



National Foreign Trade Council, Inc.

Looking Behind the Curtain:

The Growth of Trade Barriers that Ignore Sound Science

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

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I. THE OBJECTIVE OF THE TRADE AND RISK REGULATION ('TR2') 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. 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 across 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.

“We recognize that under WTO rules no country should be prevented from taking measures for the protection of human, animal or plant life or health, or of the environment at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, and are otherwise in accordance with the provisions of the WTO Agreements.”¹

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

The utility of standards and regulations within a multilateral rules-based trading system, such as the World Trade Organization (“WTO”), can be measured, in large part, by their predictability, transparency and reference to objective principles of sound science. These are the qualities that can promote harmonization of the many different and competing national interests of its participants into a unified, workable and fluid mechanism that facilitates rather than impedes the flow of international trade.

Standards and regulations express the different national interests of WTO Members and often reflect societal values.² Indeed, variations in culture and political and economic systems can be discerned by the way a society identifies, evaluates and addresses risks and/or hazards in order to protect human health and safety, animal welfare and the environment. Some societies, such as those within the European Union, embrace the mindset of precaution and presume that a product is severely hazardous until proven ‘safe’, thereby effectively requiring proof of ‘zero-risk’.³ By contrast, other societies such as the United States, which rely on the vitality and predictability of an international rules-based system such as the WTO, do not rely upon such a broad presumption. The safety of a product is instead determined on a case-by-case basis, through presentation of scientific evidence grounded in principles of sound science, taking into account the degree of hazard posed by the specific product evaluated. In these societies, unless a given product is proven ‘hazardous’ it is deemed to be safe, thereby acknowledging that a

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

² That cultural values often influence the bases of domestic laws was a subject generally touched upon at two recent Washington, D.C. seminars – “Food For Thought: The Case For and Against Biotech”, Washington International Trade Association (WITA), 3/5/03, as discussed by Tony Vanderhaegen, Minister-Counselor, Agriculture, Fisheries, Food Safety and Consumer Affairs, EU Delegation (hereinafter referred to as “WITA Seminar”), and at a CSIS - Economist seminar -- “U.S.-EU Trade Relations”, 3/11/03, as discussed by Gerard Depayre, Deputy Chief of Mission, EU Delegation (hereinafter referred to as CSIS-Economist Seminar”).

³ The EU’s continued reliance on the ‘precautionary principle’ to establish the presumption of a general hazard when scientific knowledge is incomplete can be explained as a societal and cultural difference. This difference is reflected in Title XIV (Consumer Protection), Articles 153.1 and 153.2 of the Treaty Establishing the European Community (the EC Treaty). It provides the consumer with the ‘right to know’. This ties in with what has been referred to as the ‘Fourth Criterion’ – nonscience consumer-based criteria to determine food safety. Ibid.

certain amount of risk is unavoidable in every day life.⁴ Without dispute, these are important and legitimate national interests that must be safeguarded; but at what cost? It is the ability of countries to strike a balance between the risks and benefits of industry and technological advancement, and to translate that equilibrium into increased international trade flows and economic growth that is the hallmark of WTO membership.

Ideally, the types of national or regional regulations and standards to which global industries are subject should illustrate the extent to which the nations in which they are operating have committed themselves to the WTO rules-based trading system. That system is based on the notion that predictable and clearly defined international standards grounded in sound science and adopted by recognized international bodies 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 if governments decide not to abide by them, and choose instead to impose their own regulations and standards.⁵ In this regard, U.S. industry stands to lose billions of dollars

⁴ The prevalent view within the United States is to avoid resort to 'command and control' regulations until and unless it is absolutely necessary, given the drag that it places on domestic industry and U.S. competitiveness abroad. Instead, a great deal of reliance has been placed upon voluntary industry-based standards. "Standards play a vital, yet largely unheralded, role in our nation's economy. They are fundamental components of our nation's technology base, essential to industry and commerce, crucial to the health and safety of Americans, and fundamental to the nation's economic performance. Over 30,000 voluntary standards have been developed in the United States by more than 400 organizations...In addition, there are a large number of procurement specifications, mandatory codes, rules, and regulations containing standards developed and adopted by agencies of the federal government...Today, standards are developed through a complex system administered by the private sector, with participation by industry, academia, consumers, and government. The diverse U.S. standards community has developed rules for consensus, transparency, openness, balance, and due process. As a result, the American standards-setting system has been able to meet market needs, as well as government regulatory and procurement needs. Our standards-setting system is rooted in the private sector and benefits from strong industry participation..." "Standards-Setting and United States Competition", Hearing of the Subcommittee On Environment, Technology and Standards, House Science Committee, Washington, D.C. (June 28, 2001). The U.S. approach to standards was also reflected in the "National Standards Strategy for the United States" that was adopted by the American National Standards Institute (ANSI) on August 31, 2000. It recognizes that, "voluntary consensus standards for products, processes, and services are at the foundation of the U.S. economy and society", that "the United States has a proud tradition of developing and using voluntary standards to support the needs of our citizens and the competitiveness of U.S. industry", and that "the standardization would has changed". This was cited in a Comment Letter, dated February 2003 to the USTR from ANSI, "ANSI Paper on International Standards Development and Use", at p.1.

⁵ One Wall Street Journal article has noted how the lives of Americans are increasingly being determined not by American-based standards, but rather, by standards established by the EU. "Americans may not realize it, but rules governing the food they eat, the software they use and the cars they drive increasingly are set in Brussels, the unofficial capital of the EU and the home of its executive body, the European Commission. Because of differing histories and attitudes toward government, the EU,...with the world's second-largest economy, regulates more frequently and more rigorously than the U.S., especially when it comes to consumer protection. So, even though the American market is bigger the EU, as the jurisdiction with the tougher rules, tends to call the shots for the world's farmers and manufacturers...EU rules often cause particular friction in high-tech fields, such as software, electronic commerce and biotechnology...The EU requires any product that contains even 1% of a genetically altered ingredient to say so on its label...pending European recycling rules, which are tougher than U.S. standards...would require electrical equipment makers to eschew certain hard-to-recycle plastics and chemicals, such as brominated flame retardants...the EU is considering requiring companies to test 30,000 chemicals already on the market to see whether they are hazardous, as well as thousands of products that use some of the

in the form of lost trade opportunities because of the failure of certain nations and trade blocs (primarily the EU and its Member States) to adhere to the rules and standards set forth in the WTO agreements. This is especially harmful to small and medium sized enterprises, which often operate within small, specialized market niches and serve as ‘catalysts’ for research and development in areas of new technology.

The different standards and regulatory systems of WTO Members must also be subject to the same objective procedural touchstones if the WTO rules-based system is to function properly. This means that all actors within a society (civil society, industry and government) should be permitted to participate in the promulgation of domestic rules and standards, as well as, in the formulation of the policies upon which such rules and standards are based. The degree of ‘transparency’ and ‘inclusiveness’ in the regulatory process should not vary significantly from Member to Member. That the regulatory system within the EU is less transparent and inclusive than that within the U.S. denies U.S. companies an equal role in the development of EU regulations and standards materially impacting their operations, and thereby imposes an imbalance that must be resolved if the WTO trading system is to be strengthened and enlarged. Government officials here and abroad have recognized that the procedural differences apparent within the regulatory regimes of the U.S. and the EU may largely reflect the different definitions ascribed to and the roles served by the process of ‘regulation’ within these societies. In the U.S., regulation is subordinate to legislation, whereas in the EU, regulation is legislation.⁶

Considering these challenges, it has been argued that

“The success of the multilateral trading system has also created its own set of problems...As trade barriers are reduced, the importance of standards and technical regulations...has increased markedly. Standards are a necessary component of production, consumption and commercial exchange. They can also [however] be cleverly used as a tool of protectionism. Standards thus become an issue of importance for industry, for regulators, and for trade negotiators.”⁷

chemicals in question...another EU initiative targets auto makers...” Brandon Mitchener, “Rules, Regulations of Global Economy Are Increasingly Being Set in Brussels”, Wall Street Journal, (April 23, 2002). According to U.S. Ambassador to the European Union, Rockwell Schnabel, “Although the U.S. economy is larger, the EU regulates more often and more rigorously than we do, having written an estimated 80,000 pages of regulation since 1957. These rules are forcing major strategy and product changes on the part of some very large U.S. companies, including McDonald’s, United Technologies, Microsoft and GE – to name just a few. And because they oversee such a large market, EU authorities are increasingly able to do what the U.S. market alone was able to do before – turn its own internal standards into *de facto* standards for the rest of the world...” “U.S. Envoy On the Changing U.S.-EU Relationship, Rockwell Schnabel Remarks in Athens October 15”, U.S. Department of State, International Information Programs, (Oct. 18, 2002), at: (<http://www.usinfo.state.gov>).

⁶ Comments made by Depayre, CSIS-Economist Seminar; For a brief discussion about the EU’s treaty-based institutional framework and its role in EU trade policymaking, See: Raymond J. Ahearn, “Trade Policymaking in the European Union: Institutional Framework”, CRS Report for Congress (March 27, 2002).

⁷ Gary Hufbauer, Barbara Kotschwar and John Wilson, “Trade Policy, Standards, and Development in Central America” (2000), at p. 21.

The increasing role of standards and regulations in international trade, therefore, can no longer be ignored; it has been estimated that, “up to 80 percent of all world trade is affected by standards of some kind. This implies that most sectors are affected – an estimate supported by the fact that the EU has developed some form of harmonized technical regulation for 30 sectors”.⁸

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

It is quite difficult to reconcile internally the various interests of competing constituencies in order to establish workable and balanced national standards and regulations. It is even more challenging to do so without also having to consider the extraordinary complexities surrounding the integration of those regulations and standards throughout a region. EU regional integration has been both a blessing and a burden to EU Member States⁹ and has yielded both benefits and complaints from EU trading partners. While the extent of the EU’s efforts to facilitate orderly regulatory change throughout the region should not be discounted, it may be questioned whether the EU has adequately endeavored to ensure that such regulatory initiatives are compatible with its WTO obligations. Apparently, the broad implications of these changes for global industry and trade have not been as well anticipated and thought-out as one would have expected. They have resulted in the *de facto* imposition of political decisions rendered by publicly unaccountable EU standardization bodies upon non-EU societies (e.g., the U.S. and other OECD countries, as well as, the developing world), without the latter’s representation or input. Consequently, trans-Atlantic trade flows have been interrupted and developing country institutions and exporters overwhelmed. The EU’s failure to adhere to international standards has triggered trade tensions between WTO Members, particularly the U.S. and the EU.¹⁰

⁸ Ibid, at p. 18.

⁹ According to a January 2002 article that appeared in National Geographic Magazine, “Some Europeans hope to emulate the American motto [E Pluribus Unum] and forge a United States of Europe. But what would a united Europe really be like? And what are individual nations willing to give up for unity? There’s such frustration over the reams of regulations issued from the EU’s headquarters in Brussels. Yet there is also a sense of European identity as the EU gains economic clout.” T.R. Reid, “The New Europe”, National Geographic Magazine, January 2002, at p. 36.

¹⁰ According to U.S. Ambassador to the European Union, Rockwell Schnabel, “With the European and U.S. economies so intertwined, how the EU develops its regulatory system matters to U.S. firms and citizens... There is only one way to achieve the balance between objectives and costs that produces smart regulation – regulation that meets society’s objectives without strangling innovation and growth... The solution lies in a transparent, inclusive and well-supervised – and limited – regulatory system” The website to the United States Mission to the European Union indicates that “the United States government supports the five principles set out in the European Commission’s White Paper on governance – openness, participation, accountability, effectiveness and coherence... It also says it finds the idea of minimum standards for consultation useful, provided that the consultations are ‘genuinely open and transparent to all interested parties, domestic and foreign, and take place sufficiently early in the process to be meaningful.’ Such consultations could head off trade conflicts associated with some regulations... ‘A growing number of trade concerns stem from the lack of transparency and the process by which the EU develops technical regulations.’” “U.S. View on Regulation and EU Regulatory Reform”, The United States Mission to the European Union website, at: (<http://www.useu.be/Categories/RegulatoryReform/Index.htm>).

