**The National Foreign Trade Council, Inc.**

# *EU Regulation, Standardization and the Precautionary Principle:*

## *The Art of Crafting a Three- Dimensional Trade Strategy That Ignores Sound Science©*

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**The National Foreign Trade Council** advocates an open, rules-based world economy. Founded in 1914 by a group of American companies that supported an open world trading system, the NFTC now serves nearly 400 member companies through its offices in Washington and New York. The NFTC represents its member companies on trade and investment, export finance, economic sanctions and international tax policies that affect the competitiveness of U.S. companies overseas. It supports open markets, opposes unilateral sanction restrictions on trade, and assures U.S. business access to needed risk insurance and export and project finance.

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## I. Introduction [1]

A key strategy of successful advocacy, whether in a court of law or in the court of public opinion, is to frame the terms of a debate so that they most closely reflect the views of one's client without appearing to concede to the adversary's position. A time-tested legal corollary to this principle is that when only the facts favor one's case argue the facts, and that when only the law favors one's case argue the law. In those instances when neither the facts nor the law support one's position a competent adversary is almost certain to prevail, that is, unless the advocate postpones the outcome of the debate long enough to create new law or establish new facts that alter the debate's fundamental terms.

This creative and shrewd approach to advocacy is now being pursued by the EU vis a vis the U.S. and the World Trade Organization ('WTO') membership in an attempt to recast the terms of an increasingly protracted and emotional debate over the scope of international trade law.[2] Although a positive correlation between global trade and economic growth has long been proved, the EU insists on promulgating overly stringent human health and safety, animal welfare and environmental regulations, beyond those called for by relevant international standards, that amount to technical barriers to trade. These measures, which transcend industry sectors, sometimes serve to protect ailing or lagging EU industries (e.g., agriculture and biotech) or otherwise impose unnecessary burdens and restrictions that effectively block access to the EU market for non-EU industry exports, thereby impeding global trade. In addition, certain of these measures may lead to massive job and economic losses across a spectrum of industry sectors, thereby severely impacting national employment and gross domestic production output.[3]

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[1] This paper is based on a recently released study prepared by Lawrence A. Kogan, Esq. for the National Foreign Trade Council, Inc. The study highlights and analyzes a number of foreign laws and regulations mostly enacted by the EU that claim to protect human health and safety, animal welfare and the environment, but which are actually disguised barriers to trade. The study is entitled, "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", and it is accessible on the NFTC website. (See: http://www.nftc.org/default/white%20paper/TR2%20final.pdf ) *for the* full paper and for the Executive Summary (http://www.nftc.org/default/white%20paper/Exec%20SummaryII.pdf ). The study's Executive Summary has been posted to the U.S. State Department Biotechnology website (See: (http://usinfo.state.gov/gi/global_issues/biotechnology/biotechnology_policy_archive.html ) ) (search 'NFTC') and has been posted on or linked to a number of U.S. embassy websites located in Europe, Asia and Latin America.

[2] The scope of the WTO dispute resolution process and the WTO as an institution are currently being debated within the international academic and legal communities. And officials within the U.S. Government, the U.S. Congress and U.S. industry are beginning to question whether the U.S. can continue to utilize the WTO process in its current form in the pursuit of U.S. national interests.

[3] The Federation of German Industries (Bundesverband der Deutschen Industrie e.V. (BDI), representing all manufacturing industry in Germany, recently published a study prepared by consultants at Arthur D. Little (ADL) of the impact on the German economy of the proposed EU Chemicals (Substances) policy. This business impact assessment took into account both directly affected chemicals industries as well as indirectly affected down-stream industries that use chemicals in the manufacturing of their products. It concluded that considerable production and job losses in German industry - not just in the chemicals industry - would result. The study presented three possible economic / job loss scenarios: a worst case 'hurricane' scenario of production losses of 20.2% and job losses of 2.3 million; a best case 'cloud' scenario of production losses of 1.4% and job losses of 150,000; and a middle 'storm' scenario of 7.7% of production losses and job losses of 900,000. See: "Economic Effects of the EU Substances Policy – Report

Furthermore, in many cases where developing country agricultural exports have been denied access to European markets, related biotech research and development programs have been temporarily frozen or altogether terminated.[4] Developing country industries focusing on non-agricultural products can be similarly impacted. Small and medium sized enterprises within many such countries formulate, manufacture and/or assemble many commodity products[5] that are then exported by multinationals to the EU. If those products are denied access to EU markets because they fail to satisfy stringent EU regulatory requirements, then the factories that produce them will have to reduce production or stop their operations altogether. This, in turn, would adversely impact the operations of the local multinationals that rely upon them, since the cost advantages that were once secured by placement of facilities and the training of labor within those countries would no longer be available. As a result, developing countries that seek to participate in the global trading system but lack the technical capacity to satisfy such requirements may suffer serious economic and social consequences.[6]

At least two WTO agreements, the Sanitary and Phytosanitary ('SPS') Agreement[7] and the Technical Barriers to Trade ('TBT') Agreement[8], were designed to prevent countries

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on the BDI Research Project" (Dec. 18, 2002), at pp. 60-67. An estimate of the economic impact of the proposed EU Chemicals (Substances) policy upon industry in France has also been prepared. It assumes that the cost of compliance would be between 29 and 54 billion euros over a ten-year period. The estimate, furthermore, projects a 1.7-3.6% decrease in French GDP over such period, along with a 2% rise in unemployment. Prof Lucas Bergkamp, Seminar Materials, "Regulatory Environment in Europe", Institute for International Economics (July 29, 2003).

[4] EU refusals to accept genetically modified (GM)-tainted agricultural exports (e.g., shipments originating in Africa, Asia and South America) and EU encouragement of many anti-GM food movements around the world have led many developing country governments to officially reject the importation of GM seed and food products or to condition their acceptance upon the satisfaction of rigorous labeling or other provisional requirements. As a result, some government-funded biotech research and development programs have been temporarily closed or officially shut down.

[5] "Developing countries are major suppliers in the world market of commodity chemicals, plastic resins, products made from plastics such as toys, chemical fibers and textiles and apparel made from chemical fibers…" See: "Executive Summary: Trade Implications of the EU White Paper 'Strategy For a Future Chemicals Policy', Powell, Goldstein, Frazer & Murphy, LLP (4/9/02), at p. 17, cited in "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at p. 105. These concerns are equally as valid for more technologically advanced products manufactured, processed and/or assembled in developing countries, such as electronic and electrical equipment, telecommunications equipment and computer equipment, and their many components.

[6] These consequences include lower levels of trade and economic growth, lower revenues to finance national balance of payment obligations and infrastructure development, local job losses, fewer prospects for future employment, a lower standard of living -poverty, loss of food security, loss of significant potential health benefits, more intensive land use and harm to the environment. See: "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at pp. 51-62, 104-106.

[7] Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, [hereinafter, SPS Agreement], Agreement Establishing the World Trade Organization, Annex 1A, in FINAL ACT EMBODYING THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS, MARRAKESH, 15 April 1994, at 69 (1994) [hereinafter, Final Act].

[8] Agreement on Technical Barriers to Trade, Apr. 15, 1994, [hereinafter the TBT Agreement], id. at 17. The TBT Agreement was previously known as the 'Standards Code'. It was originally executed in 1980 as part of the Tokyo Round of Multilateral Trade Negotiations that took place in Geneva, Switzerland from 1973 to 1979 under the auspices of .The General Agreement on Tariffs and Trade (GATT).

from enacting technical regulations[9] and/or standards[10] that constitute unnecessary obstacles to international trade. These agreements as currently written effectively require proof of actual risks of harm posed by specific products as determined by the application of objective principles of sound science. Unfortunately, the EU disagrees with this interpretation and continues to apply its regulations without regard to their extra-territorial impact on non-EU industries. The EU justifies its actions by referring to the 'precautionary principle', a relatively undefined and inherently nonscientific political and sociological touchstone.[11]

EU officials have frequently referred to the precautionary principle as a necessary "framework for learning in the face of uncertainty" and arguably have embraced it as a metaphor for protecting the European 'way of life' against the 'Americanization' of European commercial and agricultural practices.[12] As articulated by the politically

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[9] Paragraph 1 of Annex I of the TBT Agreement defines the term 'technical regulation' as any "document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method."

[10] Paragraph 2 of Annex I of the TBT Agreement defines the term 'standard' as any "document approved by a recognized body that provides for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method." The Explanatory Note accompanying this definition provides that …Standards as defined by ISO/IEC Guide 2 may be mandatory or voluntary. For the purpose of this Agreement, standards are defined as voluntary and technical regulations as mandatory documents…" See: "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at p. 63.

[11] "The idea at the heart of the precautionary principle is that where human activities may have damaging effects, decision-makers should not wait for full scientific proof before taking appropriate protective measures. In short, the precautionary principle places a high price on inaction…Because it focuses on situations with significant uncertainty, the *precautionary principle* should be distinguished from the *principle of prevention*, which tends to operate when there *is* sufficient scientific evidence…The most far-reaching formulations of the precautionary principle can be found in international agreements that require *proof of no harm* before proceeding with a potentially harmful activity" (emphasis added). Halina Ward, "Science and Precaution in the Trading System", Seminar Note, International Institute for Sustainable Development (IISD) and the Royal Institute of International Affairs (RIIA), Energy and Environmental Program (1999), at pp. 1, 3.

[12] The most recent of three workshops previously organized by the German Marshall Fund's U.S.-European Biotechnology Initiative to discuss U.S. and EU views toward biotechnology explains a great deal about EU reliance upon the precautionary principle. An interpretative summary of this last dialogue (prepared by a European) is extremely revealing. "The EC official stressed that the political purpose of the European rules [about GMOs] was indeed to restore consumer confidence…'Anything less than the regulations now being proposed would not restore consumer confidence and GM crops in Europe could fail'…One NGO representative was quoted as saying that, 'Why can't the Americans understand that this is not specifically about health and safety and labels and traceability; it's a rebellion against industrial agriculture. We need to be talking about the emergence of new ways of farming which take social and environmental concerns into account, not just GMOs'…An important factor often omitted from the U.S. interpretation of the European conundrum is concern over the Americanization of European agricultural practices and food habits. This concern embodies dislike and fear of globalization in general…As one European…said, 'There is a difference in what we want our countries to look like, not only with food but with all that goes with it.' This 'way of life' statement echoed similar thoughts…one European said, 'GM food was a concrete thing that gave us the feeling that the world was going to change radically with respect to food,

influential European environmental non-governmental organizations (NGOs), this preferred 'way' has effectively become doctrine within Europe. It shuns practically all risks associated with everyday life,[13] holding economically important EU industries[14], and by extension, global industries operating within the EU, hostage.

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control of food, and ultimately democracy'…The European consumer attitude to GMOs 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.'" Peter Pringle, "The U.S.-European Biotechnology Initiative", Workshop 3: Segregation, Traceability and Labeling of GM Crops – An Interpretative Summary of a Transatlantic Conservation About Biotechnology and Agriculture", The German Marshall Fund of the United States (April 29, 2002), at pp. 3 -8. Similar sentiments have been expressed by Europeans with regard to chemicals. A recent National Journal article quoted European Union Environment Commissioner Margot Wallstrom as saying during a recent 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 author notes that "the conflict over the [proposed EU] chemicals legislation goes deeper than the usual arguments over dollars and cents. The root cause is the EU's use of the precautionary principle. This is a concept codified in the European Union charter, that government can and should make policy based on the significant possibility of risk, even before all data is compiled…The European chemicals policy is pre-emptive, requiring a massive amount of testing in the hope of reducing harm before it occurs." Samuel Loewenberg, "The Chemical Industry's European Reaction", National Journal (7/12/03), at p. 2263.

[13] The EU is intent upon protecting the public from all potential risks associated with industrial and technological advancement. Suspect activities include not only those conducted by longstanding industries applying advanced technologies (e.g., chemicals, autos, aeronautics, electronic and electrical equipment, cosmetics and all related downstream industries), but also those engaged in by newer industries themselves defined by the cutting-edge technologies they employ (e.g., biotechnology, nanotechnology, biocides, etc.). This view was clearly expressed within comments made by EU Environment Commissioner Margot Wallström during an April 2002 trip to Washington. "I believe Europeans are more skeptical than Americans about the possibility for technological advance through the market solving our natural problems. I have heard this week for example that we should not worry about fossil fuels running out as new technology could soon be available to produce gas from coal. Likewise, there is a great faith here in the role of satellite technology in solving or preventing natural disasters. We too see some opportunities in this, but we are less hooked on the possibility of a technological fix. I was struck yesterday during a moment of free-time by the inscription above the entrance to Union Station which speaks about "*the old mechanic arts controlling new forces*" and promises that "*the desert shall rejoice and blossom as the rose!*" as a result of man's engineering feats.There is of course a role for technology, but we can't simply wait for the market to deliver new techniques to solve our natural problems" (emphasis added). 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), at: (http://www.eurunion.org/news/speeches/2002/020425EImw.htm)

[14] While the enactment of stringent EU environmental regulations is very likely to impact certain industry sectors more adversely than others some EU industries may, in fact, derive a benefit from such restrictions. As one commentator has pointed out, "*Some regulations create a competitive advantage for domestic producers* by making it more difficult for foreign producers to sell their products. *In fact, knowing or anticipating that the burdens of compliance will fall disproportionately on their international competitors may make domestic producers more willing to support stricter regulations* than they would have in the absence of foreign competition. Examples of alliances between environmentalists and domestic producers abound. For example, the recycling requirements enacted by Denmark and the Canadian province of Ontario have both disadvantaged foreign beer producers while improving environmental quality. The strict automobile emission controls requirements supported by German environmentalists during the 1980's protected the domestic market share of German automobile companies, since it was more difficult for French and Italian firms to comply with them….(emphasis added)". David Vogel, "Environmental Regulation and Economic Integration", Prepared for a Workshop on Regulatory Competition and Economic Integration: Comparative Perspectives, Yale Center for Environmental Law and Policy (October 1999), at pp. 8-9. Dr. Vogel argues, furthermore, that the ratcheting up of the level of strictness of environmental regulatory standards is likely to induce a 'California effect'. As a result, "foreign producers

Fortunately EU efforts to further develop the precautionary principle have encountered some temporary 'road blocks'. In order for the precautionary principle to be fully implemented within the EU region it must, in essence, be exported to, adopted and employed outside of Europe on a global basis.[15] Also, as a matter of public international law, the precautionary principle has had only a limited status.[16] However, these limitations have not prevented the EU from continuing to employ this doctrine more extensively within its regional borders[17] and from looking to do so abroad.

Indeed, despite these limitations the EU has been inspired by such environmental movements to pursue a three-dimensional strategy that seeks to define and employ the precautionary principle globally.[18] The EU has sought to inject it within the WTO system at large through creative interpretation of the SPS and TBT Agreements and

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in nations with weaker domestic standards…are forced…to design products that meet those standards, since otherwise they will be denied access to its markets. This, in turn, encourages those producers to make the investments required to produce these new products as efficiently as possible. Moreover, having made these initial investments, they now have a stake in encouraging their home markets to strengthen the standards in part because their exports are already meeting them". Id., at pp. 10-11. According to Dr. Vogel, "the relationship between product standards that disadvantage importers and those which prompt exporters to strengthen their own standards in order to maintain market access must be understood in dynamic terms. The environmental regulatory agenda is a highly fluid one. In some cases, these may create only a temporary source of *competitive advantage* until other nations have adopted them, while in other cases this advantage may prove more enduring. But the result is similar: economic integration can promote the ratcheting upward of regulatory standards" (emphasis added). Id., at p. 11.

[15]Dr. Vogel also notes that 'green' countries may seek to *export* their strict environmental standards to other jurisdictions for several reasons. Not only might such countries (e.g., the EU and its Member States) perceive economic and environmental benefits from doing so, but they may also fear that by not doing so they may trigger a 'prisoner's dilemma' for their own industries. In other words, green countries may believe that their industry could be left at a competitive disadvantage if they did not press other jurisdictions (which, left to their own devices would not be likely) to adopt such strict standards. See: David Vogel, at fn 14, supra, at pp. 23-25.

[16] The precautionary principle currently lacks a broad legal foundation outside international environmental fora. The only broadly accepted reference to the precautionary principle is contained in Principle 15 of the Rio Declaration on Environment and Development, as adopted at the UN Conference on the Environment and Development in 1992. It provides essentially 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."

[17] According to the Transatlantic Environmental Dialogue, which was established in May 1999, in response to the New Transatlantic Agenda of the EU and the US governments and their Transatlantic Economic Partnership initiative, "The *precautionary principle* – the notion that action should be taken to prevent harm to human health and the environment, even when scientific evidence is inconclusive – originated in Europe (as the German Vorsorgeprinzip) and has received European endorsement in various treaties, including the Maastricht Treaty forming the European Union..." (emphasis added). "TAED Report Card on US and EU Responses to Environmental Issues", The Transatlantic Information Exchange System, at: (http://www.tiesweb.org/taed/new/scorecard_explanation.htm ).

[18] The EU's three-pronged trade strategy appears to relate to Dr. Vogel's theory about when the 'California effect' of strict national environmental regulation applies with respect to production standards "[It] applies primarily…under three circumstances: 1) domestic political or economic pressures in a green country have targeted the environmental practices of a particular sector in a less green country; 2) the country in which the production takes place aspires to enter into a free trade agreement with the EU…; or 3) the production process is covered by an effectively enforced international environmental agreement. David Vogel at p. 18.

through incorporation within them of obligations assumed under multilateral environmental agreements. In addition, the EU has sought to incorporate the precautionary principle within international standards through active and skilled participation in the international standards development process. Furthermore, the EU has begun to incorporate it within bilateral and regional free trade and aid agreements and within EU trade capacity-building initiatives offered to developing countries. Apparently, the EU is attempting to elevate the status of the precautionary principle from a limited (provisional) WTO exception to a 'norm' of general customary international law equal in importance to general principles of international trade law.

The EU, however, bears a difficult burden. It must first show that the WTO agreements (as treaty law) permit the broad use of the precautionary principle by the national (or regional) legislatures of WTO members to address perceived threats to legitimate national interests such as human health and safety, animal welfare and the environment. The EU must then also demonstrate that WTO members themselves have largely adopted the precautionary principle both as a WTO treaty norm and as a matter of state practice and custom outside the scope of WTO law.

## II. National Health, Safety and Environmental Regulations Must Refer to International Science-Based Standards and Reflect the Least Trade-Restrictive Alternative

The SPS and TBT Agreements recognize that standards and regulations[19] can be utilized as disguised (non-tariff) barriers to trade. Generally speaking, these agreements premise national (or regional) regulatory action upon relevant international science-based standards formulated through consensus[20] by widely recognized international standards bodies, or in their absence, upon substantially equivalent national science-based standards developed by other WTO members.[21] In the event such standards do not exist, the SPS Agreement requires national (or regional) governments to conduct an objective risk analysis[22] that includes 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

[19] Standards and regulations are playing an increasing role in international trade. It is estimated that, "up to 80 percent of all world trade is affected by standards of some kind. This implies that most sectors are affected – an estimate supported by the fact that the EU has developed some form of harmonized technical regulation for 30 sectors." Gary Haufbauer, Barbara Kotschwar and John Wilson, "Trade Policy, Standards and Development in Central America" (2000), at p. 21. The growing array of regulations abroad and their negative impact on U.S. exports has caught the attention of U.S. Commerce Secretary Donald Evans, who recently announced a new initiative aimed at promoting international adoption of industry-based standards and regulations. "Commerce's New Standards Initiative", Washington Trade Daily (March 20, 2003).

[20] "…Standards prepared by the international standardization community *are based on consensus*. [However,] [t]his Agreement also covers documents that are not based on consensus" (emphasis added). Explanatory Note Paragraph 2, Annex I of the TBT Agreement.

[21] SPS Art. 3; TBT Articles. 2.4 and 2.7.

[22] Risk analysis consists of three steps: risk assessment, risk management and risk communication. SPS Articles. 5.1, 5.2 and 5.3 address the need of WTO members, to conduct a science-based 'risk assessment'. See: "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at pp. 17-18.

regulatory actions.[23] The TBT Agreement, which applies to other than food safety issues, similarly 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.[24] This requirement has been interpreted to mean that, "the regulating [WTO] member…must [consider] all parts of a relevant international standard that relate to the subject matter of the challenged requirements…the regulating member is not permitted to select only some of the relevant parts of an international standard".[25]

The commonly recognized purpose of both the SPS and TBT agreements is the facilitation of international trade. Nevertheless, these agreements respect national sovereignty to the extent they permit WTO members, when absolutely necessary, to enact temporary-provisional measures that relate to and fulfill a legitimate state objective[26] – to protect against *ascertainable* risks of harm to specific state interests– provided they do not pose an unnecessary obstacle to trade[27]. Examples of legitimate state objectives

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[23] SPS Article 3.3. Such a risk assessment must be appropriate to the circumstances and must take into account risk assessment techniques developed by the relevant international standards organizations. See: "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at pp. 16-17; See, also: "Draft Principles For the Risk Analysis of Foods Derived From Modern Biotechnology (At Step 8 of the Elaboration Procedure)", at: (http://www.codexalimentarius.net/biotech/en/ra_fbt.htm ), recently adopted during early July 2003.

[24] TBT Article 2.4 provides that, "where technical regulations are required and relevant international standards exist *or their completion is imminent*, Members *shall* use them, or the relevant parts of them, as basis for their technical regulations…" (emphasis added). TBT Article 2.8 and Annex 3 (I) provide that "*wherever appropriate*, [Members/legislators] and the standardizing body *shall* specify standards *based on product requirements in terms of performance* rather than design or descriptive characteristics" (emphasis added). "Performance criteria are, for example, related to the intended use of the product and the level of performance that the product must achieve under defined conditions. Design critera are, for example, related to the physical form of the product or the types of materials of which the product is made" (emphasis added). Report to Congress on the Agreement on Technical Barriers to Trade – "Standards Code", Office of U.S. Trade Representative, GATT Affairs, Department of Agriculture, Foreign Agricultural Service,Department of Commerce, International Trade Administration and National Bureau of Standards, Department of State, Economic and Business Affairs Bureau, (Jan. 1980 – Dec. 1982) at p. 59.

[25] EC-Trade Description of Sardines ('EC Sardines') (WT/DS231/AB/R) at par. 250. The EC Sardines case was the first in which the WTO Appellate Body held that a WTO Member was in violation of its obligations under the TBT Agreement.

[26] TBT Article 2.4 provides that WTO members need not use international standards as a basis for technical regulations "when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued…" Id., at par. 259. According to the Appellate Body, "an ineffective means is a means which does not have the function of accomplishing the legitimate objective pursued, whereas an inappropriate means is a means which is not specifically suitable for the fulfillment of the legitimate objective pursued…The question of effectiveness bears upon the results of the means employed, whereas the question of appropriateness relates more to the nature of the means employed". Id., at par. 285. TBT Article 2.2 provides that "…in taking account of the risks that non-fulfillment [of a legitimate state objective through imposition of technical regulations] would create, l relevant elements of consideration are…*available scientific and technical information, related processing technology* or intended-uses of products" (emphasis added).

[27] SPS Article 5.7. Article 5.7 has been held by the WTO Appellate Body to permit a limited and temporary application of the precautionary principle. However, a WTO Member must first demonstrate that it is able to satisfy certain tests. "The precautionary principle (other than as that expressed in SPS Article 5.7 on provisional measures) does not override the obligation to base SPS measures on a risk assessment." See: "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound

include the preservation of national security, the prevention of deceptive practices and the protection of human health or safety, animal or plant life or health, or the environment.[28] Indeed, the overarching goal of the TBT Agreement is to prevent "standards-related activities [and ultimately regulatory actions based on or giving rise to them] from intentionally *or* unintentionally impeding the flow of international commerce".[29] In other words, national (or regional) regulations enacted to protect human health and safety, animal welfare and the environment must always be proportional to the objective sought to be achieved, and they must always reflect the least trade-restrictive alternative available.[30] This means that regardless of their purposes it is the (extraterritorial) effects that such regulations have upon international trade that are determinative.[31]

## III. National Health and Environmental Regulations Must Not Discriminate Between Otherwise 'Like' Products Based on Process or Production Methods

The SPS and TBT agreements, furthermore, establish that national (or regional) regulations cannot impose different treatment upon otherwise 'like' products based on how they are produced or formulated (i.e., process or production methods). This is required especially where the final product bears no trace of such process or formulation and its performance is not otherwise affected by it. Rather, products may be distinguished only on the basis of their physical and performance characteristics or depending on their end use.[32] Given the lack of U.S. and EU consensus on this issue[33]

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Science", at p. 42, citing Joost Pauwelyn, "WTO Agreement on SPS Measures As Applied in the First Three SPS Disputes", Journal of International Economic Law 641 (1999), at pp. 649-51, citing the Appellate Body Reports in Japan – Measures Affecting Agricultural Products (the 'Japan – Varietals case'), adopted on March 19, 1999, WT/DS76AB/R and EC Measures Concerning Meat and Meat Products (Hormones) (the 'EC Hormones case'), AB-1997-4, adopted on February 13, 1998, WT/DS26/AB/R; WT/DS48/AB/R ;See, also: TBT Art. 2

[28] TBT Article 2.2.

