, Tony Cox, et al., "Does the Use of Antibiotics in Food Animals Pose a Risk to Human Health? A Critical View of Published Data," *Journal of Antimicrobial Chemotherapy* (Sept. 2003). "Essentially antibiotics are used if they are known to be effective for their indicated purpose. They must cure or prevent infection, or in the case of growth promotion, must have a significant effect on food conversion parameters, and thereby improve the economic return to the animal producer, and they should not harm the animal…Almost every case made for or against antibiotics used in animals is complicated by the use of the same antibiotics in humans, which are equally able to give rise to resistance…What has not happened in 50 years of antibiotic use in animals and man seems unlikely to happen at a rapid rate now. *The banning of any antibiotic usage in animals based on the 'precautionary principle' in the absence of a full quantitative risk assessment is likely to be wasted at best and even harmful, both to animal and to human health*" (emphasis added). Id., at p. 17.

[24] There is the risk of contracting salmonella poisoning from undercooked chickens and eggs or low pathenogenic avian influenza and the risk posed by the use of low-concentration chlorine in chicken processing as an anti-microbial treatment to address these risks. See: Lawrence Kogan, "Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science," for the National Foreign Trade Council, (May 2003), pp. 11–12. In addition, there are health risks posed by the practices of aquaculture ('farm raised' fish) that is itself an alternative chosen in response to unsustainable fisheries practices that have resulted in the depletion of the world's oceans. These risks include exposure to agricultural pesticide run-off, as well as, the use of organic fertilizers (organic wastes) and inorganic fertilizers containing trace metals, antibiotics, and genetic breeding techniques to promote fish growth and production rates. See: John E. Bardach and Michael T. Santerre, "Organic Residues in Aquaculture," East-West Resource Systems Institute, United Nations University Press, available online at http://www.unu.edu/unupress/unupbooks/80434e/80434E0g.htm; "FDA's Seafood HACCP Program: Mid-Course Correction," U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition, Office of Seafood (Feb. 13, 2001), available online at http://www.cfsan.fda.gov/~comm/shaccp1.html; "FDA Increases Sampling of Imported Shrimp and Crayfish (Crawfish)," U.S. Food and Drug Administration FDA News Release (P02-20) (June 14, 2002), available online at http://www.fda.gov/bbs/topics/NEWS/2002/NEW00815.html; "Increased Testing for Antibiotic Residues on Imports From Thailand, Vietnam and Myanmar," European Commission, DG Health and Consumer Protection, Press Release IP/02/436 (Mar. 19, 2002), available online at http://foodhaccp.com/msgboard.mv?parm_func=showmsg+parm_msgnum=1002212; Somporn Thapanachai, "New Barriers Springing Up," *Bangkok Post* (2003), available online at http://www.bangkokpost.net/yearend2002/barriers.html; "Indian Scientists Boost Growth Rate of Fish," BioScience News and Advocate, The Life

Sciences Network (Dec. 6, 2003), available online at http://lifesciencesnetwork.com/news-detail.asp?newsID=4694. And, there is also the risk of contracting mercury poisoning from consuming too much of certain types of wild fish (fresh and saltwater) and shellfish. See: "FDA and EPA Announce the Revised Consumer Advisory on Methylmercury in Fish," U.S. Department of Health and Human Services and U.S. Environmental Protection Agency, News Release PO4-33 (Mar. 19, 2004), available online at http://www.fda.gov/bbs/topics/news/2004/NEW01038.html. In each of these cases, scientists within the international community have assessed the health risks associated with such products, though they often have come to different conclusions regarding the extent of the risks and how to manage them. In some cases, zero-tolerance requirements that are higher than international standards have been imposed.

[25] According to the World Health Organization, there are three main potential risks surrounding GMOs that are being currently debated, namely, "[their tendencies to provoke allergic reaction (allergenicity), gene transfer and outcrossing…" For a discussion of these risks, See: Lawrence Kogan, "Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science," pp. 34–35, fn 146.

[26] See, e.g.,: "Biotechnology and U.S. Agricultural Trade, Questions and Answers," FASOnline, available online at http://www.fas.usda.gov/itp/biotech/Q&As.html; Tobias Buck, "Brussels Warns EU on Modified Crops, European Commission Governments Told to End Foot-Dragging on Approving Products But U.S. Attacked for Threat of WTO Challenge," *Financial Times* (Feb. 4, 2003), cited in: Lawrence Kogan, "Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science," at p. 33.

[27] See: Lawrence Kogan, "Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science," pp. 24–42.

[28] See: Lawrence Kogan, "Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science," at pp. 68–70 discussing the potential but scientifically unverified concerns about the health impact of brominated flame retardants used in fire extinguishers and plastic appliances such as TVs; at p. 71 concerning the failure of the EU to conduct risk assessments on dishwater detergents and other household products (e.g., surface and sanitary cleaning agents) that contain active chlorine compounds; at pp. 106-111, discussing the amended EU Cosmetics Directive and fn 495, which discussed scientific tests conducted by the Cosmetic Ingredient Review Panel verifying the safety of phthlates used in cosmetics. See: "Panel Reaffirms Phthalates in Cosmetics Are 'Safe For Use,' " Phthalate Information Center, American Chemistry Council (Nov. 19, 2002), available online at http://www.americanchemistry.com. The Cosmetics Directive, which was approved by the European Parliament in January 2003, "bans two commonly used cosmetics ingredients that are reproductive toxins according to EU law—dibutyl phthalate (DBP) and di-2-ethylhexyl phthalate (DEHP). Nearly 70 percent of nail polishes tested contained high levels of DBP, and many popular deodorants, perfumes, hair mousses and hair sprays contained DBP, DEHP or other types of phthalates…" See: Stacy Malkan, "Progress on Phthalates," Multinational Monitor (May 8, 2003), available online at http://www.alternet.org/story.html?StoryID=15858. During 2000, the EU temporarily banned and proposed a permanent ban on the use of six phthlates (toxic softeners) in children's teething toys that the Commission believed to be carcinogens, notwithstanding industry's claims that the Commission lacked scientific evidence proving it posed a human health risk. Medical devices and food packaging also contain phthalates. At the urging of environmental groups such as Greenpeace, the Commission subsequently required toys containing phthlates to be accompanied by a 'warning' label. See: "Phthalates Ban," (Feb. 1, 2000), available online at http://www.chemical-ndustry.org.uk/news/news.php3/talkingpoints/6/112. See, also: "Toys and Baby Care Items," Phthalates Information Centre Europe, (2003), available online at http://www.phthalates.com/index.asp?page=21.

[29] These reports highlight how some natural or synthetic chemicals, namely those which have been identified as persistent organic pollutants ('POPs'), have traveled, accumulated, and persisted in remote locations such as the North Pole, far from where they were initially emitted. The production and use of POPs has been addressed within the text of the Stockholm Convention on Persistent Organic Pollutants (the 'POPs Treaty'), a multilateral environmental agreement that will enter into force as of May 17, 2004. The import and export of POPs is governed by the Rotterdam Convention on Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (the 'PIC Procedure'), a multilateral environmental agreement that entered into force on February 24, 2004. See: Lawrence Kogan, "Unscientific 'Precaution': Europe's Campaign to Erect New Foreign Trade Barriers," at p. 56-57, fn 164; Lawrence Kogan, "'Enlightened' Environmentalism or Disguised Protectionism? Assessing the Impact of EU Precaution-based Standards on Developing Countries," for the National Foreign Trade Council (April 2004), pp. 18–20 and 24, fns 69 and 73.