As the result of EU and Member State regulatory practices, non-EU exporting companies have incurred burdensome costs in order to comply with stringent and duplicative standards and regulations. Many such standards and/or regulations deny market access to a myriad of non-EU imported products in the name of serving a legitimate 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, noncompetitive EU industries. Existing examples of disguised trade barriers imposed on agricultural products include the EU's moratorium on hormone-treated beef and on bioengineered seed, feed and food products. They also include the EU Directive on the Deliberate Release into the Environment of GMOs and related regulations (The Proposed Regulation on the Authorization of GMO Food and Feed ('GM Food and Feed Proposal') and the Proposed Regulation on Traceability and Labeling of GMOs and Products Derived from GMOs ('GM Traceability and Labeling Proposal')). Existing examples of disguised trade barriers imposed on nonagricultural products arguably include the EU Directives on Waste from Electrical and Electronic Equipment ('WEEE'), Restrictions on the Use of Hazardous Substances ('RoHS'), Electrical and Electronic Equipment ('EEE') / End-Use-Equipment ('EuE') and End-of-Life Vehicles ('ELV'). In addition, the EU Green Paper on Integrated Product Policy the EU Chemicals White Paper, the EU Cosmetics Directive Banning Animal Testing and the EU Biocidal Products Directive also constitute hidden trade barriers.

All of these examples 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 the imposition of *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. The nature and degree of regulation imposed within the EU, especially with respect to industries reliant upon science and high technology applications, such as bioengineered seed, feed and food products, electronics, automobiles, chemicals, pharmaceuticals and biocidal products is overwhelming to say the least. Given what has been called the European innovation "paradox" namely, the European Union's growing deficit in trade of high-tech products and decline in R&D relative to GDP, one would have thought that the EU would work more closely with industry than it has.¹¹

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'. And manufacturers of automobiles, electrical and electronic equipment, and chemicals have also been adversely impacted, as have all the downstream industries that use or consume these products in intermediate

¹¹ "International Science and Technology: Policies, Programs and Investment", Office of Technology Policy, U.S. Department of Commerce, Technology Administration, (December 2000), at p.39. This report is aimed at "enhancing the understanding of global technology developments and foreign technology initiatives. Its individual country reports describe what steps other governments are taking to increase national science and technology capabilities, build technology-based infrastructure, amend policies and regulations to facilitate technology-led economic growth, and invest in education and human resource development." Ibid, at Foreward.

processes or resell them as finished articles. It is no surprise that many of the exporters adversely effected are themselves operating in new growth high tech industries or involved in applying new technologies within their existing market sectors.¹² The growing array of regulations abroad and their negative impact on U.S manufacturers has caught the attention of U.S. Commerce Secretary Donald Evans, who recently announced a new initiative aimed at promoting international adoption of industry-based standards and regulations. According to Secretary Evans, promoting adoption of internationally accepted standards will ensure “we’re all playing by the same set rules”, and those rules should be industry-driven rather than government-driven.¹³

B. 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 regulations¹⁴. 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. This possibility has recently come to light in Southern Africa as an outgrowth of the EU’s moratorium against bioengineered foods. The refusal of certain Southern African countries to accept U.S food aid consisting of GM corn has been attributed, in part, to negative EU views toward biotechnology. As a result, these countries may overlook the merits of agricultural biotechnology, which could help to solve their endemic food shortage problems over a relatively short period of time.

¹² “The emergence of new technologies and new industries is at the heart of a growing number of [trade] disputes. Biotechnology as a new technology and a new industry [is an] emerging issue that has great potential for generating increases in transatlantic welfare, as well as conflict. This issue tends to be politically sensitive because it affect[s] consumer attitudes, as well as regulatory regimes.” Raymond J. Ahearn, U.S.-European Union Trade Relations: Issues and Policy Challenges – Dealing With Different Public Concerns Over New Technologies and New Industries”, Issue Brief for Congress, doc. IB10087 (Jan. 27, 2003), at p. CRS-10.

¹³ “Commerce’s New Standards Initiative”, Washington Trade Daily (March 20, 2003), at p. 7. The article notes that, “[T]he Commerce initiative will focus federal resources on promoting industry-based international standards and identifying foreign regulations and standards that are acting as barriers to U.S. products.” Commerce officials have been quoted as saying that, “Foreign standards and technical regulations have emerged as a principal non-tariff barrier in markets around the world...Standards and standards-related requirements are pervasive features of global commerce, affecting an estimated 80 percent of world commodity trade.” George Leopold, “U.S. Plans Standards Effort to Improve Market Access”, EE Times, March 17, 2003, at: (<http://www.eetimes.com/story/OEG20030317S0074>).

¹⁴ 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.

There is evidence, furthermore, of similar regulatory barriers with protectionist overtones being erected by other nations that are EU trading partners, such as China, Korea, Japan, Argentina, and Mexico; and other less developed countries are following suit. To some extent this may be attributable to the growing global economic influence of the EU and its desire to gain a competitive advantage vis-à-vis the U.S.¹⁵ This influence is being conveyed through bilateral and regional trade and aid agreements executed by the EU throughout the developing world, and such agreements are proliferating. The Cotonou Agreement with African and Pacific Island nations is one such example.¹⁶ The current

¹⁵ This observation was recently confirmed in comments made by Commerce Undersecretary for International Trade Grant Aldonas. "The European Union in particular uses standards as barriers to trade and is aggressive in promoting its standards in third countries in order to gain a competitive advantage". Ibid. The Europeans themselves are not hesitant to comment about their political and economic competition with the U.S. A recent article appearing within National Geographic Magazine places this ambition into context. "...Conflict resolution [through the United Nations] is not the only impulse driving the new Europe. Europe's desire to stand equal with the world's dominant economic power. 'If you are Germany or France or the U.K.,' says the British historian Norman Davies, 'you can't help looking at the American economy and thinking, that's a rather big elephant over there. But if your individual country becomes part of a unified European economy, then you think, Goodness – we could be even bigger.'...For at least six decades – that is, the entire life of most Americans living today – the United States has been the richest place on the planet. But... a genuinely united Europe would challenge American dominance. Today's 15-member EU has a total population of around 380 million people – about 35 percent more than the U.S. (If all of the 13 current applicants for membership [in Central and Eastern Europe] were to join up, the EU population would reach about 550 million.) The combined GDP of the 15 members is about 7.8 trillion dollars, drawing ever closer to America's 9.9 trillion. The EU's annual exports total \$857 billion dollars, and its imports come to \$938 billion dollars. With those trade volumes the new euro could challenge the U.S. dollar's status as the world's preferred reserve currency...Just as European companies must adhere to U.S. law to conduct business in America, U.S. companies likewise must comply with EU law to do business in Europe...Beyond economics, EU members have taken to lecturing Washington on political issues that Americans might think of as domestic matters, such as the death penalty, the U.S. debt to the United Nations, and industrial emissions. 'It used to be the Americans who were telling everybody else what to do,' [British Historian] Norman Davies told me with a chuckle. 'Now the tables are turning'..." T.R. Reid, "The New Europe", National Geographic Magazine, January 2002, at pp. 38, 41 and 42.

¹⁶ The Partnership Agreement between the Members of the Group of African, Caribbean and Pacific (ACP) States and the European Community and Member States (referred to as the Cotonou Agreement) was signed in Cotonou, Benin on June 23, 2000. Pursuant to the Agreement, "the Parties agreed to conclude new WTO-compatible trading arrangements, progressively removing barriers to trade between them and enhancing cooperation in all areas relevant to trade. To this end, Economic Partnership Agreements ('EPAs') will be negotiated...start[ing] in September 2002....[The Cotonou Agreement] builds on three interlinked pillars: the political dimension, economic and trade cooperation and development finance cooperation." "Explanatory Memorandum, Commission Draft Mandate", (April 9, 2002), at p. 1, at: (<http://www.europa.com>). "The Cotonou Agreement is set to replace the Lome Convention, which had provided the structure for trade and cooperation between the signatories since 1975. The Agreement is valid for a period of 20 years. It will come into force once it has been approved by the European Parliament and ratified by the national parliaments of the states concerned. It will be open to revision once every five years." "The European Community and its Member States Sign a New Partnership Agreement with the African, Caribbean and Pacific States in Cotonou, Benin", EU Press Release (June 21, 2000), Ibid. Within a "Compendium of Cooperation Strategies" accompanying the text of the Cotonou Agreement, it is mentioned that "cooperation shall give priority in their activities to...a preventive approach on the basis of the *precautionary principle* aimed at avoiding harmful effects on the environment as a result of any program or operation..."(emphasis added). See: Partnership Agreement between the Members of the Group of African, Caribbean and Pacific (ACP) States and the European Community and Member States, Compendium on Cooperation Strategies -- Sec. 4.2, Thematic and Cross-Cutting Issues --

negotiations with the Mercosur nations of Latin America is another example, as are the aid and trade agreements being negotiated with the countries of Central and Eastern Europe as part of EU enlargement.

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

There is evidence that the EU is seeking, through promulgation of national and regional standards 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 agreements include the existing Convention on Biological Diversity ('CBD') and the soon-to-be effective Cartagena Protocol on Biosafety ('the Biosafety Protocol').¹⁷ Both documents 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, specifically its Article XX exceptions¹⁸. Such rules 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. The EU is well aware of the potential for a conflict between these two legal regimes if the provisions of one of its technical regulations were deemed to fall under the jurisdiction of both a WTO Agreement and an MEA. While this is most likely to occur in the near term with respect to bioengineered food and feed products once the Biosafety Protocol enters into force, the possibility of it also occurring with respect to biocidal industrial products in the future is far from remote.¹⁹ A conflict of this sort is certain to have broad implications on international trade, and is considered an issue worthy of attention in the current Doha Round trade negotiations.²⁰

Environment", par. 138, at:

(http://www.europa.eu.int/comm/development/cotonou/compendium/comp12b_en.htm).

¹⁷ While the U.S. is a signatory to the CBD, it did not ratify it. Consequently, as a non-Party to the CBD, it is not eligible to become a party to the Biosafety Protocol. The Biosafety Protocol will "enter into force on the ninetieth day after the deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention." Without counting the European Community's ratification of the Protocol, there are, as of this writing, 44 out of the 50 ratifications needed. See: "Ratifications", Cartagena Protocol on Biosafety, Convention of Biological Diversity", at: (<http://www.biodiv.org/biosafety/signinglist.asp?sts=rtf&ord=dt>).

¹⁸ To further ensure that the GATT Article XX exceptions will be available to it, the EU has articulated within its more recent regulations another non-science-based objective, namely, the justification of 'consumer choice'. The EU has endeavored to interpret this regulatory rationale as broadly as possible (i.e., as 'consumer protection') in order to fit it within the 'legitimate objectives' clause of the Article XX exceptions.

¹⁹ Furthermore, it is also possible that the EU's new proposed environmental liability legislation which expressly articulates the 'polluter pays principle' and other legislative communications seeking to address industrial emissions of greenhouse gases as defined by the Kyoto Protocol to the United Nations Framework Convention on Climate Change, are also likely to run up against the WTO agreements.

