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

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

## EXECUTIVE SUMMARY

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## **Introduction**

A key strategy of successful advocacy is to frame a debate to reflect the views of one's client without appearing to concede the adversary's position. The EU is pursuing this approach in an attempt to recast the terms of an increasingly protracted and emotional debate over the scope of international trade law.

The EU insists on promulgating overly stringent human health and safety, animal welfare and environmental regulations, beyond those called for by international standards, that amount to technical barriers to trade. These measures serve to protect ailing EU industries or impose unnecessary restrictions that effectively block access to the EU. In many cases where developing country exports have been denied access, related research and development programs have been temporarily frozen or altogether terminated. 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.

At least two WTO agreements, the Sanitary and Phytosanitary ('SPS') Agreement and the Technical Barriers to Trade ('TBT') Agreement, were designed to prevent countries from enacting technical regulations and/or standards that constitute unnecessary obstacles to international trade. These agreements require proof of actual risks of harm posed by specific products as determined by objective principles of sound science. The EU disagrees with this interpretation and continues to apply its regulations without regard to their extra-territorial impact. The EU justifies its actions by referring to the 'precautionary principle', a relatively undefined and inherently nonscientific political and sociological touchstone.

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.

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

The EU has been pursuing a three-dimensional strategy that seeks to define and employ the precautionary principle globally: (1) The EU has sought to inject it within the WTO system at large through creative interpretation of the SPS and TBT Agreements and through incorporation within them of obligations assumed under multilateral environmental agreements. (2) The EU has sought to incorporate the precautionary

principle within international standards through active and skilled participation in the international standards development process. (3) 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 WTO exception to a ‘norm’ of general customary international law equal in importance to general principles of international trade law.

### **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 can be utilized as disguised barriers to trade. Generally speaking, these agreements premise national or regional regulatory action on relevant international science-based standards formulated through consensus by widely recognized international standards bodies, or in their absence, upon substantially equivalent national science-based standards developed by other WTO members. The purpose of both the SPS and TBT Agreements is the facilitation of international trade. Nevertheless, these agreements respect national sovereignty in that they permit WTO members, when absolutely necessary, to enact temporary provisional measures to protect against ascertainable risks of harm to specific state interests provided they do not pose an unnecessary obstacle to trade. Indeed, the overarching goal of the TBT Agreement is to prevent “standards-related activities from intentionally *or* unintentionally impeding the flow of international commerce.” (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, (Sept. 1984), at p. 4.)

### **National Health and Environmental Regulations Must Not Discriminate Between Otherwise ‘Like’ Products Based on Process or Production Methods**

The SPS and TBT agreements establish that national (or regional) regulations cannot impose different treatment upon otherwise “like” products based on how they are produced or formulated. This is required especially where the final product bears no trace of such process or formulation. However, at least two proposed EU regulations have been used to discriminate between products solely on the basis of their process or production method (PPM). They include the EU’s proposed regulation on GMO traceability and labeling and the proposed REACH regulation on high volume chemicals. In each case, the EU has applied the precautionary principle to substances and finished articles containing such substances that are presumed *a priori* to be inherently hazardous to EU society. The EU has, in effect, created a straw man 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.

## **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 among WTO Member States. However, several EU directives and regulations when proposed, including those relating to bioengineered food and feed products (GMOs), electrical and electronic equipment and automobiles, 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* the EU legislature defined its *political* objectives. 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.

Several of these directives are based on the EU's "New Approach" to technical harmonization and standardization, pursuant to which private European standards organizations have been delegated the responsibility of elaborating technical details that industry must satisfy in order to be deemed in compliance with EU law. In other instances, standards are developed voluntarily by industry to interpret technical regulations issued directly by government. U.S. and other non-EU industry members are concerned that the EU standards-setting process actually affords them *less* transparency, openness and inclusiveness than the European regulatory process.

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

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 a matter of state practice and custom. Generally speaking, 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 otherwise settle developing rules. In addition, state practice following the execution of a treaty by a substantial number of states can also rise to the level of customary international law.

Whether or not the EU can achieve this objective remains uncertain. It depends, in part, on the resolution of a larger debate concerning the scope of WTO law and its dispute resolution process and the relationship between trade and the environment that is currently taking place within the legal and academic communities and civil society.

## **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) (“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](http://www.eudel.lt/en/eu_global_player/trade.htm).)

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.