[30] See: Lawrence Kogan, "Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science," pp. 66-82, discussing the EU Directives on Waste from Electrical and Electronic Equipment ('WEEE'), Restrictions on Use of Hazardous Substances ('RoHS'), End-Use-Equipment ('EuE') and End-Of-Life Vehicles ('ELV'), and the EU Green Paper on Integrated Product Policy.

[31] "Risk Analysis," Food Safety and Inspection Service, United States Department of Agriculture, Backgrounders/Key Facts (July 2003), p. 1, available online at http://www.fsis.usda.gov/OA/background/riskanal.htm. European risk scholars agree that "risk analysis has become a routine procedure in assessing, evaluating, and managing harm to humans and the environment." However they debate the legitimate role of risk analysis for regulatory decision-making. See: Ortwin Renn and Andreas Klinke, "A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based and Discourse-Based Strategies," p. 3. The Codex definition of risk analysis is similar. "The risk analysis should follow a structured approach comprising three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the Codex Alimentarius Commission, each component being integral to the overall risk analysis." Par. 5, Draft Working Principles For Risk Analysis For Application in the Framework of the Codex Alimentarius (At Step 8 of the Procedure), Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, Twenty-sixth Session, FAO Headquarters, Rome, Italy (June 30-July 7, 2003).

[32] According to Mr. Graham, "…[T]here appears to be some agreement that the precautionary principle applies primarily to decision-making *at the risk management level*, as stated in the EC Communication… Placing precaution in the hands of policy-makers lays the groundwork for democratic control of the degree of precaution exercised *in risk management*. After all, it is accountable public officials, not scientists, who should—at least in democratic societies—make the final value judgments about what degree of precaution is appropriate for a particular technology or policy setting" (emphasis added). John Graham and Susan Hsia, "Europe's Precautionary Principle: Promise and Pitfalls," p. 378. However, Mr. Graham notes that, "When considering the role of *precaution in risk management*, it is appropriate for policy-makers and the public to inquire about the degree of *precaution embedded in the risk assessment*. If precaution is taken to an extreme, it can be very harmful to technological innovation" (emphasis added). John Graham, "The Role of Precaution in Risk Assessment and Management: An American's View," p. 4.

[33] "Risk communication not only refers to communicating the results of the risk analysis to the general public, but also to the ongoing communication among risk assessors, managers, scientists, regulators, and various stakeholders during the entire process. Risk assessors and managers must communicate in order to ensure that all affected parties fully understand the process of and information generated by the risk analysis." "Risk Analysis," Food Safety and Inspection Service, United States Department of Agriculture, Backgrounders/Key Facts.

[34] "Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. Where there is sufficient scientific evidence to allow Codex to proceed to elaborate a standard or related text, the assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard." Par. 11, Draft Working Principles For Risk Analysis For Application in the Framework of the Codex Alimentarius (At Step 8 of the Procedure), Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission.

[35] See: Ted Schettler, Katherine Barrett, Carolyn Raffensperger, "The Precautionary Principle: Protecting Public Health and the Environment," Science and Environmental Health Network (2002), available online at http://www.protectingourhealth.org/corethemes/precaution/2002-1125schettlerprecautionary.htm. "…[A] considerable amount of consistent evidence is necessary to establish factual "proof" of a cause and effect relationship. Traditionally, in a study of the relationship between two variables, a correlation is said to be statistically significant only if the results show the two to be linked, independent of other factors, with greater than 95% likelihood that the results of the study truly depict the real world. But correlation does not establish causation. In epidemiology, a series of additional criteria…are usually added before causation can be claimed… include not only establishment of a statistically significant correlation between two variables, but also require that the causal variable precede the effect, a dose-response relationship, elimination of sources of bias and confounding, coherence with other studies, and understanding of a plausible biological mechanism…When exposure to environmental hazards causes immediate and obvious harm, scientific uncertainty about cause and effect relationships is minimal. However, under other circumstances, scientific uncertainty increases dramatically and is often difficult to resolve. Conditions with long latency periods between a hazardous exposure and the appearance of an adverse health outcome are difficult to study." Id.

[36] "There is a subset of possible risks in daily life that are subject to substantial scientific uncertainty, often on all four of the [following] questions that I mentioned…[See: fn 14, supra]…but that, for one reason or another, trigger significant public concern. Under these circumstances, what is the appropriate role for precaution in the response of risk managers?" John Graham, "The Role of Precaution in Risk Assessment and Management: An American's View," supra, p. 2.

[37] "…[W]e need a conceptual bridge between assessment and management, which we have framed risk evaluation. This strategy should meet two goals, first to incorporate the best expertise of the professionals dealing with risk issues and, secondly, to include the legitimate concerns and perceptions of the public." Ortwin Renn, "Risks and Society," Presentation made at the Directorate General, Health and Consumer Protection, International Conference: "Risk Analysis and Its Role in the European Union," supra.

[38] Par. 9, Draft Working Principles For Risk Analysis For Application in the Framework of the Codex Alimentarius (At Step 8 of the Procedure), Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission.

[39] Id.

[40] A thorough analysis of the science of risk assessment is beyond the scope of this paper. This author will attempt to summarize the general principles surrounding risk assessment, and leave the details to the experts in this highly technical field.

[41] "Risk Analysis," Food Safety and Inspection Service, United States Department of Agriculture, Backgrounders/Key Facts (July 2003), p. 1, supra.

[42] Id. "Each risk assessment has four parts, as widely recognized in the international scientific and regulatory risk assessment communities and by such authoritative bodies as the National Academy of Sciences and the Codex Alimentarius Commission. First, risk assessors and risk managers must clarify the public health hazard that is the subject of the assessment and any possible policy options that are under consideration. Next, the risk assessors must evaluate the adverse health effects caused by the public health hazard. Then, an exposure assessment must be conducted to estimate the likelihood that the hazard will be present in food, and if present, at what level. Next, a dose-response model is constructed to figure out at what dose or concentration that hazard will cause illness or death." Id., p. 2.

[43] Id., p. 2.

[44] "Risk assessment should be conducted in accordance with the *Statements of Principle Relating to the Role of Food Safety Risk Assessment* and should incorporate the four steps of the risk assessment, i.e., hazard identification, hazard characterization, exposure assessment, and risk characterization. Risk assessment should be based on all available scientific data…" Pars. 19-20, Draft Working Principles For Risk Analysis For Application in the Framework of the Codex Alimentarius.

[45] "The organization of risk assessment is based on a model proposed by the U.S. National Research Council, which is widely used in public health and regulatory decision-making." See: "A Risk Assessment Model for Establishing Upper Intake Levels for Nutrients," Health Education Alliance for Life and Longevity (HEALL), The Resource Center for Body, Mind, and Spirit, citing U.S. Department of Agriculture, Food Safety and Inspection Service, available online at http://www.heall.com/medicalfreedom/codex.html.

[46] Par. 25, Draft Working Principles For Risk Analysis For Application in the Framework of the Codex Alimentarius.

[47] "Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities," p. 56.

[48] See: "Framework for Cumulative Risk Assessment," Risk Assessment Forum, United States Environmental Protection Agency, available online at http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=54944; (EPA/630/P-02/001F, April 2002), published May 27, 2003, FRL-7503-5 (Vol. 68, No. 101, p. 28825), available online at http://www.epa.gov/fedrgstr/EPA-GENERAL/2003/May/Day-27/g13179.htm. The accompanying press release indicates that the framework is merely an information document whose objective is to describe various aspects of cumulative risk—it "is not an attempt to lay out protocols to address all the risks or considerations that are needed to adequately inform community decisions." "Fact Sheet: Release of EPA's 'Framework For Cumulative Risk Assessment'—May 2003."