²⁰ The Ministerial Declaration issued at the WTO Ministerial Conference at Doha, Qatar, November 9-14, 2001. Among the many issues agreed to be negotiated during the Doha Round, is that relating to "the relationship between existing WTO rules and specific trade obligations set out in multilateral environmental agreements (MEAs). The negotiations shall be limited in scope to the applicability of such

III. **SANITARY AND PHYTOSANITARY MEASURES CONSTITUTING DISGUISED TRADE BARRIERS**

A. **Introduction**

The use of standards and technical regulations to govern the importation of agricultural produce and food products has continued since the SPS Agreement first went into force. “Major issues cited by the industry that are common to most processed food and beverage products [have include[d] export certification and registration, labeling [and traceability and]... customs procedures [such as quarantines]. In addition, “sector-specific” sanitary and phytosanitary restrictions have also been employed..”²¹

An interesting pattern that seems to have emerged recently in the agricultural products sector is the promulgation of measures to regulate and manage the use of advanced technologies in the food chain. Examples of this include hormones used to promote beef production, chlorine and other antimicrobial treatments used to safeguard poultry production, the in-line pulp wash process used in the production of fruit juices, bioenzymes and other micro-organisms used in the wine fermentation process, and genetically modified seed, feed and food used in the production of grains, flours and produce. The focus on these areas by the recently released 2003 National Estimate Report on Foreign Trade Barriers, within the section entitled “European Union”, similarly suggests such a pattern.²²

B. **Non-Science-Based Technical Regulations Serving as Trade Barriers by Sector -- Beef; Poultry; Fresh Produce and Processed Fruits and Nuts; Additives, Vitamins and Nutrients; Wines**

1. *Beef*

U.S. industry has identified a number of SPS restrictions that have been imposed on U.S. exports of meat products. The EU continues to ban (for more than ten years) U.S. beef exports derived from growth hormone-treated cattle, notwithstanding a WTO panel’s

existing WTO rules as among parties to the MEA in question. The negotiations shall not prejudice the WTO rights of any Member that is not a party to the MEA in question...” Ibid, at par. 31.

²¹ U.S. International Trade Commission Report (‘USITC Report’), “Processed Foods and Beverages: A Description of Tariff and Non-Tariff Barriers for Major Products and Their Impact on Trade”, Vol. 1: Executive Summary and Chapters 1-15, Report on Investigation No. 332-421 under section 332(g) of the Tariff Act of 1930 (Publ. 3455, Oct. 2001), at p. xiv. “The non-tariff measures reported in the text are, in many cases, derived from anecdotal information collected from industry, government, and trade association sources.” Ibid at p.1-3.

²² See: “2003 National Estimate Report on Foreign Trade Barriers”, Office of the United States Trade Representative pp. 107-115.

decision, subsequently upheld by the WTO Appellate Body in the EC-Hormones case²³, 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. The ban also continues despite the U.S. imposition of 100% retaliatory tariffs on \$116 million of EU agricultural products from mostly France, Germany, Italy, and Denmark, countries deemed the biggest supporters of the ban.²⁴ “In December of 2002, the EU permanently banned the use of estradiol-17-B, a growth promoting hormone widely used in the U.S. and which has been determined by the U.S. Food and Drug Administration (FDA) to pose no health risk to consumers.”²⁵ “The EU also presented a number of studies that analyzed the use of hormones in beef production, though none of these studies presented any new [scientific] evidence to support the EU’s hormone ban.”²⁶ It is rumored that the EU might even ask the WTO sometime in 2003 to require the U.S. to lift these sanctions.

2. *Poultry*

In addition, 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.”²⁷ The EU “[has]continue[d] to prohibit the use of antimicrobial treatments (AMT) in poultry production to prevent transmission of bacteria such as salmonella [since 1997], despite the publication of an EU study which recommended that antimicrobial treatments, other than chlorination, could be used as part of an overall strategy for pathogen control throughout the production chain.”²⁸ 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

²³ Report of the Appellate Body on EC Measures Concerning Meat and Meat Products (Hormones), AB-1997-4, adopted on February 13, 1998, WT/DS26/AB/R; WT/DS48/AB/R, (hereinafter referred to as “the EC Hormones case”).

²⁴ 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)” (“2002 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.

²⁵ President’s Trade Policy Agenda, at p. 154.

²⁶ “2003 National Trade Estimate Report on Foreign Trade Barriers”, at p. 113. “Some EU officials [had] said that the decision [would] be based on new scientific evidence showing that the six hormones -- oestradiol-17-beta, progesterone, testosterone, zeranol, trenbolone, and melengestrol acetate -- pose a significant risk to public health.” Ibid.

²⁷ President’s Trade Policy Agenda, at p. 154.

²⁸ Ibid. The report indicated that, “although some forms of treatment were deemed more acceptable, the use of chlorinated water...which is the primary means employed in the U.S. to meet strict U.S. standards designed to ensure the safety of poultry products from microbial contamination...was rejected...”; USITC Report at p. xvii. Based on this study, the U.S. government has requested that the EU approve the use of certain antimicrobial treatments. “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).

EU ban on the domestic use of chlorinated water.²⁹ These practices continue despite the existence of the 1999 U.S.-EU Veterinary Equivalence Agreement, which was designed to make trading in various livestock products, including poultry products, less restrictive.³⁰

Furthermore, some WTO Member States (e.g., Japan) have 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 pathogenic avian influenza’ within the U.S.³¹ This led to an SPS Committee request to the International Office of Epizootics (OIE), an international animal health organization, to review and modify as appropriate international standards regarding avian influenza. The OIE is one of three international scientific organizations that establish international standards, guidelines, and recommendations specifically relied upon by the SPS Agreement³². “The results of the OIE’s efforts [in this particular case] should provide updated science-based international standards to facilitate trade in poultry and poultry products.”³³ According to the OIE, “quarantine procedures are only necessary for highly pathogenic strains of avian influenza, and not for low pathogenic strains.”³⁴

3. *Fresh Produce and Processed Fruits and Nuts*

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

²⁹ 2002 NTE Report at p. 113; Russia announced, in March 2002, (what turned out to be only) a temporary ban on U.S. poultry exports, though it did not specify the reasons. U.S. experts engaged in technical discussions to address Russian concerns in order to secure the lifting of the ban. These talks led to the signing of a protocol with the Russian government that resulted in the resumption of trade flows. The “protocol established a framework for closer cooperation between U.S. and Russian veterinary officials and provided for improved certification and testing procedures.” Ibid, at p. 364; President’s Trade Policy Agenda at p.161. On April 2, 2003, the U.S. Agriculture Department announced that it and the Russian Ministry of Agriculture had “resolved the remaining technical issues in their dispute involving poultry trade.” The agreement was heralded as “an important breakthrough that should lead to resumed exports from the United States. The dispute centered around new veterinary standards agreed to last year but not fully implemented because of technical differences...Resolution of the issue involved utilizing the concept of ‘equivalency’, achieving the same objectives but with different ‘science-based’ approaches.” In addition, the USDA also announced the signing of a separate “[U.S.-Ukraine] protocol which ends a 16-month ban on U.S. poultry exports to the Ukraine...The United States exported poultry and poultry products worth \$11 million to the Ukraine during 2001.” “U.S., Russia Resolve Poultry Dispute”, Washington Trade Daily (April 7, 2003) at p. 1.

³⁰ President’s Trade Policy Agenda, at p. 154.

³¹ President’s Trade Policy Agenda, at pp. 81-82; 2002 NTE Report at pp. 223-24. Avian influenza is caused by type A influenza virus. While more avian influenza viruses have been isolated from ducks than any other species, among domestic poultry species, turkeys are more commonly infected than are chickens. Influenza viruses are very sensitive to most detergents and disinfectants, and are readily inactivated by heating and drying. There are 15 virus subtypes that can infect poultry. See: Carol J. Cardona, Extension Poultry Veterinarian, University of California, Davis, “Avian Influenza”, at (<http://www.vetmed.ucdavis.edu>).

³² The other two international standards organizations charged with attempting to harmonize food safety regulations are the Codex Alimentarius (Codex) and the International Plant Protection Convention (IPPC).

³³ President’s Trade Policy Agenda, at p. 82.

³⁴ 2002 NTE Report at p. 224.

products.³⁵ Korea has also tended to prohibit certain food ingredients, additives (e.g., food colors and dyes) and manufacturing processes that are generally recognized as safe by international standards bodies such as the Codex Alimentarius (Codex) and The Joint FAO/WHO Expert Committee on Food Additives (JECFA).³⁶ “JECFA is an international expert scientific committee that is administered jointly by the Food and Agricultural Organization (FAO) of the United Nations and the World Health Organization (WHO). It evaluates the safety of food additives, as well as contaminants, naturally occurring toxicants and residues of veterinary drugs in food... The Committee has also developed principles for the ‘safety assessment of chemicals in food’ that are consistent with current thinking on ‘risk assessment’ and take account of recent developments in toxicology and other relevant sciences... JECFA serves as a scientific advisory body to FAO, WHO, to FAO and WHO member governments, and to the Codex Alimentarius Commission. [Such] advice is provided via the Codex Committee on Food Additives and Contaminants (CCFAC) or via the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF).”³⁷

Burdensome quarantine restrictions imposed by Japan on U.S. apple exports in order to prevent the transmission of fireblight bacteria serve to limit market access and reduce competitiveness of U.S. apples in Japan.³⁸ In addition to significantly raising costs, these restrictions are not scientifically based. 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”. However, Japan has continued to refuse to modify its restrictions, thereby prompting the U.S., in March 2002, to request consultations under WTO dispute settlement procedures.³⁹

4. *Additives, Vitamins and Nutrients*

Vitamins and nutrients used in the fortification (e.g., minerals) and additives used in the preservation (e.g., preservatives) of grain-based products such as breakfast cereals, 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.

³⁵ 2002 NTE Report at p. 263; “While Korea’s plant quarantine requirements were improved in 2002 to recognize industry fumigation practices for shelled walnuts... Korean phytosanitary and sanitary certification requirements still continue to limit market access for a variety of products due to delays in Korea’s review of documentation on pest mitigation provided by the U.S.” President’s Trade Policy Agenda, at p.180.

³⁶ Ibid;

³⁷ See: “About JECFA”, at: (http://www.who.int/pcs/jecfa/what_is_jecfa.htm).

³⁸ 2002 NTE Report at p.224. “Japan’s quarantine restrictions for fireblight include: 1) the prohibition of imports of U.S. apples from any orchard containing fireblight; 2) three orchard inspections at different times in the growing season; 3) maintenance of a 500-meter fireblight-free ‘buffer’ zone surrounding export orchards; and 4) post-harvest treatment of apples with chlorine. Ibid.

³⁹ Ibid. These Japanese regulations appear to sanction practices very similar to earlier Japanese quarantine practices which led to a successful U.S. challenge of them at the WTO. (See: the WTO Appellate Body decision on Japan -- Measures Affecting Agricultural Products, (hereinafter referred to as “the Japan-Varietals case”), adopted on March 19, 1999, WT/DS76AB/R.

Japan's classification of dietary supplements, such as vitamins, minerals, herbs and non-active ingredients, 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.⁴⁰ U.S. producers of dietary supplements can make nutritional and health benefit claims, provided they are able to present 'scientific' data and information to support those claims. However, it is not certain what types of data and information will be required and whether non-Japanese test data will be acceptable.⁴¹

5. *Wines*

Non-science-based SPS-inconsistent measures have also been imposed on exports of U.S. wines. 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 from these requirements under the terms of the 1983 US-EU Wine Accords, and this exemption has been extended until December 31, 2003.⁴² EU law is contrary to U.S. law which, absent a health or safety concern, effectively grants automatic acceptance of EU wine making practices. However, as required by these accords, the EU has failed to convert this temporary exemption for U.S. wine producers into a 'permanent' exemption, even though the EU has been unable to prove that U.S. oenological practices pose a 'health' or 'safety' risk. In fact, as recently as 1998, the EU prohibited the use of more than a dozen oenological practices and additives then currently approved for use in the U.S. and several other countries.⁴³ Based on current WTO jurisprudence, the EU distinction of wines based on oenological practices bears an uncanny resemblance to a discrimination between otherwise 'like' products based on process and production methods (PPMS) rather than their end-use.