[29] "The most important and fundamental of [the]...several specific obligations...contain[ed in the Standards Code]...states that standards, technical regulations...should not create *unnecessary obstacles to trade*. Standards-related activities can be either *intentionally* prepared, adopted, and applied so as to create barriers to trade or they *unintentionally* can have the effect of creating unnecessary barriers to trade. *The language in the Standards Code covers* ***both*** *the intentional and the unintentional situation...Countries [must] formulate standards...which will be the least disruptive to international trade and still achieve the same health or safety objectives*." (emphasis added). Laurel A. Brien, "Understanding the International Agreement on Technical Barriers to Trade and Related Provisions of the U.S. Trade Agreements Act of 1979", The Tokyo Round Trade Agreements, Technical Barriers to Trade, Vol. 4, U.S. Department of Commerce, International Trade Administration, Office of Trade Policy (Sept. 1984), at p 4. In essence, national legislatures and/or administrative bodies must consider not only the nature and objectives of the measures themselves, but also their intended AND unintended extra-territorial consequences.

[30] TBT Articles 2.2 and 2.5.

[31] Whether the goal of the EU is to protect against ascertainable risks of harm, or to facilitate EU regulatory harmonization and integration, or to appease influential EU social and political movements led by environmental and consumer groups, or to protect ailing or lagging EU industries from global competition, it is still the effects that such provisions have upon international trade that are determinative.

[32] GATT Art. III; TBT Art. 2.1; SPS Art. 2.3. WTO jurisprudence identifies several factors that must be considered when determining whether products are 'like' products. They are, namely: 1) physical characteristics; 2) end-uses; 3) substitutability; and 4) tariff classifications.

[33] As concerns the labeling of biotech food products required under the proposed EU GMO regulations, the EU has conveyed to the WTO SPS Committee that it intends to distinguish between otherwise identical

and a growing EU reliance upon the precautionary principle, it is not surprising that a number of EU health and safety, animal welfare and environmental regulations (and regulatory proposals) arguably violate this concept.

For example, several EU regulations presume that a given formulation, scientific application or processing technique used in a product's manufacture poses an unacceptable hazard.[34] Relying upon the precautionary principle as justification, EU regulators have essentially ignored (or otherwise failed to demonstrate) whether the suspect technique or formulation actually exposes the product's user(s) to a greater risk of harm than any other process, application or technique. They also fail to consider whether it adversely affects the product's performance and/or physical characteristics.[35] Acting on this presumption, these regulations then effectively discriminate among 'like' products on the basis of sensitive proprietary company information describing the very formulae and production techniques in question that is secured as a condition to granting the products entry to EU markets. Whether or not the information sought is relevant to reducing the potential safety hazard identified, is considered only as an afterthought.[36] At

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biotech and non-biotech food products, in part, based on the consumer's right to know (i.e., consumer choice, which has been referred to as the 'Fourth Criterion'). The EU bases this position on an interpretation of the requirement of substitutability as including consumer taste or choice. Furthermore, the EU does not believe that the drafting of regulatory requirements in terms of process and production methods rather than in terms of product characteristics [i.e., performance] will subject it to dispute settlement procedures "unless such requirements are *intentionally* used to bypass [Standards] Code obligations (emphasis added)." "Report to the U.S. Congress on the Technical Barriers To Trade (Standards Code), Drafted by the Office of U.S. Trade Representative, GATT Affairs; Department of Agriculture, Foreign Agricultural Service; Department of Commerce, International Trade Administration and National Bureau of Standards; and Department of State, Economic and Business Affairs Bureau, (January 1980 to December 1982), at p. 12.

[34] For example, wines not produced according to EU-authorized oenological practices, hormone-injected beef and bioengineered food and feed products have been subject to such informational requirements and subsequently discriminated against even though no scientific proof has been adduced that such formulations or production methods are any more harmful than EU-prescribed practices. In addition, cosmetics products that are tested on animals or containing chemicals tested on animals may be banned from manufacture and sale within the EU, even though chemicals testing may be required for safety purposes in other jurisdictions (e.g., in the U.S.).

[35] This point relates to the distinction between product related process and production methods (PPMs) and non-product related PPMs. "The distinction between the two is based on PPM's effects on the characteristics of the final product. In non-product related PPMs, different environmental impact is caused by the way a product is produced and not by the product itself…A process is a *non-product related PPM* if it has a negligible impact on the final product…In other cases, the way a product is produced affects its final characteristics and can cause harm to environment and human health in the importing country. These PPMs where, environmental damage is caused by the product itself or by its physical constituents are known as *product-related PPMs*" (emphasis added). See: Sandeep K. Tetwarwal and Pradeep S. Mehta, "Process and Production Methods (PPMs) – Implications for Developing Countries", Briefing Paper, CUTS Center for International Trade, Economics & Environment (2000), at p. 2. Regulatory distinctions premised solely on how products are produced rather than on their end uses or final characteristics are almost always likely to constitute non-tariff barriers to trade. They involve non-product related PPMs which have no impact or a negligible impact on the final product.

[36] These regulations also threaten to compromise company intellectual property without imposing adequate safeguards or compensation. For example, under the proposed GMO and chemicals regulations as well as under the end-of-life vehicle directive and the biocides directive, the EU requires 'data sharing' among competitors and other companies along the production and supply chains (upstream and downstream,

least one European commentator has noted that, in the case of biocides (e.g., disinfectants), the Commission has gone so far as to dictate how a product should be formulated even when the relevant regulatory requirements have been satisfied.[37] And similar government constraints have been imposed on the design of automobiles and electrical and electronic equipment, without evidence that the prescribed designs or methods of production will reduce the perceived threats to human health or the environment.[38]

A prime example of regulations that may be used to discriminate between products solely on the basis of their process or production method (PPM)[39] are the EU's proposed regulations on GMO traceability and labeling.[40] During early July 2003, the EU Parliament approved a resolution containing amendments to the Council's position on

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domestic and foreign). See, e.g., "U.S. Comments on the EU's Draft Chemicals Regime", at p. 7, at; (http://www.useu.be/Categories/Evironment/July1003USEUChemicalsComments.html ). In addition, the EU requires the transfer or translation of such data into consumer labels intended to educate EU consumers about more than they could possibly want to know about each product. Whether such information could be considered useful in providing consumers with the ability to make an informed choice is highly questionable. The use of labeling schemes such as these as a form of public disclosure, furthermore, is susceptible to fraudulent and misrepresentative industry claims, and to manipulation by zealous consumer and environmental groups (e.g., GMO labeling, eco-efficiency labeling, cosmetics animal-free testing labeling and biocidal products labeling). See: "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at pp. 39-42, 70-75, 80-82, 107-109, 110-112, and 117.

[37] EU Biocidal Products Directive, 98/8/EC ; Biocidal Proposed Regulations 2001 (SI 2001 No. 880). The directive provides that where two or more active substances meet the prescribed approval criteria the 'less safe' substance can be prevented from entering the market or be otherwise subject to withdrawal, pursuant to the concept of 'comparative assessment'. Mike Freemantle, Bryan Backhouse, "Global Implications of the European Biocidal Products Directive" (2001), at p.4, at: (http://ecb.jrc.it/biocides ). See: Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at pp. 113-118.

[38] A similar problem has arisen with respect to EU end-of-life / life cycle assessment regulations imposed on autos and electrical and electronic equipment which are then coupled with additional EU integrated product policy requirements. In each case, the EU has presumed that certain manufacturing processes, formulations and designs are less eco-friendly than other processes, formulations and designs without having conducted the necessary science-based risk assessment mandated by the SPS and TBT Agreements. Rather, these EU regulations rely upon a life-cycle assessment that is substantively distinct from the risk assessment. The EU has then encouraged eco-labeling to help consumers distinguish between (discriminate against) products that do not meet the new life-cycle assessment requirements. See: "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at pp. 81-82, fn 368.

[39] As discussed in footnote 14, supra, EU industry can derive a competitive advantage by imposing strict environmental regulatory standards upon products exported to the EU by foreign competitors. And these benefits can only multiply by virtue of the 'California effect' as additional countries bring both their product and processing / production standards into line. "…Product standards constitute only one dimension of environmental regulation; many environmental harms stem from the way a product is produced or processed. *But in some cases 'greener' nations have used similar restrictions, or the threat of restrictions, on access to their markets to force their trading partners to change their production standards – notwithstanding the fact such practices may violate GATT/WTO rules. Such restrictions have generally been enacted due to some combination of pressures from domestic firms which want to create a 'level playing field' by imposing additional costs on their international competitors, and environmental groups that want to use trade as a leverage to influence the environmental practices of other countries"* (emphasis added)". David Vogel, at pp. 13-14.

[40] See: "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at pp. 29-32.

these regulations[41] that impose stringent and arguably unworkable new requirements[42] upon the agriculture and food industries in all countries. In the absence of *scientific* evidence demonstrating that GMOs and GMO products pose an actual risk of harm to human health or the environment[43], that cannot be addressed by other less trade-restrictive means,[44] these amendments set forth multiple state objectives intended to address *other than* safety issues. The Parliament has focused not only on the existence of general hypothetical, unascertainable and presumed hazards, but it has also identified possible consumer deception, fraud or confusion that may potentially arise (intentionally or unintentionally) as the result of the new burdens that will be placed upon industry by these regulations.

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[41] See: Report on the Council Common Position for Adopting a European Parliament and Council regulation on traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (15798/1/2002 – C5-0131/2003 – 2001/0180(COD)), Codecision (2nd Reading) (7/2/03), at: (http://www2.europarl.eu.int/omk/sipade2?L=EN&OBJID=30253&LEVEL=3&MODE=SIP&NAV=X&LSTDOC=N )

[42] See: Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at pp. 39-42. In general, all food and feed products intended for human and animal consumption that contain, consist of or are produced from GMOs (e.g., vegetable oils) are subject to the traceability and labeling rules whether or not there are detectable traces of GMOs in the final food products. There are however exemptions from tracing and labeling if a certain maximum threshold for adventitious or technically unavoidable presence (A/P) of GMOs is not exceeded. That level is *0.9%* for products intended for direct processing that contain 'authorized' GMOs, and is *0.5%* for products that contain GMOs that have received a favorable risk assessment but which have not been authorized. This 0.5% threshold for unauthorized GMOs will continue for a period of three years from time of enactment after which time the threshold will drop down to *zero (0)*. The proposed regulations require retailers to place labels on GMO products that have a GMO presence that exceeds the prescribed thresholds and to placed such labels on a display and in advertising used in connection with such products. It must state, "This product is produced from GMOs" or the words "This product contains [ingredients] produced from GMOs". Furthermore, industry must retain records of its data for traceability purposes for a period of ten years from each 'transaction' to correspond with the 10 year period of GMO authorization. See: Report on the Council Common Position for Adopting a European Parliament and Council regulation on traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

[43] The EU, U.S. and Canada all agree that GMOs and GMO products pose no known risk to human health and safety. Following a summit that took place between Canada and the European Union during late May 2003, Canadian officials were "cited as angrily accusing European Union members…of using 'phoney science' and caving in to political pressure to justify a five-year old ban on new genetically modified foods and that the ban is the main reason for the collapse of canola exports to the EU worth as much as US 290M dollars…The officials were cited as insisting that there is no scientific reason for the ban…One [Canadian] official was quoted as telling reporters that…'if you look at the basic political picture in Europe, you can't get elected unless you're opposed to genetically modified food. We're not trying to shove it down their throats and we're saying we understand their politics. But they can't hide phoney science. And so in that sense, there's progress, in that we're actually moving toward at least an honest assessment that science isn't the problem…'" "Canada Raps 'Phoney Science' Over GM Food Ban", Reuters (May 28, 2003).

[44] "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at pp. 34-35. Footnote 146 discusses how the potential risks of allergenicity and outcrossing can be addressed through less trade-restrictive measures than those proposed by these regulations.

The *unstated hope*[45] of Parliament, the Council and the Commission is that, the disclosure of proprietary information through the tracing and labeling of food and feed consisting of, containing or produced from GMOs will reveal a hidden but unknown and otherwise undetectable danger. The *stated aim* of the EU, however, is to provide consumers with information[46] about the composition of GMO derived products which consumers may then use to choose among and discriminate against such products. In essence, the enactment of these proposed regulations will serve a predominantly *political and social* objective namely, to reinforce European consumer preference in the EU internal market for the more natural European 'way of life'. The EU has carefully crafted this message to compliment its simultaneous use of the precautionary principle to erect a 'strawman' (of hazard) for the purpose of protecting the public against a harm that does not yet actually exist. The beauty of the strawman technique, especially as can be seen through the eyes of EU government regulators, lies in its simplicity of use and opaqueness. Strawmen are also provisional creations which can later be torn down by regulators whenever, in their sole discretion, a justification is needed for subsequent government actions whether or not they may actually be necessary.

> "The proposed regulation provides a framework for the traceability of products consisting of or containing…GMOs and food and feed produced from GMOs with the objective of, *in accordance with the precautionary principle*: [1] facilitating accurate labeling; [2] protecting human and animal health; [3] protecting the environment and ecosystems; and [4] ensuring the smooth operation of the internal market and monitoring such products by means of tracing and labeling…it recognizes the priority which must be accorded to the right of the consumer to be given the information necessary to make a free and independent choice: [a] giving consumers the right of free choice; [b] allowing effective measures to be introduced to prevent the unintended presence of GMOs or products thereof in other food or feed; and [c] enabling such products to be withdrawn immediately, rapidly and totally in the event that they should prove harmful or hazardous" (emphasis added). [47]

The EU applies the precautionary principle similarly in the case of chemical substances *and the products containing them* that are presumed *a priori* to be inherently hazardous to EU society. An extensive and rigorous substance authorization process has been set forth

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[45] This same *hope* is reflected in the EU's proposed chemicals policy. Unlike "in Washington, where the government does not usually pass broad reforms until there is concrete evidence of harm…the European chemicals policy is pre-emptive, requiring a massive amount of testing *in the hope of* reducing harm before it occurs" (emphasis added)." Loewenberg at p. 2263. See discussion infra.

[46] The European consumer's 'right to know' is based on Title XIV (Consumer Protection), Articles 153.1 and 153.2 of the Treaty Establishing the European Community (EC Treaty). It provides the consumer with the right to know, which is the basis for what has become to be known as the 'Fourth Criterion' – nonscience consumer-based criteria to determine food safety. See: "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at p. 2, fn 3.

[47] See: Report on the Council Common Position for Adopting a European Parliament and Council regulation on traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. See, e.g.: Amendment 4, Recital 10b. The justifications underlying Amendment 5 of Article 1 state that the requirements are based on the "need to prevent deception and fraud…the need to promote consumer protection without causing consumer confusion and doubt…the need to allow fair competition to develop in the market…and finally to promote the protection of human health and the environment…from the uncontrolled spread of GMOs…" Id.

within recently issued proposed regulations[48]as a condition precedent to granting those substances *and the products containing them* EU market access. In general, the satisfaction of these requirements relies largely upon the submission by manufacturers, processors, and formulators of significant amounts of testing data and proprietary information relating to the confidential formulae and production process techniques involved in their manufacture and formulation. In addition, it calls for the mandatory sharing of such information among industry competitors and downstream users of these substances and products, as well as the disclosure of such information to the public. Disclosure would be achieved through establishment of a publicly accessible central database and tracking system that would permit European consumers to find "information about the health effects, environmental effects, other serious hazards and safe instructions for use of chemical products."[49] Through imposition of these requirements it is the unstated *hope* of the Commission that information disclosure will unveil hidden but otherwise unknown and undetectable hazards. The *stated aim* of the Commission, however, is to provide consumers with the ability to choose 'safer' alternatives to existing substances and products. According to Environment Commissioner Margot Wallström,

> "Everyday, we are exposed to chemicals in our environment, at work or in our homes. However, for many of them, we do not know enough about their risks or longer-term effects. Our reform proposal therefore requires industry to provide *public information* on the chemicals they produce or import and the risks associated with their use. *This will allow the users to choose safer alternatives.* It will greatly enhance the protection of people's health and the environment because we will insist on strict authorisation procedures for the substances which cause most concern. Obliging the industry to provide information on what it produces will also help to enhance the image of the chemicals sector. Industry will finally have an interest in investing in innovation of new safe chemicals - the current trend of using old chemicals to avoid the cumbersome current evaluation procedure has stopped investment into *safer* chemicals" (emphasis added). [50]

What is apparent is that the EU has once again created a 'strawman' of hazard for the purpose of protecting the public against an unidentifiable and unmeasurable harm to humans or the environment that has not yet materialized. According to one Swedish scientist deeply involved in the development of chemicals, the precautionary principle as applied to chemicals has increasingly been shaped by and become largely a tool of

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[48]"The aims of the proposed new Regulation, which will replace 40 different pieces of current legislation, are to increase the protection of human health and the environment from exposure to chemicals while at the same time to maintain and enhance the competitiveness and innovative capability of the EU chemicals industry. In delivering both these aims, the proposal aims at fully conforming to the balanced approach required by sustainable development. Chemical substances are used in the manufacture of almost all products we use every day at home or at work. The industry that produces them plays a vital role in sustaining the competitiveness and innovative potential of many final product manufacturers downstream. The system for registering, evaluating and authorizing chemical products should therefore boost enterprise competitiveness and product innovation, to the long-run benefit of chemicals manufacturers and importers, users, consumers and the environment…" "Commission Published [New] Draft Chemicals Legislation for Consultation", EU Press Release (5/7/03), IP/03/646, at: (http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=IP/03/646|0|RAPID&lg=EN). The proposed regulations were based on a prior Commission proposal entitled, "White Paper – Strategy For a Future Chemicals Policy", Commission of the European Communities, (2/27/01) COM(2001) 88 final.

[49] Id, at p. 26. This is more information than consumers may ever want or need to know about.

[50] EU Press Release (5/7/03), IP/03/646; White Paper at p. 26.

politicians rather than true scientists. He argues that the precautionary principle serves to justify actions taken more in response to government data of harm generated for the *political purpose* of appeasing consumer concerns than hard scientific evidence of actual harm.

> "Today…politicians more or less openly admit that rather than basing their policies on 'real risk' they are mostly guided by 'risk perception', a concept heavily tainted by a new kind of superstition. Instead of making an attempt to distinguish between what are significant and insignificant risks our regulators tend to yield to media blackmail that will only accentuate the trend towards an increasing lack of rationality in risk management to the detriment of progress in our modern society. Each time regulatory action is taken that is based solely or mostly on public 'concern' and where the actual risk is negligible, the mere fact that regulatory action is taken will strengthen the belief in its absolute justification. The layman critical of experts will exclaim: 'You see, it was dangerous – we were right after all!'" [51]

## IV. National Health and Environmental Regulations Must Be Adopted Pursuant To a Transparent, Open and Inclusive Process

The SPS and TBT Agreements require that the process by which national (or regional) standards and regulations are formulated and adopted be transparent, open and inclusive, as well as, consistent within and among WTO member states. This means that all interested stakeholders (civil society, industry and government), foreign as well as domestic, should be afforded the opportunity to meaningfully participate in the regulatory and standards creation processes. They must be provided adequate and timely written notification of regulatory changes or proposals having a material impact on trade (market access and manufacturing processes) *before* such changes or proposals come into effect.[52] And stakeholder views and comments, once submitted, must actually be taken into account and discussed by the regulatory or standards bodies *before* proposed regulations have been adopted.[53] While these practices may vary among WTO Member States they must, at a minimum, offer these procedural guarantees for the benefit of all interested stakeholders.[54]

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[51] See: Robert Nilsson, "Misguided Precaution – Chemicals Control and the Precautionary Principle in Sweden" (2000), at p. 3. Dr. Nilsson's comments were discussed in "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at pp. 102-104.

[52] TBT Art. 2.9; In the case of the EU, this means that interested stakeholders, including other governments, must be informed of a regulatory proposal *before rather than after* it is sent by the European Commission to the European Parliament. SPS Art. 7 and Annex B, par. 5 to the SPS Agreement impose similar notification, transparency and participation requirements whenever a proposed national (regional) standard or regulation may have a significant effect on the international trade of other WTO members. In other words, interested stakeholders must be provided with reasonable time in which to respond to proposed legislation.

[53] TBT Art. 2.9; SPS Annex B, par. 5(d).

[54] These procedural guarantees are based on the U.S. Administrative Procedures Act, Title 5 - United States Code - Chapter 5, sections 511-599. "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: (http://usgovinfo.about.com/library/bills/blapa.htm ).

Several EU directives and regulations when proposed, including those relating to bioengineered food and feed products (GMOs), electrical and electronic equipment,[55] automobiles[56]and persistent organic pollutants (POPs)[57], have arguably violated these principles. In the case of each of these regimes interested non-EU industry stakeholders were arguably denied meaningful participation in the legislative/regulatory process *before*[58] the EU legislature defined its *political* objectives in terms of mandatory

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[55] The EU has proposed several directives on electrical and electronic equipment that would control end-of-life product disposal, phase out the use of lead and other heavy metals and regulate design for environmental impact. They include the Directive on Waste from Electrical and Electronic Equipment (WEEE) which focuses on the take-back and recycling of discarded equipment, the Directive on Restrictions on the Use of Hazardous Substances such as lead, mercury, cadmium and certain flame retardants, and the proposed Directive on the Impact on the Environment of Electrical and Electronic Equipment (EEE) which focuses on mandating environmental design requirements for electrical and electronic equipment sold in the EU. The draft EEE directive has since been broadened and revised into the Eco-Design of End-Use Equipment (EuE), and, according to unofficial industry sources, into the new draft Framework Directive on Eco-Design for Energy-using Products (EuP). See: "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at pp. 69, fn 301, 77, fns 330,335

[56] The EU Directive on End-Of-Life Vehicles (ELV Directive) encourages vehicle producers to prevent and reduce the use of potentially hazardous substances in the production of vehicles in order to prevent their release into the environment, facilitate recycling and avoid the disposal of hazardous waste. It covers all new vehicles and end-of-life vehicles as well as their components and materials, and precludes the use of heavy metals in vehicle materials after July 1, 2003. Id, at pp. 78-79.

[57] On June 12, 2003, the EU Commission, without having provided adequate public notice of a rulemaking proposal inviting interested stakeholders to submit comments and engage in consultation, issued a proposed regulation on persistent organic pollutants intended to implement the obligations the EU and its Member States will assume under two international environmental treaties – the Stockholm Convention on Persistent Organic Pollutants ('POPs') and the 1998 Protocol to the 1979 Convention on Long Range Transboundary Air Pollution ('LRTAP') when they enter into force. (See discussion infra, at fn ___ . While the EU's proposed POPs regulation (which imposes more stringent requirements than those called for by the treaties) will eventually be incorporated into the final REACH regulation at a later unspecified date, it has been presented as a separate piece of legislation intended to "facilitate the early ratification" of these two agreements, and therefore, adequate notification was required. The failure of the EU to once again adhere to international transparency rules may ultimately have a material adverse impact on U.S. and other non-EU exporters of chemicals, chemical products and articles deemed to contain such substances, who have been denied an adequate opportunity to respond to the proposal. (Indeed, recent conversations held with a number of interested U.S. industry and government stakeholders reveal that most such persons were unaware of the issuance of said proposed regulation.) These products may be subject to discrimination under the terms of the proposed regulation, which do not clearly indicate whether they apply only to chemicals currently listed as POPs and/or also to other chemicals that may potentially be treated as future additions to that list.

[58] Much of the difference between the U.S. and EU regulatory approaches (before-the-fact versus after-the-fact disclosure) may be attributable to the different views each has towards the role of transparency in the regulatory/ legislative process. Unlike in the U.S. where the APA requires U.S. regulators to provide an opportunity for direct stakeholder involvement, including the presentation and consideration of views held by non-U.S. industry members, industry stakeholders from the U.S. and other non-EU jurisdictions are effectively prevented from participating in the EU legislative/regulatory process. Perhaps this may also be a reflection of the different types of political systems within the U.S. and the EU member countries. And it may also reflect the relationship that exists between EU member governments and their citizenry. While the long-term trust of the EU public in their national governments' ability to protect them against health and environmental harm has been temporarily shattered, the EU Government has endeavored to restore that trust regionally through enactment of strict laws and regulations aimed at protecting public interests against *perceived* harms to human health, animal welfare and the environment. In the end, the EU public must trust that well-intentioned EU legislators /regulators will adequately represent their interests.

'essential requirements'.[59] While they may have been permitted to submit comments with respect to proposed legislation those comments were not actually taken into account and reflected in the final directive or regulation. This is especially problematic when the hypothetical hazards being addressed by health and safety, animal welfare and environmental directives are to be mitigated or eliminated by use of the precautionary principle. In the case of the EU's proposed REACH regulation (on high volume chemicals), although the views of interested industry and government stakeholders were evidently not taken into account or reflected within the original EU Chemicals Strategy document (the 'Chemicals White Paper'), it remains possible (though unlikely) that they may yet be reflected in a revised proposed regulation to be issued at a later date. As the result of considerable pressure having been applied by both (EU and non-EU) industry and government stakeholders[60], the EU was forced to extend its internet consultation period until July 2003 and to entertain over six thousand industry and government stakeholder comments. Only time will tell whether these comments will be actually considered and reflected in the final legislative proposal, as required by the TBT Agreement.[61]

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[59] "[Essential] requirements deal in particular with the protection of health and safety of users (usually consumers and workers) and sometimes cover other fundamental requirements (for example protection of property or the environment). [They] are designed to provide and ensure a high level of protection. They either arise from *certain hazards associated with the product* (for example physical and mechanical resistance, flammability, chemical, electrical or biological properties, hygiene, radioactivity, accuracy), or refer to the product or its performance (for example provisions regarding materials, design, construction, manufacturing process, instructions drawn up by the manufacturer), or lay down the principal protection objective (for example by means of an illustrative list). Often they are a combination of these…"(emphasis added). Id., Sec. 4.1, "Essential Requirements".