[49] For purposes of this report, " 'cumulative risk' means 'the combined risks from aggregate exposures to multiple agents or stressors'…assessments involving a single chemical or stressor are not 'cumulative risk assessments' under this definition…'Cumulative Risk assessment' in this report means 'an analysis, characterization and possible quantification of the combined risks to health or the environment from multiple agents or stressors.' One key aspect of this definition is that a cumulative risk assessment need

not necessarily be quantitative, so long as it meets other requirements." Executive Summary, p. xvii.

[50] "The framework itself is conceptually similar to the approached used in both human health and ecological assessments, but it is distinctive in several areas. First, its focus on the combined effects of more than one agent or stressor makes it different from many assessments conducted today, in which, if multiple stressors are evaluated, they are usually evaluated individually and presented as if the others were not present. Second, because multiple stressors are affecting the same population, there is increased focus on the specific populations potentially affected *rather than on hypothetical receptors*. Third, consideration of cumulative risk may generate interest in a wider variety of non-chemical stressors…biological or physical agents or an activity that directly or indirectly alters or causes the loss of a necessity such as habitat…than do traditional risk assessments…" (emphasis added). Id., pp. xvii-xviii.

[51] Par. 24, Draft Working Principles For Risk Analysis For Application in the Framework of the Codex Alimentarius (At Step 8 of the Procedure), Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission.

[52] See: "Final Report on Setting the Scientific Frame for the Inclusion of New Quality of Life Concerns in the Risk Assessment Process," Adopted by the Scientific Steering Committee at its Meeting of 10-11 April 2003, European Commission, Health & Consumer Protection Directorate-General (April 11, 2003).

[53] "Topics that have found public interest in this sense have been exposure to health hazards by chemical factors, safety of food and drinking water, natural and manmade poisons, infectious diseases, and new technologies, especially biotechnology. They include also the welfare of companion animals, wildlife and animals in general, as well as the environment as a whole." Id., p. 3.

[54] "The framework of the areas to be considered in the quality of life assessment is provided by starting off from the health definition of WHO as 'a state of complete physical, social and mental *well being*, and not merely the absence of disease or infirmity…' (WHO, 1992). As a consequence, a wide range of traits need to be analyzed. *Apart from* the classical medicinal, physical and chemical *scientific areas, psychological, and social issues* have to be dealt with…The analysis should *not only* take in[to] account the *usual objective risks but also* the fact that *a substantial part of the population is sensitive from a perception point of view to threats even from risks which have not been shown to exist, but are only assumed or presented as hypothetic. Such a perception* has a direct impact on the *well being* by its psychological component, but it can also have a *psychosomatically induced physical health effect*" (emphasis added). Id. p. 2-3.

[55] "One major reason for the perception of threats is that—admittedly—here is so far no consequent and systematic dealing in the scientific risk assessments with uncertainties that cover a wide range of evidence to non-evidence…. Interactions between scientific assessment, public communication and the resulting perception are major relevant issues in the quality of life evaluation…The importance of such an enlargement results from the idea that the risks are no more only coming from natural causes external to humans. New risks due to the human activities in particular those related to technological innovations are nowadays very important and they are *perceived* in a very different way than the 'natural ones.' " Id.

[56] See: "Descriptions of Selected Key Generic Terms Used in Chemical Hazard/Risk Assessment," OECD Series on Testing and Assessment No. 44, Environment Directorate, Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, Organization for Economic Cooperation and Development ENV/JM/MONO(2003)15 (Oct. 30, 2003). According to the report, a consensus appears to have been reached on a possible concept definition of risk assessment: It "could read: *{process} {for measuring} {a specific risk}* where *{process}* is a four-step sequence of actions, *{measuring}* is meant in a quantitative as well as qualitative manner, *{specific risk}* means the risk associated with a specific agent." Id., at par. 129, p. 34.

[57] "Risk Analysis," Food Safety and Inspection Service, United States Department of Agriculture, Backgrounders/Key Facts (July 2003), p. 2, supra.

[58] "[P]reliminary risk management activities are taken to include: identification of a food safety problem; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority; establishment of risk assessment policy for the conduct of the risk assessment; commissioning of the risk assessment; and consideration of the result of the risk assessment." (At Step 8 of the Procedure), Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, at fn 5.

[59] Id., at Par. 31.

[60] John Graham, "The Role of Precaution in Risk Assessment and Management: An American's View," p. 4.

[61] John Graham and Susan Hsia, "Europe's Precautionary Principle: Promise and Pitfalls," p. 377.

[62] "Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benefits of Federal

Regulations and Unfunded Mandates on State, Local, and Tribal Entities," Office of Management and Budget, Office of Information and Regulatory Affairs (OIRA), Part I, Report to Congress on the Costs and Benefits of Federal Regulations, Chapter III, "U.S. Approaches to Management of Emerging Risks," p. 54.

[63] Theofanis Christoforou, "The Precautionary Principle in European Community Law and Science," pp. 250-251.

[64] Id., p. 251.

[65] See: Par. 31, Draft Working Principles For Risk Analysis For Application in the Framework of the Codex Alimentarius, at fn 5. "For the purpose of these Principles, preliminary risk management activities are taken to include: identification of a food safety problem; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority; establishment of risk assessment policy for the conduct of the risk assessment; and consideration of the result of the risk assessment." Id.

[66] Ortwin Renn and Andreas Klinke, "A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based and Discourse-Based Strategies," p. 4.

[67] Id., p. 5.

[68] Id., p. 6.

[69] Theofanis Christoforou, "The Precautionary Principle in European Community Law and Science," p. 246.

[70] Theofanis Christoforou, "The Origins, Content and Role of the Precautionary Principle in European Community Law" (2001), p. 5.

[71] Id; "From a systemic point of view, this type of scientific uncertainty usually results from five sources of error in the scientific methods used to describe information and data; the variables chosen, the measurements made, the samples drawn, the models used, and the causal relationships employed." Theofanis Christoforou, "The Precautionary Principle in European Community Law and Science," p. 246.

[72] According to one EU legal commentator, "In a complex and relatively slow regulatory system, like that applicable in the EC in the area of health and environmental protection, it is often more effective to apply *default* rules both in setting the actual level of acceptable risk and in the mandatory application of the precautionary principle in the case of scientific uncertainty for certain types of clearly unacceptable risks to society (e.g., of serious or irreversible harm)." Theofanis Christoforou, "The Origins, Content and Role of the Precautionary Principle in European Community Law," (2001), 26, fn 61.

[73] Ortwin Renn and Andreas Klinke, "A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based and Discourse-Based Strategies," p. 7.

[74] Id.

[75] Id.

[76] Id.

[77] Id., pp. 8–9.

[78] "The Administrative Procedures Act (APA) is the law under which some 55 U.S. government federal regulatory agencies like the FDA and EPA create the rules and regulations necessary to implement and enforce major legislative acts such as the Food Drug and Cosmetic Act, Clean Air Act or Occupational Health and Safety Act." See: available online at http://usgovinfo.about.com/library/bills/blapa.htm. The APA provides certain procedural guarantees. "Regulatory agencies are required to follow the notice-and-comment rulemaking procedures prescribed in the (APA) and related laws designed to encourage a transparent and inclusive process. The APA requires agencies to publish in the Federal Register a notice of proposed rulemaking that references the legal authority under which the rule is proposed and a description of the subjects and issues to be addressed by the proposed rule. The APA also instructs agencies to provide the public with an opportunity to submit comments on the proposed rulemaking, and the final rulemaking must address all significant comments. Finally, if affected parties believe a Federal regulatory agency has made an unlawful decision due to procedural and/or substantive error, they may seek review of the decision in a disciplined process of judicial review under the APA…" See: "Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities," pp. 52-53. See, also: Title 5, United States Code – Chapter 5, Sections 511-599.