Given the apparent difficulties encountered with these accords, the U.S. and the EU launched a new round of negotiations on a bilateral wine agreement in 1999, which continued throughout 2001. Notwithstanding this effort, the U.S. "continues to be concerned about the EU's requirements for import certification and the review and approval of future wine making practices".⁴⁴

The EU's regulatory restrictions on imported wine products seemingly triggered the creation of an international trade organization called the World Wine Trade Group. The

⁴⁰ Ibid, at p. 227.

⁴¹ Ibid.

⁴² 2002 NTE Report, at p. 106.

⁴³ JBC International, Comments to Triennial Review of the SPS Agreement (12/9/98), in response to Federal Register Notice on "The Consistency of Foreign Trade Measures With the Provisions of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures", FR Doc. 98-29990, filed 11-6-98, at 63 FR 216. Since the 1983 US-EU Wine Accords, the EU has been studying the practices and additives used in the US. This comment letter points to Council Regulation (EEC) No. 822/87 of 3/16/87, as "a glaring example of such unjustifiable restrictions".

⁴⁴ 2002 NTE Report, at p. 106.

WWTG represents an informal grouping of industry and government officials from Argentina, Australia, Canada, Chile, New Zealand, South Africa and the U.S.⁴⁵ On 12/18/01, some of the members of this group, including the U.S., Canada, Australia, Chile and New Zealand, signed a Mutual Acceptance Agreement on Oenological Practices outside of the auspices of the WTO. Argentina subsequently signed on as a party to this agreement on 7/10/02.

Under the agreement, each country will permit the importation of wines from every other signatory country as long as these wines are made in accordance with the producing country's domestic laws, regulations, and requirements on oenological practices. In addition, the agreement recognizes that different countries use different winemaking practices due to local conditions, climatic variations and traditions, and that grape-growing and winemaking practices are constantly evolving. Furthermore, the agreement establishes transparency requirements and consultation and dispute mechanisms, and also does not limit signatories' rights or obligations under the WTO Agreements.⁴⁶

In addition to non-science based winemaking standards, the EU has enacted new labeling regulations that are concerned more about the 'consumer's right to know' than about risks to human health. The consumer's right to know has been referred to within the EU as the 'Fourth Criterion'.⁴⁷ For example, these non-science-based regulations seek the phase-out in the U.S. of semi-generic names (e.g., burgundy, champagne, Chablis) on labels of non-EU wines. And it seeks to impose similar labeling restrictions for 'traditional expressions' (e.g., terms used with certain other expressions, often geographical indications, to describe wine or liqueur).⁴⁸ These restrictions are contained

⁴⁵ The organization meets semi-annually to discuss pertinent international wine trade, and its website is hosted by the U.S. government. See: (www.ita.doc.gov/td/ocg/wwtg.htm)

⁴⁶ Ibid. Country Parties to the agreement "accept a variety of practices that "New World countries use, particularly the U.S., that the EU does not allow. These include: 1) reverse osmosis, concentration process to remove water from wine; 2) the use of malic acid to boost acidity in grapes that have had large quantities of sun exposure; 3) the use of DMDC, a chemical that is used as a yeast inhibitor; and 4) silver nitrate used to suppress sulphurous wine odors." "New World Unites Over Wine Trade to Pressure EU", St. Helena Star, (May 24, 2001), at: (http://www.sthelenastar.com/5-24-01/wine_business/wine_briefs.html).

⁴⁷ The 'Fourth Criterion', as articulated by the EU, permits SPS restrictions based on consumer concerns or other non-scientific criteria. "The U.S. must continue to oppose any efforts by the European Union or other countries to undermine the use of 'sound science' as the fundamental principle of the SPS Agreement. The so-called 'Fourth Criterion', would permit the use of illegitimate sanitary and phytosanitary measures as disguised barriers to trade. A 'Fourth Criterion', as advocated by the EU, is an entirely subjective standard which would allow a country to justify the use of virtually any sanitary and phytosanitary measure without consideration of its scientific validity. Such a standard would nullify the basic principle of the SPS Agreement." This concept was fleshed out a bit within U.S. industry comments submitted in response to the Triennial Review of the SPS Agreement (12/9/98). See: 'Pet Food Institute' Comments (1/8/98), and 'Hill's Pet Nutrition, Inc.' Comments (1/9/98) to Federal Register Notice on "The Consistency of Foreign Trade Measures With the Provisions of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures", FR Doc. 98-29990, filed 11-6-98, at 63 FR 216.

⁴⁸ Ibid. While these iterations "have been granted intellectual property protection in the EU,... the U.S. does not recognize the concept of 'traditional terms' as a form of intellectual property, nor is this subject covered by the TRIPS Agreement." Ibid, at pp.106-07.

within the April 29, 2002 adoption of EU wine labeling regulations (Commission Regulation 753/2002).⁴⁹

Although the regulation is not scheduled to be implemented until August 2003⁵⁰, its broad scope and potential impact on non-EU wine producers has triggered widespread industry concern outside of the EU.⁵¹ In fact, the Australian government has already filed a petition with the EC, explaining that the regulations have been implemented with little prior consultation. Australia has also threatened to involve the WTO, arguing that the restrictive nature of the proposed regulations render them WTO-inconsistent (i.e., they are tantamount to disguised trade barriers).⁵²

C. WTO Jurisprudence Relevant to The SPS Agreement Imposes Certain Requirements That National Regulations Must Adhere To

WTO case law, which has interpreted many of the provisions within the SPS Agreement, has essentially created a roadmap that helps to discern when a sanitary and/or phytosanitary measure constitutes a disguised trade barrier. SPS Article 2.2 requires each WTO member (including the EU and its Member States) to base its measures on ‘scientific principles’ and to maintain those measures with ‘sufficient scientific evidence’. “From this general duty flows the obligation to base SPS measures either on ‘international standards’, to the extent they exist, pursuant to Articles 3.1 and 3.2, or on other [, or even, its own] scientific justification’, pursuant to Article 3.3 (emphasis added).”⁵³ Scientific evidence has been deemed to be ‘sufficient’ if there exists “a sufficient or adequate relationship between two elements, in casu, between the SPS measure and the scientific evidence...there [must] be a rational or objective relationship between the SPS measure and the scientific evidence...Sufficiency is to be determined on a case- by-case basis, depending on the particular factual circumstances, including the

⁴⁹ President’s Trade Policy Agenda, at p. 154.

⁵⁰ 2003 NTE Report at p. 108.

⁵¹ The regulations establish an extensive list of requirements involving both the labeling and bottling of wines exported to the EU countries. It restricts the use of certain bottle types. It introduces a system to protect ‘traditional terms’ used to describe a wine that producers claim will require many of their wines to have their labeling completely changed. Also, certain grape varieties will not be recognized if they are grown outside of the EU. Consequently, they would have to be labeled as an alternative variety on bottles exported to the EU. “GMOs in the WTO – The Dispute Between the U.S. and the EU: The EC GMOs Ban under WTO Law”, Institute of International Economic Law, Georgetown University Law Center website. (Note #2 to SPS Agreement, “Sanitary and Phytosanitary Measures: Text of the Agreement – The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)”, at: http://www.wto.org/english/tratop_e/spsagr_e.htm).

⁵² At a Cape Town, South Africa meeting, the WWTG discussed elements of the new EU wine labeling regulations, which may be inconsistent with WTO rules. WWTG members raised concerns that such regulation may negatively impact on wine exports to the EU. See: “World Wine Trade Group Expresses Concern Over New EU Label Regulations” (7/5/02). See, also: “Australia Claims EC Wine Regulations Break WTO Agreement” (10/31/02).

⁵³ “GMOs in the WTO – The Dispute Between the U.S. and the EU: The EC GMOs Ban under WTO Law”, Institute of International Economic Law, Georgetown University Law Center website.

characteristics of the measure at issue and the quality and quantity of the scientific evidence.”⁵⁴

Where international standard setting bodies have not established ‘relevant international standards’ that specifically relate to a particular food product, or such standards are ‘not sufficient to achieve a WTO member’s appropriate level of SPS protection, that member is required to base its SPS measures on its own ‘scientific justification’, pursuant to SPS Article 3.3. Scientific justification must be established on the basis of an examination and evaluation of all available scientific information.”⁵⁵

Consistent with the requirement that an SPS measure must be based on scientific principles, SPS Article 5.1, requires that a WTO member’s SPS measure must be based on an assessment of the risks to human, animal or plant life or health. Such a risk assessment must be appropriate to the circumstances and must take into account risk assessment techniques developed by the relevant international organizations. There are three international standards organizations charged with harmonizing food safety regulations; they are the Codex Alimentarius (Codex), the International Plant Protection Convention (IPPC), and the International Office of Epizootics (OIE).

When undertaking a risk assessment, SPS Article 5.2 requires that the following factors be taken into account: 1) available scientific evidence; 2) relevant processes and production methods; 3) relevant inspection, sampling and testing methods; 4) prevalence of specific diseases or pests; existence of pest or disease-free areas; 5) relevant ecological and environmental conditions; 6) quarantine or other treatment. In assessing risks to health or animal or plant life, SPS Article 5.3 requires the EU to also take into account economic factors: 1) the potential damage in terms of loss of production or sales in the event of entry; 2) establishment or spread of a pest or disease; 3) the costs of control or eradication in the territory of the importing Member; and 4) the relative costs-effectiveness of alternative approaches to limiting risks.

WTO case law has articulated certain standards relating to risk assessments that a WTO member such as the EU must follow. First, “the risk evaluated must be an ‘ascertainable risk’. Theoretical uncertainty should not be assessed. The existence of unknown and uncertain elements does not justify a departure from the risk assessment requirement.”⁵⁶ In addition, “the risk to be evaluated in a risk assessment under SPS Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist – the actual potential for

⁵⁴ Joost Pauwelyn, “WTO Agreement on SPS Measures As Applied in the First Three SPS Disputes”, at p. 645, citing the Appellate Body’s decision on Japan -- Measures Affecting Agricultural Products, (hereinafter referred to as “the Japan-Varietals case”), adopted on March 19, 1999, WT/DS76AB/R.

⁵⁵ “GMOs in the WTO – The Dispute Between the U.S. and the EU: The EC GMOs Ban under WTO Law”, Institute of International Economic Law, Georgetown University Law Center website; See, also: Note #2 to SPS Agreement, “Sanitary and Phytosanitary Measures: Text of the Agreement – The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement”, at: (http://www.wto.org/english/tratop_e/spsagr_e.htm).