[60] Even "German chancellor Gerhard Schroder spoke out forcefully against the…Commission's draft policy on chemical testing and regulation at the European Chemical Industry Council ('CEFIC') general assembly meeting, held on June 27, in Hamburg, Germany…Schroder argued that 'the competitiveness of the European chemical industry must not be neglected. It is essential for Europe to have a registration system…[b]ut the current proposal poses too much of a burden on the industry'. Moreover, he added, *the legislation as proposed, 'would be attacked – probably successfully – by our overseas allies, under World Trade Organization criteria'*" (emphasis added). Patricia Short, "EU Regulatory Scheme Panned – German Chancellor Says Proposed Chemicals Policy Will Harm Industry", Chemical and Engineering News (7/3/03), reported on the Our Stolen Future website, at: (http://www.ourstolenfuture.org/press/2003/2003-0703-CEN-schroeder.htm ).

[61] The EU originally scheduled for the second quarter of 2003 an eight-week internet consultation period during which time interested stakeholders were invited to submit comments regarding the proposed REACH regulation intended to implement the policies outlined in the Chemicals White Paper. The consultation period began on May 7, 2003, the date on which the proposed regulation was issued, and effectively closed on July 11, 2003. See: Europa Chemicals website, at: (http://europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/reach.htm ). Stakeholders were strongly opposed to this form of notification and consultation, which the EU considered as "an early notice under Article 2.9.1 of the TBT Agreement." See: "REACH Regulation – Consultation", Europa Chemicals website, at: (http://europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/consultation.htm ). They continue to fear that their comments will not be taken into account or reflected, especially considering comments reported to have been made by EU Environment Commissioner Margot Wallstrom that, the consultation "[would] not focus on the substantive elements of the technical regulations and that she expect[ed] no major amendment to be made to the regulations as a result of the summary review opportunity". See: "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at fn 434, at p. 95. Their concerns may be well founded. The EU has received approximately "6,400 contributions [comments] to the consultation and a number of specific questions. *Please note it is*

It is telling that some of these regimes are based on the 'New Approach' to technical harmonization and standardization[62] pursuant to which horizontal standards can play a major role in supporting and complimenting EU cross-sectoral legislation, "depending on the *political will* of the legislator" (emphasis added).[63] "Pursuant to this approach, general

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*not always possible to respond to these queries* as the two teams involved are working hard to analyze the contributions and to make appropriate changes to the proposal" (emphasis added). See: "Contributions to the Public Consultation on REACH", (8/4/03), Europa Chemicals website at: (http://europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/contributions.htm ).

[62] The EU continues to employ a new regulatory technique and strategy known as the 'New Approach'. The objective of the New Approach is technical harmonization and standardization. It is based on several principles: 1) "Legislative harmonization is limited to 'essential requirements' that products placed on the Community market must meet if they are to benefit from free movement within the Community; 2) The technical specifications of products meeting the essential requirements set out in the directives are laid down in harmonized standards; 3) Application of harmonized or other standards remains voluntary, and the manufacturer may always apply other technical specifications to meet the requirements; and 4) Products manufactured in compliance with harmonized standards benefit from a presumption of conformity with the corresponding essential requirements…The operation of the New Approach requires that the standards offer a guaranteed level of protection with regard to the essential requirements established by the directives and that the national authorities carry out their responsibilities for the protection of safety or other interests covered by the directive…Since the New Approach calls for essential requirements to be harmonized and made mandatory by directives, this approach is appropriate only where it is genuinely possible to distinguish between essential requirements and technical specifications…In addition to the principles of the New Approach, conditions for reliable conformity assessment are necessary…" "Guide to the Implementation of Directives Based on the New Approach and the Global Approach", Office for Official Publications of the European Communities, reference C-22-99-014-EN—C (Sept. 1999), Sec. 1.1,at: (http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/document/1999/_1282_en.pdf ). The co-decision procedure by which New Approach directives are adopted can be explained generally as follows: 1) "The [European] Commission initiates a proposal to the Council and the European Parliament – such proposals concerning health, safety, environmental protection and consumer protection should, pursuant to Article 95 [of the EC Treaty,] take as a basis, a high level of protection; 2) The European Council…[after] receiving a Commission proposal…requests an opinion from the Parliament and the Economic and Social Committee before reaching its common position on the proposal; 3) Once the common position has been reached, it is transmitted to the Parliament, which may accept, reject or propose amendments during this second reading; 4) The Commission reexamines its proposal in light of the Parliament's amendments and returns the proposal to the Council, which takes a final decision within three months. If necessary, problems are referred to a conciliation committee of Council and Parliament, in which the Commission participates as a moderator….Up to the adoption of the common position, discussion is based on the Commission's proposal." Id., Sec. 1.3 "Adoption of New Approach Directives".

[63] In the EU, "Standards can play an important role in legislation, in particular in technical regulation…Unlike regulations, [standards] are not adopted by authorized public authority but within private, independent and – in case of European standards – officially recognized standards organizations. Standards are a priori not binding and their application is voluntary...If a legislator includes standards in a legal act or makes [direct] reference to them standards can obtain legal quality. The standards thus become part of the requirements of a specific legislative act or of the system…At the European level, the Community in its legislation makes broad use of the option of referencing standards…international standards, European standards and to a lesser extent national standards. The methods used vary significantly, depending on the *political will* of the legislator…Indirect references to standards are generally made when the legislator intends to allow or promote their voluntary use…Within the New Approach legislation…the European legislator clearly defines his *political objectives* by defining detailed essential requirements which a manufacturer must meet in order to comply with the legislation. Such standards if complied with give a 'presumption of conformity' with the directive for which they have been

essential requirements regarding public health, the environment and safety are set out in a framework directive, while supplementary technical specifications are drawn up by the European standards institutions CEN, CENELEC and ETSI[64] in the form of standards on the basis of mandates issued by the European Commission and EFTA [the European Free Trade Association[65]]".[66] In other words, through use of New Approach directives, which usually contain broad public safety requirements rather than technical details, European legislators[67] have the choice of either enacting technical regulations themselves or "avoid[ing] difficult technical questions [by] relying on the technical expertise of and delegating their public rule making responsibilities[68] to [private] standards developers [European standards organizations (ESOs)]". This delegation occurs pursuant to a formal mandate[69]procedure largely intended to avoid "the appearance of barriers…to trade"[70],

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written…No reference to specific standards is made in the legislation itself – the New Approach is operational without standards…However, the Commission **can** request the European standards organizations to elaborate harmonized European standards necessary to comply with the essential requirements defined in the respective legislation" [where they do not otherwise exist or are lacking] (emphasis added). Dr. Gerhard Leibrock , "Methods of Referencing Standards in Legislation With an Emphasis on European Legislation", Enterprise Guides Report, Standardization Unit of Directorate General – Single Market: Regulatory Environment, Standardization & New Approach – of the Enterprise Directorate-General, European Commission (2002), at pp. 3-4, 8-9.

[64] There are three recognized European standards organizations. The European Committee for Standardization (CEN) is responsible for standards in areas other than the electrotechnical and telecommunications fields. The European Committee for Electrotechnical Standardization (CENELEC) is responsible for standards in the electrotechnical field. The European Telecommunications Standards Institute (ETSI) is responsible for standards in telecommunications, broadcasting and some information technology. On March 28, 2003, these parties executed updated standards guidelines that "include a mutual commitment to use standardization to support legislation". "New Standards Guidelines for Europe", European Commission News Release (3/28/03), at: (http://www.cenelec.org/Documents/Pressrelease/28032003.pdf ; http://www.pressi.com/intrelease/63361.html ).

[65] The membership of the EFTA, an international governmental organization that promotes trade and economic integration, consists of Iceland, Liechtenstein, Norway and Switzerland.

[66] "Technical Barriers to Trade", Utenriksedepartmentet, Norway Ministry of Foreign Affairs, at: (http://odin.dep.no/odin/engelsk/norway/eu/032091-991530/index-dok000-b-f-a.html ).

[67] The primary European legislator is the European Parliament and the European Council, but the task of carrying out legislative responsibilities can be delegated to the administrative authority, the European Commission, which may sometimes be supported by a Committee. Dr. Gerhard Leibrock at p. 4.

[68] The New Approach has already been characterized by some as an illegal and illegitimate legislative delegation to private standardization bodies, as construed under the EC Treaty. See: Rod Hunter, Candido Garcia Molyneux and Marta Lopez Torres, "Legality of the Draft Directive on the Impact on Environment of Electrical and Electronic Equipment", Hunton & Williams, cited in "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at p. 75, fn 328.

[69] "Mandates are reference documents for standardization activities by which public authorities ask the European standardization authorities to develop technical specifications. Directive 98/34/EC provides the general framework for the drawing-up of mandates which can be complimented by provisions in individual directives…*Standardization mandates are important interfaces between public policy and the voluntary environment of standardization*" (emphasis added). "Report From the Commission to the Council and the European Parliament On Actions Taken Following the Resolutions On European Standardization Adopted By the Council and the European Parliament in 1999", COM (2001) 527 final (9/26/01), at par. 35, p. 15.

[70] EU Directive 98/34/EC sets forth a procedure for issuing mandates to the recognized standardization organizations for the timely development of standards relevant to the public interest areas. "The purpose of the directive is *to prevent the appearance of barriers to intra-Community trade*; this basic instrument for the completion of the internal market has fulfilled its purpose by initiating a dialogue between the

but which, in actuality, is neither transparent nor inclusive. While it seems clear that EU legislators have themselves drafted proposed technical regulations for GMOs and chemical substances[71] with food and/or environmental safety as the declared objective, it is not yet certain whether they will do so with respect to the end-of-life cycle directives or other food safety-related directives. [72] In any event, no comfort should be derived from

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Commission and the Member States, by promoting cooperation among the Member States and by setting up an information network linking European and national standardization bodies" (emphasis added)." See: (http://www.db.europarl.eu.int_/oeil/oeil_viewDNL.Procedure.View?lang=2&procid=2576) Europarl website; "In the New Approach method, the European legislator combines the advantages of direct referencing (legal certainty) with those of indirect referencing (*avoidance of barriers to trade*)" (emphasis added). Dr. Gerhard Leibrock p. 3, 8, 11-12. The process for developing harmonized EU standards supporting New Approach legislation can be described as follows. "The elaboration and adoption of harmonized standards is based on the General Guidelines for Cooperation between the European standards organizations and the Commission signed on November 13, 1984, [which set forth] principles and commitments concerning participation of all interested parties (e.g., manufacturers, consumer associations, and trade unions), the role of public authorities, the quality of standards and a uniform application of standards throughout the Community". Id., at Sec. 4.2, 'Harmonized Standards'. Harmonized standards are adopted as follows: 1) "[After] consultation with the [EU] Member States, the Commission formally requests (issues a mandate to) the European standards organizations to present European standards [consistent with a New Approach directive]; 2) The European standards organizations will [usually] accept the mandate…[and through] a technical committee elaborate (joint) standards; 3) European standards organizations and national standards bodies *organize a public enquiry and the technical committee considers public comments* (emphasis added); 4) National standards bodies vote on the draft standards (as amended) and the European standards organizations ratify them; 5) European standards organizations transmit Member State references to the Commission, which, after verifying that the terms of the mandate have been fulfilled, then publish the references in the Official Journal [of the European Communities] -- such standards are subject to challenge by Member States or the Commission if they do not fully meet the 'essential requirements'; 6) National standards bodies transpose the European standard; and 7) National authorities publish references of national standards." [In essence, the] "European standards organizations are responsible for identifying and elaborating harmonized standards in the meaning of the New Approach and for presenting a list of adopted harmonized standards to the Commission. *The technical contents of such standards are under the entire responsibility of the European standards organizations*. Once public authorities have agreed upon a mandate, the search for technical solutions should in principle be left to the interested parties**.** [However,] *in certain areas, such as the environment and health and safety, the participation of public authorities on a technical level is important in the standardization* (emphasis added)". Id., at Table 4/1 'Standardization Procedure Under the New Approach'; Id., at Sec. 4.2 'Harmonized Standards'; Id., at Sec. 4.4, 'Withdrawal of the Presumption of Conformity'.

[71] The proposed REACH regulations were not promulgated pursuant to the New Approach. However, it is significant that the EU decided to directly promulgate rules in the form of regulations. Regulations will immediately have the full force and effect of law when adopted, presenting stakeholders with fewer opportunities for review and comment than would otherwise be available with respect to directives proposed under the New Approach. If a directive under the New Approach has been crafted, it would then have to be transposed into law by Member States through promulgation of regulations or standards. For one thing, the time span between proposal and adoption is much shorter in the case of regulations than it is with directives. As a result, the opportunity for industry stakeholder input in the process in the case of regulations is very limited. In the case of directives, there is first the process of adopting the directive, and then the process of adopting the regulation or standard.

[72] At least one EU member website suggests that the EU will not seek standardization of essential requirements set forth in the New Approach directives relating to chemicals, vehicles and pharmaceuticals. "The EU has also developed more detailed common rules in other areas, such as chemicals, vehicles and pharmaceuticals. Framework directives, supplemented by more specific provisions laid down in separate directives govern these areas. *In these areas, therefore, the European standards institutions are not mandated to draw up supplementary technical specifications*" (emphasis added). "Technical Barriers to Trade", Utenriksedepartmentet, Norway Ministry of Foreign Affairs. However, resort to European

the fact that certain New Approach directives have not yet been finalized. "In the case of new legislation it is not always essential to await its final adoption before issuing a [standards] mandate. A mandate based on a 'common position' makes it possible to save time as regards standardization".[73]

Furthermore, once technical regulations have been promulgated, the contents of any conformity assessment standards eventually developed and/or adopted by the European standards organizations must also be considered. EU standardization in the field of conformity assessment is well developed[74]and European standards may arise from one of several sources.[75]In addition, consistent with the New Approach, "…special conformity assessment procedures have been established describing the controls to which products must be subjected before they are considered to be compatible with the 'essential requirements' and thus placed on the internal market [i.e., before they can earn a 'presumption of conformity']."[76] These procedures are set forth pursuant to what is otherwise known as the 'Global Approach'.[77]

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harmonized standards is seriously being considered in the fields of food safety, Integrated Product Policy (IPP) and environmentally-friendly design of electrical and electronic equipment. See: COM (2001) 527 final (9/26/01), at pars. 23.2, 24.2 and 24.3, at pp. 10-12.

[73] "Role, Preparation and Monitoring of Standardization Mandates Within The Framework of the New Approach", Working Paper EC Directorate-General For Enterprise, Doc. SOGSN404FR, (Brussels 4/24/01), at Sec. 3.1, p. 12.

[74] The EU standardization process has been time-consuming and may entail well over several hundred standards per directive per product. There are currently harmonized standards programs in the areas of toys, non-automatic weighing instruments, gas appliances and simple pressure vessels. "In the machinery safety area more than 360 harmonized standards have been developed…More than 700 harmonized standards are envisaged in relation to the Directive on pressure equipment…the first harmonized standards on construction products have been agreed to…harmonized standards for cement, fixed firefighting systems, geotextiles, structural bearings and lifting plants are among this first group…" COM (2001) 527 final (9/26/01), at pars. 33-34 at p. 14. For a complete list of New Approach directives and harmonized standards, See: (http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist.html).

[75] "There are several ways to start making a harmonized standard. [1] An initial document comes from the International Electrotechnical Commission (80% of the cases). [2] A document of European origin arises in one of CENELEC's own technical bodies. [3] A first draft of a European document comes from one of CENELEC's Cooperating Partners. [4] A fourth source is the National Committees themselves…" "How a Standard is Made", CENELEC website, at: (http://www.cenelec.org/Info/about.htm ). In other words, standards sometimes are developed at the request of manufacturers seeking guidance on obtaining a presumption of conformity therewith and perhaps a CE marking. Not all New Approach directives provide for the CE marking. See: "Guide to the Implementation of Directives Based on the New Approach and the Global Approach", Tables 1/ 2, and 1/ 3, at p. 13.

[76] "The extent of controls a product must undergo varies according to the risk related to the use of the product. Requirements may vary from a declaration by the manufacturer stating that certain standards have been applied to extensive testing and certification by independent, third party conformity assessment bodies. A Council Decision (93/465/EEC) was adopted in connection with the "New Approach" directives, providing an overview of all the conformity assessment procedures available under the directives, divided up into modules and grouped by category of risk. The conformity assessment procedures also apply to products imported from outside the EEA". See: "Technical Barriers to Trade", Utenriksedepartmentet, Norway Ministry of Foreign Affairs.

[77] The Global Approach to Community-wide conformity assessment sets forth the following principles: 1) "Modules [are devised] for the various stages of conformity assessment procedures and…criteria [are established] for the use of these procedures, for the designation of bodies operating these procedures and for the use of the CE marking; 2) European standards relating to quality assurance and to the European bodies' fulfillment of quality assurance procedures are generalized; 3) Accreditation systems…and inter-

There is considerable concern among U.S. and other non-EU industry members (home country exporters as well as EU-based subsidiaries) that the EU standardization process fails to provide non-EU industry stakeholders with any more meaningful participation than that currently available within the EU regulatory process, including under the New Approach. The U.S. Government has taken note of these concerns since at least 2001. In connection with the draft EEE Directive it reported that "…European standards *and* regulatory development processes are not sufficiently transparent and open to non-EU stakeholder input."[78] In 2003, its comments became more specific.

> "…There are concerns related to the respective procedures, responsibilities (e.g., accountability, redress) and transparency *in both the Commission and the European standards bodies* that require careful monitoring and more frequent advocacy efforts…The European standardization organization, CEN, is in the process of drafting a standard for gas connector hoses…*the U.S. manufacturer has experienced considerable difficulties in gaining access to the standardization process,* and has been unsuccessful in countering assertions by the CEN Technical Committee that only fixed/welded connections can be considered safe methods for gas hose connectors…Both U.S. industry and the U.S. Government have argued in favor of performance based standards…and [have] persistently raised this case with national CEN members and Commission officials to press for more transparency and performance criteria in the CEN standardization process" (emphasis added).[79]

The U.S. Congress has also been apprised of the lack of transparency and inclusiveness within and the lack of accessibility to EU and other international standards organizations. In testimony previously given to the House of Representatives Science Committee, Subcommittee on Technology, Environment and Standards, the Chairman of the Board of Directors of the American National Standards Institute (ANSI)[80] stated that, "The U.S. has consistently argued in the WTO as well as in ISO, IEC and other international fora that the principles of transparency and openness that is practiced within ANSI are essential requirements in international standardization. The U.S. [ANSI] has strenuously

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comparison techniques [are established] at the national and Community levels; 4) Differences of existing quality infrastructures (such as calibration and metrology systems, testing laboratories, certification and inspection bodies and accreditation bodies) are minimized; 5) Mutual recognition agreements concerning testing and certification in the non-regulatory sphere are promoted; and 6) Mutual recognition agreements and cooperation and technical assistance programs [are utilized to] promote international trade. Id., at Sec. 1.1, 'Concept of the New Approach and the Global Approach'.

[78] See: "2002 National Trade Estimate Report on Foreign Trade Barriers", Office of the United States Representative (2002 NTE Report) at p. 116; "2001 Country Reports on Economic Policy and Trade Practices, European Union", Released by Bureau of Economic and Business Affairs, U.S. Department of State, Sec. 5, 'Significant Barriers to U.S. Exports' (Feb. 2002), cited in "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at p. 75, fn 327.

[79] "2003 National Trade Estimate Report on Foreign Trade Barriers," Office of the United States Representative, (2003 NTE Report), at pp. 111-112. Another difficulty that was cited relates to the EU Pressure Equipment Directive (PED), 97/23/EC, DN/IP/02/807 (6/4/02). The Report states that manufacturers of such equipment are concerned that they can no longer use ASME Code material specifications to demonstrate conformity assessment with the PED, even though there are only slight differences between European standards and those of the U.S. ASME Code. The report states, furthermore, that no European Approval of Materials (EAMs) requests filed thus far have been approved. Id., at p. 112.

[80] ANSI is the official U.S. representative to the International Organization for Standardization (ISO) and to the International Electrotechnical Commission (IEC) via the United States National Committee (USNC).

objected to the *'closed door'* approach of some organizations outside the U.S." (emphasis added).[81]

In fact, some members of U.S. industry have argued that the European standards setting process actually affords them *less* transparency, openness and inclusiveness than does the European regulatory process. This point was made in a recent letter submitted to the U.S. Commerce Department by the National Electric Manufacturer's Association (NEMA).

> "…New Approach Directives such as those relating to Chemicals and Environmentally Friendly End-Of-Use-Equipment (EuE)…would have significant impact on NEMA members' products. The chemicals proposal, while nominally not about our sector, features important implications and reporting requirements for downstream users…Typically these regulations are developed with procedures that are *not transparent* to all stakeholders, including the U.S. electrical manufacturing industry and other trading partners. Further, stakeholders have no way to hold EU authorities *'accountable'* for the regulations produced. In short, the EU's *regulatory* process fails to meet applicable international obligations set forth in the [TBT Agreement]. On a related level, *the important standards-setting bodies CEN and CENELEC are even more lacking in transparency and openness inasmuch as they absolutely deny access to participation by a U.S. interested party.* This is particularly significant when there is specific knowledge that the CEN/CENELEC standards resulting from New Approach directives will be developed into requirements" (emphasis added). [82]

These claims are not made without merit; a review of the websites of both CEN and CENELEC reveals that it is extremely difficult if not impossible for U.S. and other non-EU industry stakeholders, including ANSI, to gain a membership with actual voting rights in either organization. Where voting rights are available to U.S. and other non-EU industry members or national standards bodies, as in ETSI, they are circumscribed by detailed parliamentary rules such as 'weighted voting' and subject matter voting restrictions that effectively dilute the voting right itself.[83] Consequently, the ability of

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[81] Statement of Oliver R. Smoot, Chairman of the Board of Directors, ANSI, before the House Science Committee, Subcommittee on Technology, Environment and Standards, "Standards Setting and U.S. Competitiveness", (June 28, 2001) at p. 9.

[82] Comment Letter, dated December 5, 2002, to U.S. Department of Commerce, Office of Trade and Economic Analysis, from National Electrical Manufacturer's Association, in response to federal register notice for public comments in preparation of the Annual National Trade Estimate Report on Foreign Trade Barriers, cited in "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at pp. 75-76, fn 329..

