



National Foreign Trade Council, Inc.

Looking Behind the Curtain:

The Growth of Trade Barriers that Ignore Sound Science

Executive Summary

May 2003

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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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Executive Summary

THE OBJECTIVE OF THE TR2 TRADE AND RISK REGULATION PROJECT

The TR2 project was conceived to provide a response to U.S. industry concerns that costly and burdensome national standards and technical regulations were increasingly being used by foreign countries to protect ailing foreign industries and block market access to U.S. exports. While many of these complaints originally emphasized U.S. agricultural exports, an increasing number of grievances have focused on industrial and high tech industry exports with significant future economic growth potential.

The aim of the TR2 project is to identify and analyze national technical regulations, standards and procedures that have been proposed or implemented for the stated purpose of promoting human health and safety, animal welfare, and/or environmental protection, but which are not based on sound science. We believe that when these regulations and standards are not based on sound science or international standards formed through consensus, they violate the terms of WTO Agreements that serve as part of the foundation of the multilateral trading system, namely, the Sanitary and Phytosanitary (SPS) Agreement and the Technical Barriers to Trade (TBT) Agreement. Furthermore, when regulations and standards are not based on sound science they serve as *de facto* trade barriers and have a negative impact on a wide variety of U.S. export sectors, as well as, those of developing countries.

To provide substance to this debate, we have gathered evidence of circumstances: 1) where regulations and/or standards are not based on sound science or subject to a rational and balanced risk assessment, but are instead grounded in the ‘precautionary principle’, an inherently nonscientific touchstone; 2) where regulations and/or standards are not based on or do not adhere to internationally agreed upon standards developed by international standardization bodies (such as the Codex Alimentarius concerning food safety and the International Program on Chemical Safety concerning global chemicals management), or otherwise do not recognize equivalent U.S. standards and/or regulations (i.e., equivalent sanitary and phytosanitary measures or TBT ‘conformity assessment’ rules); and 3) where U.S. and other non-EU based exporters are effectively prevented from participating fully in the regulatory drafting and review processes and do not receive adequate and timely notification of regulatory changes having a material impact on market access and manufacturing processes (i.e., the regulatory processes are not fully transparent and inclusive).

Although the TR2 White Paper has divided these anecdotes and analyses between sanitary and phytosanitary measures and non-food technical measures, many of the same issues and concerns arise in both areas, impacting many different industry sectors. It is the goal of the TR2 White Paper to unmask these disguised trade barriers and to discern an analytical pattern and rationale for their adoption and implementation. Through this exercise, the TR2 White Paper hopes to promote meaningful dialogue between industry and government officials here and abroad about how to eliminate these barriers and reduce their impact on developed and developing country exports.

THE ROLE OF OBJECTIVE SCIENCE-BASED STANDARDS AND REGULATIONS WITHIN THE WTO RULES-BASED TRADING SYSTEM

The utility of standards and regulations within a multilateral rules-based trading system can be measured, in large part, by their predictability, transparency and reference to objective principles of

sound science. The WTO rules-based trading system is based on the notion that predictable and clearly defined international standards devised and adopted by recognized international bodies through consensus is the preferred platform from which to facilitate increased cross-border and international trade flows. Global businesses are not well served in the absence of such standards, or in the event governments in which they operate decide not to abide by them, and choose instead to impose their own regulations and standards.

Non-Science-Based National Standards and Regulations Can Constitute Disguised Trade Barriers

Many regulations and/or standards deny market access to a myriad of imported products in the name of serving a national objective, such as the preservation of health and safety, animal welfare and the environment, and more recently, the protection of consumer choice. However, they may actually be intended to protect ailing or otherwise noncompetitive industries.

The numerous examples cited in this paper suggest a broad approach to governance that is both insular and presumptive of the existence of unacceptable hazard or risk, even in the face of scientific evidence to the contrary. And that approach has resulted in *de facto* product bans without a prior science-based risk assessment having been conducted, as called for by the Sanitary and Phytosanitary ('SPS') and the Technical Barriers to Trade ('TBT') Agreements.

U.S. industry, in particular, has been placed at a competitive disadvantage because of these regulations. Producers of agricultural and industrial products derived from bioengineering have been effectively 'quarantined'. Manufacturers of automobiles, electrical and electronic equipment, and chemicals have also been adversely impacted, as have the many downstream industries that use or consume these products in intermediate processes or resell them as finished articles.

Non-Science-Based National Standards and Regulations Can Adversely Influence Developing Country Attitudes Toward New Technologies and Thereby Impede Their Technological Advancement

While U.S. industries appear to have the most at stake commercially, they have certainly not been the only victims. Developing countries, as well, particularly those least developed, which have little influence and play a minor role in the global trading system are hurt by the use of protectionist regulations¹. However, they stand to lose much more than just market access. In addition to lost trade opportunities, and formidable technical obstacles and compliance costs, these countries may have to pay with the lives of their citizens. For example, negative EU views toward biotechnology may cause many developing countries to overlook the merits of agricultural biotechnology, which could help to solve their endemic food shortage problems over a relatively short period of time.

Furthermore, there is also evidence of similar trade barriers being erected by less developed countries. To some extent this may be attributable to the growing global economic influence of the EU and its desire to gain a competitive advantage. This influence is being conveyed through bilateral

¹ One of the primary aims of the Doha Round world trade negotiations is "to make positive efforts designed to ensure that developing countries, and especially the least-developed among them, secure a share in the growth of world trade commensurate with the needs of their economic development. In this context, enhanced market access, balanced rules, and well targeted, sustainably financed technical assistance and capacity building programs have important roles to play." The Ministerial Declaration issued at the WTO Ministerial Conference at Doha, Qatar, November 9-14, 2001, WT/MIN(01)/DEC/W/1, at par. 2.

and regional trade and aid agreements executed by the EU throughout the developing world, and such agreements are proliferating.

The Relevance of the Precautionary Principle as Employed in the Biosafety Protocol to the WTO Rules-Based Trading System

There is also evidence that the EU is seeking, through promulgation of national and regional laws and regulations, to implement international obligations assumed under multilateral environmental agreements ('MEAs'), which it and its Member States (unlike the U.S.) have ratified. These articulate the broadest expression available of the precautionary principle as a non-science based justification for enactment of regulations to protect human health and the environment. It is possible that, by resorting to such a broad application of the precautionary principle, the EU believes it can utilize the broader provisions of the GATT, which appear to be easier to satisfy than the more narrowly construed science-based risk assessment and international standardization rules of the SPS and TBT Agreements.

SANITARY AND PHYTOSANITARY MEASURES CONSTITUTING DISGUISED TRADE BARRIERS

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.

Beef in the EU

For more than ten years the EU has banned U.S. beef exports derived from growth hormone-treated cattle, notwithstanding a WTO panel's decision, subsequently upheld by the Appellate Body in the EC-Hormones case, holding that such measures lacked a 'scientific justification' (there was no scientific evidence of health risk and no scientific risk assessment had been performed) and were thus inconsistent with EU's obligations under the SPS Agreement.²

Poultry in the EU and Japan

U.S. exports of poultry and poultry products have been subject to questionable SPS restrictions. The EU, in particular, has banned U.S. poultry exports "because U.S. producers have regularly used washes of low-concentration chlorine as an antimicrobial treatment (AMT) to reduce the level of pathogens in poultry meat production."³ The inconsistency of this ban with the terms of the SPS Agreement has become more apparent since recent European Commission audits uncovered that Member States are not complying with the EU ban on the domestic use of chlorinated water.

² Raymond J. Ahearn, Foreign Affairs, Defense, and Trade Division, "U.S.-European Union Trade Relations: Issues and Policy Challenges", at p.CRS-9; See, also: 2002 National Trade Estimate Report on Foreign Trade Barriers (NTE) ('NTE Report'), at pp. 112-113; 2003 Trade Policy Agenda and 2002 Annual Report of the President of the United States on the Trade Agreements Program ('President's Trade Policy Agenda'), at pp. 153-54.