⁵⁶ Joost Pauwelyn, “WTO Agreement on SPS Measures As Applied in the First Three SPS Disputes”, at p. 646, citing the EC Hormones case.

adverse effects on human health in the real world where people live and work and die.”⁵⁷ Furthermore, a “qualitative assessment of risk is sufficient; a quantitative assessment is not required...In other words, a risk assessment does not require the establishment of a certain magnitude or threshold level of risk.”⁵⁸ Moreover, a risk assessment must be specific as to each substance evaluated and must evaluate each potential risk presented. In other words, “a separate risk assessment must be conducted for each substance – a generic risk assessment for a class of substances is not enough...[And,] the studies part of a risk assessment must be specific enough to address the particular kind[s] of risk[s] at stake; general studies showing the existence of a general risk of harm [are] not enough.”⁵⁹ Accordingly, “if a measure is not based on a ‘risk assessment’, it can be presumed not to be based either on ‘scientific principles’, or to be maintained without ‘sufficient scientific evidence’”⁶⁰

Lastly, a WTO member such as the EU must demonstrate that the SPS measures it has adopted are “objectively based on the risk assessment – it must not involve a subjective or procedural examination into the regulator’s decision-making process. There must be a rational relationship between the measure and the risk assessment...Even minority scientific opinions can justify this rational relationship...The risk assessment could set out both the prevailing view representing the mainstream of scientific opinion, as well as the opinions of scientists taking a divergent view...coming from qualified and respected sources”.⁶¹

D. Genetically Modified (Biotech) Food Products

Agricultural biotechnology presents the U.S. and other agriculturally oriented countries, especially LDCs, with an invaluable opportunity to improve standards of living while securing trade and economic growth prospects for future generations. Although the U.S. is currently the leading global producer of bioengineered seed and food products, it is closely followed by China, Argentina and Mexico. In addition, a number of LDCs in Asia and Africa are currently engaged in bioengineering research in order to exploit this technology for their national economies. However, the regulatory practices of certain WTO members, most notably the EU and its Member States, which presumes genetically modified food products are harmful unless proven ‘safe’, have disrupted trans-Atlantic trade flows⁶² and cast a ‘chilling effect’ on this burgeoning sector. The greatest cost, in

⁵⁷ Ibid, at p. 648, citing Appellate Body decision in EC-Hormones.

⁵⁸ “GMOs in the WTO – The Dispute Between the U.S. and the EU: The EC GMOs Ban under WTO Law”, Institute of International Economic Law, Georgetown University Law Center website, citing par. 186.

⁵⁹ Joost Pauwelyn, “WTO Agreement on SPS Measures As Applied in the First Three SPS Disputes”, at p. 646, citing EC-Hormones, at fn 28.

⁶⁰ Ibid, at p. 646, citing the Report of the Appellate Body on Australia - Measures Affecting the Importation of Salmon (hereinafter referred to as “the Australia Salmon case), adopted on November 6, 1998, WT/DS18/R and WT/DS18/AB/R.

⁶¹ Joost Pauwelyn, “WTO Agreement on SPS Measures As Applied in the First Three SPS Disputes”, at p. 649, citing the Appellate Body’s decision in EC-Hormones.

⁶² “Differences between the United States and the EU over genetically engineered (GE) crops and food products that contain them pose a potential threat to, and in some cases have already disrupted U.S.

this regard, is likely to be borne by the developing countries, which are desperately looking for ways to address their endemic food shortage problems and to actively participate within the global trading system.

1. *The EU / EU Member State Moratorium* ⁶³

Since October 1998, the EU has both facilitated and failed to resolve an EU-wide moratorium on any new approval of genetically engineered products. This *de facto* ban, which resulted from a breakdown in the EU approval process for GMO products⁶⁴, has halted \$300 million in U.S. corn shipments and threatens trade in soya as well.⁶⁵ Dairy products derived from livestock fed GMO feed, such as eggs or beef, are also at risk, as are flour and flour-based exports, such as soy protein concentrate, grain-based products, vegetable oil derived from soy beans, and pet food products derived from any of the above. There are 18 biotech food products approved for import by the EU and 13 more applications pending.⁶⁶ As a result, “food processors and exporters are either reformulating or seeking non-biotech sources.”⁶⁷ U.S. exporters of bioengineered seeds and foods, however, are not alone. Farmers and biotech companies in Canada, Argentina and Mexico have also been adversely affected.⁶⁸

agricultural trade.” Raymond J. Ahearn, U.S.-European Union Trade Relations: Issues and Policy Challenges at p. CRS-10.

⁶³ The EU and its Member States are not the only WTO Members that have imposed import bans of bioengineered food and feed. This conflict extends also to other members such as Australia, New Zealand and Zambia. “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, at: (http://www.law.georgetown.edu/iel/current/gmos/gmos_ec.html).

⁶⁴ “Since that date, applications for ‘market placement’ of GMOs basically got stuck at various stages. Hence, while there is no ban on GMOs resulting from a legislative measure in the EC, the application of the regulations relating to GMOs resulted in a ‘de facto’ ban on GMOs. By October 2001, 12 applications under Directive 90/220/EEC and 12 applications under Regulation 258/1997/EC were pending affecting non-EC companies as well as EC companies...”

⁶⁵ Raymond J. Ahearn, Foreign Affairs, Defense, and Trade Division, “U.S.-European Union Trade Relations: Issues and Policy Challenges”, at p. CRS-10.

⁶⁶ Berta Gomez, “U.S. Continues to Seek Changes in EU Biotech Policy”, U.S. Mission to the European Union, Washington File, Feb. 13, 2003, at:

(<http://www.useu.be/Categories/Biotech/Feb1303BiotechEUPadillahtml.html>). These 18 products have been approved for commercial release since October 1991. “Since October 1998 no further authorizations have been granted and there are currently 13 applications pending. Two genetically modified plants, a variety of soybean and a variety of maize have been authorized under EC Directive 90/220/EEC prior to entry into force of the Novel Foods Regulation (258/97/EC), to be on the European market for the use in food. Under the Novel Foods Regulation, no products produced from, consisting of or containing live GMOs have so far been authorized under the full procedure. Eleven (11) applications concerning such products are pending at different stages in the procedure. Several products produced from GMOs have been notified to the Commission as being ‘substantially equivalent’.” “Question and Answers on the Regulation of GMOs in the EU”, European Commission (Oct. 17, 2002), at p. 4. at: (<http://www.health.fgov.be>).

⁶⁷ 2002 NTE Report at p. 111.

⁶⁸ “Canada, Argentina and Mexico are the only other countries in which there has been significant use of modern agricultural biotechnology, although many other countries are starting to increase their use of living modified organisms in agriculture. China has approved a small number of transgenic varieties of cotton and expects to proceed to the commercial production of modified rice in the next two years.” Julian Kinderlerer, “Regulation of Biotechnology: Needs and Burdens For Developing Countries”, Sheffield

The EU Member State ban on GM products has been precipitated by environmentalist forces that have stoked consumer fears about the ‘safety’ of GM foods. These forces have argued that, because not all of the long-term effects of GM foods on health and the environment are known, they pose an unascertainable, and consequently, an unacceptable risk of harm to human health and environment.⁶⁹ This rush to judgment (presumption of harm) is devoid of any presentation of scientific evidence and/or scientifically based risk assessment of harm to consumers, animals or environment, as required by the SPS Agreement.⁷⁰ For this reason, U.S. government and industry view the U.S.-EU biotechnology dispute as “more of a ‘political’ than a ‘scientific’ issue in Europe...”⁷¹

The moratorium on GMOs effectively began at the Member State level during the spring of 1998, and since that time, “no new GMOs have been authorized for planting or use in the EU. [It] was made ‘official’ at an EU Environmental Ministers Council Meeting [during] June [24-25,] 1999,”⁷² at which a replacement directive for the management of GMOs was then being debated.⁷³ “In an annex to the press release of the Environmental

Institute of Biotechnological Law & Ethics, The University of Sheffield, Sheffield, UK (2002), at p. 3, at: (<http://www.unep.ch/biosafety/BtregulationJK.pdf>).

⁶⁹ According to an earlier Congressional Research Service report, “the biotechnology issue is affected by the widespread concern among consumers in the EU about the quality and safety of the foods they consume. Some observers believe that official handling of the BSE (bovine spongiform encephalopathy) or ‘mad cow disease’ crisis has undermined the public’s confidence in scientific assurances and exacerbated consumer concerns about food safety. The environmental group Greenpeace has been particularly vocal in protesting the use of products made from GMOs. It argues that the long-term effects of GMOs on health and the environment are unknown and that products made from GMOs should bear cautionary labels to inform consumers about their contents. Views espoused by Greenpeace are widely shared by organized consumer groups throughout the EU”. Charles E. Hanrahan, “U.S.-European Agricultural Trade: Food Safety and Biotechnology Issues”, CRS Report for Congress 98-861 ENR, (October 21, 1998), at p. 3.

⁷⁰ Former Reagan trade official Clyde Prestowitz summarized the U.S.-EU biotech dispute as follows: “Without any scientific grounds, but on the basis of the so-called precautionary principle -- that is, if we can’t prove absolutely that it is harmless, let’s ban it -- the union has prevented genetically modified food from the United States from entering its markets. This is almost certainly a violation of the WTO rules, which don’t recognize the precautionary principle...”⁷⁰ Clyde Prestowitz, “Don’t Pester Europe on Genetically Modified Food”, The New York Times, nytimes.com, Jan. 25, 2003, at: (<http://www.nytimes.com/2003/01/25/opinion/25PRES.html>).

⁷¹ Ibid; Assistant USTR Christopher Padilla, while attending a recent forum sponsored by the Pew Initiative on Food and Biotechnology, was quoted as describing the four year old EU moratorium on new approvals of biotech food imports as, “completely irrational” and based on “politics, not science”. Berta Gomez, “U.S. Continues to Seek Changes in EU Biotech Policy”, U.S. Mission to the European Union, Feb. 13, 2003.

⁷² “EU’s Moratorium on GMOs”, Friends of the Earth website, at: (<http://www.foeeurope.org/GMOs/moratorium.htm>)

⁷³ At that time, the relevant directive on the release of GMOs into the Environment (Directive 90/220/EC) was in revision and the Council of the EU was debating a new Directive (later Directive 2001/18/EC. “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. Also, the Friends of the Earth website discusses the circumstances underlying the issuance of the moratorium declaration. “Since spring 1998, no new GMOs have been authorised for planting or use in the EU. This de facto” moratorium was made ‘official’ at an EU Environment Ministers Council meeting in June 1999 when five Member States - Denmark, France, Greece Italy and Luxembourg - issued a declaration that they would effectively block new GMO approvals until the European Commission proposed legislation for

Council meeting, the Danish, Greek, French, Italian and Luxembourg delegations declared:

“The Governments of the following Member States (Denmark, Greece, France, Italy and Luxembourg), in exercising the powers vested in them regarding the growing and placing on the market of genetically modified organisms (GMOs), [...] point to the importance of the Commission submitting without delay full draft rules ensuring labeling and traceability of GMOs and GMO-derived products and state that, pending the adoption of such rules, in accordance with preventive and precautionary principles, they will take steps to have any new authorizations for growing and placing on the market suspended.” (Press Release 2194th Council) ⁷⁴

Within the EU, Austria⁷⁵, Luxembourg, and Italy⁷⁶ are the three Member States that have imposed marketing bans on some biotechnology products, despite existing EU marketing approvals.⁷⁷ Portugal and Germany⁷⁸ are two other Member States that have suspended approvals for planting certain biotechnology products.⁷⁹ While according to Assistant USTR Chris Padilla, it is a small blocking minority” which is responsible for keeping the moratorium in place for four years,⁸⁰ environmental groups, such as Greenpeace⁸¹ and

traceability and labeling of GMOs and products derived therefrom. [They declared that, ‘new authorizations for bringing under cultivation and for the placing of GMOs on the market are suspended until effective arrangements are adopted for the thorough traceability of GMOs enabling reliable labeling of all GMO-derived products to be guaranteed’ ...”

⁷⁴ “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, Ibid.

⁷⁵ Austria has imposed a marketing ban on some biotechnology products despite existing marketing EU approvals. It has been reported that Austria will be introducing a regulation in 2002 under which unapproved biotechnology events must not be detected in conventional seeds (‘zero tolerance’), but EU approved events may be present in conventional and organic seeds up to 0.1 percent. NTE Report at p.112.