[83] For CEN, "representation is secured first through the national standards bodies which have the duty of sending balanced delegations to the policy-making bodies and technical committees. [While] industry…also ha[s] seats in the various policy-making committees…the formal adoption of European standards is decided by *weighted majority vote* of all CEN *national members*…all are national standards bodies of EU or EFTA member countries or of countries likely to become EU or EFTA members…*The National Members are the 'only effective members*…There can be only one National Member per country….*Associates* are broad-based *European* organizations representing particular sectors of industry…They participate in the General Assembly *without voting rights*…*Affiliates* consist of the national standards bodies of Central and Eastern European countries which can in principle become members of the EU or EFTA and which therefore can become national members…*Affiliates have no voting rights*…The national standards organization of any country outside Europe or any country not eligible for membership [of the European Union or EFTA] may apply for status of 'Corresponding Organization' for a fee…[which will entitled it to a copy of all publications issued by CEN, including draft European standards and the ratified texts of adopted European standards" (emphasis added). ANSI is not listed as a

Corresponding Organization. See: "European Committee for Standardization, About CEN", at: (http://www.cenorm.be/default.htm ); (http://www.cenorm.be/boss/or000.htm ). For CENELEC, "the General Assembly makes all policy decisions…It is comprised of delegations from each of the twenty-two National Committees…*There is one National Committee for each [EU] country...The Technical Board is made up of one permanent delegate from each National Committee*. [It] decides on ratification on the basis of National Voting of draft standards prepared by the technical bodies. The Technical Board establishes Technical Committees with precise scope to prepare the standards…*[The National Committees are in effect the only CENELEC members]*. *Members* have *weighted votes* corresponding to the size of the country they represent (10votes for large countries like France, Germany, Italy and the UK; 1-2 votes for smaller countries). For ratification of a standard, the vote must yield a majority of National Committees in favor and at least 71% of weighted votes cast" (emphasis added). There are thirteen CENELEC *Affiliates*, one organization from each of thirteen countries that border the EU. *Cooperating Partners* consist of industry sector organizations located within the Euro region. *'Other Standards Organizations'* consist of the other two of the three recognized European Standards Organizations (CEN and ETSI) as well as the three recognized international standards organizations (ISO, IEC and ITU). Several EU Government Agencies also participate in and/or oversee the standards development process at CENELEC. See: "Info About CENELEC", at: (http://www.cenelec.org/info/about.htm ). For ETSI, "full membership may be obtained by a legal person…which is established in a country falling within the geography of the European Conference of Postal and Telecommunication Administration (CEPT)…[CEPT countries cover almost the entire geographical area of Europe]. *Associate membership* may be obtained by a legal person not established in a country falling within such geographical area and not eligible for full membership…*Associate Members have the right to participate in the work of ETSI by attending meetings of the General Assembly special committees and the bodies established within the technical Organization with the right to vote…Observership* may be obtained by a legal person entitled to become a full *or* Associate Member…Observers have the right to attend the meetings of the General Assembly *without the right to vote*…Associate Members have the right to vote on all matters EXCEPT where: 1) weighted National voting by National Delegations applies; or 2) weighted individual voting by *Full Members* applies. Weighted National voting shall apply… *in the case of the elaboration, approval and implementation of European standards. Weighted individual voting* shall apply [when]: *1) taking decisions on matters concerning documents intended for regulatory use by the EU [e.g., harmonized standards relating to New Approach directives]; 2) setting down standardization policies intended to meet the needs of the EU; and 3) taking decisions on priorities in the work program on matters that apply exclusively to the EU.* [*There are seventy-three U.S. companies serving as Associate Members. There is one observer – ISO/IEC JTC1 Secretariat U.S. – perhaps ANSI???]*...Each National Delegation shall inform the Director General of the recognized National Standards Organization have the exclusive responsibility for carrying out…the establishment of a National Position for the vote…A draft telecommunications standard (EN)shall be approved by weighted National voting…When the vote on a draft EN has taken place, a separate counting of the votes of the EU countries shall take place…The result of the separate counting shall determine whether or not the standard shall be adopted in the EU countries. A standard thus adopted in the EU countries shall also be adopted in other countries having voted in favor of the said standard…The deliverable shall be adopted for use *within Europe if at least 71% of the weighted votes cast by Full Members are positive*...For purposes of *weighted individual voting,* the votes of Associate Members shall have a weighting equal to the number of units of the 'class of contribution'…Contributions to ETSI…which are to be made by Full and Associate Members…[similarly] shall be proportional to the number of units of the 'class of contribution' applicable to its category of Membership…The class of contribution for Administrators will be determined by reference to country GDP. The class of contribution for Non-Administrators will be determined by reference to Telecommunication Turnover (TTO)– the worldwide turnover generated by all the Member's products and services for which ETSI is competent for developing standards…In the event it is not possible to identify a Member's annual TTO or its equivalent, then such Member shall contribute with one unit" (emphasis added). See: "European Telecommunications Standards Institute", at: (http://www.etsi.org ); (http://portal.etsi.org/portal_common/home.asp ); "Rules of Procedure of the European Telecommunications Standards Institute" Articles 1.2.3; 1.2.4; 11.2.1; 11.2.2; 13.1; 13.5; 13.5.3; 14.

and actually influence the development of EU standards is highly questionable. Therefore, it is unlikely that the EU's use and implementation of the precautionary principle through promulgation of regional regulations and development of complimentary standards pursuant to a top-down approach can be prevented. And given the breadth of the New Approach directives being developed and the EU's focus on standardization, it is only a matter of time before a critical number of agricultural and industrial sectors worldwide will be adversely affected.[84]

## V. Establishing the Precautionary Principle as a Norm of Customary International Law

Aware that the precautionary principle has not yet risen to the level of a general norm of customary international law[85], the EU has devised a three-dimensional trade strategy that is intended to lay the groundwork for its ascension. And, in order to achieve this goal, the EU seems poised to exploit the current debate concerning the scope of WTO law and its dispute resolution process that is taking place both within the legal and academic communities and civil society.[86]

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[84] "More than 20 directives are based on the New Approach…although the number of directives is low, the products covered by them represent a large proportion of products that are placed on the market. It is estimated that the trade of products covered only by the major sectors regulated by the New Approach directives largely exceeds the volume of 1500 billion euro (1.5 trillion euro) per year." COM (2003) 240 final (5/7/03), at p.3. See, also fn 31, supra.

[85] "Outside the international context, the precautionary principle remains difficult to apply in domestic tribunals, and its effect as a legal principle at the national level should not be exaggerated. In contrast, the body of international environmental law and policy contains many formulations of the precautionary principle. In this international context, it can at the very least be claimed an emerging principle of international environmental law. And, at best, a good argument can now be made that the precautionary principle has become a general principle of international environmental law." Halina Ward, "Science and Precaution in the Trading System", supra, at note 11, at p. 4. The EU Commission articulated a somewhat stronger view of the status of the precautionary principle within international law, during an April 2000 Codex Secretariat meeting. "…[W]hat is important to note is that the principle according to which responsible governments should act on the basis of precaution when there is established scientific uncertainty in order to achieve the chosen level of protection is so widely and universally accepted that it has already become a rule of customary international law in the areas of health and environmental protection. Consequently, some divergence in the terminology used in the various international conventions or agreements is no significance…It follows that, in accordance with the generally accepted theory of international law, the precautionary principle has already (or is in the process of) been crystallized as a customary rule of international law, because all the requisite elements of *usus* and *opinio necessitatis* in this case exist and have met with very strong, consistent and widespread acceptance. In any case, international law does not necessarily require that there should be a consistent and unanimous repetition over time of the acts or a conduct for a new customary rule to take shape and become acceptable." "Comments for the European Commission Services to the Codex Secretariat – The Role of the Commission's Proposed 'Precautionary Principle' in International Law", in Response to a Conference Room Document CX/GP 00/3-ADD.6, under Agenda Item 3.1, for the 15th Sess. Of the Codex Committee on General Principles (April 10-14, 2000), at Sec. E., par. 33, p. 4, at: (http://www.tradeobservatory.org/library/uploadedfiles/European_Commissions_Responses_to_Codex_on_tth.htm )

[86] Much has been debated about the scope and legitimacy of WTO law and its dispute resolution process in political terms. Some WTO critics have argued that, WTO legitimacy has been compromised by the privatization of decision-making by a standards-setting body comprised of persons though, unskilled in the technical nuances of WTO law, nevertheless engage in judicial activism through ambiguous or ambitious

interpretation of WTO agreements to create WTO common law. These critics have thus advocated architectural reform of the WTO to correct these and other deficiencies. See: John Ragosta, Navin Joneja and Mikhail Zeldovich, "WTO Dispute Settlement: The System Is Flawed and Must Be Fixed", at pp. 2-3. Other commentators have called for more fundamental changes to the WTO. While they have similarly characterized WTO law and process as a "delegation of governance to actors who are insulated from the rough and tumble of daily democratic politics…", they have argued for a more fundamental kind of institutional reform. They claim that, although it appears to reflect "institutions of representative democracy", the WTO has actually been "vulnerable to capture by the most powerful interests to demagogical manipulation, to rational ignorance and indifference to the public..." Consequently, it is alleged that the WTO has not kept pace with the growing role of non-State actors within the international political process. "The very notion of *governance* and the *problematique* of legitimacy and justice which has become so prominent today rests on the progressive obsolescence of the traditional model of international politics as inter-state diplomacy – that is the international version of delegation and insulation." In order for the WTO to regain its legitimacy within the new dynamic of global governance, these critics argue that it "needs to be more democratic [and] more political than [even] domestic institutions" (emphasis added). See: Robert Howse and Kalypso Nicolaidis, "No Global Governance Without Politics: Why the Legitimacy of the WTO Cannot Be Won By Architectural Reform But Demands a Political Ethics", Draft Paper prepared for Conference, Legitimacy, Democracy and Justice in International Governance, NYU School of Law (October 3-4, 2002), at pp. 1 and 3. See, also fn 45, infra. One commentator has viewed the relationship between public international law and WTO law, including its dispute settlement mechanism, in different terms. He has characterized it as involving a political decision rendered at the level of inter-State relations that focuses on whether and how to link non-trade issues to trade. "All 'trade and…' linkages are constructed, in the sense that the decision to link trade to other issues is always a political decision and is not otherwise determined by the nature of things. Governments link trade concessions to the satisfaction of other, non-trade policy interests, either politically or legally, whenever they find such linkage useful to the achievement of their goals. Linkages to trade may be unilateral ad hoc policies limited to a particular situation or type of situation… On the other hand, states may develop institutions, political or legal, to effect or constrain linkage in the future: these may be bilateral or multilateral. *Particular linkages may be, and are, constrained by international law, including WTO law*. These rules of international law have been established and validated through the normal, and presumably legitimate, processes of international legislation. However, they are neither complete nor immutable. Our continuing choice is institutional: what institutions, if any, with the authority to manage linkage--that is, to enable states effectively to negotiate and agree on linkage--will best allow us to achieve our goals?" (emphasis added). Jose E. Alvarez and Joel P. Trachtman, Symposium: "The Boundaries of the WTO – Institutional Linkage: Transcending Trade and…", 96 American Journal of International Law 77 (Jan. 2002), at p. 77. According to Professor Trachtman, "the question of linkage is, first, a question of allocation of jurisdiction horizontally among states and, second, of allocation of jurisdiction between states and international organizations, of subsidiarity. Third, and of growing importance, is the question of allocation of jurisdiction among international organizations. Today, because of the softness of their law and the weakness of their dispute resolution, as well as the imbalance between adjudicative capacity and legislative capacity in the international system as a whole, the WTO's competitors do not seem to be strongly contesting the WTO's authority, at least in formal terms. Informally, and in the world of nongovernmental organizations and public opinion, of course, the WTO's authority is strenuously debated. And the WTO itself recognizes that it might be more successful, or at least less vulnerable, if other organizations took on a greater role. Other organizations could increase their role in legislation--in establishing treaty norms--or in adjudication, raising either choice-of-law or choice-of-forum issues between themselves and the WTO. In either instance, they cannot do so without encountering the WTO. These encounters raise questions of institutional devices for the allocation of jurisdiction between international organizations." Id., at p. 88. See discussion at pp. 80-88. This conceptualization of the debate has been found lacking by others. "Attempts to distribute exclusive or shared competencies or jurisdictions to the level(s) of governance 'best' able to deal with the matter (howsoever defined) have been ineffective in addressing [political] legitimacy, and particularly accountability concerns about multi-level governance." See: Howse and Nicolaidis, supra, at p. 11.

In order to establish the precautionary principle as a general norm of international law, the EU must demonstrate that the EU Member States and most WTO members are actually employing the precautionary principle as matter of State practice and custom. This is a difficult burden to satisfy. The EU must show not only that the SPS and TBT Agreements (as multilateral treaties) reflect the intent of WTO members to adopt the precautionary principle as a WTO treaty norm (thereby permitting its broad use within national (regional) standards and regulations), but also that WTO members have actually adopted the precautionary principle as a matter of State regulatory and 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).

In general, international customary law consists of the regular practices and rules among States that States follow. These practices and rules become rules of international law when they satisfy two conditions. First, State practice must demonstrate that States engage in acts consistently within their borders and with other 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. Thus, something more than actual practice is needed to evidence that States are, in fact, doing or not doing something, and State actions must be based on more than morality, habit or convenience. Rather, States must be acting out of obligation; they must be acting because they believe that they must follow a rule.[87] Once a custom has become established, it is, with certain exceptions, universally binding, even upon States that did not participate in the formation of the rule. Since customary international law is based on the consent of States, treaties (such as the WTO agreements), as well, can become customary international law if they codify preexisting rules or crystallize or

[87] According to one commentator, "the theory of customary law defines custom as a practice that emerges outside of legal constraints and which individuals and organizations spontaneously follow in the course of their interactions out of a sense legal obligation. Gradually individual actors embrace norms that they view as requisite to their collective well being. An enforceable custom emerges from two formative elements: a) a quantitative element consisting of a general or emerging practice; and b) a qualitative element reflected in the belief that the norm generates a desired social outcome. The quantitative element requirements …concern both the length of time and the universality of emerging practice. Regarding the time element, there is generally no universally established minimum duration for the emergence of customary rules. Customary rules have evolved from both immemorial practice and a single act. Still, French jurisprudence has traditionally required the passage of forty years for the emergence of an international custom, while German doctrine generally requires thirty years. (citing G.I. Tunkin, "Remarks on the Juridical Nature of Customary Norms in International Law." *California Law Review* 49: 419 (1961); N.M. Mateesco, "La Cotume dans les Cycles Juridique Internationaux" (Paris 1947)). Naturally, the longer the time required to form a valid practice the less likely it is for custom to effectively anticipate intervention of formal legislation and to adapt to changing circumstances over time. Regarding the condition of universality, international legal theory is ambivalent…Rather than universality, recent statements of international law refer to 'consistency' and 'generality'. Where it is impossible to identify a general practice because of fluctuations in behavior, the consistency requirement is not met. Similarly, the more recent cases in international law restate the universality requirement in terms of 'increasing and widespread acceptance', allowing special consideration for emerging general norms (or local clusters of spontaenous default rules) that are expected to become evolutionarily stable over time." Franco Parisi, "The Formation of Customary Law", Presented at the 96th Conference of the American Scientist Association, George Mason University School of Law (Aug. 31-Sept. 3, 2000), at pp. 4-5, at: (http://www.gmu.edu/departments/law/faculty/papers/docs/01-06.pdf ).

otherwise settle developing rules. And, subsequent State practice following the execution of a treaty by a substantial number of States can also rise to the level of customary international law.[88]

## VI. Invoking the Precautionary Principle to Justify EU Regulations and Standards Not Based on Sound Science – Creative SPS/TBT Treaty Interpretation

The EU is determined to creatively interpret existing WTO rules so that they may be read to take into account non-science considerations such as politics, cultural and moral values and consumer interests. It has expressly stated that,

> "...[T]he WTO must be reformed...Its rulebook needs to be rewritten and civil society more closely involved so that environmental and social concerns can be considered alongside trade and development issues...In the EU's view...a new round of WTO negotiations should...address a number of civil society concerns, by clarifying WTO rules on trade and the environmental agreements, labeling, public health and the application of the *precautionary principle*..." (emphasis added) [89]

Should this view of the scope of WTO law ever prevail, it would undoubtedly result in the adoption and use internationally by caution-minded countries of a very broad form of the precautionary principle, one which does not require robust scientific evidence of harm prior to the imposition of protection measures. In other words, the mere perception of a hypothetical threat to public health and safety, animal welfare and/or the environment would trigger the imposition of the precautionary principle.

However, this does not appear to be all that the EU is advocating in connection with the Doha Round negotiations. The EU seeks not only to clarify existing WTO rules so that they protect the right of EU and WTO members to take precautionary measures, but also to change WTO rules to permit members to discriminate in favor of sustainable production by providing greater market access for sustainably-produced goods. In other words, the EU would like WTO rules to sanctify the use of the precautionary principle as a legitimate means of encouraging global sustainable development initiatives.

> "The EU wants a new WTO Round to have a strong environmental component so that trade and

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[88] See: Anthony D'Amato, "Trashing Customary International Law", 81 American Journal of International Law 101 (1987), at (http://anthonydamato.law.northwestern.edu/Adobefiles/a87a-trashing.pdf). According to Professor D'Amato, "A treaty is obviously not equivalent to custom; it binds only the parties, and binds them only according to the enforcement provisions contained in the treaty itself. However, rules in treaties reach beyond the parties because a treaty itself constitutes state practice…Treaties were indeed invented to harmonize competing interests without recourse to threats or forcible measures, and in this fashion are a much more civilized way of creating custom than the normal process…Under the rules of interpretation of international treaties, the subsequent practice of states can modify and change the meaning of the original treaty provisions."

[89] "Trade: Removing Barriers, Spreading Growth -- The European Union: A Global Player", The European Commission Delegation to Lithuania, at: (http://www.eudel.lt/en/eu_global_player/trade.htm ). See, also: "Implementing Policy For External Trade in the Fields of Standards and Conformity Assessment: A Tool Box of Instruments", Commission of the European Communities, Commission Staff Working Paper, SEC (2001) 1570 (9/28/01), at p. 5.

> environment issues can be addressed and resolved…Trade and environment policies can enhance sustainable development…The EU wants a new Round to be especially attentive to areas where boosting trade can help sustainable development, for instance by producing environmentally-friendly goods…*The EU believes it is better to encourage sustainable production by providing greater market access for sustainably-produced goods*, for instance, through lower tariffs or by eco-labels which help consumers identify environmentally-friendly products…*WTO rules allow Members to adopt measures necessary to protect human, animal or plant life, or health, or relating to the conservation of exhaustible natural resources. But there are some grey areas…The EU wants the relationship between trade and environment clarified and is pushing for an environmentally-friendly interpretation of the rules…There are three key areas where [the] rules need clarifying: eco-labeling, precaution and multi-lateral environmental agreements…The EU is urging the international community to accept its Life Cycle Analysis (LCA) – an essential component of the EU's labeling system.* The LCA approach means that all aspects of the production, potential use and disposal of a product should be taken into account when it is being considered for an eco-label. Policy makers apply the precautionary principle when scientific evidence regarding assessment of a risk to the environment or health is incomplete or contradictory, though action is in the public interest…Sometimes the potential risk is so great that we simply cannot wait until all scientists agree before acting. *The EU wants to ensure that WTO rules do not stop its members from taking precautionary measures*" (emphasis added). [90]

These statements have not gone unnoticed by American business. According to the Business Roundtable,[91]

> *"Several countries particularly the EU, are seeking to incorporate a new 'precautionaryprinciple' in the WTO that would weaken the sound scientific risk-based approach embodied in the WTO/GATT, and reflected in national legislation in many countries*. Such action would also greatly increase the ability of countries to take restrictive action under the guise of that 'precautionary principle'. Within the context of the WTO, precaution-related issues have been

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[90] "Trade and the Environment: Support Sustainable Development", DG Trade (Oct. 2001), at: (http://europa.eu.int/comm/trade/index_en.htm ). A recent EU strategy document expressly links the EU's reliance upon the precautionary principle with its broader agenda of promoting sustainable development. "…The Commission proposes that the [EU Sustainable Development] Strategy focus on a small number of problems which pose severe or irreversible threats to the future well-being of European Society: global warming…and climate change; severe threats to public health [e.g.,]…antibiotic resistant strains of some diseases, longer term effects of the many hazardous chemicals currently in everyday use, increasing threats to food safety…loss of biodiversity…Many of the challenges to sustainability require global action to solve them. Climate change and biodiversity are obvious examples…To achieve sustainable development requires changes in the way policy is made and implemented both at [the] EU level and in Member States…Sustainable Development should become the central objective of all sectors and policies…To assess proposals systematically better information is needed…. However, *in line with the precautionary principle*, lack of knowledge must not become an excuse for lack of action or for ill-considered action…The role of science and research is to help identify the nature of the risks and uncertainties we face, so as to provide a basis for solutions and political decisions. Policy makers have a responsibility to manage risk effectively and to explain its nature and extent clearly to the public" (emphasis added). "Communication from the Commission – A Sustainable Europe for a Better World: A European Union Strategy for Sustainable Development (Commission's Proposal to the Gothenburg European Council)", COM(2001) 264 final (5/15/01), at pp. 2-6.

[91] "The Business Roundtable is the association of chief executive officers of leading U.S. corporations with a combined workforce of more than 10 million employees in the United States. The Roundtable is committed to advocating public policies that foster vigorous economic growth, a dynamic global economy, and a well-trained and productive U.S. workforce essential for future competitiveness…The Roundtable believes that the basic interests of business closely parallel the interests of the American people, who are directly involved as consumers, employees, shareholders, and suppliers."" See their website at: (http://www.brtable.org/newsroom_about.htm ).

> raised in a number of committees and working groups including: the Committee on Agriculture; the Committee on Trade and Environment (CTE); the Committee on Sanitary and Phytosanitary Measures (SPS); and the Committee on Technical Barriers to Trade (TBT). Examples of precaution-related issues within the WTO include food safety labeling and non-trade concerns for agriculture" (emphasis added). [92]

The Business Roundtable, furthermore, believes that the EU is seeking to gain leverage at the Doha Round negotiations by holding back progress on agricultural issues until due attention is paid to its non-trade concerns, namely precaution.

> "[E]ven though precaution was not included explicitly in the Doha Ministerial Declaration as a negotiating objective, efforts are underway…*to use the Doha Development Round as an opportunity to expand the interpretation of precaution in the WTO*… In the WTO, the debate on labeling has primarily taken place in the CTE and TBT Committees. While the CTE agenda deals specifically with eco-labeling, the same issues that arise concerning the functioning of labeling in the environmental context are likely to arise in the context of food safety. The Committee on Agriculture has addressed non-trade concerns in the context of tariffs and other market access issues. Non-trade concerns (e.g., food safety, labeling, precaution, and animal welfare) threaten to negate improvements in agricultural market access negotiated in the Doha Round. There is a strong interrelationship and degree of interdependency among the various WTO committees and working groups, whereby, for example, a concession in the SPS committee could undermine market access gains in the Committee on Agriculture. Pursuing this strategy, some countries like the EU have threatened to forestall their concessions in agricultural negotiations unless their non-trade concerns (e.g., labeling and precaution) are met…" (emphasis added). [93]

Moreover, the Business Round Table believes that, "there is growing evidence that some WTO members will try to use the WTO/MEA negotiations as a 'backdoor' to justify a highly conservative, non-risk-based approach to precaution via provisions in MEAs. Similarly, there is a looming threat that governments will use MEAs as a vehicle to replace current science-based WTO rules with restrictive labeling and other obligations based on perceptions of potential harm and uncertainty…" [94]

## VII. EU (Regional) Regulatory Practice and the Precautionary Principle

The EU does not believe that the TBT Agreement's general mandate that industry standards be used as the basis for technical regulations (a bottom-up approach) goes far enough to address civil society's more specific concerns. Consequently, it has developed an extremely 'cautious' regulatory and standardization approach (a top-down approach) to protect potentially threatened European public policy interests.[95] According to the EU, while industry-based standards are important to facilitate trade, "standards cannot replace

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[92] "A Business Roundtable WTO Policy Paper: A Balanced Approach to Precaution and Risk", The Business Round Table (May 2003), at pp. 3-4, at: (http://www.brtable.org/document.cfm/922 ).
[93] Id., at p. 4.
[94] Id., at pp. 4-5.
[95] "...The TBT Agreement represents a major step forward. However, the breadth of its scope, and the number of its signatories, means that for practical reasons there must be a certain amount of 'lowest common denominator' in its regulatory approach. It should also be observed that there is considerable scope to improve its implementation." SEC (2001) 1570 at p. 10.

government responsibility to safeguard a high level of protection concerning health, safety and the environment."[96]

EU regulatory practice within recent years, especially with respect to food safety and GMOs[97] and high volume chemicals,[98] has gravitated toward a hazard-based rather than a risk-based approach to governance. There is increasing evidence that the EU premises regulatory treatment of and distinctions between products and substances on an administratively created presumption of hazard, which assumes a priori that certain products and activities are inherently hazardous to human health and safety, animal welfare and the environment.[99]

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[96] "European Policy Principles on International Standardization", Commission Staff Working Paper, Commission of the European Communities SEC (2001) 1296 (7/26/001) at p. 3. To the contrary, the prevalent view within the United States is to avoid resort to 'command and control' regulations until and unless it is absolutely necessary, given the drag that it places on domestic industry and U.S. competitiveness abroad. Instead, a great deal of reliance has been placed upon voluntary industry-based standards which have been able to meet market as well as government regulatory needs.

[97] An interesting pattern that seems to have emerged recently in the agricultural products sector is the promulgation of measures to regulate and manage the use of advanced technologies in the food chain. Examples of this include hormones used to promote beef production, chlorine and other antimicrobial treatments used to safeguard poultry production, the in-line pulp wash process used in the production of fruit juices, bioenzymes and other micro-organisms used in the wine fermentation process, and genetically modified seed, feed and food used in the production of grains, flours and produce. The focus on these areas by the recently released 2003 National Estimate Report on Foreign Trade Barriers, within the section entitled 'European Union', similarly suggests such a pattern. See: Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at pp. 10-16. The EU has banned (for more than ten years) U.S. beef exports derived from growth hormone-treated cattle, notwithstanding a WTO panel decision, subsequently upheld by the WTO Appellate Body, holding that such measures lacked a 'scientific justification' (there was no scientific evidence of health risk and no scientific risk assessment had been performed). See, also: Report of the Appellate Body on EC Measures Concerning Meat and Meat Products (Hormones), AB-1997-4, adopted on February 13, 1998, WT/DS26/AB/R; WT/DS48/AB/R (the EC Hormones case). See, also: "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at pp. 10-11. See, also: Proposal for a Regulation of the European Parliament & of the Council on Genetically Modified Food & Feed COM (2001) 425 final (July 25, 2001) (the 'GM Food and Feed Proposal'), implementing 2001/18/EC Directive On the Deliberate Release into the Environment of Genetically Modified Organisms; Proposal for a Regulation of the European Parliament and of the Council Concerning Traceability and Labeling of Genetically Modified Organisms and Traceability of Food and Feed Products from Genetically Modified Organisms ('the 'GM Traceability and Labeling Proposal') COM (2001) 182 final. See, also: "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at pp. 18-42.

[98] The EU regime proposed to regulate chemicals management within the EU was originally set forth in the EU Chemicals White Paper 'Strategy for a Future Chemicals Policy' (COM) 2001 88 final (Feb. 27, 2001). The proposal seeks to establish a single system for assessing existing and new chemical substances called 'REACH' (Registration, Evaluation, and Authorization of Chemicals). Certain provisions within the EU Chemicals White Paper proposal have been revised since their introduction. According a recent National Journal article, "The most recent version of the legislation relaxes testing requirements for polymers and so-called intermediates, the chemicals used in creating compounds; intermediates account for about 15 percent of all chemicals…The legislation is unlikely to emerge out of the EU before 2005. The Commission is expected to produce a final draft of 1,200 pages by the end of the year [2003], after which the legislation will go to the European Parliament and the environmental and trade ministers of the various member states". Samuel Loewnberg at p. 2263, supra.