[79] In the U.S., Executive Order No. 12866 "Regulatory Planning and Review" instructs federal agencies to evaluate all of the costs and benefits associated with a proposed regulation. See: 58 Fed. Reg. 51735 (Sept. 30, 1993), available online at http://www.whitehouse.gov/omb/inforeg/eo12866.pdf. "In deciding

whether and how to regulate, [12866 provides that] agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and by qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Furthermore, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental public health and safety and other advantages; distributive impacts; and equity) unless a statute requires another regulatory approach." Id. at Section 1(a) "Statement of Regulatory Philosophy and Principles—Regulatory Philosophy." "Executive Order 12866 states that Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well being of the American people..." See: "Circular A-4—New Guidelines for the Conduct of Regulatory Analysis," Office of Management and Budget, Office of Information and Regulatory Affairs (Sept. 17, 2003), at pp. 3-4. Circular A-4 "became effective for economically significant proposed rules. It becomes effective for *economically significant* final rules on January 1,2005. *Economically significant* rules generally are rules that have an annual effect on the economy of $100 million of more…The final guidelines are designed to help analysts in the regulatory agencies by encouraging good regulatory impact analysis and standardizing the way that benefits and costs of Federal regulations are measured and reported. *They include several significant changes from previous OMB guidance*. For example, they include (1) more emphasis on cost-effectiveness analysis, (2) formal probability analysis for rules with more than a $ billion dollar impact on the economy, and (3) more systematic evaluation of qualitative as well as quantified benefits and costs." (emphasis added). John Graham, "Memorandum for the President's Management Council," Regarding OMB's Circular No.A-4, New Guidelines for the Conduct of Regulatory Analysis, p. 1.

[80] "Although the U.S. has taken such a [precautionary] approach for years—the 1958 Delaney Clause overseeing pesticide residues in food, for instance, and requirements for environmental impact statements—the more stringent requirements of the precautionary principle have not generally been welcome." David Appell, "The New Uncertainty Principle," *Scientific American (*Jan. 2001), available online at http://www.biotech-info.net/uncertainty.html.

[81] "Unlike the situation in US law, there is no general guideline in Community law that obliges the regulatory authorities to analyze systematically the economic impact or cost of risk management measures…considerations of the level of economic impact or cost from adopting a future precautionary action do not play a decisive role in the determination *whether* to adopt a measure, but only in the actual choice or design of the measure to be taken and the acceptable level of risk…Some have argued in favor of adopting a detailed cost-benefit analysis in nearly all risk management decisions in the EC, based on the multirisk nature of our world and on reasons of efficient allocation of resources (Wiener 2001; Majone 2001). These arguments are not only misconceived and flawed but also potentially dangerous." (bold emphasis added). Theofanis Chrisotoforou, "The Precautionary Principle in European Community Law and Science," p. 249.

[82] Theofanis Chrisotoforou, "The Precautionary Principle in European Community Law and Science," p. 249. For example, the World Wild Life Fund has argued that the U.S. government should not employ an economic cost benefit analysis to review the future designation by the U.N. Secretariat of additional chemicals as persistent organic pollutants, pursuant to the 'adding mechanism' of the Stockholm Convention on Persistent Organic Pollutants (POPs). "Proposals put forward earlier this year, coordinated by the White House's Office of Management and Budget, risk bogging down that mechanism in lengthy and cumbersome cost-benefit related proceedings that would make it extremely difficult if not possible for EPA to take action when POPs are added to the treaty." This statement was made in a letter submitted by WWF to the Senate Foreign Relations Committee Chair, Senator Lugar, in connection with the Senate's review of the POPs Treaty for U.S. ratification. See: Brooks B. Yeager, Vice President, Global Threats Program, World Wildlife Fund, Letter to Honorable Richard Lugar, Chairman, Senate Foreign Relations Committee (June 16, 2003), available online at http://www.worldwildlife.org/toxics/whatsnew/pr_37.htm, cited in Lawrence Kogan, "'Enlightened' Environmentalism or Disguised Protectionism? Assessing the Impact of EU Precaution-based Standards on Developing Countries," p. 20, fn 51.

[83] The terms 'precautionary principle,' 'precautionary approach,' 'precautionary measures' and 'precautionary safeguards' appear within various international environmental conventions, sometimes as an adjective and other times as an adverb.

[84] "…[I]in the real world many government officials behave as if their primary duty is not to protect our common heritage, but to 'balance' the interests of the polluters against the interests of public health and

the environment. In such a balancing act, money weighs heavily, and so we end up with a damaged natural world and large numbers of people killed each year and many more made sick…Usually in such 'balancing' acts, government officials use 'risk assessment' to show that their decisions will only cause 'acceptable' harm. But risk assessments are easily manipulated to get almost any desired answer. As a result—whether they intend to or not—risk assessors usually provide nothing more than a false veneer of 'sound science,' justifying the destruction and the killing. As William Ruckelshaus (the first administrator of U.S. Environmental Protection Agency) said in 1984, 'We should remember that risk assessment data can be like the captured spy: If you torture it long enough, it will tell you anything you want to know…' Risk assessment is still the main defense offered by 'balancing act' governments on behalf of polluters, even though most risk assessments are scientifically indefensible and are therefore about as phony as a three-dollar bill." See: Carolyn Raffensperger and Peter Montague, "Land Use and the Precautionary Principle," Rachel's Environment and Health News, No. 787 (March 18, 2004), available online at http://www.organicconsumers.org/corp/landuse032304.cfm, citing also: Peter Montague, "Chemical Wars," *New Solutions* vol. 14, no. 1 (2004), pp. 19-42.

[85] "The concept of risk appears at first glance to render environmental problems more tractable. The term has long been used in the financial sector to refer to a measurable probability of one or another adverse societal outcome. *Risk is actuarial in spirit*. One can (indeed, one often *mus*t) insure oneself against various kinds of risks for which actuarial data are available, such as fires, floods, earthquakes, catastrophic illnesses or automobile accidents. *When used in environmental decision making, risk retains the connotation of something that can be defined and quantified, hence managed*. It is a relative concept: risks can always be offset against benefits, and risk-based laws often explicitly prescribe that the benefits of policy action should outweigh the risks. Importantly as well, risks can be compared against one another, so that policymakers can meaningfully be instructed to focus attention on large risks over small ones, and to ignore altogether risks that are *de minimis,* or too tiny to matter" (emphasis added). Sheila Jasanoff, "Risk, Precaution and Environmental Values," Carnegie Council on Ethics and International Affairs (1998), p. 5, available online at http://www.carnegiecouncil.org/media/683_jasanoff.pdf.

[86] Id; See, also: Theofanis Christoforou, "The Precautionary Principle in European Community Law and Science," at p. 246. "Risk is a function of at least two variables: the likelihood (or probability) of an adverse effect and its severity or magnitude (Codex Alimentarius Commission, 2000). "A formal definition of risk, therefore, is a condition under which it is possible to describe the possibilities (or probabilities) of occurrence of nearly all possible outcomes, and their magnitude." Id.