⁷⁶ Italy previously announced, in October 2001, that it would no longer block consideration of EU market access for new biotechnology products. However, Italy has not pressed the EU to restart the biotechnology product approvals process despite the Italian policy shift. Ibid. In fact, on March 13, 2002, Europe’s top legal advisor upheld Italy’s right to ban genetically modified corn flour. Michael Schroeder, “U.S.-EU Trade Fight Isn’t Over, Just Sidetracked”, Wall Street Journal, 3/14/03, at p.A8.

⁷⁷ These Member States likely banned GMOs as a ‘safeguard measure’ permitted under Article 12 of the Novel Foods Regulation or Article 23 of Directive 2001/18/EC. “Both provisions require ‘new information’ that provide ‘detailed grounds for considering’ whether the GMO in question endangers ‘human health or the environment’” “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.

⁷⁸ Germany, in June 2001, postponed “for further study of legal issues” an impending approval of what would have been Germany’s first biotechnology products available for commercial cultivation. Prior thereto, in January 2001, Germany indefinitely postponed the “Chancellor’s Initiative”, a discussion between industry and government on biotechnology policy. NTE Report at p. 112.

⁷⁹ 2002 NTE Report at p. 111.

⁸⁰ Berta Gomez, “U.S. Continues to Seek Changes in EU Biotech Policy”. According to Padilla, “the EU’s policy runs directly contrary to its own commitment to base policy decisions on ‘sound science’ At the end of the day, we’re only asking them to follow their own laws and procedures”.

⁸¹ According to Mr. Vanderhaegen of the EU Commission, Greenpeace has long been an opponent of biotechnology and was probably most responsible for the European biotech scare. He indicated that, “a few years back, EU biotech manufacturers labeled their products as containing biotechnology and there were no reported drops in consumer sales of those products. Greenpeace was not happy with this result, so they ran a public campaign against biotech manufacturers...” (from notes taken at WITA Biotech Seminar 3/5/03).

Friends of the Earth⁸², have emphasized that the moratorium involves more than the five original countries.⁸³

2. *The Potential Benefits of Agricultural Biotechnology That May Never Be Realized if the EU GMO Ban Continues*

By effectively prejudging, at the level of politics rather than science, that the potential harms posed by agricultural biotechnology outweigh its potential benefits, the EU Member State's continued ban of GM foods has foreclosed the possibility of public debate on a fundamentally important issue and has unwittingly placed a 'chilling effect' on the use of biotechnology in global agriculture. As the result of this action, the realization of whatever promising benefits and markets for such products may exist has been indefinitely delayed. Both the EU and the U.S. recognize the importance of this technology to human sustainability and its prospects for industrial and economic growth, though they have each expressed this understanding in starkly different ways.

'Biotech foods' are the result of the application of biotechnology to agriculture. Agricultural biotechnology has been described as "a collection of scientific techniques, including genetic engineering, that are used to create, improve, or modify plants, animals, and microorganisms. Using conventional techniques, such as selective breeding, scientists have been working to improve plants and animals for human benefit for hundreds of years. Modern techniques now enable scientists to move genes (and therefore desirable traits) in ways they could not have before – with greater ease and precision".⁸⁴ "The International Food Information Council (IFIC) refers to agricultural biotechnology as 'an evolution of traditional agricultural products'.⁸⁵

⁸² Although "Denmark, Italy, France, Greece Austria and Luxembourg are usually named, others have not taken a final position on the issue." The Friends of the Earth website indicates that, following the revision of the Deliberate Release Directive regulating the release of GMOs into the environment (Directive 2001/18/EC repealing Directive 90/220/EEC, adopted by the European Parliament in February 2001), these five countries, subsequently joined by Austria, again declared that they would not lift the moratorium until the issue of traceability and labeling is resolved. The moratorium has been consolidated over recent months by similar declarations from Germany (October 2001) and Belgium (December 2001). "EU's Moratorium on GMOs", Friends of the Earth website, at: (<http://www.foeeurope.org/GMOs/moratorium.htm>).

⁸³ A 1998 study performed in Scotland by Arpad Pusztai claimed that "genetically modified potatoes were toxic and harmful to rats. Activist groups, such as Friends of the Earth and Greenpeace, held press conferences to call a halt to bioengineered foods. Newspapers across the UK and elsewhere carried articles on 'Frankenfood'. Yet, toxicologists and other scientists who took a close look at the data found that genetic modification didn't seem to be the culprit. It appeared that the rats likely suffered from starvation or from the force-feeding of known toxins in potatoes." Frances B. Smith, "The Biosafety Protocol: The Real Losers Are Developing Countries", James V. DeLong, Editor, National Legal Center For the Public Interest, (2000), at p. 8.

⁸⁴ "Biotechnology Questions and Answers", U.S. Department of State, International Information Programs (Jan. 3, 2003), at p.1. This information can be accessed in the U.S. Department of Agriculture website at: (<http://fas.usda.gov/itp/biotech/Q&As.html>).

⁸⁵ This statement was referenced on the American Farm Bureau Federation (AFBF) website. The AFBF goes on to say, "According to the IFIC, by using new technologies, scientists are now able to pinpoint the gene responsible for a particular trait, then extract it, or add that gene to a specific plant." "Biotechnology – The Farm Perspective", American Farm Bureau Federation, at: (<http://americanfarmbureau.com>).

According to the American Farm Bureau Federation (AFBF), “biotechnology has already [been used in the production of] many of the...foods we eat today...[including] red, green and yellow peppers, tomatoes, strawberries, and vegetable oils lower in saturated fats.”⁸⁶ In addition, genetically modified soy has made its way into soy protein concentrates used in conjunction with other ingredients in a number of traditional food products. These products include: bakery products (such as, non-fat-dry-milk replacers, cakes, cookies, pastries, pancakes, doughnuts and pasta products); dairy products (such as, beverage powders, cheeses, frozen desserts, and whipped toppings); meat products (such as, bologna, frankfurters, sausage, seafood, ground beef, pizza toppings and ham); candies, dietary items and soup mixes.⁸⁷

The U.S. Department of State has noted several of the potential benefits that could be realized through the use of bioengineered crops.

“Biotechnology can help farmers increase crop yields and feed even more people. [It has been] used...to pinpoint a gene that could help wheat, a major food staple, grow on millions of acres worldwide that are now hostile to the crop...Scientists have also developed an experimental potato hybrid that contains genes to resist a new more virulent strain of the so-called ‘late blight’, the disease that caused the Irish potato famine in the 1840’s. Biotechnology can also help farmers reduce their reliance on insecticides and herbicides. For example, Bt cotton, a widely grown biotech crop, kills several important cotton pests.”⁸⁸

The European Commission has drawn similar conclusions:

“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...Plant genome analysis...has already led to the genetic improvement of a traditional European cereal crop (called ‘spelt’) with an increased protein yield (18%) which may be used as an alternative source of protein for animal feed. 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...”⁸⁹

At the multinational level, the role being served by the first generation of agricultural biotechnology was also elaborated upon by the World Health Organization (WHO) of the United Nations.

⁸⁶ “Biotechnology – The Farm Perspective”, American Farm Bureau Federation, at p. 4.

⁸⁷ See: Joseph G. Endres, Ph.D., “Soy Protein Products - Characteristics, Nutritional Aspects, and Utilization”, AOCS Press and the Soy Protein Council © 2001.

⁸⁸ “Biotechnology Questions and Answers”, U.S. Department of State, International Information Programs, at p. 1.

⁸⁹ COM (2002) 27 final, “Life Sciences and Biotechnology – A Strategy For Europe”, European Commission (Jan. 23, 2002), at p.11.

“The initial objective for developing plants based on GM organisms was to improve crop protection. The GM products currently on the market are mainly aimed at an increased level of crop protection through the introduction of resistance against plant diseases caused by insects or viruses or through increased tolerance towards herbicides. Insect resistance is achieved by incorporating into the food plant the gene for toxin production from the bacterium *Bacillus thuringiensis* (BT). This toxin is currently used as a conventional insecticide in agriculture and is ‘safe’ for human consumption. GM crops that permanently produce this toxin have been shown to require lower quantities of insecticides in specific situations, e.g., where pest pressure is high. Virus resistance is achieved through the introduction of a gene from certain viruses which cause disease in plants. Virus resistance makes plants less susceptible to diseases caused by such viruses, resulting in higher crop yields. Herbicide tolerance is achieved through the introduction of a gene from a bacterium conveying resistance to some herbicides. In situations where weed pressure is high, the use of such crops has resulted in the reduction in the quantity of herbicides used.”⁹⁰

According to a report prepared by the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), which has been cited both by the European Commission and the U.S. Department of State, there has been a steady increase in the area sown with genetically modified seeds. As of 2001, there were 53 hectares of transgenic crops grown worldwide⁹¹; 88 million of those approximately 130 million acres were grown in the United States.⁹² The WHO has reported that, “all genetically modified (GM) crops available on the international market today have been designed using one of three basic traits: resistance to insect damage; resistance to viral infections; and tolerance towards certain herbicides.”⁹³

3. *The Distinct Ways In Which The U.S. and the EU Have Approached Agricultural Biotechnology and Interfaced With Industry*

Notwithstanding their common appreciation for the potential benefits that agricultural biotechnology can bring to society, however, the United States and the European Union have taken divergent paths to the realization of these benefits. In the United States, “over 5,000 field trials have been approved by the USDA’s Animal and Plant Health Inspection Service (APHIS)⁹⁴ since 1987”, 2,300 of which were likely conducted during 2001

⁹⁰ “Fact Sheet: WHO Answers Questions About Biotechnology Foods”, U.S. Department of State, International Information Program, (October 15, 2002).

⁹¹ COM (2002) 27 final, “Life Sciences and Biotechnology – A Strategy For Europe”, at p. 12.; “Biotechnology Questions and Answers”, U.S. Department of State, International Information Programs, at p. 3.

⁹² “Biotechnology Questions and Answers”, U.S. Department of State, International Information Programs, at p. 3.

⁹³ The crops and their related traits are as follows: 1) maize – insect resistance; 2) maize – herbicide resistance; 3) soybean – herbicide resistance; 4) oilseed – herbicide resistance; 5) rape chicory – herbicide resistance; 6) squash – virus resistance; 7) potato – insect resistance/herbicide resistance. “Fact Sheet: WHO Answers Questions About Biotechnology Foods”, U.S. Department of State, International Information Program, at p. 4.

⁹⁴ “APHIS is responsible for protecting American agriculture against pests and diseases. It regulates the field testing of genetically engineered plants and certain microorganisms. APHIS also approves and licenses veterinary biological substances, including animal vaccines, that may be the product of biotechnology...APHIS is the [U.S.] government’s lead agency regulating the safe testing, under controlled circumstances of biotechnology-derived new plant varieties. A company, academic or research institution,

alone.⁹⁵ In addition, “about 40 new agricultural products have completed all the federal regulatory requirements and may be sold commercially. They range from longer-lasting tomatoes to pest-resistant corn.”⁹⁶ “As of June 2002, the USDA’s National Agricultural Statistics Service (NASS)” has calculated that, “of all U.S. corn, cotton and soybeans planted, 34 percent, 71 percent, and 75 percent, respectively, are biotechnological varieties.”⁹⁷ The European Union, by contrast, had conducted only 44 biotech field trials during 2001.⁹⁸ In effect, “spending twice as much on research and development, and employing twice the numbers of people, the U.S. is creating more biotechnology products and services than Europe...[In 2001], market capitalization of U.S. firms was 5 times that of EU companies.”⁹⁹

From these data, one might conclude that the U.S. and the EU not only hold disparate views toward the role of scientific advancement and risk in society, but that, they also have developed starkly different working relationships with their respective industries.¹⁰⁰ The U.S. has endeavored to support its biotech industry by encouraging research and development of genetically modified seed and food products and biotech crop field-testing, authorizing the introduction of bioengineered foods and feed into the marketplace following government reviewed scientific risk assessments, and communicating the benefits of scientific progress to the public. The EU, by contrast, has managed to work against the interests of the European biotech sector, by holding back authorizations of biotech crop field testing, blocking introduction into the marketplace of biotech crop food and feed products, and failing to educate the public about the potential scientific benefits to be derived from agricultural biotechnology. The EU moratorium and subsequent GMO legislation, in effect, more closely reflect the interests of environmentalist groups than those of industry.