[99] The New Approach requires that "…a wide range of products…be sufficiently homogeneous, *or a horizontal hazard identifiable*, to allow common essential requirements. *The product area or hazard concerned must also be suitable for standardization.* (emphasis added)" "Guide to the Implementation of

While the EU claims that it has engaged in the type of case-by-case scientific risk analysis prescribed by the WTO regime[100], it has actually utilized a far broader form of risk analysis that incorporates the precautionary principle into each of its several steps.[101] In other words, the precautionary principle has been utilized: 1) as a risk assessment tool to justify the establishment of an administrative presumption that identifies a general hazard potentially posed by a given economic activity to humans, animals and/or the environment; 2) to identify a legitimate public objective, namely the eradication of that potential hazard, which is premised on social and political considerations such as consumers' right to know and consumer distrust for European institutions of science and government;[102] 3) as a risk management tool to justify the creation and imposition of a regulatory framework deemed 'necessary' to fulfill that objective - namely the establishment of the highest level of protection possible for the European public. This framework manages the assessed threat by controlling the testing and authorization of given products within the EU and by regulating their subsequent introduction into the EU marketplace through imposition of onerous tracing and labeling rules; and 4) as a risk communication tool to justify to EU consumers through the media all that it has done on their behalf, namely its exercise of precaution in order to protect them.[103] For this reason,

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Directives Based on New Approach and Global Approach", European Commission, at Sec. 1.1. Furthermore, the "e*ssential requirements must be applied as a function of the hazard inherent to a given product.* Therefore, manufacturers need to carry out risk analysis to determine the essential requirement applicable to the product. This analysis should be documented and included in the technical documentation. Essential requirements define the results to be attained, *or the hazards to be dealt with*...The wording is intended to be precise enough to create, on transposition into national legislation, legally binding obligations that can be enforced, and to facilitate the setting up of mandates by the Commission to the European standards organizations in order to produce harmonized standards…" (emphasis added) Id., at Sec. 4.1 'Essential Requirements'.

[100] For example, SPS Articles 5.1 and 5.2 and WTO jurisprudence prescribe very detailed risk analysis rules that must be adhered to. See discussion, supra at p. 9, fn 22. Generally speaking, they require that regulatory treatment be based on actual risks or evidences of harmful exposure to existing or identifiable hazards.

[101] The nature of the risk analysis that must be performed under the Biosafety Protocol is very different than that required under the SPS and TBT Agreements. While the WTO regime emphasizes links to various scientific organizations and the idea of scientific justification is limited to natural science determinations of hazard or risk, risk assessments under the Protocol broaden the definition of science to include both natural science and social science. The significance of this distinction becomes apparent at the risk management stage -- under the WTO regime, science essentially makes the regulatory decision, while under the Protocol, science informs but does not decide regulatory matters. See: "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at p. 46-48.

[102] Politically influenced and constrained by environmental organizations and unnerved by consumer distrust stemming from previous European government public health debacles, it is arguable that the EU is attempting to manipulate the international trading system, harness the European activist community to its position and promote public misunderstanding of the use of high technology to improve the everyday lives of Europeans. An incidental (unintentional) and perhaps an intended benefit of these actions is the protection of ailing or otherwise lagging European industries such as biotech or chemicals.

[103] The EU has employed this 'self-justifying' principle most notably in connection with its proposed GMO and chemicals regimes. The NFTC study has largely found that the nonscientific rationale often invoked to justify these regulations and standards (i.e., *the precautionary principle*) has been widely accepted among EU institutions and member states, and seriously considered by many EU trading partners (e.g., Japan and Korea). This has largely occurred because of the failure of foreign governments to educate their citizens properly about the merits and uses of biotechnology in every day life. Public fears triggered by this lack of

U.S. and European commentators have claimed that the EU has employed the precautionary principle as a 'self-justifying' rationale in violation of the SPS and TBT Agreements.[104] It is arguable therefore that the precautionary principle as currently defined by EU regulatory practice is perceived, at least, within the European Community as a nascent norm of customary international law.

## VIII. EU Standards Practice and the Precautionary Principle

The EU, in addition, has sought to inject the precautionary principle into what it considers a flawed international standards development process,[105] recognizing full well that the ultimate goal of such a process is to create 'one applied [global] standard and one accepted [global] test for each product, process or service'. The EU has done so in several ways.

First, in light of the growing link between regional standards and regulations, the Commission has emphasized the need to involve all relevant stakeholders, including non-governmental consumer representatives and environmental interest groups (i.e., civil society) in the EU standards making process to ensure that environmental considerations are taken fully into account.[106] This practice, in turn, has resulted in more health and safety and environmental requirements being incorporated into EU regional regulations (e.g., end-of-life / life cycle initiatives).[107]

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knowledge (as in the case of biotech foods) are then exacerbated by the anti-biotech campaigns organized by environmental NGOs wielding substantial political influence (and energized by prior government health and safety debacles). As a result, foreign legislatures find themselves constrained by the popular support that these campaigns engender. This, in turn, prevents them from minimizing the extraterritorial and discriminatory impact that such regulations have upon non-host country industries.

[104] See, e.g.: "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at pp. 101-102.

[105] The EU finds the following defects in the international standards process: 1) "there is a proliferation of bodies… [i.e., governments, standards bodies, industry federations, commercial enterprises] that draw up conflicting technical specifications for international use"; 2) "it is painfully slow...it is difficult to establish timely responses to regulatory needs"; and 3) "there is no established mechanism by which governments can call upon international standards bodies (as distinct from intergovernmental bodies) to draw up international standards that can then be used in support of a common regulatory structure." SEC (2001) 1570, at pp. 18-19.

[106] The EU's effort with respect to standards appears related to a much broader concern articulated by some commentators that, "global power ha[s] come to reside to a great extent in those holding key positions in the knowledge structure – a claim bolstered with each stage of the rise of professional elites and of the scientific revolution (genetics, risk assessment, etc.). Reliance on the combination of trade law expertise and the scientific method (with its legitimacy enhancing claim to consistency, reliability and transparency) becomes the basis for deriving 'truths' on which to pass judgment over domestic policies. The problem for many today is compounded by the 'privatization' of decision making by standard setting bodies, international professional bodies and the likes, able to highjack the authority for their own purposes." Robert Howse and Kalypso Nicolaidis, supra, fn 31 at p. 2.

[107] EU end-of-life / life cycle initiatives include the EU Directives on Waste from Electrical and Electronic Equipment (WEEE) 2002/96/EC (Jan. 27, 2003); Restrictions on Use of Hazardous Substances (RoHS) 2002/95/EC; and End of Life Vehicles (ELV) 2000/53/EC, as amended by 2002/525/EC (June 27, 2002);and the Proposed Directives on Electrical and Electronic Equipment (EEE)/End-Use Equipment (EuE) 2000/55/EC (Sept. 18, 2000)/ Eco-Design for Energy Using Products (EuP) and the Green Paper on Integrated Product Policy (IPP) COM (2001) 68 final (Feb. 7, 2001). The idea is to "put environmental

Second, the EU has broadened and strengthened its regional standardization policy through use of cooperative agreements between the European political and technical communities (i.e., the European Commission, the European Free Trade Association and the three official European Standards Organizations (ESOs)). As a result, it has raised the profile of European standards both regionally and abroad. In addition, cooperative agreements reached between the European standards organizations and the international standards organizations have "offer[ed] [the EU] a systematic framework to *take over* international standards and/or to contribute to the international standards making process" (emphasis added). [108]

The 'bootstrapping' of international standards to EU standards (and vice versa) has effectively enhanced the EU's ability to incorporate the precautionary principle within international standards.[109] According to EC Enterprise Commissioner Erkki Liikanen, "In the global marketplace Europe is in a very strong position because it has *linked* European standardization as closely as possible to international standardization" (emphasis added).[110] In other words, the EU has "realized the value of [using] national and regional standards as *stepping-stones* to international standardization..." (emphasis added).[111] At least one commentator has noted that a similar phenomenon has been taking place within the Codex Alimentarius Commission, the international standards organization charged with developing international food safety standards. The Codex, for example, has been increasingly pressured by the EU "to move away from standard-setting based on scientific principles toward a precautionary approach".[112]

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protection into practice" by incorporating environmental requirements into regional standards. See: "Commission Marks World Standards Day With Focus on Environment and Standards", EU Institutions Press Release, IP/01/1408 (10/12/01), at: (http://europa.eu.int/rapid/start/cgi ).

[108] SEC (2001) 1296 at par. 26, p. 10. "Cooperative agreements already exist between international and regional or national standards organizations" include "the Vienna and Dresden Agreements between ISO and CEN [and between] IEC and CENELEC – [they] are useful examples how to enable for input, to avoid double work or to speed up standardization work. These agreements provide, if wished, for development in one body and approval, by parallel voting, in both. These agreements provide at the international scale for early information and the possibility to provide comments. Another example of a cooperative agreement is the one between [the International Telecommunications Union] (ITU) and ETSI..." Id, at par. 25. See, also: COM (2001) 527 final, at par. 49 at p.20.

[109] "Both Commissioners [Commissioner for the Environment Wallstrom and Commissioner Liikanen] thank the European standards bodies...for their excellent relations with the Commission and their partnership with the international standards organizations ISO, IEC and ITU. The Commission considers this close relationship to be an important lever for increasing the effectiveness of international standards in the promotion of trade and environmental considerations on a global scale." See: "Commission Marks World Standards Day With Focus on Environment and Standards", supra.

[110]"European standards provide a powerful means of enhancing the competitiveness of companies in Europe and creating the single European market. This success also ensures Europe a very powerful position in world-wide standardization." Ibid. Comments of European Enterprise Commissioner Erkki Liikanen. Ibid.

[111] According to the EU, while "generally regional or national standards should be aligned to the greatest possible extent to international standards...the value of national and regional standards as stepping-stones to international standardization should also be recognized." SEC (2001) 1296 at par. 9, p. 5.

[112] Frances B. Smith, "The Biosafety Protocol: The Real Losers are Developing Countries", James V. DeLong, Editor, National Legal Center For the Public Interest (2000) at pp. 22-23.

Third, the EU seeks to alter the composition of the international standards bodies themselves, and through them, the international standards ultimately adopted.[113] Consistent with European standards practice, it has sought to liberally interpret the provisions of TBT Annex 4. According to those provisions, "all relevant bodies of WTO members need to be provided with meaningful opportunities to participate in international standards development" and that "international standards need to be relevant and to effectively respond to regulatory and market needs as well as scientific and technological developments." In light of these requirements, the EU has sought to ensure the involvement of *any* interested stakeholder "including environmental and consumer interests" (emphasis added).[114] "From a European perspective, not only the standards

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[113] In other words, the EU seeks to expand the universe of interested stakeholder groups participating in the ISO so that social and environmental concepts such as the precautionary principle that are championed by the EU can be considered along with qualitative and technical standards to define how products are to be manufactured. The migration of environmental managements standards from the EU to the ISO has already occurred, and there is no sign of it abating. "ISO TC 207 has published international standards on environmental management systems, eco-labeling, life-cycle assessment, environmental auditing, and many others. The best known of these standards is the ISO 14001 Environmental Management System standard to which over 30,000 companies have obtained certification." "The Future of International Environmental Management Standards -- Standards and Trade – International Standards Policy", International Institute for Sustainable Development, at: (http://www.iisd.org/standards/policy.asp). The problem with this approach, however, is that it can lead to the further watering down of the WTO rules through the insertion of subjective and less precise 'soft' political, social and value-driven standards unrelated to a product's quality or performance (technical standards) that States may later adopt and implement as regulations. Such (harmonized) standards are likely to require extensive external stakeholder (consumer and environmental NGO) verification and auditing which, in turn, is likely to lead to the imposition of higher costs on industry. In addition, there should be concern that the establishment of international standards based on soft science without the requirement to conduct a risk assessment will lead to the creation of additional non-tariff barriers to trade. This is likely to occur if products are distinguished on the basis of whether NGOs are able to verify that companies have implemented such environmental standards. EU efforts to insert soft standards into the ISO have also yielded results in the area of corporate social responsibility. This is reflected in a recent report prepared by the Consumer Protection in the Global Market Working Group of COPOLCO, the Consumer Policy Committee of ISO. The report is entitled, "The Desirability and Feasibility of ISO Corporate Social Responsibility Standards" (Final Report, May 2002) [hereinafter referred to as the 'ISO CSR Report'], and it is based largely on a previous European Commission Green Paper entitled "Promoting a European Framework for Corporate Social Responsibility" [COM (2001) 415 final]. The ISO CSR Standards Report notes that the Green Paper "put forward a holistic approach to corporate responsibility, consisting of integrated management, reporting and auditing, quality in work, social and eco-labels, and socially responsible investment. [In addition, the Green Paper stated that] the role of voluntary approaches figures prominently although the report notes that *voluntary approaches are not a replacement for laws*." (emphasis added), ISO CSR Report, Sec. II.1.6, at p. 23. The ISO CSR Report, furthermore acknowledges that, "*In undertaking the development of CR management systems standards, it is clear that ISO would be entering a new era in standardization activity, moving away from the technical-oriented standards which were its initial focus of attention, toward 'softer' more variable and less precise notions of responsibility…*(emphasis added)*"* ISO CSR Report, Sec. III.13 at p. 82. Apparently, the EU has been successful in utilizing the international standards bodies as a venue to translate EU values on sustainable development and corporate social responsibility into nascent global norms that, together with MEAs, may ultimately serve as the basis for national regulation and State practice. (See, discussion infra).

[114] Section C, paragraph 8 of Annex 4 provides that, "All relevant bodies of WTO members should be provided with meaningful opportunities to contribute to the elaboration of an international standard." Section D, paragraph 10 provides that, "In order to serve the interests of the WTO membership in facilitating international trade and preventing unnecessary trade barriers, international standards need to be relevant and to effectively respond to regulatory and market needs, as well as scientific and technological

development process, but also the constitution of the bodies developing international standards plays an important role if public authorities were to use international standards as a basis for regulation."[115]

Fourth, the EU Government has participated in standards development within both politically and technically oriented regional[116]and international standards bodies, and has methodically expanded its reach and influence in each venue over time. In addition to "the classical international standards bodies" such as the International Standards Organization (ISO) and the International Electrotechnical Commission (IEC) that "have been established for many years...at the world level", the EU has also worked with intergovernmental (political and economic) organizations whose recommendations "in some industrial sectors...and often for historical reasons…are also considered as international standards. Such bodies are generally referred to as standardizing bodies and their work tends to be used as a basis for harmonization of [EU] legislation."[117] The Organization for Economic Cooperation and Development (OECD) is one such international organization that the EU has held out as a science-based international standards body whose position on chemicals it has relied upon in drafting its chemicals proposal.[118]

While the OECD can be viewed as a legitimate forum for the discussion and adoption of global chemical management principles[119], it has arguably been used by the EU as a

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developments..." "The principles for the development of international standards [set forth in Annex 4], although not explicitly comprising criteria applicable to the bodies that draw up international standards, ensure that participation in a particular international standardization activity is open to the relevant bodies of at least all WTO members. [They] stress that participation should take place, where possible, through one delegation representing the relevant standardization activity in the territory of a WTO member…From the Commission's point of view, international bodies that operate on the basis of national representation are suitable for implementing these principles". COM (2001) 527 final, at par. 46.2 at p. 19.

[115] SEC (2001) 1296, at par. 16, p. 8. "The Community considers the status of the bodies that draw up international standards important. Constitution as an international body is seen as a condition for guaranteeing impartial treatment of national positions and for ensuring consistency between international standards." COM (2001) 527 final, at par. 46.1 at p. 18.

[116] In fact, "three European standards organizations [have created closer links with regional standards entities in South and Latin America, such as with AMN, the Mercosur Association for Standardization". COM (2001) 527 final, at par. 48 at p.20.

[117] SEC (2001) 1570 at p. 18. The EU has strategically chosen to work within and among these particular organizations depending on the issues to be addressed and results desired (i.e., it engages in selective 'forum shopping').

[118] "The benefits of [EU- based] standards-receptive regulatory models have been subject to discussions in the OECD. In this field the OECD has analyzed and discussed some of their members' experiences with regulatory reform. It concluded that international harmonization of technical rules, for instance, through international standards may be one means of avoiding unnecessary barriers to trade". COM (2001) 527 final, at par. 46.4 at p. 19.

[119] According to the Report to the U.S. Congress on the Standards Code, "The Chemicals Program of the Organization for Economic Cooperation and Development (OECD) is responsible for much of the work that is expected to lead to broad international acceptance of test results. The Chemicals Program…has as its goal the harmonization of approaches to the control of toxic substances, primarily toxic industrial chemicals. Based on internationally agreed principles of 'good laboratory practices' (GLPs) and test guidelines, regulatory officials will be able to have confidence in the foreign data submitted to them." Report at p. 18.

vehicle to develop a regional hazard-based approach to high volume chemicals and to further sanctify the precautionary principle. At least one commentator has noted that, "parts of the EU Chemicals Strategy [e.g., the REACH proposal] were developed within the OECD…[whose] chemicals testing framework endorses hazard-based assessments…[and whose] documents try to present the 'precautionary principle' as part of customary international law."[120] And, certain OECD documents seem to confirm this allegation.[121] This view also appears to have been referenced within recent U.S. Government comments to the EU's draft chemicals regime. The problem, apparently, is that while the EU's REACH proposal is, in part, based on OECD principles that were adopted by member governments, including the U.S., pursuant to a consensus-driven process, it also transcends those very principles and is distorting of them. Consequently, the resultant neither expresses the original OECD consensus, nor reflects the application of sound science that was likely cited as the basis for it.

> "We continue to support multilateral efforts in the OECD to promote greater international regulatory cooperation and harmonization in the area of chemicals. We note that the Commission's approach in developing its [Chemicals] proposal has departed from this ongoing OECD cooperation. We suggest that the Commission approach should be consistent with international efforts and seek to complement activities that are underway at the national and international level to address the testing needs and risks posed by existing chemicals. We are

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[120] See: Eileen Ciesla, "Will the United States Let the European Union Regulate Our Chemicals Industry Through the OECD?", Competitive Enterprise Institute (CEI) (April 15, 2002) at p. 2, at: (http://www.cei.com ), citing John D. Graham, "The Role of Precaution in Risk Assessment and Management: An American's View", OMB, remarks prepared for "The U.S., Europe, Precaution and Risk Management: A Comparative Study Analysis of the Management of Risk in a Complex World", (January 11-12, 2002) at: (http://www.whitehouse.gov/omb/inforeg/eu_speech.html ), and "Uncertainty and Precaution: Implications For Trade and the Environment", OECD, COM/ENV/TD (2000) 114/REV1(May 1, 2001). See, also: "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at pp. 97-100.

[121] See: Organization for Economic Cooperation and Development (OECD), About OECD, Environment, "Chemical Safety - Chemicals Hazard/Risk Assessment; Chemicals Classification and Labelling; Chemicals Risk Management", at: (http://www.oecd.org/about/0,2337,en_2649_34365_1859424_1_1_1_1,00.html; http://www.oecd.org/about/0,2337,en_2649_34373_1845596_1_1_1_1,00.html ). See, also: "OECD Environment Strategy for the First Decade of the 21st Century", Adopted May 16, 2001. "This OECD Environmental Strategy…is intended *to provide clear directions for environmentally sustainable policies* in OECD Member countries, and will guide the future work of the OECD in the field of the environment…*Underlying the Strategy is a need to further develop environmental policy towards fostering sustainable development within and among OECD countries* in a way that is responsive to non-member countries in their search for sustainable development. The success of implementing this Strategy will therefore also depend on strengthened cooperation with non-member countries, including developing countries and countries with economies in transition…Four specific criteria can be defined for environmental sustainability: I. Regeneration…II. Substitutability…III. Assimilation…IV. Avoiding irreversibility…*When designing policies for environmental sustainability which operationalise these criteria, countries should apply precaution as appropriate in situations where there is lack of scientific certainty.* Principle 15 of The Rio Declaration on Environment and Development of 1992 includes the precautionary approach, and precaution has subsequently been addressed by various Multilateral Environmental Agreements (MEAs), such as the Framework Convention on Climate Change, the Convention on Biological Diversity and its Protocol on Biosafety, the Convention on POPs, etc. Policies and measures for environmental sustainability should also be implemented in a cost-effective manner, and contribute to the full and consistent application of the Polluter Pays and User Pays Principles" (emphasis added). Id., at pp. 3, 5-6.

> concerned that the Commission's proposal imposes an approach that could undercut progress achieved to date under these other programs, such as the OECD Screening Information Data Set (SIDS) program and the ICCA HPV initiative."[122]

Also, there is evidence that the EU is utilizing the good offices of the United Nations to project its standards-receptive regulatory model[123] and its social values globally as a universally legitimate doctrine grounded on the precautionary principle[124] in an attempt to join the issues of trade and the environment. Such efforts have been made in connection with and furtherance of the EU sustainable development[125] and corporate

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[122] "U.S. Comments On the EU's Draft Chemicals Regime", The United States Mission to the European Union, (Brussels 7/10/03), at pp. 4-5, at: (http://www.useu.be/Categories/Evironment/July1003USEUChemicalsComments.html )

[123] "The United Nations Economic Commission for Europe (UN/ECE), in particular its Working Party on Technical Harmonization and Standardization Policies, provides an interface between the regulatory and standardization community. For two years, an ad-hoc group of experts on standardization and regulatory techniques has been working on an international model for technical harmonization via the use of international standards". COM (2001) 527 final, at par. 46.5 at p. 19. The EU Chemicals White Paper also refers to work that the EU is involved in with the UN Conference on Environment and Development (UNCED). See: COM (2001) 88 final, at p. 9.

[124] The precautionary principle is articulated within Principle 7 of the Nine Global Compact Principles. Business enterprises must adopt these principles in some way within the sphere of their daily business activities in order to maintain their participation in the Global Compact. "*Principle 7: support a 'precautionary approach' to environmental challenges*". While this principle expressly uses the term 'precautionary approach' rather than 'precautionary principle' the underlying intent seems to be much broader - to incorporate and expand the soft norms contained within the international environmental legal regime as set forth in Rio Declaration Principle 15. The Global Compact website states that: "*The Secretary-General asked world business to support a precautionary approach to environmental challenges*. The essence of the precautionary approach is given in Principle 15 of the Rio Declaration which states: "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. *A key element of a precautionary approach is prevention rather than cure – it is more cost-effective to take early actions to ensure that the irreversible environmental damage does not occur.* This requires developing a life-cycle approach to business activities to manage the uncertainty and ensure transparency…Investing in production methods that are not sustainable, that deplete resources and that degrade the environment has a lower, long-term return than investing in sustainable operations. In turn, improving environmental performance means less financial risk, an important consideration for insurers…[There are several] ways to apply the precautionary approach. [They include] analyzing potential environmental impacts of production processes and products (technology assessment), building-in safety margins when setting standards in areas where significant uncertainty still exists, *banning or restricting an activity whose impact on the environment is uncertain*, promoting the best available technology, implementing cleaner production and communicating with stakeholders" (emphasis added). See, at: (http://www.wfsgi.org/_wfsgi/new_site/meetings/Meet_sum02/UN_Global_compact_progress/thenine.htm). (http://www.wfsgi.org/_wfsgi/new_site/meetings/Meet_sum02/UN_Global_compact_progress/prin7.htm).

[125] See, fn 90, supra, at p. 31. For example, the EU chemical substances policy is based on the need to achieve sustainable development. "This White Paper presents Commission proposals for a strategy on future chemicals policy in the Community *with the overriding goal of sustainable development*" (emphasis added). In general, the principle of sustainable development advocates that "all states and peoples shall cooperate in good faith and in the spirit of global partnership to conserve, protect and restore the health and integrity of the Earth's ecosystem in accordance with our common but differentiated responsibilities. Although we may each place different pressures upon the global environment and may possess different capabilities, we must nevertheless recognize our ultimate and joint responsibility to address environmental problems based on international consensus". Rio Declaration Principles 7 and 27. "Implicit within this notion is the conclusion that the earth's natural ecosystem is capable, with proper stewardship of

social responsibility agendas,[126]which serve as the basis of official policy within the European Community.[127] A common aim of these agendas appears to be the development of globally harmonized product and service[128] standards that can be used to make industry more accountable to society.[129] According to the views of European civil

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regeneration, and that it has the capacity to assimilate in response to physical and human phenomena." Herman Daly, "Sustainable Growth" An Impossibility Theorem", Chapter 14, pp. 267-73, Valuing the Earth. "This means that we need not abandon economic growth in order to achieve sustainability. Rather we are free to satisfy our economic needs provided we do not impoverish our successors." Robert Solow, "Sustainability, an Economist's Perspective", at p. 3 (Woods Hole Oceanographic Institute 1991), cited in 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) at pp. 69-70.

[126] In this regard, the EU is working very closely with the United Nations Global Compact Office to facilitate the development of new global sustainability standards through a new standards body called the Global Reporting Initiative (GRI). Supported by U.N. Secretary General Kofi Annan, the Global Compact Initiative is intended to provide a human face to the global market. It is essentially an international forum (a nesting network) for industry, governments and civil society to pursue, on a voluntary basis, socially responsible corporate activities. This is demonstrated through annual compliance with one or more of Nine (Shared) Principles that are based on a set of core human rights, labor and environmental values drawn from United Nations and international conventions. (See: http://www.globalcompact.org). The GRI was "informally established in 1997 by the Coalition for Environmentally Responsible Economies (CERES) and the U.N. Environmental Program (UNEP)…to provide a global sustainability reporting standard…The GRI's mission *as an international standards body***,** is to develop, promote and disseminate a generally acceptable framework for sustainability reporting – that is, reporting on the environmental, economic and social performance of organizations…" (emphasis added). "UN Inaugurates International Sustainability Reporting Body", Edie Weekly Summaries (4/12/02), at: (http://www.edie.net/news/Archive/5406.cfm ).