[87] Sheila Jasanoff, "Risk, Precaution and Environmental Values," p. 5.

[88] See: David Appell, "The New Uncertainty Principle," quoting Carolyn Raffensperger, SEHN's executive director. "For science to evolve along the lines envisioned by Raffensperger, researchers will have to develop a broader base of skills to handle the multifaceted data from complicated problems." Id. See, also: discussion, supra.

[89] See, definition, supra, at fns 48 and 49. …[S]cientific uncertainty should be distinguished from *risk*. (emphasis added). Theofanis Chrisotoforou, "The Precautionary Principle in European Community Law and Science," p. 246. "Recognition of scientific uncertainty is central to the precautionary principle…Understanding cause and effect relationships in complex systems is limited by different kinds of uncertainties. Uncertainty sometimes results from more than a simple lack of data or inadequate models and is not easily reduced because of the nature of the problem being studied…Most complex problems have a mixture of three general kinds of uncertainty—statistical, model and fundamental—each of which should be explicitly considered before deciding how to act." Ted Schettler, Katherine Barrett, Carolyn Raffensperger, "The Precautionary Principle: Protecting Public Health and the Environment."

[90] "Uncertainty should be distinguished from *ignorance*, where some of the possible outcomes, at the time of assessing the activity or substance, are completely unknown or unknowable and, thus, fail entirely to be assessed (EEA, 2001). Although distinguishable, uncertainty and ignorance may co-exist in a risk assessment and this can further increase the potential for error *in the degree of confidence* regarding the existence of harm to health, the environment or in the workplace…*However, allowing fears from ignorance and indeterminancy to guide any risk regulation is likely to halt technological progress*." (emphasis added). Theofanis Chrisotoforou, "The Precautionary Principle in European Community Law and Science," p. 246.

[91] "[T]he perception people have of risk is wider than that of experts and reflects a number of legitimate concerns (e.g., familiarity with risk, catastrophic potential, irreversibility of harm, threat to future generations, risk control possibilities, whether exposure is voluntary, etc.), which are frequently omitted from an expert risk assessment. It follows that…risk management measures, instead of trying to patronize consumers with positivist views on science, should also take into account their legitimate concerns and

perceptions." Id., p. 248.

[92] For example, the EU's proposed REACH regulation potentially covering some 30,000 chemicals imposes a 'Duty of Care' on all manufacturers, importer and downstream users of such substances to fulfill their obligations under the REACH system and under other related legislation. The Duty of Care provisions "help to ensure that substances are used safely at all stages in their life cycle." The EU has imposed a similar duty of care on these economic actors within a related proposed regulation covering persistent organic pollutants (POPs) intended to implement the Stockholm Convention on Persistent Organic Pollutants.

[93] Timothy Riordan, "The Precaution Principle in Environmental Management," Robert U. Ayres and Udo E. Simonis, eds., in *Industrial Metabolism: Restructuring for Sustainable Development*, Appendix Part 3: Further Implications. (United Nations University Press, The United Nations University: 1994), p. 8, available online at http://www.unu.edu/unupress/unupbooks/80841e/80841E0o.htm#12.%20The%20precaution%20principle.

[94] Sheila Jasanoff, "Risk, Precaution and Environmental Values,"supra at pp. 5–6.

[95] Ted Schettler, Katherine Barrett, Carolyn Raffensperger, "The Precautionary Principle:

Protecting Public Health and the Environment," supra.

[96] Andrew Jordan and Timothy Riordan, "The Precautionary Principle in Contemporary Environmental Policy and Politics," Paper presented for the Wingspread Conference on Implementing the Precautionary Principle, Racine Wisconsin (Jan. 23-25, 1998), available online at http://www.johnsonfdn.org/conferences/precautionary/jord.html.

[97] Timothy Riordan, "The Precaution Principle in Environmental Management," p. 6.

[98] Id, pp. 6, 8.

[99] Andrew Jordan and Timothy Riordan, "The Precautionary Principle in Contemporary Environmental Policy and Politics." As the author reveals, this notion can be traced back to a 1984 German Federal Government report on air quality. That report, in pertinent part, states the following: "The principle of precaution commands that the damages done to the natural world…should be avoided in advance and in accordance with opportunity and possibility. [Precaution] further means the early detection of dangers to health and environment by comprehensive, synchronized…research…[I]t also *means acting when conclusively ascertained understandings by science [are] not yet available*" (emphasis in original). Id.

[100] In general, "the burden to produce evidence (burden of production) is assigned to a Party who must generate information or proof [whereas] the burden of persuasion is an assignment of responsibility to a Party to provide sufficient proof or to remove uncertainty to the satisfaction of a fact-finding body. A common reason for assigning both burdens to a Party is that such Party is in the best position to have the information to resolve the factual and legal issues in question." See: Carl F. Cranor, "Some Legal Implications of the Precautionary Principle: Improving Information-Generation and Legal Protections," *Eur. J. Oncol*. Library, vol. 2, p. 37, available online at http://www.collegiumramazzini.org/links/CRANOR.PDF.

[101] Id., p. 5.

[102] Theofanis Chrisotoforou, "The Precautionary Principle in European Community Law and Science," p. 251.

[103] A legal standard of proof "specifies degrees of certainty that a decision maker must have before finding that the Party with the burden of proof carried it. They specify how much 'uncertainty' must be removed (or may be tolerated) in order to change some aspect of the legal status quo. In the US, one of the more demanding standards of criminal law is that the moving party, the state, must establish its case 'beyond a reasonable doubt.' " By comparison, "[I]n civil litigation, the plaintiff must establish her case by a 'preponderance (or balance) of the evidence.' " Carl F. Cranor, "Some Legal Implications of the Precautionary Principle: Improving Information-Generation and Legal Protections," p. 37.

[104] According to the 'polluter-pays' principle, an operator causing environmental damage or creating an imminent threat of such damage should, in principle, bear the cost of the necessary preventive or remedial measures.

[105] Directive 2004/35/CE of the European Parliament and of the Council on Environmental Liability With Regard to the Prevention and Remedying of Environmental Damage (April 21, 2004), available online at http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_143/l_14320040430en00560075.pdf.

The purpose of the new Directive is to "to establish a framework of environmental liability based on the 'polluter-pays' principle to prevent and remedy environmental damage. Article 1. "The new directive will, in effect, create a generalized offence of environmental pollution governed by a strict (no fault) liability

regime. Environmental damage will include damage to species and natural habitats protected by the 1992 Habitats and 1979 Birds Directives, damage to waters covered by the 2000 Water Framework Directive, and land contamination which causes significant risk of harming human health…" " 'Polluters Pays' Directive Finally Agreed," Environment Zone, (2/21/04), available online at http://lawzone.thelawyer.com/cgi-in/item.cgi?id=109329&d=204&h=243&f=209. "The significance of any damage that has adverse effects on reaching or maintaining the favorable conservation status of habitats or species has to be assessed by reference to the conservation status at the time of the damage, the services provided by the amenities they produce and their capacity for natural regeneration. Significant adverse changes to the baseline condition should be determined by means of measurable data…" Annex I. "*The Directive does not apply to cases of personal injury, to damage to private property or to any economic loss* and does not affect any right regarding these types of damages" (emphasis added). Preamble par. 14. "Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 April 2007." Article 19(1).