4. *The EU GMO Legal Regime*

a. *Directive 2001/18 and Related Proposed Regulations*

non-profit organization or public sector scientist wishing to field test or move (via importation or interstate movement) a biotechnology-derived plant must generally obtain APHIS approval before proceeding.” “Biotechnology Questions and Answers”, U.S. Department of State, International Information Programs, at p. 1-2.

⁹⁵ “Biotechnology Questions and Answers”, U.S. Department of State, International Information Programs, at p. 3; Vanderhaegen 3/5/03 notes – “In 2001, there were 2,300 biotech field trials in the U.S.”

⁹⁶ “Biotechnology Questions and Answers”, U.S. Department of State, International Information Programs, at p. 3.

⁹⁷ Ibid.

⁹⁸ Vanderhaegen notes 3/5/03.

⁹⁹ “European Competitiveness Council To Agree Road Map For European Life Sciences and Biotechnology : EU – The Way Ahead for Biotech”, Agrifood News Archive, Agrifood Awareness Australia,(Nov. 26, 2002), at: (<http://www.afa.com/au/news/news-1056.asp>).

¹⁰⁰ According to this note, “A de facto moratorium on research and development of biotechnology derived plants has been in place since 1998, a biotech patent directive is unimplemented in 9 out of the 15 Member States and layers of legislation are lining up to regulate biotechnology products and services. In such a climate, Europe’s investors are fleeing to regions where biotech is encouraged.” Ibid.

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.¹⁰¹ 2001/18/EC, “in general, put in place a step-by-step approval process [requiring] a 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.”¹⁰² It has been described as embodying a ‘horizontal regime’ that covers both the prior authorization and labeling of GM food and feed.¹⁰³ As drafted, this directive covered “any GMO or product consisting of or containing GMOs, such as maize, tomatoes, insects or microorganisms”.¹⁰⁴ However, [the directive did not govern] “products derived from GMOs, such as paste or ketchup from a GMO tomato, [which was] Instead... covered by vertical, sectoral legislation (e.g., the Regulation on Novel Foods and Novel Food Ingredients.”¹⁰⁵ The objective of 2001/18/EC has been to ensure, ‘in accordance with the precautionary principle’, the protection of human health and the environment, as well as, the proper functioning of the internal EC market.¹⁰⁶ 2001/18 came into force on October 17, 2002.¹⁰⁷

The new directive’s entry into force, however, did not satisfy the concerns of the EU Member States upholding the moratorium. Because of perceived flaws within the directive, they refused to lift the GMO moratorium and to restart the GMO approval process, unless and until additional rules on labeling and traceability of GM food and feed are enacted. This reaction 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 and traceability of food and feed products produced from GMOs

¹⁰¹ 2002 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 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.

¹⁰² “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.

¹⁰³ The legislation contains three parts: 1) process-based labeling for food and feed products that contain or are derived from biotech ingredients; 2) provisions for event-specific identity markers; and 3) a tolerance for adventitious (unintended or accidental) presence of unapproved varieties. “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).

¹⁰⁴ “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.

¹⁰⁵ Ibid. 258/97/EC – “Regulation on Novel Foods and Novel Food Ingredients” (Jan. 27, 1997).

¹⁰⁶ 2001/18/EC, Article 1; Joanne Scott, “European Regulation of GMOs and the WTO”, cited in the Institute of International Economic Law, Georgetown University Law Center (2002), at pp. 1 and 4.

¹⁰⁷ “Since October 17, 2002, EC Member States have been required to have implemented the obligations of the new Directive 2001/18/EC on the deliberate release into the environment of GMOs.” “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

that will amend Directive 2001/18/EC.”¹⁰⁸ The need for these regulations has been described as follows:

“The Deliberate Release Directive only provides a general framework for the regulation of GMOs and does not address key environmental problems, like the genetic pollution of seeds and liability for environmental problems caused by GMOs. These problems will have to be addressed in separate pieces of legislation (Seeds Directive (SANCO/1542/02) and Environmental Liability Directive (COM (2002) 17 final). [These directives] are still in the pipeline and will not be finalized before the end of 2003. [Furthermore,] the Deliberate Release Directive does not provide a legal basis for the labeling of genetically modified (GM) food and (GM) animal feed. It will take at least another half year before the laws that will secure the full labeling of GM food and GM animal feed are fully operational. [During] October [2002], the Council of EU Ministers will vote upon two proposals (COM (2001) 182 final¹⁰⁹ and COM (2001) 425 final¹¹⁰ to extend the mandatory labeling regime to all GM food and GM animal feed. [And], these proposals – if adopted by the Council- will have to go back to the European Parliament for a second and possibly third reading before they can enter into force.”¹¹¹

b. *Proposed GMO Food and Feed Authorization Regulations Implementing Directive 2001/18/EC*

The new proposed regulation on GM food and feed amends directive 2001/18/EC and considerably broadens its policy objective. In addition to ensuring the protection of human health, the environment, and the proper functioning of the internal EC market, the proposed regulation is also intended to ensure animal health and welfare and consumer protection (defined broadly as ‘consumer interests’).¹¹² More problematic, however, is the ‘scope’ of application of the proposed GM Food and Feed regulation which continues to be debated between the European Commission and the European Parliament.

The European Parliament has advocated a broader scope than has the European Commission. One legal commentator has noted, that “the Commission accepts that [the scope] should extend only to GM food and feed containing or consisting of GMOs, and encompass food and feed produced *from* GMOs...the European Parliament, [however, wishes] that it extend [also] to GM food or feed *produced with* GMOs.”¹¹³ The

¹⁰⁸ “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.

¹⁰⁹ “Proposal for a Regulation of the European Parliament and of the Council Concerning Traceability and Labeling of Genetically Modified Organisms and Traceability of Food and Feed Products From Genetically Modified Organisms” (July 25, 2001) -- the ‘GM Traceability and Labeling proposal’.

¹¹⁰ “Proposal for a Regulation of the European Parliament & of the Council on Genetically Modified Food & Feed” (July 25, 2001) -- the ‘GM Food & Feed Proposal’. “The proposed regulation repeals existing regulations and amends other regulations and directives. It establishes new procedures for the authorization and labeling of biotech foods that will supersede those contained in regulation (EC) No. 258/97 (Novel Foods). All food will now be required to go through a lengthy food safety review.” U.S. Comments, Proposal for a Regulation on Genetically Modified Food and Feed, WTO Notification G/TBT/N/EEC/6” (Dec. 6, 2001), at p. 1.

¹¹¹ “EU’s Moratorium on GMOs”, Friends of the Earth website

¹¹² Joanne Scott, “European Regulation of GMOs and the WTO”, cited in the Institute of International Economic Law, Georgetown University Law Center (2002), at p.4.

¹¹³ Joanne Scott, “European Regulation of GMOs and the WTO”, at p. 2.

implications of this widened scope can be significant. The European Commission, in its explanatory memorandum, describes it as follows:

“The proposed regulation would cover products ‘produced *from* a GMO’, but not products ‘produced *with* a GMO’. The former [view] implies that a proportion of the end product, whether it is the food or feed itself or one of its ingredients has been derived from the original genetically modified material. The latter [view] is produced with the assistance of a genetically modified organism, but no material derived from the genetically modified organism is present in the end product. Thus, cheese produced with a genetically modified enzyme that does not remain in the final product and products obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products would be subject neither to the authorization nor to the labeling requirements laid down in the proposed regulation.”¹¹⁴

In other words, if the Parliament’s view prevails, the regulation’s scope would encompass food or feed produced with the aid of GMOs, food produced from animals fed with feed produced from or with GMOs, including a GM processing aid, or from animals to which GM medicine has been administered”, whether or not they remain in the finished product.¹¹⁵

Another issue that remains unresolved as between the Commission and the Parliament concerns whether “Directive 2001/18/EC and the Regulation on GM food and feed will apply in parallel, with the result that an individual would have to seek approval under *both* procedures. The Commission is vehemently opposed to that view and advocates a ‘one door-one key’ approach (emphasis added).”¹¹⁶

¹¹⁴ Ibid, at p. 2, citing the European Commission’s explanatory memorandum accompanying the original proposal. See: COM (2001) 425 final, p.3.

¹¹⁵ Ibid. Although the European Commission is charged with drafting this proposed regulation, the European Parliament retains the authority to review it. “Since the regulation must be adopted pursuant to a ‘co-decision’ procedure, the Parliament’s position is an important step in the enactment process.” “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. As a result, the regulation’s scope of application will not be resolved until these two bodies are able to reconcile their differences. See: Raymond J. Ahearn, Foreign Affairs, Defense, and Trade Division, “U.S.-European Union Trade Relations: Issues and Policy Challenges”, at p. CRS-11. For a brief discussion of the relative roles and functions of key European institutions in the formulation of EU trade policy, See: Raymond Ahearn, Specialist in International Trade and Finance Foreign Affairs, Defense, and Trade Division, “Trade Policymaking in the European Union: Institutional Framework”, CRS Report for Congress, March 27, 2002.

¹¹⁶ Ibid. The relationship between Directive 2001/18/EC and the proposed regulation on GM food and feed products under the Directive’s so-called ‘equivalent sectoral legislation’ provision is allegedly still being debated. Under this provision, sectoral legislation is deemed equivalent to the Directive if it “provides for a specific environmental risk assessment, as the Directive mandates, and imposes equivalent risk management, labeling, monitoring, and information requirements and procedures.”¹¹⁶ Directive Article 12, as cited in “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. Pursuant to the ‘equivalent sectoral legislation provision, “where no sector legislation exists, or where existing sectoral legislation is non-equivalent, GMOs will have to be approved under the Directive, *in addition to...*under the procedures provided for by the non-equivalent sectoral legislation (emphasis added). Ibid.” While the Parliament and Commission agree that the Novel Foods Regulation 258/97 is non-equivalent to Directive 2001/18/EC, they disagree as to whether the new proposed regulation on GM

A third unresolved issue in connection with these regulations concerns the establishment of a threshold for adventitious (accidental) presence of GMOs. Should accidental amounts fall under the threshold, no approval for market placement would be required. However, “the accidentally present GMO must have already been subject to a risk assessment by the relevant EC Scientific Committee that concludes that the material does not present a risk for human health or the environment.”¹¹⁷ While the Commission has proposed a no-higher-than 1% threshold (i.e., no more than 1% of food or feed can consist of or be produced from GMOs), “the Parliament has proposed to remove the article on adventitious or technically unavoidable presence of GMOs altogether.”¹¹⁸ They reason that, “such a threshold applying to non-authorized crops would undermine the European Union’s legislation on biosafety.” What remains certain is that the threshold amount is still subject to political negotiation among the relevant EU bodies.^{119*}

c. *Proposed GMO Food and Feed Traceability and Labeling Regulations Implementing Directive 2001/18/EC*

The traceability component of the proposed regulations on GMO Traceability and Labeling “requires business operators to transmit and retain information about products that contain or are produced from GMOs at each stage of food and feed production and distribution, including their placement on the market”. However, “operators that deliver food to the ultimate consumer do not have to retain information detailing to whom [GMO] products were sold”.¹²⁰ Traceability is thought of as “providing a ‘safety net’ in case unforeseen adverse effects on human health or the environment are established.”¹²¹

food and feed authorization is equivalent to the Directive. In the event it is deemed non-equivalent (as the Parliament believes), both Directive 2001/18 and the GMO authorization regulation would apply. Ibid.