[127] Article 2 of the section on Principles within the EC Treaty states that the role of the EU is to promote "harmonious, balanced and *sustainable development* of economic activities" and "a high level of protection and improvement of the quality of the environment…" Article 174, Section 2 reiterates that the Community environmental policy "shall be based on *the precautionary principle* and on the principle that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay" (emphasis added). Also, Article 6 of the EC Treaty provides that "environmental protection requirements must be integrated into the definition and implementation of Community policies."

[128] The EU has recently published a report containing policy conclusions about the role of standardization in services. The report was prepared as part of a study commissioned by the European Commission in January 2002 (Contract no. 20010671), "to assess the current role of standards in the services sector [considering existing EU and ISO 9000 service standards], to identify future needs concerning service standards and to derive policy conclusions". See: Dr. Knut Blind, Fraunhofer Institute for Systems and Innovation Research, Germany, "Standards in the Services Sectors: An Explorative Study", European Commission, Enterprise Directorate-General, Conformity and Standardization, New Approach, Industries Under New Approach (April 2003).

[129] The EU has devoted considerable resources to and has focused on issues related to international standardization and CSR, and is very likely behind the evolving global movement to further develop and adopt the United Nations "Draft Norms On Responsibilities of Transnational Corporations and Other Business Enterprises With Regard to Human Rights". These "Norms are based on international human rights law and existing norms relating to transnational corporations and other business enterprises such as the ILO Tripartite Declaration of Principles concerning Multinational Enterprises and Social Policy, OECD Guidelines for Multinational Enterprises, the United Nations Global Compact, and the Draft United Nations Code of Conduct on Transnational Corporations". They were drafted by a working group of the United Nations Sub-Commission on the Promotions and Protection of Human Rights (its Working Group on the Working Methods and Activities of Transnational Corporations). (See: U.N.Doc E/CN.4/Sub.2/RES/2001/3). "The latest version of the Draft Norms can be found at E/CN.4/Sub.2/2002/13 (annex) (2002). In addition, the members of the Working Group also prepared the Commentary on the Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard

society, as reflected in the EU Green Paper on Integrated Product Policy (IPP),[130] companies are responsible not only to their shareholders but also to society at large (in their capacity as agents of transparency and consumer choice and as social and environmental 'stewards'). Indeed, the frequent aim of EU regulations and standards intended to address deemed environmental hazards relates to a perceived need to minimize potential and often unknown threats to the local environment or the 'global commons' before they can materialize by removing the often non-quantifiable 'externalities' that give rise to them.[131] The risk, however, is that the precautionary principle will be used (as it now is) by EU civil society to impose further pressure upon EU governments to enact trade-restricting mandatory standards or regulations, such as *social labeling*, that are likely to constitute additional non-tariff barriers to trade.[132]

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to Human Rights [Commentary] to serve as a reference for the practical interpretation and further development of the Norms. Both these documents have been widely disseminated to governments, intergovernmental organizations, non-governmental organizations, transnational corporations, other business enterprises, unions, and other interested parties seeking any suggestions, observations, or recommendations". See: (http://www1.umn.edu/humanrts/ataglance); (http://www1.umn.edu/humanrts/links/CommentApril2003.html). It is rumored that these Draft Norms will be approved and adopted by the subcommittee some time during August 2003, and will then be sent to the Office of the Secretariat of the High Commissioner for Human Rights for endorsement. It is not believed that the Draft Norms will be pushed up to the U.N. Human Rights Commission level for at least three years.

[130] The IPP reflects an extension of the concepts of producer responsibility and product stewardship that have been integrated into the ELV, WEEE and RoHS Directives and the proposed EEE/EuE/EuP directives. "The concept of consumer responsibility relates to the integration of costs occurring once the product has been sold into the price of new products. This [is meant to] encourage prevention at the design stage and allows consumers to bring back end-of-life products free of charge". Green Paper on Integrated Product Policy COM (2001) 68 final (Feb. 7, 2001), at p. 11.

[131] Generally speaking, environmental externalities are non-recoverable costs imposed on society in the form of pollution and misuse of natural resources incident to or as the result of the manufacture, use and/or disposal of products. These costs generally are neither reflected in the prices charged for the products nor absorbed by manufacturers. Environmentalists believe that, since externalities relate to products, such costs should be borne primarily by the manufacturers, processors, formulators, assemblers, and distributors of products. In this way, the externalities can be reflected in the prices ultimately charged for the products or services, thereby providing consumers with the choice of buying those products that are most environmentally friendly. EU policy on chemical substances and the proposed EU policy on climate change seem to reflect the need to de-carbonize and de-chemicalize the environment, respectively.

[132] While compliance measures remain voluntary at the present time, there is considerable pressure being applied by EU legislators and EU consumer and environmental NGOs to impose mandatory verification, compliance and reporting standards within the Global Compact initiative. Given the public mood in the EU and the fluid relationship between the Global Compact Office and other U.N. agencies, there is genuine concern within industry circles that such measures may ultimately serve as the basis for both EU (mandatory) regulation and international regulation. These concerns are not unfounded. While the European Parliament agreed in May 2002 "to a new European framework for corporate social responsibility [based on voluntary standards set forth within] European Commission proposals published in the form of a Green Paper… Euro MPs [nevertheless] underlined that legislation on company disclosure had a role to play." Consequently, "they voted [among other things,] : to set up a European CSR Forum to give rights to stakeholders such as consumer groups and NGOs to oversee policies alongside business and trade unions; to establish *a European Social Label* to endorse products where there is respect for human and trade union rights; to introduce the wider social and environmental impacts of companies' performance into negotiations between employers and trade unions; to make *all* EU financial assistance to business subject to compliance with *basic standards*, including setting up a blacklist of companies guilty of corruption; and to mobilize the EU's trade and development programs to tackle abuses by companies in

In sum, the EU is determined to incorporate the precautionary principle into the international standards development process upon which the SPS and TBT Agreements are based, and to change the composition of the international standards bodies themselves so that they reflect the interests of stakeholders that support the precautionary principle. The EU also utilizes political and economic bodies to accomplish this objective. If left unchecked, it will not take long for these efforts to cumulatively result in the proliferation of non-science-based international standards serving as the basis for national and regional health and safety, animal welfare and environmental regulations for other WTO members. As a consequence, the economic competitiveness of U.S. (and global) industry will be threatened [133] as the higher design, production and market entry costs incurred

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developing countries." According to one MP, the "preferred solution would be not to opt for a British or European standard, but to [instead] support the emerging Global Reporting Initiative (GRI). This is being developed through genuine multi-stakeholder consultation, and is potentially applicable throughout the world. The GRI has already decided to move its base to Europe and has revised its format in response to criticisms of its approach to labor issues. *Support for the GRI would mean the EU could use this voluntary standard as the basis for mandatory financial reporting requirements*" (emphasis added). Richard Howitt MEP, European Parliament Rapporteur on Corporate Social Responsibility, "European Parliament Votes For Regulation", appearing in "Human Rights and Business Matters, Business Group Newsletter, (Autumn/Winter 2002), at: (http://www.amnesty.org.uk/business/newslet/autumn02/regulation.shtml ). It was precisely these issues that were discussed during a recent Global Compact Policy Dialogue entitled, "Supply Chain Management and Partnerships" that took place in New York at the United Nations during June 12-13, 2003. Further evidence of EU efforts to link regional corporate social responsibility initiatives to external EU bilateral and regional trade and aid agreements (including the Cotonou Agreement) as well as with international standards and regulatory development at the U.N. (via the GRI and possible launch of a Global Convention on Corporate Accountability), ILO, OECD (e.g., through the improved implementation of the OECD's 1997 Convention Against Corruption and further development of OECD CSR standards) and WTO (via the establishment of international investment criteria and through the Doha Development Round negotiations) appears within a recent European Parliament report and resolution. See: European Parliament Report and Resolution On the Communication From the Commission Concerning Corporate Social Responsibility: A Business Contribution to Sustainable Development", (COM(2002) 347-2002/2261 (INI)), European Parliament Session Document Final A5-0133/2003 (4/28/03), at: (http://europa.eu.int/comm/employment_social/soc-dial/csr/sipade2.pdf ).

[133] The importance of ensuring the objectivity of science-based standards created by recognized international standards bodies as required by the TBT and SPS Agreements cannot be overstated. The ability of a country or group of countries to influence the development of these standards is critical to maintaining their global competitiveness. The current conflict between the EU and the U.S. is as much about the place of non-scientific considerations within international standardization bodies as it is about which standards and bodies should be recognized. Since the formalization of the international standards process, ANSI has had great difficulty convincing other nations to recognize standards that have been developed through the decentralized ANSI standards facilitation process by organizations such as ASTM, ASME, IEEC and NFPA because they "have not gone through the ISO/IEC process…Much of the rest of the world insists that only formal international organizations such as ISO & IEC should be recognized as international standards [bodies] under the WTO TBT Agreement." Statement of Oliver R. Smoot, Chairman of the Board of Directors, ANSI, before the House Science Committee, Subcommittee on Technology, Environment and Standards, "Standards Setting and U.S. Competitiveness", (June 28, 2001) at p. 9. The ultimate prize is the 'securing of the heights', so to speak, namely global harmonization around the standards they champion. This objective motivates States to choose among these organizations, thereby impacting the relative global statures of the organizations themselves. See: "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at p. 99. In contrast to regional and national standardization in Europe, ANSI does not itself develop standards. Rather, it works with accredited entities

regionally are reflected in higher wholesale and retail prices. If such businesses are then unable to pass on these higher costs to consumers they may lose critical market share which may ultimately cause them to withdraw their products from the affected marketplace altogether. This, in turn, would likely result in less consumer choice – the very antithesis of what the EU is arguably seeking to promote through regulation.

## IX. EU Bilateral and Regional Trade and Aid Practice and the Precautionary Principle

The EU has also endeavored to incorporate the precautionary principle directly and indirectly within EU bi-regional and bilateral free trade and preferential trade agreements (FTAs and PTAs). [134] Among the EC's trade objectives is "the adoption overseas [by EU trading partners] of standards and regulatory approaches based on, or compatible with international and European practices, in order to improve the market access and competitiveness of European products."[135] Indeed, one EU external trade policy document expressly indicates that European Community regulatory experience in protecting public policy interests such as health and safety, the environment, and consumers' interests, particularly its application of the precautionary principle, should be taken into account in negotiating such agreements.

> "...Developments in the Community's legal framework have propelled the EU towards improving the effectiveness of regulatory authorities in protecting an ever-increasing number of public policy interests such as health and safety, the environment, and consumers' interests. In this respect, it is worth mentioning the application of the principle of proportionality and the recent Commission Communication on the *precautionary principle*, where the Commission considers that the principle has a scope to cover measures for protection of human, animal and plant health in addition to environmental aspects" (emphasis added).[136]

Many of these bi-regional and bilateral and preferential free trade agreements have been executed with developing countries located "on the EU's periphery in Eastern Europe and the Mediterranean, countries linked to the EU's colonial past, South America and South Africa. These are countries in transition attempting to join the EU or developing countries dependent on the EU market for trade."[137]At least one commentator has noted that, "the

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which provide the 'deliverables'. It also ensures the necessary principles for standardization of consensus, due process and openness.

[134] "Beyond the role standards play for the functioning of the internal market and for contributing to the protection of public interest, they are also an important element in the Community's enlargement process and in external trade agreements...Whilst the character of the European Single Market and its political will to build it may be unique, it may be beneficial for third countries to understand and work with European principles. Especially countries engaged in efforts to set up or review a standardization system and its possible links with regulation may take an interest in European principles, as well as regions which want to further integrate." Id, at par. 7, at p. 5.

[135] SEC (2001) 1570 at p. 8, citing "Communication From the Commission on the Community External Trade Policy in the Fields of Standards and Conformity Assessment", COM (1996) 564 final (11/13/96).

[136] SEC (2001) 1570 at p. 5.

[137] Adrian van den Hoven, Jean Monnet Fellow at the Robert Schuman Centre for Advanced Studies, European University Institute, Draft Paper, "Enlargement & the European Union's Common Commercial Policy", presented at the 'Bigger and Better? The European Union, Enlargement Reform ESCA-C

main purpose of these bilateral arrangements [has been] to build developing country support for [the EU's] position in the WTO..." which presumably includes the adoption of the Biosafety Protocol and its implementation of the precautionary principle.[138]

The Cotonou Agreement executed between the EU and the African and Pacific Island nations contains an addendum requiring such a consideration.[139]Within the "Compendium of Cooperation Strategies" accompanying the text of the agreement it is mentioned that, "cooperation shall give priority in their activities to...a preventive approach on the basis of the *precautionary principle* aimed at avoiding harmful effects on the environment as a result of any program or operation..."(emphasis added). Indeed, a close look at the Biosafety Protocol's Ratifications list will reveal that forty-one of the fifty-one ratifications have been deposited by developing countries located within the geographic regions noted above.

The EU, furthermore, has endeavored to project the precautionary principle into its ongoing trade negotiations with the Mercosur countries (Argentina, Brazil, Paraguay and Uruguay). At least one commentator has argued that the EU has "… attempted to gain the support of the Mercosur members in the WTO" to counter the position of the U.S.[140],

While the EU's negotiators have thus far refrained from referring directly to the precautionary principle, at least one trade association representing "the EU poultry industry, which is the second largest meat-producing sector in the EU", has publicly called for its implementation in the name of ensuring food safety and animal welfare in connection with any future agreement.

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Conference (May 30-June 1, 2002) Toronto, CN, at pp. 17-18, at: (http://web.uvic.ca/ecsac/toronto/papers/on/line/pdf/7C_avandenhoven.pdf ).

[138] Id.

[139] See: Partnership Agreement Between the Members of the Group of African, Caribbean and Pacific (ACP) States and the European Community and Member States, Compendium on Cooperation Strategies – Sec. 4.2, Thematic and Cross-Cutting Issues – Environment", par. 138 at: (http://www.europa.eu.int/comm/development/cotonou/compendium/comp12b_en.htm ). The Partnership Agreement Between the Members of the Group of African, Caribbean and Pacific (ACP) States and the European Community and Members States (referred to as the Cotonou Agreement) covers seventy-seven nations and was signed in Cotonou, Benin on June 23, 2000. The agreement is valid for a period of 20 years. The European Commission has also entered into preferential trade agreements (Euro-Med Association Agreements) with certain Mediterranean countries (e.g., Morocco, Tunisia, Algeria, Jordan, Israel) pursuant to its Euromed Policy, the aim of which is to establish free trade agreements with all of the Mediterranean countries by 2010. The European Parliament, however, has strongly criticized the Commission for failing to expressly reference within its strategy "the need to draw up sustainability studies that would make it possible to assess the social and environmental impact of the economic measures provided for under the free trade area on the basis of the *precautionary principle*" (emphasis added). European Parliament, Opinion of the Committee on Industry, External Trade, Research & Energy for the Committee on Foreign Affairs, Human Rights, Common Security & Defense Policy on the Common Strategy of the EU on the Mediterranean Region as Laid Down by the Feira European Council of June 19, 2000 (C5-0510/2000—2000/2247(COS)) (1/11/01), at p.5, at: (http://www.europarl.eu.int/meetdocs/committees/afet/20010116/429140en.doc ).

[140] Adrian van den Hoven at p. 22.

> "Our view in a.v.e.c. (Association of Poultry Processors and Poultry Import and Export Trade in the EU Countries) concerning the EU-Mercosur negotiations is, given the current state of play, that the disadvantages for European poultry producers overweigh the advantages of a free trade agreement…If trade in poultry meat is liberalised, the EU poultry producers as well as its suppliers (animal feed, cereal) will be subject to fierce competition, which will be difficult to fend off…The Commission has indicated that whereas a liberalisation of trade cannot be achieved without detrimental effects on the main interests of EU agriculture, the sensitivity of agricultural products, such as poultry meat, will be taken into consideration. I take the liberty of proposing some measures, which could ensure that the EU poultry industry's interests are taken into consideration and that consumer safety is not jeopardised…First of all the EU should carry out a wide benchmarking exercise in the Mercosur countries in all the relevant fields (e.g. food safety, animal welfare, veterinary inspections, hygienic requirements) to compare the performance between these countries and between these countries and the EU. For instance, the Commission is in the process of establishing minimum standards for animal welfare on the basis of information from third countries… Secondly, we should only introduce a greater liberalisation of the poultry market, through progressive concessions within preferential tariff quotas, to the extent these exports comply with requirements pertaining to food safety, animal welfare, hygiene and environment. It is important that written declarations are made and control mechanisms (export certification programmes) introduced to verify compliance. In situations of doubt, the EU should apply the precautionary principle… Thirdly, we should ensure that imported poultry products are clearly and indelibly labelled providing the EU consumers with sufficient information about the origin of the product, the characteristics of the product, ingredients etc…" (emphasis added) [141]

Moreover, consistent with TBT Article 11[142], the EU recognizes that developing countries will find it difficult to participate in bilateral trade "until they have reached an adequate level of regulatory sophistication. The roles of technical assistance and capacity-building initiatives are [therefore] important in this area."[143] With this in mind, the EU has increased its bilateral and regional technical assistance to developing countries. However, the initiatives it has pursued are often intended to help establish national regulatory institutions and standards bodies that are then trained to prepare and adopt technical regulations and standards that are more stringent than objective science-based international standards. Technical assistance programs "can help developing

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[141] Henning Christophersen, "Some Aspects of Agricultural Trade Trade – The Case of the European Poultry Industry", II Conference With Representatives from the European Civil Society, Business Community & Academic Community on EU-Mercosur & the EU-Chile Association Negotiations (2/12/02), at: (http://europa.eu.int/comm/external_relations/mercosur/conf/hc.htm ). It appears that Mr. Christophersen is a Partner in KREAB, a consulting firm representing the interests of AVEC.

[142] TBT Article 11 provides that "Members shall, if requested, advise other Members, especially developing country Members, on the preparation of technical regulations…the establishment of national standardizing bodies…regulatory bodies, or bodies for the assessment of conformity with technical regulations…the establishment of bodies for the assessment of conformity with standards adopted within the requesting Member…and the establishment of institutions which would enable the relevant bodies within [requesting Members] to fulfill the obligations of [WTO] membership or participation." Arts. 11.1, 11.2, 11.3.1, 11.4, and 11.7. TBT Article 12.7 provides that "Members shall, in accordance with the provisions of Article 11, provide technical assistance to developing country Members to ensure that the preparation and application of technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles to the expansion and diversification of exports from developing country Members. In determining the terms and conditions of the technical assistance, account shall be taken of the stage of development of the requesting Members and in particular of the least developed country Members."

[143] This will ensure that "the necessary certification bodies, standards bodies, laboratories and other facilities exist and [are] sufficiently effective." SEC (2001) 1570 at p. 8.

countries to develop a regulatory, standards and conformity infrastructure, to encourage the adoption by developing countries of international *and European standards*, to improve their infrastructure and set up accreditation and standardizing systems, and to train officials in developing technical regulations and standards" (emphasis added).[144] According to DG Enterprise, "geographical areas of special interest are the Mediterranean countries (MED), the South-East European countries, the newly independent states of the former Soviet Union (NIS), the South American countries (MERCOSUR) and the South-East Asian countries (ASEAN). Presently, input and participation in the development of technical assistance in the WTO TBT Committee is of high importance."[145]

Evidence of EU efforts to indirectly inject the precautionary principle, as incorporated within EU regulations and standards, into bilateral trade and technical assistance initiatives can be found within two recent EU documents. One document sets forth a comprehensive strategy for future EU relations with ASEAN (the Association of Southeast Asian Nations) and the countries of Southeast Asia,[146] while the other sets forth a framework for trade facilitation between the EU and the ten Asian countries participating in ASEM (the Asia-Europe Meeting).[147] Both documents address the important goal of achieving regulatory cooperation and convergence (harmonization).

The Trade Facilitation Action Plan (TFAP) for ASEM, in part, focuses on promoting "continued alignment on international standards and conformity assessment [practices developed by ISO and IEC] for agreed priority product categories (electrical and mechanical equipment, machinery, telecom terminal equipment, medical devices), best regulatory practice for the telecommunications and electrical safety sectors [benchmarking]…, [and an initial] dialogue on environmental standards, including the area of environmental product standards, environmental management standards and

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[144] Id, at p. 20. Several case studies set forth within this document indicate the types of technical assistance that can be rendered. See: pp. 21-22.

[145] "External Aspects of the Internal Market – Technical Barriers to Trade: Technical Assistance", European Commission, Enterprise DG, at: (http://europea.eu.int/comm/enterprise/regulation/trade/tech_assist.htm ).

[146] The document is entitled, "Communication From the Commission: A New Partnership With South East Asia", COM (2003) 399/4 (7/9/03). "This communication, adopted by the Commission on July 9, 2003, proposes revitalizing the EU's relations with ASEAN and the countries of South East Asia." See: (http://europa.eu.int/comm/external_relations/asia/reg/sea.htm ); (http://europa.eu.int/comm/external_relations/asia/doc/com03_sea.pdf ). The ASEAN countries consist of Indonesia, Malaysia, Philippines, Singapore, Thailand, Brunei Darussalam, Vietnam, Lao People's Democratic Republic, Burma/Myanmar and Cambodia. See: "ASEAN, A Key Partner for Europe", at: (http://europa.eu.int/comm/external_relations/asean/intro/index.htm ).

[147] The document is entitled, "The Trade Facilitation Action Plan" (TFAP), Concrete Goals 2002 – 2004" (1998). Its purpose has been to "reduce non-tariff barriers, increase transparency and promote trade opportunities between the two regions…" See: "Framework for Trade Facilitation Action Plan (TFAP)", at: (http://europa.eu.int/comm/external_relations/asem/other_activities/tfap_02_04.pdf ) Seven of the ten Asian countries are also members of ASEAN. They are Brunei, Indonesia, Malaysia, the Philippines, Singapore, Thailand and Vietnam. The remaining three countries are China, Japan and South Korea. See: "The Asia-Europe Meeting (ASEM) – Overview", at: (http://europa.eu.int/comm/external_relations/asem/intro/index.htm).

environmental measurement standards."[148] It also focuses on "simplification and rationalization of quarantine and SPS procedures…enhancement of transparency, [and] the interaction between risk assessment and risk management [in the context of food safety]", as called for by international standards developed by IPPC, Codex Alimentarius and OIE.[149]

Similarly, Annex III of the ASEAN strategy document entitled, "Menu For A Strengthened Dialogue With South East Asia", focuses, in part, on the importance of the many countries…exporting food products to the EU market…to comply with *European* [SPS] standards…and the need to increase [their technical] capacity [to do so]…the enhancement of regulatory cooperation on industrial products…to facilitate trade while safeguarding a high level of health, safety, environment and consumer protection…by increasing compatibility and the importance of bridging gaps in the area of standards, conformity assessment procedures and technical regulations" (emphasis added).[150]In addition, the strategy seeks to promote the "implementation of sustainable development… [through] future cooperation on climate change and energy efficiency, environmental and clean technologies, capacity building in implementing and negotiating *multilateral environmental agreements*..." (emphasis added).[151]

The EU's evolving political and economic relationship with China, furthermore, reveals both a bilateral trade component and a development (technical assistance and capacity-building) component as discussed above. Their common *stated* objective is to "support…and sustain…China's economic and social reform process…while integrating China further into the international community and world economy."[152] According to the EU's Country Strategy Paper for China, a significant part of the EU's development efforts will be to

> "Help China build the institutions, policies…*regulatory framework, standards*…and other supporting instruments that constitute the fabric of a modern outward looking economy…In particular, programs to support the changes to the rules, *regulations* and norms *and standards* which are required in view of China's accession to the WTO will be implemented…Actions in specific innovative industrial sectors in which China is an important global player, such as aeronautics and information society and its technologies may be developed, and collaborative projects to support future policies and *integration into China of EU technical standards*, in such

[148]"The Trade Facilitation Action Plan" (TFAP), Concrete Goals 2002 – 2004", at pp. 4-5.
[149] "The Trade Facilitation Action Plan" (TFAP), Concrete Goals 2002 – 2004", at pp. 5-6.
[150] COM (2003) 399/4 (7/9/03), at pp. 32-33.
[151] Id., at pp. 42-43.
[152] "Commission Working Document - Country Strategy Paper 2002-2006 & China and National Indicative Program 2002-2004", European Commission, IP/02/349 (Brussels 3/1/02), at pp. 4-5. "The Country Strategy Paper (CSP) for China…sets out the framework for EU cooperation with China during the period 2002-2006." See: (http://europa.eu.int/comm/external_relations/china/csp/index.htm ). See, also: "Communication From the Commission To The Council And The European Parliament, EU Strategy Towards China: Implementation of the 1998 Communication and Future Steps for a More Effective EU Policy", COM (2001) 265 final (Brussels 5/15/01); "Report From the Commission To The Council and the European Parliament On the Implementation of the Communication 'Building a Comprehensive Partnership with China'", COM (2000) 552 final (Brussels 9/8/00); "Communication Of the Commission, A Long Term Policy For China-Europe Relations", COM (1995) 279 final (Brussels 1995).