[106] "These are listed exhaustively in the Directive…Certain industries including oil and nuclear will fall outside of the Directive's scope and will continue to be covered by their own liability regimes…A controversial aspect of the proposal, at least as far as industry is concerned, is the wide definition of 'environmental damage' [contained in Article 2]. Not only does it cover land and water pollution but also damage to the biodiversity of any protected species or habitat." Id.

[107] See: "The Application of the Precautionary Principle in the European Union, EU-Project: 'Regulatory Strategies and Research Needs to Compose and Specify a European Policy on the Application of the Precautionary Principle' (PrecauPri)," 3. Executive Summary at p. Stuttgart (April 2003). "The PrecauPri-project was supported by the STRATA Programme of the European Commission and embedded within the scope of the Fifth Framework Programme of the European Community for research, technological development and demonstration activities." Id.

[108] Id., p. 4.

[109] Id.

[110] Id.

[111] Jeremy Rifkin, "A Precautionary Tale—The EU Plans New Regulations for Scientific Risk-Taking, Based on the Principle of Sustainable Development—US Big Business is Furious," Guardian Unlimited (May 12, 2004), available online at http://www.guardian.co.uk/life/opinion/story/0,12981,1214686,00.html.

[112] Id.

[113] According to one commentator, "the [precautionary] principle formed one of the basic principles of environmental policy…together with the *cooperation principle* and the *polluter pays principle*." In addition, this commentator believes that, "The fact that the [precautionary] principle came side by side to the *prevention principle* implies that these two principles do not mean the same" (emphasis added). See: Wybe Th. Douma, "The Precautionary Principle," T.M.C. Asser Institute, The Hague, The Netherlands (1998), available online at http://www.eel.nl/virtue/precprin.htm. The cooperation principle was essentially founded by the Social Democrat-Free Democrat coalition government formed within the Federal Republic of Germany during the early 1970s. It reflected "a desire to create corporatist relations between government, industry, and the trade unions…the main parties [then] concerned" for purposes of developing environmental, social and economic policy. See: Timothy Riordan, "The Precaution Principle in Environmental Management," p. 4. In addition, there is also the *principle of proportionality*, which "requires that measures adopted by Community institutions do not exceed the limits of what is appropriate and necessary in order to attain the objectives and legitimately pursued by the legislation in question…" Theofanis Chrisotoforou, "The Precautionary Principle in European Community Law and Science," p. 250. The polluter's pay principle was recently enacted as an EU directive that "will force industries guilty of polluting the environment [for land and water pollution] to pay for the clean-up." It officially became law during March 2004. See: "EU Agrees to Make Polluters Pay for Environmental Damage," Agence France Presse (Feb. 20, 2004), available online at http://www.eubusiness.com/afp/040220192846.bp8uy8zi.

[114] Sheila Jasanoff, "Risk, Precaution and Environmental Values."

[115] Claude Henry, Marc Henry, "Formalization and Applications of the Precautionary Principles," Department of Economics, Columbia University, Discussion Paper #:0102-22 (March 2002), p. 3, available online at http://www.columbia.edu/cu/economics/discpapr/DP0102-22.pdf.

[116] Wybe Th. Douma, "The Precautionary Principle," supra.

[117] Id.

[118] Id.

[119] Id; "By 1990, at the third conference in The Hague, the parties declared that they 'will continue to apply the *precautionary principle*, that is to take action to avoid potentially damaging impacts of substances that are persistent, toxic and liable to bioaccumulate even when there is no scientific evidence to prove that a causal link between emissions and effects.' At the most recent North-Sea Conference, the Esbjerg Declaration of 1995 was adopted. It recommends that the *precautionary principle* is also applied where fisheries management policies are concerned. One of the reasons for this is that there is a recognized connection between fisheries and the marine ecosystem but gaps exist in the scientific knowledge of the impact of fisheries upon the ecosystems and (a conclusion of special importance to nations dependent on fisheries) of the impacts of environmental changes and pollution upon fisheries (emphasis added)." Id.

[120] Principle 15, the Rio Declaration on Environment and Development, United Nations Conference on the Environment and Development (June 1992).

[121] See: Daniel Bodansky, "Scientific Uncertainty and the Precautionary Principle," 33 Environment 4 (Sept. 1991), cited in David Hunter et al., *International Environmental Law*, Chap. 7, "Principles and Concepts of International Environmental Law—The Precautionary Principle," pp. 360–363.

[122] "[Rio Principle 15 reflects] a compromise between the Hague formulation of the *precautionary principle* and the US view that the lack of clear scientific evidence for a causal relationship between human behavior and the *greenhouse effect* meant that taking expensive measures was not acceptable. *As a result, there is no question of 'principle,' but of mere 'approach,'* and the scope of the declaration is limited to damage which is either 'serious' or 'irreversible' and the measures are to be 'cost-effective.'" Claude Henry, Marc Henry, "Formalization and Applications of the Precautionary Principles," p. 4. See, also: Lawrence Kogan, "The U.S. Response to the Kyoto Protocol: A Realistic Alternative?" *Seton Hall Journal of Diplomacy and International Relations*, vol. III, no. 2 Sustainable Development (Summer/Fall 2002), p. 70, citing fns 137–138.

[123] "Commission of the European Communities, Communication From the Commission on the Precautionary Principle," COM (2000) (Brussels, Feb. 2000), available online at http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub07_en.pdf.

[124] "[I]n Article 130 R [of the Treaty on the European Union], the precautionary principle is added to the list of environmental principles which was introduced at an earlier stage in 1987 via the Single European Act… Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the *precautionary principle* and on the principles that preventative action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay" (emphasis added). Wybe Th. Douma, "The Precautionary Principle," supra.

[125] As one commentator notes, that "the Helsinki Convention underlines the importance of *precaution* at several stages. First of all, the parties to it shall take all appropriate measures to prevent, control and reduce pollution of waters causing *or likely to cause* transboundary impact (Article 2(2)(a), emphasis added). Secondly, Article 2(5)(a) expressly states that in taking the measures called for, the parties 'shall be guided by' a number of principles. The first one to be mentioned is the *precautionary principle*, 'by virtue of which action to avoid the potential transboundary impact of the release of hazardous substances shall not be postponed on the ground that scientific research has not fully proved a causal link between those substances, on the one hand, and the potential transboundary impact, on the other hand.' " Id.

[126] Id.

[127] According to Paragraph 2 of the Chairman's conclusions, "Reflecting the variety of legal systems, incorporation of the Rio principles should be done in accordance with the legal culture and tradition of each state. This can be accomplished through explicit codification of principles, the elaboration of the principles into legislation and regulations, administrative policy, negotiated and/or voluntary agreements as well as case law." See: "International Environmental Conference on Codifying Rio Principles in National Legislation," The Peace Palace in The Hague (May 22-24, 1996), available online at http://www.eel.nl/int/denhaag.htm.

[128] Id., at pars. 1, 6 and 7.

[129] Preamble, the Kyoto Protocol to the United Nations Framework Convention on Climate Change.

[130] Article 3.3., the United Nations Framework Convention on Climate Change (UNFCCC).

[131] The Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD), otherwise known as the 'Biosafety Protocol.'

[132] Article 8(g) of the CBD entitled, 'In-Situ Conservation,' provides that, "Each Contracting Party shall, as far as possible and appropriate…(g) Establish or maintain means to regulate, manage or control the

risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health…"

[133] Preamble, the Biosafety Protocol.

[134] Article 1, The Biosafety Protocol.

[135] Article 10(6), the Biosafety Protocol.