³ President's Trade Policy Agenda, at p. 154/

Furthermore, Japan has restricted, without sufficient scientific justification, U.S. exports of poultry and poultry products since the occurrence, in 2002, of a geographically limited outbreak of ‘low pathenogenic avian influenza’ within the U.S.

Fresh Produce and Processed Fruits and Nuts in Korea and Japan

Extensive pre-clearance inspection requirements of shelled walnuts and significant delays in reviewing U.S. documentation of pest mitigation for cherries and apples exported to the Republic of Korea has effectively precluded market access for such products. Korea has also tended to prohibit certain food ingredients, additives and manufacturing processes that are generally recognized as safe by international standards bodies such as the Codex Alimentarius and the Joint FAO/ WHO Expert Committee on Food Additives (JEFCA).

Furthermore, burdensome quarantine restrictions imposed by Japan on U.S. apple exports in order to prevent transmission of fireblight bacteria serve to limit market access and reduce competitiveness of U.S. apples in Japan. The scientific evidence derived from joint research conducted by U.S. and Japanese government scientists “does not support Japan’s assertion that mature, symptomless apples can transmit said bacteria.”

Additives, Vitamins and Nutrients in Japan and Other Countries

Additives used in the fortification or preservation of grain-based products as well as certain food colorings, have been banned by several WTO Members, including Canada, Chile, Japan, EU, Korea, Thailand and Malaysia. In addition, shelf-life restrictions and registration requirements have been imposed upon such U.S. exports in certain Middle East markets.⁴

Japan’s classification of dietary supplements as drugs, has resulted in the imposition of severe restrictions on the shape, dosage and retail format for such supplements. The resulting costs and compliance difficulties faced by U.S. exporters has served to severely limit market access of these products in Japan.⁵

Wines in the EU

Non-science-based SPS-inconsistent measures have also been imposed on wine imports. The EU, in particular, has enacted regulations which “require imported wines to be produced with only those oenological practices that are authorized for the production of EU wines.” The EU has continued to grant U.S. wine exports a temporary exemption. However, the EU has failed to convert this temporary exemption for U.S. wine producers into a permanent exemption as dictated by the US-EU Wine Accords. The EU has been unable to prove that U.S. oenological practices pose a ‘health’ or ‘safety’ risk

Genetically Modified Food Products in the EU

The refusal by the EU and its Member States to admit biotech food and feed products into their markets has arguably resulted in one of the most volatile trade disputes in a long while. This practice

⁴ USITC Report at p. xix.

⁵ Ibid, at p. 227.

continues even though the European Commission has acknowledged the potential benefits offered by this technology.

"Biotechnology...in the 'agro-food' area, has the potential to deliver improved food quality and environmental benefits through agronomically improved food crops...Food and feed may be linked to disease prevention and reduced health risks. Foods with enhanced qualities ('functional foods') are likely to become increasingly important as part of lifestyle and nutritional benefits...Considerable reductions in pesticide use have been recorded in crops with modified resistance. The enhancement of natural resistance to disease or stress in plants and animals can lead to reduced use of chemical pesticides, fertilizers and drugs, and increased use of conservation tillage – and hence more sustainable agricultural practices, reducing soil erosion and benefiting the environment. Life sciences and biotechnology are likely to be one of the important tools in fighting hunger and malnutrition and feeding an increasing human population on the currently cultivated land area, with reduced environmental impact..."⁶

Since October 1998, the EU has facilitated and failed to resolve an EU-wide moratorium on any new approval of genetically engineered products. This *de facto* ban has halted \$300 million in U.S. corn shipments and threatens trade in soy as well.⁷ Products derived from livestock fed GMO feed are also at risk, as are flour and flour-based exports, grain-based products, vegetable oil derived from soy beans, and pet food. Contrary to popular belief, however, U.S. exporters of bioengineered seeds and foods are not alone. Canada, Argentina and Mexico have also been adversely affected.⁸

The GM product ban has been precipitated by concerns that these products pose an unascertainable, and consequently, an unacceptable risk of harm to human health and the environment. This presumption of harm is devoid of any presentation of scientific evidence and/or scientifically based risk assessment as required by the SPS Agreement. For this reason, the EU biotechnology dispute appears to be more of a political than a scientific issue.

The moratorium on GMOs effectively began at the Member State level. The EU, however, has upheld these moratoriums and devised a clever regulatory mechanism that operates by means of an administratively created presumption that identifies biotech crops, related food products and feed as presenting possible, unacceptable hazards to human health and the environment. Having already assessed the existence of a 'general' hazard, the regulatory scheme then seeks to manage or even eliminate the 'perceived' risks by mandating a burdensome and costly testing, authorization and market access regimen that many in industry, especially non-EU exporters, have found unworkable.

Since March 12, 2001, when it was adopted by both the European Parliament and the European Council, 2001/18/EC 'Directive On the Deliberate Release into the Environment of Genetically Modified Organisms' has represented the EU's overall view towards genetically modified foods and has signaled its future treatment of products derived from such technology within the EU marketplace.⁹ 2001/18/EC, "in general, put in place a step-by-step approval process [requiring] a

⁶ COM (2002) 27 final, "Life Sciences and Biotechnology – A Strategy For Europe", European Commission (Jan. 23, 2002), at p.11.

⁷ Raymond J. Ahearn, Foreign Affairs, Defense, and Trade Division, "U.S.-European Union Trade Relations: Issues and Policy Challenges", at p. CRS-10.

⁸ Julian Kinderlehrer, "Regulation of Biotechnology: Needs and Burdens For Developing Countries", Sheffield Institute of Biotechnological Law & Ethics, The University of Sheffield, Sheffield, UK (2002), at p. 3, at: (<http://www.unep.ch/biosafety/BtregulationJK.pdf>).

⁹ NTE Report at pp. 111-112. Before the adoption of 2001/18, the EU/European Community legislation covering the approval of genetically modified organisms, including bioengineered food, was EC Directive 90/220/EEC. This prior regime, however, was subsequently deemed inadequate by the European Commission and was repealed by 2001/18. 2001/18 required all Member States to change their existing legislation by October 17, 2002. "GMOs in the WTO – The

case-by-case assessment of the risks to human health and the environment, before any GMO or product consisting of or containing GMOs can be released into the environment or placed on the market.”¹⁰

Directive 2001/18/EC did not, however, satisfy the concerns of the EU Member States upholding the moratorium. They have refused to lift their *de facto bans* and restart the GMO approval process until additional rules on labeling and traceability are enacted. This reaction has prompted the Community bodies to discuss two new regulations, “a Regulation on GM food and feed and a Regulation concerning traceability and labeling of GMOs of food and feed products produced from GMOs.”¹¹ While the authorization regulations are certain to impede significant amounts of trade in GM food and feed produced by non-EU exporters, its precise impact is currently unknown. The ‘scope’ of application of the proposed GM Food and Feed authorization regulation continues to be debated by the European Commission and the European Parliament. One legal commentator has noted, that “the Commission accepts that it should extend only to GM food and feed containing or consisting of GMOs...the European Parliament, [however, wishes] that it extend [also] to GM food or feed produced with GMOs.”¹²

GMO Traceability and Labeling

Traceability is thought of as “providing a ‘safety net’ in case unforeseen adverse effects on human health or the environment are established.”¹³ Practically speaking, “the Regulation [would] apply at all stages of the placing on the market to products consisting of GMOs. Every operator has to assure that information is passed on to the next operator receiving the product in the process of market placement.