> areas as the environment, energy, transport, food safety and consumer protection may be supported" (emphasis added). [153]

"On commercial issues, actions proposed would be in line with the trade policy of the EU and the common interest of China and the EU in the WTO".[154] In addition to services,

> "Particular consideration will also be given to the inclusion of the area of *phytosanitary standards* and inspection, with a view to bringing Chinese standards and inspection procedures in line with the WTO SPS Agreement and *relevant international practice*. In addition, attention will be paid to the area of technical barriers to trade in line with the WTO TBT Agreement and *relevant international practice*. Elements in the TBT domain that could be addressed would include *technical regulations, standardization,* conformity assessment (including accreditation), metrology and information exchange in such sectors as medical devices, construction, machinery and electrical products" (emphasis added). [155]

One of the most obvious benefits that the EU is likely to derive from this strategy is increased bilateral trade with China. The EU may also benefit by ensuring a level playing field, to the extent product supply chains originating in China satisfy the same strict environmental, health and safety requirements applicable to domestic EU industry.[156]

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[153] IP/02/349, at p. 26. Furthermore, consistent with current EU development policy, "Europe should offer its environmental energy know-how to China to help develop efficient and clean industrial processes and energy production…The EC should in particular help China integrate environmental priorities such as the prevention of industrial pollution and greenhouse gas emissions, and the conservation of biological diversity further into national economic policy-making processes…" Id at p. 28. Also, EU environmental efforts also deal with "global issues that cannot be solved at the national or even European level. Activities will benefit China, the EU, both sides' citizens and companies and the world as a whole, in contributing to the reduction of pollution, prevention of climate change, the preservation of natural resources and the conservation of biodiversity." Id., at p.30. In fact, one of the primary stated objectives underlying EU efforts to help China integrate into the world information society, is the "promot[ion of] the EU branding (covering EU policies, regulatory frameworks, technologies, industrial practices, etc.)". The "program targets issues such as policy, *regulation, standardization,* conformity assessment…" (emphasis added). Id, at pp. 56-57.

[154] Id., at p. 30.

[155] Id., at p. 55.

[156] It is quite likely that the EU is seeking to export the precautionary principle and to impose extra-territorial process and production (PPM)-based regulatory standards upon foreign industries, in part, to shore-up its product supply chains. The EU Directives on Waste Electrical and Electronic Equipment (WEEE) and the Restriction of the Use of Certain Hazardous Substances (RoHS) in electrical and electronic equipment, as well as, the End of Life Vehicle Directive (ELV) will leave manufacturers throughout the supply chain to cope with a number of problems. See: "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at pp. 67-79. See, also: Abstract For Asian Green Electronics Conference (AGEC) and the International IEEE Conference on Asian Green Electronics Scheduled in Hong Kong for Jan. 5-6, 2004, at: (http://www.ee.cityu.edu.hk/~agec/short.htm ). One of the segments of this conference will address supply chain management. An abstract of this segment prepared by four European professors from the Fraunhofer Institute for Reliability and Microintegration, Berlin, Germany reads as follows: "*Asian companies are intensively integrated in supply chains for manufacturing of electronic products. The large international companies, which also supply the Japanese and European market, will pass the new demands for products to their Asian (sub-)assembly manufacturers in the near future. As a result of adoption of the European directive on the use of certain hazardous substances in electrical and electronic equipment at the beginning of 2003 a transition to lead free products with high quality and reliability has to take place in China till July 1, 2006 as well*. Another issue is the European directive on waste from electrical and electronic equipment. Certainly, this directive influenced the

This outcome, however, is dependent, in part, on the EU's ability to persuade China to adopt the precautionary principle as part of its environmental and trade policy and practice in order to facilitate harmonization and implementation of Chinese and EU regulations and standards.

A recent report on EU-China Science and Technology (S&T) Relations indicates how the EU has methodically sought and actually helped to shape China's regulatory policy and practice and to bring it into line with that of the EU.

> "In the last two years, the period concerned by this report, EU-China S&T relations have made a large step forward - both in terms of policy and of its operational consequences… Our S&T relations clearly contribute to the overall positive political relations between the EU and China… The INCO programme has successfully supported selected policies like health, environment, food security and safety, sustainable agriculture, and overall policy development research. *It has contributed to move China towards European models: China has a de-facto moratorium on GMO food, uses European car emission standards, supports bio-energy and sustainable agriculture, and even China tries to copy elements of our way to manage the Framework Programme…Our projects already show an impact on regulatory activity in China…* Trade issues are increasingly reliant on scientific support, like radiation emissions of mobile phones, certified BSE free cosmetics, or hormones in chicken meat… *China's policies for GMO food follow the EU positions closely and are subject to strong pressures from the US"*(emphasis added). [157]

These EU efforts and the potential for increased trade may have perhaps motivated China, in January 2002, to issue strict rules implementing EU-like regulations on agricultural biotechnology safety, testing and labeling. In the absence of U.S. Government intervention , those rules would have seriously impacted U.S. soybean exports.[158] "Among other things, the regulations require a new Chinese government

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activities of the Chinese government to prepare a similar ordinance. According to this the responsibility for take back and recycling of discarded products and the costs will be put on the manufacturers. In order to reduce the costs and to profit in the global competition by their marketing electronics industry is thinking about Design for Environment or/and Design for Recycling and invests extensive resources in the optimisation of Green products. In this seminar we will help to prepare Chinese companies for transfer to eco-efficient products and processes. Starting from future legal requirements and other frameworks for electronics and the environment an overview of the status quo in this field will be shown. Improvement potentials and case studies will be presented. Special lectures will be held on: *Sustainability, Supply Chain in Electronics and Future European Directives i.e. EuE (EU directive on establishing a framework for eco-design of end use equipment); Legal Requirements and Environmental Optimised Manufacturing of PCBs and Semiconductor components; RoHS (EU directive on restriction of use of certain hazardous substances in electrical and electronic equipment) and Demands on Green Products, especially lead free; and WEEE (EU directive on waste from electrical and electronic equipment) and Recyclability of Electronic Products"* (emphasis added). Id.

[157] See: J. Sanders, EU Science Counsellor Beijing, "EU-China S&T Relations", (Nov. 2002), at: (http://europa.eu.int/comm/research/iscp/countries/china/cn-doc5.pdf ). "…European companies are rapidly building up research facilities in China. Sectors especially interested to extend the Framework Programme into China are: IT, aeronautics, automotive, pharmaceutical, and biotechnology… Our significant biotechnology networks with China have now led to a number of collaboration projects, in addition to a number of INCO projects. The new EFBIC accompanying measures project promises a more pro-active approach. The CNCBD (China National Center for Biotechnology Development) will propose a list of about 20 top projects for EU collaboration…" Id.

[158] "Following high-level U.S. interventions, in March 2002, [China's Ministry of Agriculture] MOA issued 'interim measures' to allow imports to continue until December 20, 2002…Following [another]

agency to issue safety certifications attesting that the products are *harmless* to humans, animals and the environment before the commodities are cleared for import" (emphasis added).[159] These factors may also have influenced China's decision to propose EU-like national regulations that would control the use of hazardous substances in electrical and electronic equipment that will adversely affect U.S. industry interests. The A*e*A has reported that "[t]he Chinese Government proposes regulations to eliminate the use of lead in electronics products…[the] draft regulation[s]…would require U.S. high-tech companies to eliminate the use of certain hazardous substances in their products (including lead) and to recycle waste electronics. These draft regulations entitled, 'Management Methods for the Prevention and Control of Pollution from Production of Electronic Information Products' referred to as "China RoHS," [are] based on an early draft of a recently passed European Union law. [The Ministry of Information Industries] MII intends to host a conference on this draft from July 15-17 in Beijing and to adopt a regulation by the end of this year."[160]

According to the Electronic Industries Alliance (EIA),

> "This news is disturbing for two reasons. *First*, it illustrates that *some developing countries are now looking to the EU as models for environmental regulation.* Second, the Chinese proposal does not currently include exemptions and, therefore, the industry could face two RoHS Directives – one in Europe and one in China and both requiring different things. EIA has also learned that Chinese officials may seek to add other environmental requirements to the proposal including recycling mandates, labeling provisions, and design requirements, which makes this proposal very troubling…. *Perhaps even more worrisome is the fact that Europe, which often imposes the most stringent product design requirements on the electronics industry, is actively proselytizing other countries to adopt similar standards. The thought that non-science-based product regulation*

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high-level U.S. intervention in September 2002, MOA published new interim measures that delayed implementation…until September 30, 2003. Substantial concerns with China's biotechnology regulation and implementing rules remain, particularly with respect to risk assessment (including administration of field trials), labeling and inter-ministerial coordination of biotechnology policy." See: 2003 NTE Report at p. 56. "China has not presented any science to support these regulations. As drafted these regulations fail to provide a transparent and predictable framework for exports and importers…China's new regulations are of great concern to U.S. soybean exporters. Last year [2001], China accounted for more than 20 percent or $1 billion worth of all U.S. soybean exports." "Joint Statement of U.S. Agriculture Secretary Ann M. Veneman and U.S. Trade Representative Robert B. Zoellick Regarding China's Biotechnology Regulations (2/7/02), at: (http://www.usda.gov/news/releases/2002/02/0039.htm ). U.S. exporters and officials [were] concerned that the new regulations could be used to block imports and to protect China's own emerging biotech sector…" "Row Over China's Biotech Regulations", On the Plate, (2/8/02), at: (http://www.foodstuff.org/News/OnThePlate/OTP020208.htm#G ). Although "China has yet again delayed the imposition of [these] rules …until April 20, 2004", it has already triggered reluctance among many U.S. soybean traders "to line up more purchases for arrival in China later this year [2003]. "China Extends Interim Import Rules Until April 2004", Pesticide News Briefs for the Week of May 25, 2003, at: (http://www.pestlaw.com/news/newadd/20030525.html ).

[159] "Thomas C. O'Connor, Randall C. Gordon, "Agricultural Biotechnology – Who's Deciding the Rules of the Road?", National Grain and Feed Association, Vol. 20, No. 1 (2/7/02), at p. 7, at: (http://www.ngfa.org/members/focus2-7-02.pdf ).

[160] "Product Design: Regulation of Materials in Electronics Products", A*e*A, Technology Business Issues Update,Vol. IV, Issue Eight (7/11/03) at: (http://www.aeanet.org/PressRoom/gamb838_TBIU_24.asp.)

*could spread to a large, emerging high-tech market such as China is a real concern for our industry"* (emphasis added). [161]

A less obvious but, perhaps, more significant motivation for expanding the EU's economic and political relationship with China may be the EU's desire to cultivate China as an ally at the WTO[162], particularly with respect to the issues of trade and the environment, sustainable development and the precautionary principle. The EU has endeavored to table these issues during recent Doha Round negotiations. This would be consistent with current EU bilateral trade and technical assistance practice with smaller developing countries.[163]That practice has arguably resulted in the ratification by a large number of developing countries of two multilateral environmental agreements, the Biosafety and Kyoto Protocols, which endeavor to expand the definition of the precautionary principle.

Comments made by EU Trade Commissioner Pascal Lamy on a trip to China during October 2002 suggest that this might just be what the EU has in mind.

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[161] ). "Chinese RoHS Proposal - Chemical Restrictions", A Public Policy/ Legislative Issues Update, Electronic Industry Alliance (EIA), (May 2003), at: (http://www.ecaus.org/pdf/eia_policy_may03.pdf ); See, also: Terry Costlow, "Making Recycling and Reuse More Efficient: Tough New Regulations Call for Engineers to Think Green", Today's Engineer, May 2003, at: (http://www.todaysengineer.org/May03/green.asp.) "Governments around the globe are tightening measures aimed at keeping electronic products out of landfills by demanding that companies find ways to lengthen the products' life cycles and make them less harmful to the environment... *Europe continues to be a driving force in the green movement.* Legislators there have adopted two regulations that will affect every electronics company that ships products to Europe… International interest in ecology continues to rise, even among countries that traditionally looked the other way. *China, whose lax laws have made it a veritable dumping ground for electronic products and other harmful materials, has taken uncharacteristically aggressive action*. It [is proposing to adopt] RoHS in its strictest form and does not plan to allow any of the exemptions or extensions that are already softening the regulation's impact in Europe. China's strict adherence to RoHS may pose "a real problem" in the coming years for companies that export RoHS-targeted goods to China, Guhl said" (emphasis added).

[162] The EU believes that it is crucial to build a broad long-term relationship with China for the following reasons: 1) It is the world's seventh largest economy and the world's tenth largest exporter; 2) China is the EU's fourth largest trading partner and the EU is China's third largest trading partner; 3) Since 1998, the EU has been China's biggest foreign investor (excluding Hong Kong) – China is the world's third largest recipient of foreign direct investment (FDI) after the U.S. and the EU; 4) China's accession to the WTO, which means that China will require EU assistance in developing its capacity to respond to WTO requirements, either stated or implicit, at the international agreement level; 5) China's permanent seat on the U.N. Security Council and its increasing political role on the international stage, particularly as spokesperson for the developing world; 6) China is the world's second largest consumer of energy and the third largest producer – the size of its energy sector renders the country's energy policy and its potential impact on the world scene a matter of great international importance, particularly in the matter of air pollution and climate change; 7) China and the EU are signatories to several multilateral environmental agreements and have a mutual interest in pursuing common objectives; and 8) China is interested in supporting a global multipolarity and resisting perceived U.S. hegemony - Although China shares a growing mutual commercial interest with the U.S., it is also facing difficult political differences with the U.S., thereby prompting it to seek new strategic partnerships (e.g., with Russia) and to develop new economic ties. See: "Commission Working Document - Country Strategy Paper 2002-2006 & China and National Indicative Program 2002-2004", European Commission, IP/02/349, at pp. 11-12,16, 63-65; COM (2001) 265 final, at pp. 6-7, 12-13.

[163] See: discussion supra, beginning at p. 43.

> "I would like to say a word about the importance of the growing collaboration on the [Doha Development Agenda] DDA between the EU and China… this project is of critical global importance if we are to keep the WTO relevant, and *I have found the Chinese remarkably open to European ideas in the DDA*... We have…started to develop a very close working relationship on all the key issues, and *I think we have found many common interests*. We are impressed by the quality of Chinese contributions to the debates in Geneva, by the level of commitment to the DDA not just in the WTO but also in regional forums such as the ASEM and APEC, and by the practical and businesslike solutions which China is putting forward…*We are intensifying our work with the Chinese government, and so we are very keen to hear your priorities so we can put together an ambitious result in the Round…it is in both China's and the EU's interest to have an ambitious outcome in the Doha Development Agenda*… We are now assembling a major *bilateral dialogue* with China on the new Round…We are particularly keen to work on a number of areas of interest, such as… *technical barriers to trade, and agriculture*…together - the EU and China can make an enormous contribution to keeping markets open, to keeping the WTO steaming ahead, and to strengthening global economic governance" (emphasis added). [164]

At the very least, the EU has been and continues to be lobbying the developing world, including China, in support of its views concerning the role of precaution in international trade.[165] The EU's conduct at the upcoming Cancun Ministerial negotiations should therefore be instructive in this regard.

EU trade policy documents clearly indicate that the precautionary principle should be incorporated within as many bilateral and preferential trade agreements and technical assistance programs as possible in order increase EU influence in the WTO. However, due to the costly and time-consuming nature of this endeavor and the contentious issues at stake, the EU's proliferation of this approach has not yet been as extensive as envisioned. Since, at the present time, the precautionary principle has not expressly found its way into many such agreements it would be difficult to argue that bilateral State practice with respect to the precautionary principle has already risen to the level of customary international law.

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[164] Pascal Lamy - EU Trade Commissioner, "EU-China trade relations", Beijing, China, 17 (October 2002), at: (http://www.delchn.cec.eu.int/en/press_and_information/EU-China%20trade%20relations.htm). Mr. Lamy made similar remarks on the eve of his most recent trip to China this past June. "China has become a key EU partner and together we can make an enormous contribution to keeping the Doha Development Agenda steaming ahead. Close collaboration is also going to be increasingly vital to address the specific trade problems we may face." See: Press Release, "Pascal Lamy visits China to strengthen trade relations", Bilateral Trade Relations – China June 11, 2003, at: (http://europa.eu.int/comm/trade/bilateral/china/pr110603_en.htm ).

[165] Given the higher level of protection sought by EU health and safety and environmental regulation and standardization, the EU's successful lobbying of China to adopt a hazards-based approach rather than a risk-based approach may adversely impact U.S. goods and services exports to China and other similarly-minded developing countries. It is indeed possible that, in due time, with China as a willing partner, the EU may be able to enlist other developing countries to its cause and thereby influence the development of WTO law and WTO member practice enough to ultimately curtail U.S. economic and political leadership globally. At the very least, further research is warranted to unveil the true purposes behind EU engagement of China.

## X. EU Multinational Environmental Practice and the Precautionary Principle

The EU is also attempting to expand the reach of the precautionary principle beyond the multinational environmental realm and into the WTO global trading system. It has sought to accomplish this by implementing through national and regional regulations and standards international obligations assumed under multilateral environmental agreements ('MEAs') that it and its Member States (unlike the U.S.) have ratified, which it then argues are WTO (SPS and TBT) -consistent. These agreements include the United Nations Framework Convention on Climate Change ('UNFCCC') and the Kyoto Protocol intended to implement it -- which is only one country ratification shy of coming into force.[166] They also include the Convention on Biological Diversity ('CBD') and the soon-

[166] While the U.S. was a signatory to the Convention it did not ratify the Protocol. It is possible that any new greenhouse gas emission regulations later proposed by the EU in order to implement the Protocol will conflict with the TBT Agreement's Article 2.1 national treatment clause and prohibition against discrimination of 'like' products. They may also conflict with the TBT Agreement's Article 2.2 prohibition against enactment of technical regulations that are a 'disguised restriction to international trade' (its 'more trade-restrictive than necessary' clause). This has become a very real possibility since December 18, 2002. On that date, Canada became the 100th nation to ratify the Kyoto Protocol. The Protocol will come into force when ratified by 55 countries, including developed countries representing at least 55% of that group's 1990 carbon dioxide emissions. "With Canada's ratification, and that of Poland on December 13, 2002, developed country ratifications now account for 43.7% of the 1990 CO2 emissions…[If Russia ratifies the Kyoto Protocol, its] 17.4% [of 1990 developed country CO2 emissions] will push the tally over the required 55% [threshold]." Press Release – "Kyoto Protocol Receives 100th Ratification – Widespread Political Support Suggests Protocol May Enter into Force in Early 2003", United Nations Framework Convention on Climate Change Secretariat (12/18/02), at: (http://unfccc.int/press/prel2002/pressrel181202.pdf ). There is also a potential conflict brewing between the TBT Agreement and the ban imposed on certain CFCs pursuant to the EU's proposed chemicals regime. These regulations are likely designed, in part, to implement the Montreal Protocol on Substances That Deplete the Ozone Layer, which implements the Vienna Convention on Protection of the Ozone Layer. Furthermore, the relationship between WTO and MEA principles may again be tested as the result of proposed EU rules intended to implement obligations that will be assumed under the Stockholm Convention on Persistent Organic Pollutants ('POPs') and the 1998 Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution ('LRTAP') when they enter into force. These rules, which impose more stringent requirements than those called for by the treaties, are grounded on the EU's broad interpretation of the precautionary principle. Although the precautionary principle appears within the Preamble to the Stockholm Convention, it is, nevertheless, expressly narrowed to the Rio Principle 15 definition. Precaution is only obliquely referred to again within Article 8(9) as a possible risk management tool, to be considered among others, following the performance of a detailed risk analysis procedure outlined in Article 8 and Appendix E. The risk analysis procedure, which is to be grounded in sound science, must be performed before the Conference of the Parties can recommend that any chemical be added to the list of POPs as set forth in Annexes A, B or C of the Convention. Notwithstanding this process and other safeguards built into the Convention to prevent abuse, however, the EU endeavors to go beyond the mandate of the Convention in several ways that may ultimately impose economic and administrative burdens on future U.S. industry exports of chemicals, chemical products and articles containing them which are not currently listed in the Convention. See: "Proposal for a Council Decision concerning the conclusion, on behalf of the European Community, of the Stockhom Convention on Persistent Organic Pollutants", COM (2003) 331 (6/12/03), Explanatory Memorandum at par. 3, p. 2 and par. (4), at p. 3; "Proposal for a Regulation of the European Parliament and of the Council", COM (2003) 333 final (6/12/03), Explanatory Memorandum, at p. 3, par. 6 at p. 10, par. 2 at p. 11, par. 2, at p. 12, pars. 2 and 6 at p. 14, par. 5, at p. 20; Statement of Environment Commissioner Margot Wallstrom, cited in

to-be effective Cartegena Protocol on Biosafety ('the Biosafety Protocol') that implements Article 8(g) of the CBD.[167] The Biosafety Protocol [168] recently received its fiftieth instrument of ratification (excluding that of the European Community) on June 13, 2003. This means that the Biosafety Protocol should become international law effective September 11, 2003.[169]

By incorporating MEA obligations in national (regional) health and safety and environmental regulations and standards the EU has found an apparently legitimate means of utilizing a more expansive interpretation of the precautionary principle to reinforce European consumer concerns and political and social values. The Biosafety Protocol articulates the broadest expression available of the precautionary principle as a non-science-based justification for the enactment of regulations and standards to protect human health and safety, animal welfare and the environment.[170] The EU believes that, by resorting to such a broad application of the precautionary principle, it can utilize the broader provisions of the GATT, specifically the Article XX (a), (b) and (g) exceptions to the GATT's Article III national treatment and nondiscrimination clauses. [171] The EU is

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"Persistent Organic Pollutants: Commission Urges EU to Ratify the International Agreements", EU Institutions Press Releases IP/03/842 (6/16/03).

[167] Article 8 of the CBD entitled, 'In-Situ Conservation' provides that, "Each Contracting Party shall, as far as possible and as 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…" See: Text of the Convention on Biological Diversity, at: (http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-22#top).

[168] While the U.S. is a signatory to the CBD it did not ratify it. Consequently, as a non-Party to the CBD it is not eligible to become a party to the Biosafety Protocol, and thus cannot endeavor to modify its provisions. Nevertheless, according to one commentator, "the U.S. is very concerned that the implementation of the CBD will result in a range of regulatory approaches that will frustrate its goals of international regulatory uniformity. The U.S…would prefer an international arrangement where U.S. regulatory approval allows imports into any country in the world. Many countries fear such an outcome as preempting their national rights to regulate the health and environment of their country as they feel necessary." William A. 'Skip' Stiles, Jr., "Background Paper On: Traceability, Segregation and Labeling GM Crops", Presented at the German Marshall Fund of the United States U.S.-European Biotechnology Initiative Workshop 3 (Dec. 2001), at p. 31.

[169] The Biosafety Protocol will "enter into force on the ninetieth day after the deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention." Without counting the European Community's ratification of the Protocol, all 50 of the required number of 'ratifications' (50) have already been secured. The fiftieth ratification was secured from the country of Palau on June 13, 2003. See: "Ratifications, Cartegena Protocol on Biosafety, Convention of Biological Diversity", at: (http://www.biodiv.org/biosafety/signinglist.asp?sts=rtf&ord=dt ).

[170] The strongest expression of the precautionary principle is found within the Cartegena Protocol to the United Nations Convention on Biological Diversity. See: the Articles 1 and 10(6) as well as the Preamble. See, also: "Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science", at pp. 43-50.

[171] Generally, GATT Article XX permits the enactment of national (or regional) measures (a) on grounds of public morality, (b) 'necessary' to protect human, animal or plant life or health, or (g) relate to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption, provided they do not constitute a disguised restriction on international trade, and do not otherwise discriminate between 'like' products from different countries. Chapter 2 of the Treaty of the European Union entitled, "Chapter 2 Prohibition of Quantitative Restrictions

well aware of the potential for conflict between these two international legal regimes in the event national (or regional) technical regulations intended to implement the Biosafety Protocol are deemed in violation of the provisions of the SPS Agreement, and the WTO dispute settlement process is subsequently triggered.[172] In fact, this process has already been initiated with the U.S. filing of a WTO suit against the EU on May 13, 2003, with respect to the EU Member States' GMO moratorium. And, it may also lead to another WTO suit being brought by the U.S. Government against the EU in regard to its proposed GMO traceability and labeling regulations.[173]

The EU has proposed a solution to this dilemma. It is "to seek confirmation that WTO rules and MEAs are separate but equal bodies of international law, and that accordingly, MEAs are not subordinate to WTO rules and vice versa…WTO rules should not be interpreted in clinical isolation of complementary bodies of international law, including MEAs." [174] This solution might not only require the treatment of MEA trade measures

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between Member States" ostensibly parallels these provisions within Articles 28 and 30. These articles read as follows: Article 28 provides that, "Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States." Article 30 provides, however, that "Article 28… shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of *public morality, public policy or public security; the protection of health and life of humans, animals or plants;* the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States" (emphasis added).