[136] "Stockholm Convention on Persistent Organic Pollutants (POPs) To Enter Into Force On May 17, 2004," United Nations Environmental Program Press Release (Feb. 18, 2004), at: http://www.pops.int/documents/press/pr2-04SC.pdf. "The 90-day countdown to the treaty's entry into force was triggered on 17 February 2004 when France became the 50th state to ratify the agreement." Ibid. The Stockholm Convention is currently undergoing ratification proceedings within the U.S. Senate Foreign Relations and Environment and Public Works Committees. Apparently two federal statutes (TSCA and FIFRA) must be modified to implement the requirements of the Convention, and senators are examining how U.S. ratification of this treaty will impact both the activities of US industry domestically and the economic competitiveness of US industry internationally.

[137] Preamble, the Stockholm Convention on Persistent Organic Pollutants (the 'POPs Treaty').

[138] Article 1, the POPs Treaty.

[139] Article 8, the POPs Treaty. It reads as follows: "The Committee shall, based on the risk profile referred to…and the risk management evaluation…recommend whether the chemical should be considered by the Conference of the Parties for listing in Annexes A, B and/or C. The Conference of the Parties, taking due account of the recommendations of the Committee, including any scientific uncertainty, *shall decide in a precautionary manner*, whether to list the chemical and specify its related control measures…"

[140] See: FAO News Room: "Rotterdam Convention Enters Into Force," (Feb. 24, 2004), available online at http://www.fao.org/newsroom/en/news/2004/37667/.

[141] See: Article 5, The Rotterdam Convention on Prior Informed Consent for Certain Hazardous Chemicals and Pesticides in International Trade ('PIC Procedure'); Article 14 (1)(a) and (3)(d), available online at http://www.pic.int/en/ViewPage.asp?id=104.

[142] Annex V (1)(e) 'Information Requirements For Export Notification,' PIC Procedure.

[143] Preamble, Montreal Protocol on Substances that Deplete the Ozone Layer, to the Vienna Convention for the Protection of the Ozone Layer.

[144] See: "Resolution 9.24—Criteria for Amendment of CITES Appendices I and II of the Convention." The Resolution has been revised several times. The most recent proposed version of this Resolution reads as follows: RESOLVES that, when considering proposals to amend Appendices I and II [of the Convention], the following applies: f) species included in Appendix I for which sufficient data are available to demonstrate that they do not meet the criteria listed in Annex 1 should be transferred to Appendix II only in accordance with the *relevant precautionary measures* listed in Annex 4; g) species included in Appendix II in accordance with Article II, paragraph 2(a), that do not meet the criteria listed in Annex 2a, should be deleted only in accordance with *the relevant precautionary measures* listed in Annex 4; and species included in accordance with Article II, paragraph 2(b), because they look like the species subject to the deletion, or for a related reason, should also be deleted only in accordance with the *relevant precautionary measures*…" Annex 4 entitled, *'Precautionary Measures,'* provides that, "When considering proposals to amend Appendix I or II, the Parties shall*, by virtue of the precautionary approach* and in case of uncertainty either as regards the status of a species or the impact of trade on the conservation of a species, act in the best interest of the conservation of the species concerned and adopt measures that are proportionate to the anticipated risks to the species." See, also: Annexes 5 and 6.

[145] The Ministerial Declaration issued at the WTO Ministerial Conference at Doha, Qatar, November 9-14, 2001, WT/MIN(01)/DEC/W/1, at par. 6.

[146] BNA Environmental Reporter (Nov. 23, 2001), p. 1.

[147] Indeed, the mission of the WTO's Committee on Trade and Environment (CTE) has been to discuss trade-environment policy linkages. During a March 2002 CTE special session meeting, the European Communities suggested that the "MEAs and WTO are equal bodies of international law." WTO CTE Special Session (March 21, 2002), at par. 19.

[148] The relevant passage of Article XX of the GATT provides that "subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail…[pursuant to Article III(4)]…nothing in this Agreement shall be construed to prevent the adoption or enforcement by any

Member of measures: b) necessary to protect human, animal or plant life or health; or g) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption."

[149] Lawrence Kogan, The National Foreign Trade Council, "Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science," supra at pp. 16-18; Lawrence Kogan, "Unscientific 'Precaution': Europe's Campaign to Erect New Foreign Trade Barriers," supra at p. 7, citing SPS Articles 3, 4.1, 5.1, 5.2 and 5.3.

[150] Joost Pauwelyn, "The WTO Agreement on Sanitary and Phytosanitary (SPS) Measures as Applied in the First Three SPS Disputes," J*ournal of International Economic Law* (1999) 641-664, at pp. 646, 648 citing the Appellate Body decision in the EC Hormones case, infra.

[151] TBT Articles 2.4 and 2.7.

[152] TBT Art. 2.2; TBT Annex 3 (E).

[153] TBT Art. 2.2. It also means that existing regulatory requirements shall not be maintained, if such legitimate state objectives can be addressed in a less trade-restrictive manner. TBT Art. 2.3.

[154] TBT Art. 2.2 and 2.5. This has been interpreted by some to mean that, regardless of their purposes it is the extraterritorial effects that such regulations have upon international trade that are determinative. See: Lawrence Kogan, "Unscientific 'Precaution': Europe's Campaign to Erect New Foreign Trade Barriers," supra at p. 9.

[155] TBT Art. 2.2.

[156] Id. When determining how to fulfill state objectives, "WTO Members, where appropriate shall specify technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics. TBT Art. 2.8; Annex 3(I) "Code of Good Practice for the Preparation, Adoption and Application of Standards."

[157] SPS Art. 5.6.

[158] SPS Art. 2.2

[159] Joost Pauwelyn, "WTO Agreement on SPS Measures As Applied in the First Three SPS Disputes," at pp. 649-50, citing the Appellate Body Report on 'Measures Affecting Agricultural Products,' hereinafter referred to as the Japan-Varietals case, adopted on March 19, 1999, WT/DS76AB/R.

[160] See: the Appellate Body Report on 'EC Measures Concerning Meat and Meat Products (Hormones),' hereinafter referred to as the EC –Hormones case, adopted on February 13, 1998, WT/DS26/AB/R; WT/DS48/AB/R.

[161] Joost Pauwelyn, "WTO Agreement on SPS Measures As Applied in the First Three SPS Disputes," supra at p. 651.

[162] The six hormones in dispute are: oestradiol-17-beta, progesterone, testerone, zeranol, trenbolone, and melengestrol acetate.

[163] The ban imposed by the Commission was subsequently adopted by the European Parliament and the Council of Ministers on July 22, 2003, through adoption of EC Directive 2003/74/EC, amending EC Directive 96/22/EC. This new directive "confirms the prohibition of substances having a hormonal action for growth promotion in farm animals. "The European Commission, Food Safety: Hormones in Beef," DG Health and Consumer Protection. "Moreover, it drastically reduces the circumstances under which oestradiol 17b may be administered for other purposes to food producing animals. See: "The European Commission, Food Safety: Hormones in Meat," Europa website.

[164] According to the EU Commission, it has acted in accordance with WTO law because of the manner in which it has responded to the WTO Appellate Body's ruling in the Beef Hormones dispute. The Commission argues that it has complied with this ruling by mandating a new assessment of the risks to human health from hormone residues in bovine meat products treated with the six hormones used for growth promoters. Now, since the Commission has taken account of emerging scientific data and gathered what it considers 'a substantial body of scientific evidence' showing that these substances indeed pose risks to human health, it is justified in imposing the ban. Id.

[165] Tobias Buck, "Transatlantic Dispute—EU Says It Obeys WTO Over Beef Hormones," *Financial Times* (Oct. 16, 2003).