The labeling component of the proposed regulations would require that all food and feed which consist of, contain or are produced from GMOs be labeled as such. One of the more problematic aspects of the labeling regulations is that they would “extend the current labeling provisions to all genetically modified food or feed, *irrespective of the detectability* of genetically modified DNA or protein” (emphasis added).¹⁴ This issue would seem to go right to the heart of the ‘like products’ test within the ‘national treatment’ clauses of the SPS, TBT and GATT Agreements.

The EU and its Member States have justified the traceability and labeling measures not on safety grounds, but on the need to inform and provide their consumers with a choice about biotechnology and bioengineered foods. This rationale ignores the fact that “the genetically modified products currently on the international market have all passed thorough [science-based] risk assessments conducted by national authorities following the same basic principles, which do not indicate any [actual] risk to human health.”¹⁵ Instead, the EU and its Member States justify their perception of

Dispute Between the U.S. and the EU: EC Regulation of GMOs and its Application”, Institute of International Economic Law, Georgetown University Law Center website.

¹⁰ “Question and Answers on the Regulation of GMOs in the EU”, European Commission, (Oct. 17, 2002), at: (<http://www.health.fgov.be>), at p 1.

¹¹ “GMOs in the WTO – The Dispute Between the U.S. and the EU: EC Regulation of GMOs and its Application”, Institute of International Economic Law, Georgetown University Law Center website.

¹² Joanne Scott, “European Regulation of GMOs and the WTO”, at p. 2.

¹³ Directive Article 12, as cited in “GMOs in the WTO – The Dispute Between the U.S. and the EU: EC Regulations of GMOs and its Application”, Institute of International Economic Law, Georgetown University Law Center website.

¹⁴ “Question and Answers on the Regulation of GMOs in the EU”, European Commission, at p. 8.

¹⁵ “Fact Sheet: WHO Answers Questions About Biotechnology Foods”, U.S. Department of State, International Information Program, at p. 4.

risks and their management and communication of them by reference to the ‘precautionary principle’.

The GMO Moratorium and Proposed Regulations Are Disguised Trade Barriers

Members of the Bush Administration have pointedly warned the EU that the U.S. would pursue a WTO case if the EU does not follow-through on its end of the bargain to implement a long awaited plan that would restart the GMO approval process. During November 2002, the EU supposedly began this process by ordering resumption of approvals of new GMO products in return for a new process of labeling and tracing the true origin of imported GMO agricultural products.¹⁶ However, many EU Member States continue to uphold the moratorium.

During February 2003, the European Commission warned EU governments to end their foot-dragging over approval of new GM crops. Mr. David Byrne, EU Commissioner for Health and Consumer Safety, expressed his frustration with the position of some member states. “Member states have been unduly timid about this [lifting the moratorium]… We have various prestigious scientific institutions that have said *GM foods do not cause any harm to consumers. There is no evidence that this food is any more unsafe than conventional foods* (emphasis added).” He urged governments to do more to persuade consumers that GM products were safe.¹⁷ This statement followed the December 2002 admission by EC Commissioner Walstrom that, the moratorium was “illegal and unjustified.” Nonetheless, Europe’s top legal advisor, on March 13, 2003, upheld Italy’s right to ban genetically modified corn flour.¹⁸

The Bush Administration believes that the enactment of the new GMO food and feed authorization regulations and the continuation of the EU moratorium until new regulations on GMO traceability and labeling have been enacted, both violate the SPS Agreement. Absent evidence of any specific instance of harm, the EU has nevertheless proceeded to invoke the ‘precautionary principle’ pursuant to which it has established an administrative presumption of a general risk of harm to justify these measures.

The regulations’ requirement that “biotech food and feed must not present a risk for animal health, human health or the environment imposes an insurmountable evidentiary burden upon exporters of such products. As the U.S. Government has noted, “this level of assurance is wholly unobtainable for any food or feed product, regardless of production method, as the absence of risk can never be proven.”¹⁹ The regulation may also be discriminatory and a disguised trade barrier to the extent this standard differs from any other applied by the EU to non-biotech food and feed safety standards or standards established for food additives or pesticide residues.²⁰ Furthermore, the regulatory provision that requires “applicants [to] supply a method for sampling and detection of each event in

¹⁶ “No GMO Case Against EU for Now”, Washington Trade Daily, Feb. 6, 2003 at p.1.

¹⁷ Tobias Buck, “Brussels Warns EU on Modified Crops, European Commission Governments Told to End Foot-Dragging on Approving Products But U.S. Attached for Threat of WTO Challenge”, Financial Times, Feb. 4, 2003.

¹⁸ Michael Schroeder, “U.S.-EU Trade Fight Isn’t Over, Just Sidetracked”, Wall Street Journal, 3/14/03, at p.A8.

¹⁹ U.S. Comments to Proposal for a Regulation of the European Parliament and of the Council on Genetically Modified Food and Feed, at p. 3.

²⁰ In its comment letter, the USTR posed the following question: “How does this [proposed food and feed safety standard] relate to [...] other food and feed safety standards and existing standards established for food additives, or pesticide residues in food” Ibid.

foods and feeds,” imposes undue administrative, economic and evidentiary burdens on exporters.²¹ A related concern is that, biotech food products will be distinguished from conventional food products having essentially the same physical and DNA characteristics, based on their differing processing and production methods (‘PPMs’). Aside from the potential issue surrounding the imposition of different levels of protection on equivalent levels of risk, there remains the broader obligation to accord ‘like-kind’ products similar treatment.

U.S. officials have also remained publicly concerned that the regulatory and administrative process pursuant to which the proposed regulations have been drafted has been neither transparent nor stakeholder inclusive. In particular, they have alleged that, the EU has failed to provide the U.S. and other Member States with documentation on the appropriate EU risk assessment procedures and relevant factors that the EU will consider when undertaking such assessments of biotech products, prior to the effective date of the regulations. In addition, if no actual hazard or risk of harm has been assessed with respect to a specific biotech product, the additional tracing and labeling of that product would not contribute to consumer health or safety. Consequently, these measures could not be justified as necessary to protect human health, within the meaning of Article 2.2 of the SPS Agreement. Similarly, traceability and labeling requirements imposed on products that have already undergone a scientific risk assessment and been approved for use are not likely to enhance consumer safety.

The EU justifies its labeling requirements on the basis of consumer choice, and by extension, consumer protection. However, “if consumer choice were truly the objective of the proposal”, the EU would have devised a measure that identified “what would constitute a food that has not been produced through biotechnology.”²² The labeling requirements are also susceptible to fraud and misinformation. U.S. officials have noted that in some cases, “it [would] be impossible to verify, by testing, a claim that product ingredients are non-biotech.”²³

The traceability requirements of the proposed regulations, unlike the labeling requirements, are more clearly classified as an SPS measure. “According to the EU’s proposal, traceability is used to facilitate the withdrawal of products due to unforeseen adverse effects to human health or the environment. Given the stated objective of the proposed regulation, it would be U.S. understanding that the proposed traceability regulation is therefore a measure defined as a sanitary or phytosanitary measure under the WTO.” However, these regulations present their own difficulty. In light of the EU’s determination that GMO products are as safe as conventional products²⁴, it would appear that they would not provide any added margin of safety. Furthermore, there exists a less costly, administratively burdensome and less trade-restrictive measure that the EU could have adopted to accomplish its objective, namely the U.S. trace-back system, which has worked effectively for years.²⁵ Given these facts, the ‘necessity’ of the proposed traceability regulations as an SPS measure, would be in doubt.

GMOs and the Precautionary Principle

²¹ “U.S. Comments to Proposal for a Regulation of the European Parliament and of the Council on Genetically Modified Food and Feed, at p. 4.

²² “U.S. Comments to Proposal for a Regulation of the European Parliament and of the Council on Genetically Modified Food and Feed, at p. 7.

²³ Ibid.

²⁴ “A Review of Reports: EC-Sponsored Research of Genetically Modified Organisms”. Ibid.

²⁵ Ibid.