[172] A conflict of this sort is certain to have broad implications on international trade, and is considered an issue worthy of attention at the current Doha Round of trade negotiations. (See: The Ministerial Declaration issued at the WTO Ministerial Conference at Doha, Qatar, November 9-14, 2001). Among the many issues agreed to be discussed during the Round, is that relating to "the relationship between existing WTO rules and specific trade obligations set out in MEAs. The negotiations [however] shall be limited in scope to the applicability of such existing WTO rules as among parties to the MEA in question. The negotiations shall not prejudice the WTO rights of any Member that is not a party to the MEA in question…" Id, at par. 31.

[173] According to one commentator, "One of the greatest U.S. fears is that a successful EU provision for labeling with its 1% [or less] threshold will become the de facto global standard, given the size of the European Market and the influence of the EU nations in international forums. And if the EC approach is successful, then the underlying philosophy of the U.S. regulatory system may be called into question and domestic forces may seek to reopen the regulatory system in the U.S., something that the biotechnology industry and the food and agriculture sectors would find extremely disruptive." William A. 'Skip' Stiles, Jr., "Background Paper On: Traceability, Segregation and Labeling GM Crops" at p. 31.

[174] Three declarations inserted at the end of the Preamble to the Biosafety Protocol are believed by the EU to provide a sufficient legal basis to treat MEAs and the WTO agreements as legally equivalent. They include the following: "Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development; Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements; Understanding that the above recital is not intended to subordinate this Protocol to other international agreements…" According to the EU Commission Delegation, these preambular declarations represent a political compromise reached between the U.S. and the EU that, "arguably does not shed any clarity on the Protocol's relationship with WTO rules…[but which needs to be resolved.] The US likes to point to the second statement as the Protocol's so-called savings clause, whereas the EU does not recognize that the Protocol includes a savings clause, pointing to the first and third statements. The jury is clearly still out on this one. Some US Government officials have apparently argued that the first and third statements are merely political statements; whereas some EU officials have argued that the second and third statements

as a legitimate GATT Article XX exception, but could also entail the reversal of the burden of proof. In the event of such a reversal, "a WTO complainant challenging an MEA trade measure would have to prove that the measure does not meet the conditions of Article XX, rather than the defendant having to defend its measures under Article XX [as is currently required]." [175]

While the EU appears to be well on its way to establishing the precautionary principle as a norm of customary international environmental law, it remains uncertain whether it can succeed in utilizing this principle to alter the WTO regime. At the very least, it would take a good amount of time and considerable effort. Unfortunately the U.S. is a non-Party to the Biosafety Protocol, and thus, it can have only a limited influence over how Protocol parties that are also WTO members implement their Protocol obligations through enactment of national legislation and standards (e.g., the EU proposed GMO authorization, labeling and traceability regulations). As a result, although the U.S. Government is not legally bound by the Protocol's provisions, U.S. companies doing business within EU Member States or other Protocol Parties will be adversely affected if a ratifying country decides for political/social (non-scientific) reasons to adopt the broadest form of the precautionary principle.

## XI. Establishing the Precautionary Principle as a Norm of WTO Treaty Law

Even if the EU through its multiple practices were able to establish the precautionary principle as a norm of customary international law (i.e., as a non-WTO treaty norm), however, its ability to incorporate that norm within the SPS and TBT Agreements remains uncertain. There is a continuing debate within the legal and academic

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cancel each other out, thus leaving the mutually supportive language. This is a clearly creative compromise that facilitated the conclusion of an important agreement, but it appears unhelpful in clearing up this muddled issue." Id. However, a review of the provisions of the CBD which the Biosafety Protocol is intended to implement supports the U.S. position that the rights and obligations of WTO members remains unaffected by the Protocol. Article 22 of the Convention entitled, 'Relationship with Other International Conventions' provides that, "1. The provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity."

[175] "In order to address the problem of potential challenges by [WTO members who are] non-parties [to an MEA], we think there should be some type of accommodation mechanism that would ensure that specifically mandated trade measures taken pursuant to MEAs are recognized as being necessary and justified under WTO rules. One possibility that we are exploring in this regard – and which has been debated in the CTE (Committee on Trade and Environment) – is a reversal of the burden of proof. In practice, this would mean that that a WTO complainant challenging an MEA trade measure would have to prove that that measure does not meet the conditions of Article XX, rather than the defendant having to defend its measures under Article XX. Such a reversal of proof would render a non-party's challenge more difficult, but would reserve the rights of that party to undertake a challenge before the WTO. It might also have the effect of encouraging the non-party to join the MEA. Since it would only be applicable to trade measures taken pursuant to an MEA, it could not be used in case of unilateral and potentially eco-protectionist measures." Speaking Points of Charlotte Hebebrand, "The WTO and MEAs – Friends or Foes?", Trade Section, European Commission Delegation, Panel Discussion, Washington International Trade Association (5/3/01), at: (http://www.eurunion.org/news/speeches/2001/010503ch.htm ).

communities about the relationship between WTO law and non-WTO sources of international law, and it is not likely to be resolved in the immediate future.

As with any debate, there exist two contrary positions. The views of at least one commentator seem to approximate the U.S. position. Essentially, that position focuses on how specific provisions within the WTO 'covered agreements' themselves express the intentions of the WTO parties to be bound by certain prescribed rules regardless of the much broader system of international law of which the WTO institution is a part. In general, he argues that only WTO substantive law (and not public international law) may be considered and applied directly by WTO decision-making bodies to resolve WTO cases.

> "The mandate to WTO dispute resolution panels, to the Appellate Body, and to the Dispute Settlement Body is clear: *apply (directly) only WTO law*…While panels and the Appellate Body are only permitted to apply WTO law, they refer to non-WTO international law in two types of cases. First, as specifically authorized by article 3.2 of the DSU, they refer to customary rules of interpretation of international law. This reference does not appear to include substantive non-WTO international law. While article 31(3)(c) of the Vienna Convention, which is taken as reflective of customary rules of interpretation, refers to applicable international law, it does so only to indicate what materials should be taken into account in interpreting treaty texts. Thus, other international law is not directly applicable but is taken into account in a manner similar to the U.S. Charming Betsy rule: interpret so as to avoid conflict where possible. Second, substantive non-WTO international law may be incorporated by reference in WTO law, either by treaty language such as the references in TRIPS to intellectual property treaties or by a waiver such as the Lomé waiver in the recent Bananas III decision. More subtly, substantive non-WTO law may indirectly be incorporated by reference in provisions such as article XX(b) of GATT…Article XX(b) (as well as paragraphs (a) and (d)) contains a requirement that measures excepted thereunder be "necessary." This requirement has been read on several occasions to require multilateral or bilateral efforts to address the domestic regulatory need...*[T]he WTO legal system…[however] 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*." (emphasis added). [176]

In essence, the failure of WTO dispute settlement to take into account non-WTO international law generally can be explained in one of two ways. On the one hand, WTO law (a framework treaty) can be viewed as analogous to an incomplete contract executed by willing private parties who have partially opted-out of the broader institutional setting of public international law that otherwise serves to fill in the gaps of an incomplete treaty. They have done so by ensuring that the WTO agreements "do not provide general international law with a dispute resolution forum".[177]"The role of general law in

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[176] See: Joel P. Trachtman, "The Domain of WTO Dispute Resolution", 40 Harvard Int'l Law Journal 333 (1999), at pp. 342-343, fn 51, 349, fn 71. According to Mr. 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'.

[177] "…WTO dispute settlement only applies WTO law, and international law as a whole is not part and parcel of WTO law. The WTO agreements did not on a wholesale basis 'contract out' of general international law – they simply do not provide general international law with a dispute resolution forum. Importantly, the recognition that the WTO is an at least partially autonomous legal system allows us to understand that WTO law does not trump *jus cogens* or subsequent treaties as a matter of public international law generally. Rather, it is only that those bodies of law are not a directly applicable part of

completing contracts reminds us that no institution is an island: each exists in a broader institutional setting. This setting penetrates the institutions at various points, to complete contracts and to supply broader institutional rules where appropriate. Thus, each particular institutional setting is really a complex of interacting institutional settings. However, the WTO generally isolates itself from much of the broader institutional setting of public international law." [178]

Alternatively, the provisions within WTO law can be viewed as a combination of rules and standards that are intended to address potential treaty gaps in advance. They are different from one another insofar as standards, unlike rules, prescribe conduct in general (non-specific) and incomplete terms.[179] The choice made to develop a norm as a standard rather than as a rule may reflect a decision grounded in political expediency not to immediately address a difficult, contentious or otherwise costly issue, as well as a decision to allow for the possibility of judicial balancing in the future. [180]

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the WTO legal system – they have the consequences they were intended to have at general international law – where they were intended to, and do, exist, and it was not the intent of the parties to the WTO agreements to give them special enforceability by virtue of the WTO dispute settlement system." Joel P. Trachtman, "'Transcending Trade and…' An Institutional Perspective", Discussion Draft, (May 29, 2001) at p. 16, Social Science Research Network Electronic Library, at: (http://papers.ssrn.com/sol3/delivery.cfm/ssrn_id271171_code010529500.pdf?abstractid=271171)

[178] Joel Trachtman, "The Domain of WTO Dispute Resolution", fn 176, supra, at p. 347. However, unlike incomplete contract disputes that always have an answer in domestic common law, international treaty disputes may not. "The domestic institutional setting is thick with experience and legislation; it reflects the choices of a complex and relatively comprehensive society. The international institutional setting is thin by comparison. And again, more saliently, the international institutional setting may permit non-liquet: where positive law does not exist, the complainant may simply lose by default." Id. In other words, the decision to partially isolate WTO law from the broader institutional setting of public international law may simply acknowledge the limitations inherent in the international legal system itself. "In international law, there are fewer institutional and legal structures to complete contracts. First, in international law, there is not a very complete body of customary or other general law that can be applied to supply missing terms to incomplete treaties… Second, in general international law, as opposed to the WTO system, there is usually no dispute resolution tribunal with mandatory jurisdiction. Thus, it is often difficult to rely on the ability to complete contracts through dispute resolution mechanisms…[Consequently,] even if international treaty gaps are potentially filled by valid international law, there may be gaps in the dispute resolution structure that leave the international law unenforceable although valid." Id., at pp. 349-350.

[179] "A related literature examines the economics of rules and standards…Each law is comprised of a combination of rules and standards…Instead of dealing with incomplete contracts, this literature deals more directly with different types of law, accepting in advance that there is no non liquet in common law. This literature addresses the fact that laws are sometimes established more specifically in advance as rules, or less specifically in advance as standards. In the rules versus standards literature, a law is a 'rule' to the extent that it is specified in advance of the conduct to which it is applied…On the other hand, a 'standard' is a law that is, in relative terms, farther toward the other end of the spectrum. It establishes general guidance to both the person governed and the person charged with applying the law but does not, in advance, specify in detail the conduct required or proscribed. The relativity of these definitions is critical. A standard is more apparently and intentionally specified in advance in an incomplete manner." Id., at pp. 350-351.

[180] "Incompleteness of specification may not simply be a result of conservation of resources. It may be a more explicitly *political decision* either (i) to agree to disagree for the moment in order to avoid the political price that may arise from immediate hard decisions or (ii) to cloak the hard decisions in the false inevitability of judicial interpretation. It is important also to recognize that the incompleteness of specification may represent a failure to decide how the policy expressed relates to other policies. This is critical in the trade area, where the incompleteness of a trade rule often relates to its failure to address, or

At least one commentator holds a contrary position that approximates what the EU is arguing. According to this view, WTO law is a part of, inextricably linked with and reflects within its provisions the broader dynamic of international law into which it was born. Consequently, non-WTO law can be and must be incorporated within the WTO 'covered agreements'. In general, this commentator argues that,

> "*Both the WTO treaty and WTO dispute settlement are integral parts of public international law. They are not 'closed' or 'self-contained' regimes: they were created in the wider context of general international law, as well as other treaties.* This other international law continues to apply in the WTO unless the WTO treaty has contracted out of it...the WTO treaty, WTO panels and the Appellate Body were not only created in the wider context of public international law; they continue to exist in that context. [Since] the WTO treaty is not static, [but rather] inherently dynamic…[d]epending on the relevant conflict rules, pre-1994 [as well as] post-1994 non-WTO rules [e.g., MEAs] may prevail over the WTO treaty. [A]lthough the substantive jurisdiction of WTO panels is limited to claims under WTO covered agreements…the international law they may apply in resolving these claims is not limited. It potentially includes all rules of international law. In practice, this inclusiveness means that a defendant should be allowed to invoke non-WTO rules as a justification for breach of WTO rules, even if the WTO treaty itself does not offer such justification. [This result should obtain] only when both disputing parties are bound by the non-WTO rule and that rule prevails over the WTO rule pursuant to conflict rules of international law. [In this way], public international law fills gaps left open by the WTO treaty and the WTO treaty must be interpreted in the light of other rules of international law. More important, non-WTO rules may actually apply before a WTO panel and overrule WTO rules" (emphasis added). [181]

In light of this broad-minded view of international law and WTO law's place within it, this commentator generally argues that WTO treaty interpretation can have only a limited role in defining the relationship between WTO law and public international law and

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incorporate, non-trade policies… Rules are more expensive to develop ex ante than standards because rules entail specification costs, including drafting costs, negotiation costs, and strategic costs involved in ex ante specification. In order to reach agreement on specification and to legislate specifically, there may be greater costs in public choice terms. This is particularly interesting in the trade context where treaty-making would be subjected to intense domestic scrutiny while application of a standard by a dispute resolution process would be subjected to reduced scrutiny… In short, while rules require clear decision, standards may serve as an agreement to disagree or they may help to mask or mystify a decision made. Under standards, both sides in the legislative process, at least initially, may claim victory" (emphasis added). Id., at pp. 351-352. "Another distinction between rules and standards…is the institutional distinction: with rules, the legislature often "makes" the decision; with standards, the adjudicator determines the application of the standard, thereby "making" the decision…At least in the international trade system, however, rules are largely made by treaty and standards are largely applied by tribunals. But the difference between legislators and courts is an important one; it may affect the outcome. The choice of legislators or courts to make particular decisions should be made using cost-benefit analysis." Id, at pp. 353-354. Viewed in this light, "[t]ariff bindings under article II of GATT have more the character of *rules*, while norms such as the definition of 'like products' under article I or III, the necessity test of article XX(b) and XX(d), the 'primarily related' test of article XX(g) or the chapeau of article XX of GATT seem more like *standards*. These "standards" involve complex judicial balancing" (emphasis added). Id at p. 356.

[181] Joost Pauwelyn, "The Role of Public International Law in the WTO: How Far Can We Go?, 95 American Journal of International Law 535, 560-61, 577-78. "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.

resolving conflicts between them. While treaty interpretation may avoid "apparent conflicts", it does not usually "resolve genuine conflicts between WTO rules and other rules of international law." [182] In effect, WTO treaty interpretation must be viewed as a holistic exercise that takes into account "the common intentions of all WTO members…not merely those of the disputing parties".[183]

Furthermore, this commentator advocates that the WTO covered agreements should be viewed as living, breathing documents (rather than as static documents) that ought to take into account and reflect the ongoing political, social and legal changes occurring within the global community. In this regard, it is very important to recognize "the distinction between amending the WTO treaty and accepting *inter se modifications* to it…Strict requirements that have been imposed to amend the WTO treaty have been strongly invoked as an obstacle to allowing inter se modifications to the treaty."(emphasis added). To the contrary, this commentator argues that inter se modifications to the WTO treaty are possible among members in certain instances.[184] In sum, this commentator argues that the international legal system is a dynamic and multidimensional one and that, the WTO agreements as part of that system should both incorporate and contribute to it. "The interaction between WTO law and public international law is not one-sided. [Rather,] it is a continuing process of cross-fertilization. Just as public international law enriches WTO law, so WTO law should further develop international law".[185]

## XII. Conclusion

A successful advocate is usually able to persuade most of its audience that it can identify with their concerns and that the goal it is pursuing is in their best interests. In the present case, the EU and the U.S. are striving to define WTO law so that it best reflects their respective national/ regional interests.[186] At the same time, they are competing for the

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[182] Id., at p. 577.
[183] Id.
[184] An inter se treaty modification is an agreement reached only by some of the parties to a multilateral agreement to modify the treaty as between themselves. In contrast to an amendment, the WTO treaty does not provide for an equally extensive contracting out of general international law rules on modification. Parties can agree amongst themselves to further liberalize trade or alternatively to restrict trade under certain conditions set forth under either the WTO treaty or general international law rules, such as Article 41 (1) of the Vienna Convention . Id at 547-550; 577-78.
[185] Id., at 578.
[186] Beyond the debate surrounding the scope of WTO law, it has been argued that states' competing interests are reflected also in the broader context surrounding the development of customary international law. Professor Michael Byers claims that opinio juris, the second element of customary international law, has been imposed in order to compensate for the disparities in national wealth and military power that historically enabled more powerful countries to have a greater influence upon the development of customary international law through state practice. "…Opinio juris has traditionally served two closely-related functions: First, it was used to distinguish legally relevant from legally irrelevant State practice. Secondly, and perhaps less obviously, it was used to control the abuse of power by States within the process of customary international law. In short, the requirement of opinio juris meant that only some instances of state practice counted for the purposes of the customary process, since a State had to believe that its behaviour was already required by customary international law. This test controlled the abuse of power and promoted stability and determinacy, by excluding a great deal of state practice which might otherwise have contributed to the development, maintenance or change of customary rules. It thus fulfilled

hearts and minds of the developing world with respect to the role of international trade in global affairs.

Thus far, the EU has been able to alter the terms of this debate by endeavoring to inject within the WTO regime the precautionary principle, a nonscientific touchstone that ostensibly reflects many of the health, social and environmental concerns of EU civil society. The EU's application of the precautionary principle, which 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, however, violates the terms of the SPS and TBT Agreements as they are currently written. It is to these agreements that all WTO members remain legally bound, and to which much of the developing world has aspired.

Fortunately, EU attempts to elevate the precautionary principle from a limited provisional WTO exception to a norm of customary international law have thus far fallen short of the mark, and the ability of the EU to establish it as a customary WTO norm, in the short-term, remains in question.[187]The failure of the EU to achieve this goal, however, may

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what would appear to be an essential function within any developed society, that of socialising the behaviour of society's members by imposing the framework of a legal system upon them, of enabling them to think rationally about the future and not to focus on short-term calculations of interest and risk." Michael Byers, "Power, Obligation and Customary International Law", Introduction, 11 Duke J. of Comp. & Int'l L. 81 © 2001, at: (http://www.law.duke.edu/journals/djcil/articles/djcil11p81.htm). Similarly, Professor D'Amato argues that, "What makes international custom authoritative is that it consists of the resultants of divergent state vectors (acts, restraints) and thus brings out what the legal system considers a resolution of the underlying state interests. Although the acts of states on the real-world stage often clash, the resultant accommodations have an enduring and authoritative quality because they manifest the latent stability of the system. The role of opinio juris in this process is simply to identify which acts out of many have legal consequence." Anthony D'Amato, fn 88, at p. 30.

[187] Although the outcome of this debate is not yet certain, even Professor Trachtman acknowledges that the 'European position is gaining ground. **"**While present WTO law seems clearly to exclude direct application of non-WTO international law, this position seems unsustainable as increasing conflicts between trade values and non-trade values arise". As he suggests, "*These conflicts may be addressed through standards such as the exception provisions of Art. XX, or by legislated rules regarding the more specific interaction between trade values and non-trade values"* (emphasis added). Joel Trachtman, "The Domain of WTO Dispute Resolution" at p. 376. Professor Trachtman admits in another essay that, while "[t]he WTO dispute settlement system does not directly admit other treaty norms to be applied as law…, the WTO treaty could be amended to incorporate other norms directly…The effect of such an amendment would be to establish a particular kind of response to [trade/non-trade] linkage claims: one of integration of the relevant environmental norms with the relevant trade norms…" Jose E. Alvarez and Joel P. Trachtman, Symposium: "The Boundaries of the WTO – Institutional Linkage: Transcending Trade and…", at pp. 89. Prior to going forward with such a change, states would need to decide "whether this approach would be less costly in transaction cost terms, and distributively satisfactory, as against other approaches… Multiple institutional options can be adduced for allocating jurisdiction among international organizations. The default option…is simply to leave these organizations in a state of nature, or at least under the general system of public international law. Under these circumstances, they would negotiate with one another, and negotiations would take place between their constituent states, reaching varying degrees of resolution. The second option…is to use specific rules in treaties to allocate jurisdiction. The third option is to use standards in treaties as a basis for allocation by a tribunal. Id.,at p. 90. In the end, according to Professor Trachtman, "international society needs expanded institutional alternatives, as well as tools with which to evaluate them in ways that recognize both the diversity and the concurrence of state interests." Id., at p. 93.

have as much to do with the difficulty of the endeavor itself[188] as with U.S. short-term initiatives to oppose it. Given this uncertainty, the U.S. should not be lulled into a false sense of security and complacency that leads it to believe its efforts have already succeeded. To the contrary, EU efforts to sanctify the precautionary principle appear to comprise part of a broader, long-term three-dimensional strategy to influence the scope and application of WTO law within the international legal system. Such an approach is consistent with the gradual and incremental pace by which states and civil society contribute to the development of customary international law.[189] If, therefore, U.S.

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[188] Identifying whether the elements of customary international law have been established in a given case, especially considering the subjective nature of opinio juris, is indeed a difficult task. In addition, it is not always agreed when that occurs. According to Professor Byers, "customary international law is traditionally considered to be comprised of two elements: state practice and opinio juris, with opinio juris being a subjective feeling of legal obligation regarding the practice in question. *Since subjective feelings are difficult to identify*, the analysis of customary rules has almost always focused on state practice. The questions asked include the following: what kinds of behavior count as state practice, how many states need to participate in the practice, and over how long a period of time?" (emphasis added). Michael Byers, supra, at fn 186. The EU seems to argue that state practice can arise from non-binding political declarations such as the Rio Declaration on Environment and Development and Agenda 21 and from more formal UN resolutions such as the UN "Draft Norms On Responsibilities of Transnational Corporations and Other Business Enterprises With Regard to Human Rights" (See discussion in fn 129, at p. 41, supra.) To the contrary, Professor D'Amato has argued that, a customary rule arises out of state practice; it is not necessarily to be found in UN resolutions and other majoritarian political documents…opinio juris has nothing to do with 'acceptance' of rules in such documents. Rather, opinio juris is a psychological element associated with the formation of a customary rule as a characterization of state practice…If voting for a UN resolution means investing it with opinio juris, then the latter has no independent content; one may simply apply the UN resolution as it is and mislabel it 'customary law'…" Anthony D'Amato, supra, at fn 86. Furthermore, the ever-changing nature of customary law makes it difficult to know what the customary law rule in a given jurisdiction is at a given moment in time. As noted by Professor D'Amato, "customary rules are not static…They change in content depending upon…state interests…the customary rules that survive the legal evolutionary process are those that are best adapted to serve the mutual self-interest of all states. The process of change and modification over time introduces a complex element." Id.

[189] See discussion in footnote 87, at p. 29, supra. The EU has proved itself adept at harnessing the resources of the NGO community to help it develop EU regional environmental norms, soft international norms such as non-binding U.N. political declarations on the environment, human rights and labor (including those noted in footnote 188), and multilateral environmental and human rights agreements (treaty norms). It then proclaims that, in the aggregate, these expressions reflect the political intent of the international community to change customary international law. Once national courts begin to cite these articulations as sources of international law, they may, over time, present evidence of the existence of custom. Professor Parisi has noted how social and political norms, by virtue of being judicially recognized, can become 'hard' legal norms that offer persuasive (although not binding) evidence of the existence of custom. "In the social contract framework, customary rules can be regarded as an implied and often non-verbalized exercise of direct legislation by the members of society. Those legal systems which grant direct legal force to customary rules regard custom as a primary, although not exclusive source of law. In such legal traditions, courts enforce customary rules as if they had been enacted by the proper legislative authority. Custom thus amounts to a *spontaneous norm* which is recognized by the legal system and granted enforcement as a proper legal rule. Judicial recognition of *spontaneous norms* amounts to a declaratory (rather than constitutive) function that treats custom as a legal fact. The legal system 'finds' the law by recognizing social norms, but does not create law. The most notable illustration is the system of international law, where, absent a central legislative authority, custom stands next to treaties as a primary source of law". See: Franco Parisi, "The Formation of Customary Law", at p. 3, citing Article 38 (1) of the *Statute of the International Court of Justice*; and Restatement 102 of the *Foreign Relations Law of the United States*, supra at fn 87. " …With regard to [customary] rules at the national or local level, the varying pace at which social norms are transformed suggests that no general time or consistency

advocacy is to prevail and the role of objective sound science in the WTO agreements is to be preserved, the U.S.[190] must adopt a long-term view as it quickly responds to the EU's complex challenge, ever mindful of the important transatlantic relationship and north-south interests at stake.

requirement can be established as an across-the-board condition for the validity of custom…A flexible time requirement is particularly necessary in situations of rapid flux where exogenous changes are likely to affect the incentive structure of the underlying relationship" (emphasis added). Id., at p. 6. During the preparation of this paper it has come to the author's attention that several courts within various national and local jurisdictions have cited several of these sources as support for invoking the precautionary principle in their rulings. Although a discussion of these cases is beyond the scope of this paper, it is the author's opinion that the U.S. must remain vigilant in monitoring such cases to ascertain whether a pattern of state practice has begun to emerge.

[190] The U.S., in this sense, refers to the U.S. government, including all of its relevant agencies, U.S. private organizations dedicated to developing standards and facilitating standards creation and both manufacturing and service oriented industry sectors.