[166] Id. According to the Financial Times, "Research undertaken by an EU committee on veterinary health had concluded that one of the six hormones banned by Brussels should be considered a cancer-inducing substance. The committee argued that there were strong indications that the five other hormones also posed a health risk, though they found no conclusive evidence. The new law therefore bans these five

hormones *on a provisional basis* pending further scientific evidence." (emphasis added)

[167] Id.

[168] See: Lawrence Kogan, " 'Enlightened' Environmentalism or Disguised Protectionism: Assessing the Impact of EU Precaution-based Standards on Developing Countries."

[169] "About 99% of genetically modified crops are grown in just six countries: the U.S., Canada, Argentina, Brazil, China and South Africa." Scott Kilman, "U.N. Backs Gene-Modified Crops To Help the World's Poor Farmers," *Wall Street Journal* (May 18, 2004), p. B10.

[170] See: Lawrence Kogan, "Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science," National Foreign Trade Council, pp. 50-62; fns 218-219 (May 2003).

[171] "Bowing to pressure from Washington, the European Union lifted a six-year moratorium on new biotech foods Wednesday by allowing onto the EU market a modified strain of sweet corn, grown mainly in the United States…The corn-genetically modified to resist corn borer insect damage would only be imported and not grown in Europe, although an application for cultivation is pending. The corn had been developed by Syngenta, a Swiss-based company." Paul Geitner, "European Union Ends Six-Year Biotech Moratorium with Approval of Sweet Corn Imports," Associated Press, (May 19, 2004), available at http://www.washingtonpost.com/wp-dyn/articles/A40180-2004May19.html.

[172] On May 12, 2003, the U.S. filed a WTO suit against the EU to invalidate a moratorium against GMO products imposed by at least seven EU Member States in October 1998. The moratorium covered any new approval of genetically engineered products. The U.S. claimed that since it was the primary producer of such products, the moratorium had primarily targeted U.S. exports. See: Lawrence Kogan, "Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science," pp. 19-22. The U.S. case "was supported by Canada, Argentina and more than a dozen other countries." Paul Geitner, "European Union Ends Six-Year Biotech Moratorium With Approval of Sweet Corn Imports."

[173] Id.

[174] Id., quoting Richard Mills, spokesman for the U.S. trade representative in Washington.

[175] Id.

[176] Paragraph 8 of Directive 2001/18/EC provides that, "The precautionary principle has been taken into account in the drafting of this Directive and must be taken into account when implementing it."

[177] China has also recently issued proposed regulations on GMOs said to mirror EU legislation. See: Lawrence Kogan, "Unscientific 'Precaution': Europe's Campaign to Erect New Foreign Trade Barriers," The National Foreign Trade Council, Washington Legal Foundation Critical Legal Issues Working Paper Series No. 118 (Sept. 2003), pp. 53-54, available at http://www.wlf.org/upload/kogan.pdf. See, also: Lawrence Kogan, "EU Regulation, Standardization and the Precautionary Principle: The Art of Crafting a Three Dimensional Trade Strategy that Ignores Sound Science," National Foreign Trade Council (Sept. 2003), available at http://nftc.org/default/white%20paper/WLFfinaldocumentIII.pdf.

[178] Tobias Buck, "Brussels Warns EU on Modified Crops, European Commission Governments Told to End Foot-Dragging on Approving Products But U.S. Attacked for Threat of WTO Challenge," *Financial Times* (Feb. 4, 2003); Id. p. 33. See, also: Paul Geitner, "European Union Ends Six-Year Biotech Moratorium With Approval of Sweet Corn Imports." "Byrne said the Bt11 had undergone 'the most rigorous pre-marketing assessment in the world. It has been scientifically assessed as being as safe as any conventional maize." Id.

[179] Id; Lawrence Kogan, "Unscientific 'Precaution': Europe's Campaign to Erect New Foreign Trade Barriers," supra at pp. 11-13.

[180] See: Commission Published [New] Draft Chemicals Legislation for Consultation," EU Press Release (May 7, 2003), available online at http://europa.eu.int/comm/press_room/presspacks/reach/pp_reach_en.htm; http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=IP/03/646|0|RAPID&lg=EN.

[181] Lawrence Kogan, "Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science," supra at pp. 82-87; Lawrence Kogan, "Unscientific 'Precaution': Europe's Campaign to Erect New Foreign Trade Barriers," supra at pp. 14–16.

[182] See: Commission Published [New] Draft Chemicals Legislation for Consultation."

[183] On October 29, 2003, the EU Commission issued revised regulations "on testing chemicals for risks to health and the environment that could ban substances not registered by a certain date." This revision, in some respects, reflected changes called for in comments the Commission had received from interested foreign stakeholders in response to its initial draft legislation, issued the previous May. See: "FACTBOX-

EU's Draft Chemicals Regulations," Reuters (10/29/03), available online at http://www.forbes.com/markets/bonds/newswire/2003/10/29/rtr1127225.html.

[184] Lawrence Kogan, "'Enlightened' Environmentalism or Disguised Protectionism: Assessing the Impact of EU Precaution-based Standards on Developing Countries."

[185] Lawrence Kogan, "Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science," supra at pp. 87-104; See, also: "U.S. Comments on the EU's Draft Chemicals Regime," The United States Mission to the European Union (July 10, 2003), available online at http://www.useu.be/Categories/Evironment/July1003USEUChemicalsComments.html.

[186] Id., at pp. 65-82.

[187] Id.

[188] Lawrence Kogan, "Unscientific 'Precaution': Europe's Campaign to Erect New Foreign Trade Barriers," supra at pp. 28-29.

[189] Id.

[190] Joel P. Trachtman, "The Domain of WTO Dispute Resolution," *Harvard Int'l Law J.* vol. 40, 333 (1999), at pp. 342-343, fn 51, p. 349, fn 71. According to Professor Trachtman, several provisions of the Dispute Settlement Understanding provide this limitation – Articles 3(2), 7 and 11 require WTO panels to refer specifically to the 'covered agreements.' Draft at p. 10.; Lawrence Kogan, "Unscientific 'Precaution': Europe's Campaign to Erect New Foreign Trade Barriers," supra at pp. 61-63.

[191] Joost Pauwelyn, "The Role of Public International Law in the WTO: How Far Can We Go?" *Am. J. of Int'l Law* vol. 95, pp. 535, 560–561, 577–78. According to Professor Pauwelyn, "WTO Members can conclude…new treaties [e.g., MEAs] that may have an impact on the WTO treaty. These new post-1994 treaties may simply add to or confirm preexisting WTO rules, but they may also terminate, contradict or suspend WTO rules [depending] on the conflict rules set out in the WTO treaty, in the new post-1994 treaty or those of general international law…" Id. at p. 547; Lawrence Kogan, "Unscientific 'Precaution': Europe's Campaign to Erect New Foreign Trade Barriers," supra at pp. 63–65.

Georgetown Journal
International Affairs

The topics we cover change to reflect the dynamic world, but unchanging is our commitment to

Style and Substance.

Sponsored by the Edmund A. Walsh School of Foreign Service at Georgetown University, the *Georgetown Journal of International Affairs* values keen thinking and good writing, delivered with visual panache. The result is a synthesis of style and substance that will remind you why the study of world affairs matters.

Winter/Spring 2004
Forum on

Pipelines & Global Security

Pick up something new.

Call 202.687.1461 or visit our Web site at http://journal.georgetown.edu to subscribe for one year (two issues) at the rate of $14.00.