The EU's approach of identifying, assessing and addressing the perceived hazards posed by GMOs and the food products derived from them appears consistent with the approach taken by the Cartagena Protocol on Biosafety, a multilateral environmental agreement. Although it has not yet entered into force, the Biosafety Protocol is already having an impact on the way countries are handling biotech products awaiting shipment across their borders.

A careful examination of the Protocol also indicates that, it creates "a precedent for genetically modified crops to be treated differently from hybridized crops, even when there is no scientific evidence that they represent a threat to anything. As such, these crops are being judged on the basis of the process used to produce them rather than on the level of risk represented by the product itself."²⁶ Given the Biosafety Protocol's inclination towards precaution, it is not surprising that the EU has chosen an approach to assessing and managing hazards that approximates the Protocol's approach to risk analysis. This approach favors processes over products and non-science over science, and as a result is in conflict with the hard fought scientific and objective principles contained within the WTO Agreements, which seek to establish a stable, clear, predictable and consistent regulatory approach.

The EU's efforts to incorporate the Protocol's expression of the precautionary principle and risk analysis rules into other international bodies and instruments indicate an attempt at sanctification throughout WTO legal jurisprudence. This would, in effect, elevate the status of the precautionary principle from a provisional WTO exception to a norm of customary international law. As noted by one commentator, "it appears that the building blocks are being placed to make the precautionary principle into a keystone of international agreements."²⁷

New EU GMO Legislation and the Developing World

The GMO authorization rules would effectively block several types of developing country trade in seed and food products. Traceability and labeling rules would impose additional costs and administrative burdens upon developing countries that already lack the institutional and technical capacity to adhere to more workable international standards on food safety. The resulting trade loss would deprive developing countries of sorely needed revenues from which to finance their balance of payment obligations and infrastructure development. Also, it would reduce the number of currently available jobs and prospects for future employment, especially within least developed countries lacking a manufacturing infrastructure.

From a social and humanitarian perspective, the new EU GMO authorization rules would deprive developing countries of a number of significant potential health benefits offered by agricultural biotechnology, and thereby deny their citizens the ability to sustain and possibly improve their lives. As noted by African scientist, Dr. John Wafula, of the Kenya Agricultural Research Institute (KARI), "Biotechnology in Africa hinges on averting mass starvation and alleviating rampant poverty."²⁸ The technical, administrative and economic burdens that will be borne by developing country governments as the result of the EU's new GMO regulatory regime would only worsen their ability to satisfy international food safety standards.

²⁶ Frances B. Smith, "The Biosafety Protocol: The Real Losers Are Developing Countries", at pp. 19-20.

²⁷ Frances B. Smith, "The Biosafety Protocol: The Real Losers Are Developing Countries", at p. 25.

²⁸ Catherine Mgendi, "Local Scientists Snub the West in Biotech War – "Need for Biotechnology in Africa is Very Clear".

NON-FOOD REGULATIONS CONSTITUTING DISGUISED TRADE BARRIERS

Just like the bioengineered products banned by the EU moratorium, many non-agricultural products are currently evaluated not by how they perform but rather by their intrinsic properties and by the deemed dangers, both known and unknown, that are associated with them. Unfortunately, the decisions made by the relevant EU institutions regarding these supposed dangers are influenced not by scientific evidence of actual risk, but rather, by a fear of hypothetical hazards grounded in political, social and moral principles.

The following discussion highlights and analyzes a number of technical regulations mostly imposed by the EU that constitute disguised barriers to trade.

Aviation Hushkits in the EU

A primary example of a safety and environmental regulation lacking an objective scientific rationale, a grounding in predictable international standards, and a transparent and inclusive legislative process involved the EU's aircraft noise regulation, EU Council Regulation 925/99 (the aviation "hushkits" regulation). That regulation was allegedly aimed at reducing noise around airports, but actually had little impact on noise. It disproportionately impacted U.S. manufacturers and airlines by limiting registration and use within the EU of certain aircraft modified and recertified to meet the International Civil Aviation Organization's (ICAO) most stringent noise certification standards.²⁹ These were essentially recertified aircraft that were equipped with "hushkit" noise reduction devices or "re-engined" with engines of a certain design.³⁰

Because of the one-sided impact of the regulation, it appeared that U.S. aviation industry interests had not been equitably represented and taken into account during the EU legislative process. A further study of this regulation showed that it was grounded on an EU-established design standard, without regard to the international standards created by the ICAO. The regulation was eventually repealed by the EU and replaced with an international framework called the Balanced Approach.³¹

End-of-Life Initiatives in the EU

The EU has proposed a trio of 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. These directives could effectively 'lock out' U.S. manufacturers of everything from computers and telecommunications equipment to clock radios and toasters, from the European market.³²

²⁹ NTE Report at p. 118.

³⁰ "2001 Country Reports on Economic Policy and Trade Practices, European Union", Released by the Bureau of Economic and Business Affairs, U.S. Department of State, Sec. 5, 'Significant Barriers to U.S. Exports' (Feb. 2002).

³¹ During March 2000, the U.S. brought the matter before the ICAO pursuant to dispute resolution proceedings under the 1944 Convention on International Civil Aviation, and ultimately entered into settlement with the EU. In June 2001, the ICAO Council adopted a new aircraft noise standard, which the ICAO General Assembly unanimously approved. The resolution established an international 'framework' on how states should manage noise around airports called the 'Balanced Approach'. The EU Commission then stated its commitment to implement an ICAO-consistent noise management framework directive and to repeal the hushkits regulation. Ibid; NTE Report at p. 118.

³² Dave Bell, "Europe Targets Environmental Impacts of Electrical and Electronic Equipment", ChipCenter.com, (Feb. 20, 2002) at: (<http://www.chipcenter.com/eexpert/lgoldberg2/dbell021.html>).

The WEEE and RoHS Directives

The WEEE Directive aims at establishing measures for the prevention of waste from electrical and electronic equipment, on the collection of such waste as well as their treatment, recycling and recovery.³³ The Directive also seeks to promote product stewardship by “encouraging the design and production of electrical and electronic equipment” in order to “facilitate their repair, possible upgrading, reuse, disassembly and recycling”.³⁴ The directive would apply not only to ‘brick and mortar’ local sellers, but also to long distance and electronic sellers, to importers, as well as to resellers if they market products under their own brands that were originally manufactured by other companies.³⁵ Much of the controversy surrounding the WEEE directive regards its finance provisions which require producers to bear not only the collection, treatment, recovery and disposal costs for their own products but also to share proportionately the costs of ‘historical waste’ and to provide for appropriate financial guarantees for the recycling of *its own products* sold after September 2005.

The RoHS Directive bans the use of certain substances in electrical and electronic equipment that are deemed to cause significant environmental problems during the waste management phase. Unlike the WEEE Directive, RoHS also requires manufacturers to find ‘substitutes’ for these substances, and with few exceptions, manufacturers would have only until July 1, 2006, to phase these materials out of their products.³⁶

While the U.S. has supported the underlying objectives of the WEEE and RoHS Directives, it is argued that the processes by which these directives were drafted and adopted lacked transparency and were inequitable.³⁷ That the proposals would, in part, ban certain materials and impose comprehensive collection and recycling requirements for end-of-life equipment on a *retroactive* basis amounts to a technical trade barrier. Furthermore, trade would be damaged to the extent that no alternatives to the banned products could be developed.³⁸

An EU Committee itself found vulnerabilities in the process by which WEEE and RoHS were developed. “An EU substance ban not supported by appropriate risk assessment is contrary to international trade law, as it would create a technical barrier to the trade of electronic and electrical equipment without the requisite demonstration of justification.”³⁹ Efforts made by three of Europe’s largest semiconductor manufacturers to voluntarily team up to develop proposed standards for defining and evaluating lead-free assemblies and packaging (i.e., alternative technologies) before the RoHS Directive became effective, does not rise to the level of a scientific risk assessment.