“The EU wants a new WTO Round to have a strong environmental component so that trade and 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...*” (emphasis added). (“Trade and the Environment: Support Sustainable Development”, DG Trade (Oct. 2001), at: ([http://europa.eu.int/comm/trade/index\\_en.htm](http://europa.eu.int/comm/trade/index_en.htm).)

## **EU (Regional) Regulatory Practice and the Precautionary Principle**

EU regulatory practice within recent years has moved toward a hazard-based rather than a risk-based approach. 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.

While the EU claims that it has engaged in the type of case-by-case scientific risk analysis prescribed by the WTO regime, it has actually utilized a far broader form of risk analysis that incorporates the precautionary principle into each of its several steps – risk assessment as well as risk management and risk communication. For this reason, 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. 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.

### **EU Standards Practice and the Precautionary Principle**

The EU has sought to inject the precautionary principle into the international standards development process in several ways: (1) The Commission has emphasized the need to involve all relevant stakeholders, including non-governmental consumer representatives and environmental interest groups in the EU standards making process. (2) The EU has broadened and strengthened its regional standardization policy through use of cooperative agreements between the European political and technical communities and between European standards organizations and international standards organizations. This has “offer[ed] [the EU] a systematic framework to *take over* international standards and/or to contribute to the international standards making process” (emphasis added). (“Commission Staff Working Paper – European Policy Principles on International Standardization”, SEC (2001) 1296, (7/26/01), par. 26, at p. 10.) (3) The EU seeks to alter the composition of the international standards bodies themselves, and through them the international standards ultimately adopted. (4) In addition to the classical international standards bodies, the EU has participated in standards development within both politically and technically oriented regional and international standards bodies and has methodically expanded its reach and influence in each venue over time (e.g., the Organization for Economic Cooperation and Development (OECD)). Also, there is evidence that the EU is utilizing the good offices of the United Nations to project its standards-receptive regulatory model and its social values globally as a universally legitimate doctrine grounded on the precautionary principle in an attempt to join the issues of trade and the environment.

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.

### **EU Bilateral and Regional Trade and Aid Practice and the Precautionary Principle**

The EU has also tried to incorporate the precautionary principle directly and indirectly within EU regional and bilateral free trade agreements. Many of these free trade agreements have been executed with developing countries located on the EU’s periphery or those linked to its colonial past. Other initiatives are being pursued with countries in South America, and with South Africa, which are dependent on the EU market for trade. At least one commentator has noted that, “the main purpose of these bilateral arrangements [has been] to build developing country support for [the EU’s] position in the WTO...” (Adrian van den Hoven, Draft Paper, “Enlargement & the European Union’s Common Commercial Policy”, presented at the ‘Bigger and Better?’, The European Union, Enlargement Reform ESCA-C 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](http://web.uvic.ca/ecsac/toronto/papers/on/line/pdf/7C_avandenhoven.pdf)).

The EU recognizes that developing countries will find it difficult to participate in bilateral trade without greater regulatory sophistication. 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 modeled after those in the EU that are more stringent than objective science-based international standards.

### **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 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, and the Convention on Biological Diversity ('CBD') and the soon-to-be effective Cartagena Protocol on Biosafety ('the Biosafety Protocol') that implements Article 8(g) of the CBD.

By incorporating MEA obligations in national or regional health and safety and environmental regulations and standards, the EU has found a creative means of utilizing a more expansive interpretation of the precautionary principle to reinforce European consumer concerns and political and social values.

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

Even if the EU were able to establish the precautionary principle as a norm of customary international law, its ability to incorporate that norm within the SPS and TBT Agreements remains uncertain. There is a continuing debate within the legal and academic 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.

### **Conclusion**

A successful advocate is usually able to persuade most of his audience that he can identify with their concerns and that the goal he 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 interests. At the same time, they are competing for the hearts and minds of the developing world with respect to the role of international trade in global affairs.

Thus far, the EU has been attempting to alter the terms of the debate by injecting the precautionary principle into the WTO. The EU's application of the precautionary principle, which aims to preserve long-held European social and political values 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 toward which much of the developing world is moving.

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 succeed remains in question. The EU's failure to achieve this goal, however, may have as much to do with the difficulty of the endeavor itself 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 that leads it to believe its efforts have already succeeded. To the contrary, EU efforts to legitimize 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 pace by which states and civil society contribute to the development of customary international law. Therefore, if U.S. advocacy is to prevail and the role of objective sound science in the WTO agreements is to be preserved, the U.S. 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.