This declaration was highlighted and elaborated upon by the European Brominated Flame

³³ Rod Hunter and Marta Lopez Torres, “Legality Under International Trade Law of Draft Directive on Waste From Electrical and Electronic Equipment”, Hunton & Williams, Brussels, (August 17, 1999), citing Draft WEEE Directive, art.1.

³⁴ 2002/96/EC, Preamble par. 12.

³⁵ CECED Press Release, Dec. 18, 2002, at p. 4.; 2002/96/EC, Preamble, pars. 12 and 13; Art. 3(i).

³⁶ “EU Directives – RoHS and WEEE Now EU Law”, Reported by ERA Technology Ltd.; 2002/95/EC, Art. 4(3).“Commission Tackles Growing Problem of Electrical and Electronic Waste”, Brussels, 13 June 2000, at: (<http://www.europa.eu>).

³⁷ NTE Report at pp. 115-16; “2001 Country Reports on Economic Policy and Trade Practices, European Union”, Released by the Bureau of Economic and Business Affairs, U.S. Department of State, Sec. 5, ‘Significant Barriers to U.S. Exports’ (Feb. 2002).

³⁸Ibid, at p. 116.

³⁹ “Initial Discussion Paper on the Proposed WEEE and RoHS Directives”, EU Committee Comments, (October 5, 2000).

Retardant Industry Panel of CEFIC, which had analyzed the quality of the perfunctory assessment alleged to have been conducted by the Commission:

“The EC’s proposal to restrict the use in electrical and electronic equipment of a number of substances calls into question the fundamental role of the EU’s ‘risk assessment’ process under EU Reg. 793/93/EC and its relationship to trade law... The EC’s proposal represents a ‘radical shift’ towards policy based on isolated scientific studies instead of an agreed ‘risk assessment process which is a ‘life-cycle’ assessment thus including potential end-of-life impacts... This is an invitation for a whole series of substance phase-outs which would lead to the introduction of alternative untested substances...and contentious international trade barriers ... The Commission’s proposal is backed up by erroneous statements and references to outdated scientific studies...”⁴⁰

The EEE and EuE Directives

The EU previously developed a proposed directive that would “comprehensively regulate the product design of electrical and electronic equipment, with the objective of minimizing harmful effects on the environment.” The proposed directive was described by the European Commission as a ‘New Approach’ Directive. The EEE Directive essentially would hold manufacturers responsible for an assessment of the magnitude of environmentally relevant inputs and outputs and, to the extent possible, of the related environmental impacts.⁴¹ In addition, manufacturers of components and subassemblies integrated into a final EEE product are also subject to the directive, insofar as they are required to provide information about material composition and consumption of energy and resources relating thereto.⁴²

The US industry had expressed concern that the EEE Directive “ha[d] the potential to interfere with design flexibility, delay new product development and introduction, and impose extensive administrative burdens”. U.S. industry was also concerned that the “European standards and regulatory development processes were not sufficiently transparent and open to non-EU stakeholder input.”⁴³

The ‘New Approach’ directives, such as the EEE, furthermore, would not likely be WTO compliant, to the extent they fail to incorporate or otherwise reflect standards established by internationally recognized standardization bodies. Similar international trade concerns were expressed in a comment letter jointly prepared and submitted by the AeA, the EIA, the NEMA and the SIA, four leading U.S associations in the electrical and electronics industries, in response to the then proposed EEE Directive.⁴⁴ The letter articulated several trade-related arguments. First, it alleged that the broad scope of the EEE Directive would make producing clear measurable standards difficult within the EU. As a result, a company’s design decisions would not be immune from questioning by individual Member States. Second, it alleged that because the supply chain in the electrical and electronics industry is worldwide, the design choices made by European standardization bodies would have ‘extra-territorial’ environmental and economic impacts on non-EU countries and

⁴⁰ European Brominated Flame Retardant Industry Panel Comments to the RoHS Directive (12/14/00).

⁴¹ “A Study Into the Impacts of the Proposed Electrical and Electronic Equipment (EEE) Directive, Appendix A – The Requirements of the Draft Electrical and Electronic Equipment (EEE) Directive”, by Entec, UK (Environmental and Engineering Consultancy UK) at: (http://www.entecuk.com/client/ec/fr_appendixa.html).

⁴² Proposed EEE Directive, Art.3.

⁴³ NTE Report at p. 116; “2001 Country Reports on Economic Policy and Trade Practices, European Union”, Released by the Bureau of Economic and Business Affairs, U.S. Department of State, Sec. 5, ‘Significant Barriers to U.S. Exports’ (Feb. 2002).

⁴⁴ See: “AeA, EIA, NEMA and SIA Position Paper on EEE” (August 2001), at: (http://www.europa.eu.int/comm/enterprise/electr_equipment/eee/comments.htm).

industries that had not previously participated in the underlying EU standardization process. The joint letter, furthermore, alleged that, the process, which was intended to “fill in the regulatory and compliance details which companies have to follow, did not include all stakeholders”. In addition, the letter alleged that, “...the use of regional standards to provide a presumption of conformity may lead to trade-distorting and anti-competitive effects by implicitly favoring EU products and approaches to design-for-environment.”⁴⁵

The proposed EEE Directive (and a sister directive, the EER Directive -The Directive on Energy Efficiency Requirements for End-Use Equipment⁴⁶) will soon be replaced with a new proposal, the EuE Directive (Eco-Design of End-Use Equipment).⁴⁷ The EU Commission is now considering industry comments received in response to this new proposal, which “includes [a number of] paragraphs of the EEE Directive which large groups within industry have always objected against”.⁴⁸

At least one European electrical and electronic industry recycling consultant has noted the broad scope of the proposed EuE Directive. It’s objective is

“To ensure the free movement of end-use equipment by integration of environmental aspects in the design & development of equipment and by setting eco-design requirements. The draft defines EuE as, equipment which is dependant on energy input (electricity, fossil and renewable fuels) to work as intended and equipment for the generation, transfer and measurement of such energy. Presumption of conformity to the directive is through a CE mark as well as established EU schemes such as the Eco-Label”.⁴⁹

⁴⁵ Ibid.

⁴⁶ European Parliament and Council Directive 2000/55/EC, (September 18, 2000). The purpose of the directive is to achieve cost-effective energy savings in fluorescent lighting, which would not otherwise be achieved with other measures. This directive covers only newly produced ballasts, which are responsible for high energy consumption and offer considerable potential for energy savings.

⁴⁷ The EuE Directive is intended to incorporate material portions of both these directives. “The Commission is currently examining strategies as to how other policy areas can integrate environmental aspects. The EU proposal demonstrates how such integration can be achieved in practice.

The working paper contains an initial draft text for a directive which harmonizes requirements concerning the design of end use equipment to ensure the free movement of these products within the internal market, aiming to improve their overall impact on the environment, and thus providing an efficient use of resources and a high level of environmental protection compatible with sustainable development.

The intention is to shape one framework directive by merging two initiatives - the EEE (impact on the environment of electrical and electronic equipment) and the EER (energy efficiency requirements) - on which previous consultations already took place.” See: “Environmentally Friendly End Use Equipment – Proposal for an EuE Directive”, at: (http://europa.eu.int/comm/enterprise/electr_equipment/eee) (January 20, 2003).

⁴⁸ See: “CECED Revised Critique on the Commission Services’ Draft Proposal for a Directive on Establishing a Framework for Eco-Design of End-Use Equipment”, (Dec. 2002). CECED represents the household appliance industry in Europe.

⁴⁹ “The directive requires manufacturers to perform a conformity assessment of the EuE with the relevant requirements of applicable implementing measures. The implementing measures specified in the directive include Internal Design Control and an Environmental Management System. The implementation measures introduce eco-design requirements and specific eco-design requirements for selected environmental aspects which have a significant adverse effect on the environment. The eco-design requirements require manufacturers to consider the entire life cycle of equipment and to assess the ecological profile of the equipment. This includes a life cycle analysis of equipment looking at: raw materials; acquisition; manufacturing; packaging, transport and distribution; installation and maintenance; use; and end of life. At each phase of this manufacturers are required to assess consumption of materials and energy, emissions to air and water, pollution, expected waste and recycling / re-use.” “RID UK: Environmentally Friendly End Use Equipment”, Rid UK Limited, Electrical and Electronic Recycling Consultants, at: (<http://www.getrid.UK.com/pages/eue.html>)

The proposed EuE Directive is itself undergoing an evolution of sorts and may be replaced with a more expansive draft directive later this year (2003).⁵⁰

Vehicles in the EU

The objective of the Directive of End-of-Life Vehicles (ELV Directive) is to encourage vehicle producers to prevent and reduce the use of hazardous substances in the production of vehicles in order to prevent their release into the environment, to facilitate recycling and to avoid the disposal of hazardous waste.⁵¹ These substances include lead, mercury, cadmium, hexavalent and chromium (heavy metals), as well as, all plastics, including PVC.⁵² The directive covers all new vehicles and end-of-life vehicles, as well as their components and materials, and it precludes the use of hazardous heavy metals in vehicle materials and components after July 1, 2003.⁵³

The ELV Directive encourages vehicle manufacturers to work in concert (share proprietary information and resources) with material and equipment manufacturers to promote standards for the design of eco-friendly vehicles.⁵⁴ Similarly, it encourages vehicle producers and component manufacturers to share product and design information with treatment facilities to ensure proper identification, dismantling, storage and recycling of such items.⁵⁵ The directive, furthermore, places the financial burden of collecting end-of-life vehicles from consumers almost entirely upon vehicle manufacturers and importers.⁵⁶

While it may be agreed that the EU objective of protecting the environment from improperly disposed vehicle waste is a legitimate public objective, it is arguable that the costly and burdensome measure selected to achieve this objective is neither ‘necessary’ nor ‘the least trade-restrictive’ measure available. In addition, its focus on *existing* vehicles discriminates against ‘like’ products based on processing and production methods rather than performance or ‘end-use’. Also it is questionable whether U.S. stakeholder interests have been adequately considered and reflected in the final legislation.

Eco-Design and Eco-Labeling in the EU

⁵⁰ Unofficial sources have recently confirmed that the EU is considering the issuance of a new draft Framework Directive on Eco-Design for Energy-using Products (EuP). The draft directive would incorporate and replace the proposed EuE Directive, which had combined certain provisions from earlier, separate draft proposals on Energy Efficiency Requirements (EER) and the Impact on the Environment of Electrical and Electronic Equipment (EEE). The draft directive is broad-minded and would require manufacturers of **all** products that use energy and that are sold in the EU to perform an assessment of the environmental impacts of such products throughout their lifecycles. It would also require manufacturers, based on that assessment, to design and manufacture the product in a manner which lessens its impact on the environment. The purpose of the draft directive is to reduce energy usage within the EU and to help it meet its obligations under the Kyoto Protocol to the United Nations Convention on Climate Change (UNCCC), a multilateral environmental agreement. The new draft directive may become official as early as June 2003. It is believed that this new formulation presents problems similar to those described with respect to the draft EuE and the EEE directives.

⁵¹ Directive 2000/53/EC on End-of-Life Vehicles of the European Parliament and of the Council (Sept. 18, 2000), as amended by 2002/525/EC (June 27, 2002), at Preamble, par. 11; Arts. 1 and 2(1).

⁵² Ibid, at Preamble, par.11.

⁵³ Ibid, at Art. 4(2)(a); Annex II.

⁵⁴ Ibid, at Arts. 2(2), 3(1), 4(1)(c).

⁵⁵ Ibid, at Art. 8

⁵⁶ Ibid, at Preamble, par. 7 and Art. 5(4).

The Green Paper on Integrated Product Policy (IPP) is intended to cover all product systems and their environmental effects, taking a lifecycle perspective as the lead principle.⁵⁷ It “intends to complement existing environmental policies by using so far untapped potential to improve a broad range of products and services throughout their lifecycle, from the mining of raw materials to production, distribution, use, and waste management.”⁵⁸ The overriding objective is to use the “synergies of environmental improvement and business development …to contribute to the goals of [s]ustainable [d]evelopment”.⁵⁹

The IPP reflects an extension of the concepts of producer responsibility and product stewardship. It promotes an approach that focuses “on the ‘eco-design’ of products and the creation of information and incentives for an efficient take-up and use of greener products”.⁶⁰ To this end, the IPP calls for generating consumer demand for such products through ‘eco-labeling’. According to the IPP, eco-labels “have an important role to play in sustainable consumption as they define in a credible, transparent way, a threshold for distinguishing the more environmentally friendly products from less environmentally friendly ones.”⁶¹ The problem here is that the IPP appears to rely almost exclusively on European standardization bodies for developing eco-design and eco-label guidelines, while paying only ‘lip service’ to the notion of meaningful stakeholder involvement.⁶²

What is most troublesome about this initiative is the almost certain extra-territorial impact that it will have, particularly upon developing countries with which the EU has or intends to enter into trade agreements. The scope of the IPP initiative is broad enough and the potential for political manipulation and abuse of the eco-label scheme great enough that there is a real likelihood EU products would be favored over U.S. and other country products in contravention of the GATT and TBT Agreements.

Chemicals in the EU

Probably the EU regulatory proposal that has generated the most industry concern has been the EU Chemicals White Paper (“Strategy for a Future Chemicals Policy”). The proposal seeks to establish a single system for assessing existing and new chemical substances called ‘REACH’ (Registration, Evaluation, and Authorization of Chemicals). The REACH legislation would require some 30,000 chemicals now in use, some for decades, to be immediately registered with EU authorities. Chemical manufacturers, as well as downstream users of products would then be subject to bans of certain chemical substances and these bans would be based on the precautionary principle.

The number of downstream industries potentially impacted by the White Paper is staggering, ranging from formulators of preparations using different substances, to manufacturers of finished products that use chemical substances in ‘intermediate’ processes, to end-users of the chemicals themselves. Impacted sectors could include: textiles, clothing, leathers, agriculture, metals, mechanical and electrical engineering, services (including lodging and catering, transport), construction, automotive, paper and printing products, and final consumption products.⁶³

⁵⁷ Green Paper on Integrated Product Policy COM(2001) 63 final (Feb. 7, 2001), at p. 5.

⁵⁸ Ibid, at p.3.

⁵⁹ Ibid.

⁶⁰ Ibid, at p. 5.

⁶¹ Ibid, at p. 13.

⁶² See: fn 145.

⁶³ Ibid, at p.2. See, also: “Business Impact Study – Sectoral Fact Sheets”, CEFIC (December 2002).

It is not unreasonable to conclude that the application of REACH to finished products is meant to protect European companies in these downstream industries. Evidence of the seriousness with which European industry views the risks posed to their global competitiveness is clearly expressed within a comment letter prepared by Eurochambres, the Association of European Chambers of Commerce and Industry. In the document, Eurochambres argued that, “there must be a ‘level playing field’ for chemicals (particularly *imported* chemicals) as constituents of finished products (e.g., toys, textiles). Substances with potential impact on human health and/or environment imported to the EU as constituents of products must not be exempt from notification. Controls must be in place to ensure that finished products *imported* to the EU do not contain untested and unregistered substances. This should ensure that EU manufacturers remain *competitive* with finished products from outside the EU (emphasis added).”⁶⁴ The problem with this position, however, is that the approach it advocates, namely the banning of imports of an article simply because it contains an unregistered chemical, presumably violates existing WTO jurisprudence. Even CEFIC, the primary European chemical industry trade association, recognizes that the WTO rules prevent EU legislation from banning the import of substances or finished articles containing non-registered substances in order merely to maintain home country competitiveness.⁶⁵

Like many other EU directives, the White Paper is a hazard-based rather than a risk-based initiative. This means that it premises regulatory treatment of, and distinctions between such substances and downstream products on an administratively created presumption of risk⁶⁶ based on the ‘precautionary principle’. Though among the White Paper’s objectives are the protection of human health, animal welfare and the environment, the issues addressed by the White Paper appear to focus on systemic problems within the EU rather than scientific evidence of actual risk or harm.⁶⁷

The White Paper has the potential to violate the GATT Article III and TBT Article 2.1 ‘national treatment’ clauses⁶⁸. It has been argued, furthermore, that finished ‘like’ products having different chemical ‘inputs’ would arguably be subject to dissimilar and perhaps more burdensome regulatory requirements based on differing volumes of production or importation of inputs.⁶⁹

The White Paper’s regulatory presumption of risk potentially affects the way the public perceives certain items in the marketplace. In effect, the Commission and Member State governments would be creating consumer expectations and inducing consumer distinctions, and by virtue of them, would be justifying the regulatory measures proposed to address the risks perceived by such a presumption.⁷⁰ This is tantamount to creating a “self-justifying” trade barrier” that can adversely and illegally “affect the competitive conditions of imports”.⁷¹

The White Paper’s creation of a data-sharing obligation among chemical manufacturers, formulators, processors, and downstream industrial users, including importers could potentially be discriminatory

⁶⁴ Eurochambres, “European Business Position on the ‘White Paper on the Strategy for a future Chemicals Policy’” (Sept. 2001), at p.6.

⁶⁵ “EU Chemicals Policy Review – The View of European Mid-Sized and SME Chemical Manufacturers”, CEFIC, (Nov. 28, 2002) at pp. 1,2 and 4; “Barometer of Competitiveness 2002: Business Impact of New Chemicals Policy”, CEFIC, at p. 4.

⁶⁶ Legal Opinion of Crowell & Moring, “White Paper, Strategy for a Future Chemicals Policy” (‘White Paper’), (Nov. 7, 2002), at p. 6.

⁶⁷ COM (2001) 88 final, “Major Problems Identified By Review”, at p.6.

⁶⁸ Crowell & Moring, *infra*.

⁶⁹ Crowell & Moring at p. 5.

⁷⁰ COM (2001) 88 final, ‘Political Objectives of the Proposed Strategy’, at p.7.

⁷¹ Crowell & Moring, at p. 6, fn 20.

against ‘imported’ products if “the EU program on evaluation of existing chemicals is operated so that the first registrants are mostly EU manufacturers and the subsequent registrants are mostly foreign, or if testing information provided by foreign importers is not accepted.”⁷²

At least one industry comment letter received from a prominent U.S. trade association, the American Chemistry Council (‘ACC’), has stated that its members have been denied the opportunity to effectively participate in the drafting and review process involving the promulgation of regulations to implement the proposed Chemical White Paper.⁷³ What particularly has irked the ACC membership is the EU’s planned Internet consultation on the new chemicals policy, scheduled to take place sometime during the second quarter of 2003.⁷⁴ The ACC argued that the Internet consultation “should not be considered, in either substance or process, an effective notice of either a new regulatory technical regulation or a meaningful opportunity for parties and other stakeholders to comment”.⁷⁵

A further argument that can be advanced against the Chemicals White Paper focuses on the EU’s failure, when formulating the proposed regime, to take into account existing or imminent relevant international standards⁷⁶. Alternatively, it can be argued that, in the absence of such standards, the EU has failed to give positive consideration to equivalent technical regulations of other Member States that could adequately fulfill the White Paper’s objectives in a less trade restrictive manner.

A review of the White Paper’s requirements reveals that the EU arguably did not use existing relevant international standards or the relevant parts of them as a basis for the White Paper. Two international standards bodies are involved in the development of global standards for chemicals. The International Program on Chemical Safety (IPCS), which was created specifically to develop a scientific basis for global chemicals management, is one such organization. The Organization for Economic Cooperation and Development (OECD), which is neither a law-making body nor a scientific organization, is the other.⁷⁷ It has been alleged that “parts of the EU Chemicals Strategy 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.”⁷⁸

EU Chemicals Policy and the Developing World

Since many commodity products are formulated, manufactured and/or assembled in overseas developing country factories, developing country exporters of such products and their upstream

⁷² Ibid, at p.8.

⁷³ Comment Letter dated February 28, 2003, from American Chemistry Council submitted to the USTR in response to “Operation and Implementation of the WTO Technical Barriers to Trade (TBT) Agreement, 68 Fed. Reg. 5237 (Feb. 3, 2003)”.

⁷⁴ “The European Commission is planning an Internet consultation on the practical considerations that may arise with respect to the new chemicals regulations, perhaps as early as mid-April 2003. Various media outlets have reported that Mrs. Margot Wallstrom, the Director General for the Environment of the European Commission, has indicated that the consultation will not focus on the substantive elements of these technical regulations, and indeed that she expects no major amendment to be made to the regulations as a result of this summary review opportunity”. Ibid, at pp. 1-2.

⁷⁵ Ibid.

⁷⁶ See: the Appellate Body’s decision in EC-Sardines, pars. 240, 242, 243, 245, 248, 250, and 259, for an interesting discussion of the meaning of the terms ‘relevant international standards or the relevant parts thereof’.

⁷⁷ Eileen Ciesla, “Will the United States Let the European Union Regulate Our Chemicals Industry Through the OECD?”, (April 15, 2002), Competitive Enterprise Institute (CEI), at p. 2, at: (<http://www.cei.com>).

⁷⁸ Ibid, at p. 2.

producers are likely to bear the brunt of these EU regulations, though in most instances, they lack the technical capacity to satisfy them. If they are now compelled to undertake the rigorous testing, registration, and downstream risk assessment obligations imposed by the EU Chemicals White Paper, the cost advantages they had secured in order to compete effectively with the developed world would no longer be available. This would severely set back their economic advancement.

The WTO's TBT Agreement clearly suggests according developing countries special and differential treatment in order to help them participate in the global economy. Based on a review of the EU's Chemical White Paper, it does not appear that the EU has taken these TBT requirements or the WTO's Doha Declaration into account. To do so, would require making the EU's proposed chemicals regime a workable, affordable and non-discriminatory initiative for developing countries, which is simply not the case.

Cosmetics in the EU

The EU Commission and the EU Parliament have recently enacted two amendments to the EU Cosmetics Directive 76/768/EEC, both of which are contained within new Directive 2003/15/EC. One proposed amendment imposes a ban on the manufacture and sale of *existing* and *new* cosmetic products if their ingredients or the final formulation of the products themselves were tested on animals for safety purposes, where OECD-approved alternatives to animal testing exist.⁷⁹ The other proposed amendment bans the use in cosmetics of substances that cause cancer or pose reproductive mutagenic hazards.⁸⁰ The amendments are to take effect no later than 2009.⁸¹ Interestingly, with regard to both these amendments, the EU and non-EU cosmetics industries are united in their opposition. As a result, these two amendments illustrate that even when a trade restrictive measure is not discriminatory against foreign producers, it stifles innovation and reduces consumer choice.

The European Cosmetics, Toiletry and Perfumery Association (COLIPA) has argued that the animal testing ban is unnecessary because very few animals tests are currently done. The imposition of the ban on existing cosmetics would, however, effectively require the reformulation of all current cosmetics products. "Since all cosmetic products on the market to date, whilst they may have not been tested on animals in their final state, contain ingredients that have been tested on animals."⁸²

It is arguable, furthermore, that the animal test ban violates the TBT Agreement. The ban effectively distinguishes between otherwise 'like' cosmetic products based on differences in process and production methods rather than on the basis of differences in product characteristics or performance.⁸³ Furthermore, it does not appear that the views of stakeholders have been taken at all into account. Consequently, it is arguable that the legislative process was neither transparent nor inclusive for these stakeholders who were effectively denied an opportunity to participate in the process of drafting the regulations.

As for the use of chemicals in cosmetics, "(t)he general principle of the directive is that cosmetics must not cause damage to human health when applied under normal or reasonably foreseeable

⁷⁹ "Business Alert – EU – New Commission Directive Lays Down Restrictions for Cosmetics Sold EU-Wide", TDCTrade.com website (June 2002) at (<http://www.tdctrade.com/alert/eu0211b.htm>), new Article 4a (1).

⁸⁰ Ibid, new Article 4b.

⁸¹ Ibid, new Article 4b (2.2)

⁸² "Animal Testing Labeling: Information or Misinformation?, The EU Cosmetics Directive – Issues and Debates," at (<http://www.colipa.com>).

⁸³ Ibid.

conditions of use.”⁸⁴ While the directive would impose an outright ban on the use of CMR category 1 and category 2 substances in the manufacture of cosmetics⁸⁵, it may allow the use of category 3 substances⁸⁶ if a full risk assessment establishes the safety of such substances.⁸⁷

It is not clear how this directive relates to the chemicals regime outlined in the EU Chemicals White Paper, although it would seem that chemicals used in the production of cosmetics would generally need to be registered pursuant to the White Paper registry requirement. The cosmetics directive apparently relies upon the same CMR list of substances relied upon by the Chemicals White Paper, and establishes the same presumption of hazard posed by the category 1 and 2 substances to human health. It also seems that such presumption is based on the precautionary principle, rather than upon scientific proof of actual harm caused by any one of the specific substances mentioned.

The banned substances amendment to the cosmetic directive would require full ingredient identification and labeling of all cosmetic substances.⁸⁸ This labeling mandate is intended to protect consumers who suffer from fragrance allergies (less than 0.1% of the EU population).⁸⁹ However, this rule would require listing non-allergens on the label as well. This would impose an undue administrative burden on manufacturers, distributors and importers that is unnecessary considering other less trade-restrictive alternatives. For instance, while listing the specific (26) fragrance allergens would be sufficient to assist dermatologists in making a diagnosis of skin reactions ('sensitization') suffered by their patients, the listing of hundreds of substances would not serve any purpose other than to confuse the consumer, and divulge proprietary trade industry information.⁹⁰

Biocidal Products in the EU

The EU Biocidal Products Directive (BPD), which was entered into in 1998, covers any product that “is an active substance or a preparation containing at least one active substance, intended to destroy, deter, render harmless, prevent the action of or exert some controlling effect on harmful or unwanted organisms by chemical or biological means.”⁹¹ Biocidal products may be used as “disinfectants for home and industrial use; chemical preservatives for manufactured and natural products; and non-agricultural pesticides...While some biocidal products are sold directly to consumers, many such products are used only in industrial situations.”⁹²

The EU believes that the use of biocidal products must be properly controlled in order to avoid unintended harmful effects on human health, animals, plants and the wider environment.⁹³ The objective of the BPD is therefore to ensure that biocidal products pose no unacceptable risk to

⁸⁴ Bengt Ljung, “EU Reaches Agreement to Impose Ban on Use of Toxics in Cosmetic Products”, International Environment Daily, (Nov. 27, 2002).

⁸⁵ Ibid.

⁸⁶ Ibid.

⁸⁷ Ibid; 2003/15/EC, amended Article 7(a)(1)(d).

⁸⁸ Amended Article 6 (1)(g).

⁸⁹ “Animal Testing Labeling: Information or Misinformation?, The EU Cosmetics Directive – Issues and Debates”.

⁹⁰ Ibid.

⁹¹ Directive 98/8/EC, Article 2(1)(a).

⁹² “Biocidal Products Regulations 2001 (SI 2001 No. 880) – A Guide to Applicants: Applying For Active Substance Inclusion to Annex 1 etc., of the Biocidal Products Directive, and Authorization /Registration of Biocidal Products Under the Biocidal Products Regulations”, Biocides and Pesticides Assessment Unit, Health and Safety Executive, Great Britain, HSE Books, UK, at p. 1. (2001).

⁹³ European Chemicals Bureau, “Overview of Biocidal Products Directive”, at: (<http://ecb.jrc.it/biocides/content1.htm>).

humans, animals or the environment, and endeavors to facilitate this through the establishment of a single European market in biocidal products.⁹⁴

The BPD requires that all *new* biocidal products must obtain formal authorization before marketing. All *existing* biocides (existing active substances) placed on the EU market prior to May 14, 2000, will be reviewed retrospectively during a 10 year transitional period.⁹⁵ During this transitional period, Member States may continue to apply their national rules until the Commission decides whether to include the particular substance in one of the directive's annexes.⁹⁶ The substance's inclusion will be denied if there are less harmful suitable substitutes available for the same purpose.⁹⁷

It would appear that the BCD legislation contains many of the same problems posed by other EU legislation. There seems to be a presumption of a hazard to human health and environment posed by biocidal products without any real evidence of actual harm. This presumption is most likely premised on the precautionary principle and on the perceived need to keep consumers informed, a nonsafety concern. Also, the labeling provision distinguishes between products based on process and production methods rather than on the basis of product characteristics and performance.

Furthermore, the information sharing rules would likely threaten intellectual property. The comparative assessment provision and animal testing waiver provision are troubling because they would once again impose distinctions on products not based on end-use but rather on process. Overall, the EU could have chosen a less-trade restrictive alternative to protect human health and the environment from possible harm caused by biocidal products. The U.S. EPA approach provides such a model, but, there is no evidence that the EU sought reference to any equivalent national standards; nor does it appear that the EU considered any international standards or guidelines based on scientific method.

Lastly, it is arguable that the BCD violates the WTO rights of developing countries. If the requirements are as onerous and unworkable as they are claimed to be by companies in industrialized nations, it would be even worse for developing countries. Since the Earth Summit at Rio de Janeiro in 1992, biotechnology has been publicly recognized as a necessary part of the vision for Sustainable Development.⁹⁸ To the extent that the BCD would discourage or otherwise preclude developing country exports from entering the EU marketplace and thereby deter developing country research and development efforts in industrial biotechnology, it would discriminate against such countries and their businesses in contravention of the TBT Agreement and the WTO Ministerial Declaration.

CONCLUSION

The EU has invoked the precautionary principle, a non-scientific touchstone, to justify its identification and assessment of such risks as well as its enactment of technical measures to manage and eliminate them. By so doing, it has effectively banned U.S. and other non-EU exports of products deemed hazardous, stifled scientific and industrial innovation and advancement and, in the process, has ignored a basic reality, namely that a certain amount of risk is unavoidable in every day life. The EU continues to incorporate the precautionary principle into trade agreements both at the multilateral and bilateral levels, and this dual-level strategy has prompted the U.S. government to

⁹⁴ Ibid, at p. 2.

⁹⁵ Mike Freemantle, Bryan Backhouse, "Global Implications of the European Biocidal Products Directive" (2001), at p. 1, at: (<http://ecb.jrc.it/biocides>).

⁹⁶ Biocidal Products Directive (98/8/EC), europa website.

⁹⁷ Biocidal Products Directive (98/8/EC), europa website.

⁹⁸ Chapter 16 of Agenda 21 refers to its potential.

take a competing approach that advances sound science, risk analysis and transparency. As the two largest global economies anchoring the WTO rules-based system, it is incumbent upon the U.S. and the EU to try to harmonize the many differences among the WTO membership into a unified, workable and fluid mechanism that facilitates rather than impedes the flow of international trade. Ultimately, it will be important to reconcile these different approaches if the cause of trade liberalization is to advance.