¹¹⁷ Ibid. These provisions are intended to address a problem that is increasingly likely to occur “with ‘bulk shipments of agricultural goods, especially grains, for which a ‘non-contamination’ with GMOs cannot be guaranteed anymore.” Ibid.

¹¹⁸ Ibid.

¹¹⁹ Ibid. * “On November 28, 2002, the European Agricultural Council reached a ‘political’ agreement, endorsed by the Commission, that the threshold level should be set at 0.5%. The marketing of such bulk shipments would only be allowed for a transitional period of three years, and only for GMOs that have been assessed as being risk-free prior to the entry into force of the new regulation.” Ibid.

¹²⁰ Ibid. In this way, EU retailers are spared the burden of tracing GMO products sold to consumers.

¹²¹ Ibid. The term ‘traceability’, however, is not defined by Directive 2001/18/EC. These rules require that: 1) generally, operators have systems and procedures in place to identify to whom and from whom products are made available; 2) *for GMOs intended for deliberate release into the environment*, operators transmit specified information on the identity of the individual GMOs a product contains; 3) *for GMOs intended for food, feed or for processing*, business operators either transmit the specified information mentioned above or transmit a declaration that the product shall only be used as food or feed or for processing, together with the identity of the GMOs that the product may contain; 4) *for food and feed produced from GMOs*, operators inform the next operator in the chain that the product is produced from GMOs; and 5) operators retain the information for a period of 5 years and make it available to competent authorities on demand (emphasis added).” “Question and Answers on the Regulation of GMOs in the EU”, European Commission, at p. 7. The last requirement sounds very similar to the ‘data-sharing’ required by the EU’s Chemicals White Paper proposal and other chemicals management directives.

Practically speaking, “the Regulation [would] apply at all stages of the placing on the market to products consisting of GMOs, including food and feed. Every operator has to assure that information is passed on to the next operator receiving the product in the process of market placement.”¹²² Hence, the process of tracing a GMO would begin with the company that develops a GMO (e.g., a genetically modified seed). That company would have to inform any purchaser of the seed that it is genetically modified, and provide specific information that would permit the specific GMO to be precisely identified. That company would also be required to prepare and maintain a register of business operators who have bought the seed. Similarly, a farmer of the seed would have to inform any purchaser of the harvest that it is genetically modified, and would be required to prepare and maintain a register of operators to whom he has made the harvest available.¹²³ The costs that will be borne by non-EU exporters of GM foods and feed in order to comply with the proposed regulation on traceability are likely to be significant, considering the unworkable low threshold for ‘adventitious’ amounts, which has yet to be conclusively determined¹²⁴

The labeling component¹²⁵ of the proposed regulations on GMO Traceability and Labeling, would require that all food and feed which consist of, contain or are produced from GMOs be labeled as such. In doing so, it would extend and consolidate all current labeling regulations dealing piecemeal with individual products containing GMOs. This would include Regulation (EC) 49/2000, which addresses the problem of ‘adventitious’ contamination of GM material in conventional food by imposing a 1% threshold for such presence.¹²⁶

The proposed labeling requirements would also implement and extend the more general labeling requirements set forth in Directive 2001/18/EC. Those general rules require that, “a labeling proposal be accompanied with every application for market placement of a new GMO. According to that directive, the labeling has to clearly state that a GMO is present and the words ‘this product contains genetically modified organisms’ have to appear in the labeling or the accompanying document”.¹²⁷

¹²² “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.

¹²³ “Question and Answers on the Regulation of GMOs in the EU”, European Commission, at pp. 7-8.

¹²⁴ It has been reported that, “the Environmental Council of December 9, 2002, reached a ‘political’ agreement that the traceability regime should not apply to adventitious traces of GMOs intended for processing for non-food/ feed purposes, in a proportion no higher than 0.9%”. Ibid. “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.

¹²⁵ Other WTO Member States, besides the EU, require labeling of products containing GMOs, including China, Australia, New Zealand, Korea, Japan, Switzerland and the Slovak Republic. Ibid.

¹²⁶ “Question and Answers on the Regulation of GMOs in the EU”, European Commission, at p. 5.

¹²⁷ [Also,] “The labeling and packaging of GMOs placed on the market as or in products must comply with the relevant requirements specified in the ‘written consent’”. That is likely to include requirements imposed by other sectoral legislation on labeling such as, the Novel Foods Directive. “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.

One of the more problematic aspects of the labeling regulations is that, just like the GMO authorization regulations, 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).¹²⁸ As the Commission notes, “the [current] special labeling requirements for foods derived from GMOs, but no longer containing GMOs are more complicated and based on the concept of ‘equivalence’.”¹²⁹ For example, “if a characteristic or property (composition, nutritional value or nutritional effects, intended use) renders a food or food ingredient no longer equivalent to an existing counterpart, it has to be labeled indicating the method (i.e., genetic modification) by which the characteristic or property was obtained.”¹³⁰ 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 current GM labeling system is based on the *detectability* of genetically modified DNA or protein in the final food product. In practice, this means that highly processed foodstuffs produced from GM material, such as highly refined oils, do **not** need to be labeled. [However,] the proposed labeling rules extend the labeling requirements to all food and ingredients produced from GMOs *to allow consumers to exercise their freedom of choice*. Genetically modified feed will need to be labeled along the same principles to give livestock farmers accurate information on the composition and properties of feed. This will mean that a large number of feedstuffs currently not subject to GM labeling requirements, such as GM soy meal in feed or compound feedstuffs and the four genetically modified feed plants authorized under Directive 90/220/EEC will, in the future, need to be labeled (emphasis added).”¹³¹

Furthermore, the proposed labeling regulations would also extend the scope of the directive beyond the initial [GMO] notifier, to include operators, [at all stages who,] ‘when placing pre-packaged products consisting of, or containing GMOs on the market, [must] put the words [...] noted above on the label’.¹³² Moreover, they would continue to exempt from labeling food and feed products containing adventitious amounts of GMOs, provided such presence is technically unavoidable and falls below a specified threshold amount.¹³³ As with similar thresholds imposed for GMO authorization and traceability, the threshold for labeling has been the subject of extensive internal EU political negotiations.¹³⁴

¹²⁸ “Question and Answers on the Regulation of GMOs in the EU”, European Commission, at p. 8.

¹²⁹ Ibid, at p. 5.

¹³⁰ Ibid, at p. 23, fn 1.

¹³¹ Ibid, at p. 8.

¹³² This would seem to imply that retailers, as well, would be held responsible for such labeling. However it is questionable whether this will ultimately be the case, given that the traceability requirements are not imposed on EU “retailers down the line that bought the product from the original notifier”. “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.

¹³³ Ibid.

¹³⁴ “According to the Commission’s initial proposal, thresholds would have been approved by the Member States on a proposal by the Commission once the Regulation enters into force according to a regulatory committee procedure. [...] The European Parliament, while retaining the possibility for a lowering of the thresholds in a regulatory committee procedure, has proposed to include a 0.5% in the new regulation. Such products would still need market approval though. The Agricultural Council of November 28, 2002, with the consent of the Commission, reached a political agreement on a 0.9% threshold that subsequently could be lowered under the proposed procedure...” Ibid.

5. *The EU and Member States' Moratorium and the GMO Directive and Proposed Regulations Discriminate Against U.S. and Other Non-EU Exports and Are Thus Disguised Trade Barriers*

a. *The U.S. Government's Response -- Generally*

The EU has devised a clever regulatory mechanism that operates by means of an administratively created presumption that, biotech crops, related food products and feed present 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' hazards by mandating a burdensome and costly testing, authorization and market access (e.g., labeling and traceability) regimen that many in industry, especially non-EU exporters, will find unworkable.

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, the very information they had failed to convey to the public in the first place.¹³⁵ That "the genetically modified products currently on the international market have all passed thorough [science-based] risk assessments, following the same basic principles, conducted by national authorities, which do not indicate any [actual] risk to human health", does not seem to matter.¹³⁶ Instead, the EU and its Member States rationalize their perception of risks and their management and communication of them by reference to the 'precautionary principle'.

Members of the Bush Administration, notably USTR Robert Zoellick and Agriculture Secretary Ann M. Veneman, do not believe that the enactment of new regulations alone will reverse the EU market access (moratorium) problem. They have thus 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.¹³⁷ 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.¹³⁸ Those within the European Commission believe that once the public is 'informed and provided a choice' about GMOs food products (through promulgation of labeling and

¹³⁵ According to Environment Commissioner Margot Wallstrom, "The provisions for traceability ensure a high level of environmental and health protection and pave the way for a proper labeling system. Certainly there is a cost for the producers and for trade, but what is at stake is our ability to build public confidence. European companies will only be able to seize the opportunities provided by biotechnology if this confidence is established." "Commission Improves Rules on Labeling and Tracing of GMOs in Europe to Enable Freedom of Choice and Ensure Environmental Safety", European Commission, doc. IP/01/1095, (7/25/01), at p. 1. at: (<http://www.europa.eu.be>).

¹³⁶ "Fact Sheet: WHO Answers Questions About Biotechnology Foods", U.S. Department of State, International Information Program, at p. 4.

¹³⁷ According to James Murphy, Assistant USTR, Agriculture, "The U.S. has been patient for over four years, but no EU progress has been shown". (Comments made by James Murphy, WITA Seminar).

¹³⁸ "No GMO Case Against EU for Now", Washington Trade Daily, Feb. 6, 2003 at p.1.

traceability regulations), consumer fears about GMOs will disappear. However, even despite these recent machinations at the European Community level, many EU Member States continue to uphold the moratorium.

During February 2003, the European Commission, once again, warned European Union governments to end their foot-dragging over approval of new GM crops, in an attempt to stave off the growing threat of a U.S. challenge at the WTO. 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.¹³⁹ This statement followed the December 2002 admission by EC Commissioner Walstrom that, the moratorium was “illegal and unjustified”, insofar as it is neither WTO compliant nor consistent with internal EU law.

Mr. Fischler indicated during his February 2003 trip to Washington that, a case against the EU in the WTO would likely stop the process in its tracks and turn sensitive European public opinion against such imports. “I find it surprising that this is happening at the very point in the process [the process by which the European Parliament is expected to adopt a proposed EU regulation on the ‘traceability and labeling of GM products’] at which everything is falling into place”, he said. Mr. Fischler assured U.S. officials that the EC would bring the five EU member states to the European Court of Justice if they continue their moratorium on imports after the European Parliament signs off on the new procedures.¹⁴⁰ This assurance is certain to be tested, as Europe’s top legal advisor, on March 13, 2003, upheld Italy’s right to ban genetically modified corn flour.¹⁴¹

These assurances notwithstanding, the Bush Administration believes that, the enactment of the new GMO food and feed authorization regulations, and the continuation of the EU moratorium on pending GMO applications and those already approved until new regulations on GMO traceability and labeling have been enacted, each violates the SPS Agreement.¹⁴² The EU has implemented these measures without providing any scientific

¹³⁹ 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. The French Academy of Science also apparently drew the conclusion that there is no scientific evidence that shows that GMO foods are not ‘safe’.

¹⁴⁰ “No GMO Case Against EU for Now”, Washington Trade Daily, Feb. 6, 2003 at p.1.

¹⁴¹ Michael Schroeder, “U.S.-EU Trade Fight Isn’t Over, Just Sidetracked”, Wall Street Journal, 3/14/03, at p.A8. The author notes that “the case is widely seen as one of the most contentious to confront the WTO’s dispute settlement mechanism so far, and could have serious repercussions for the current Doha round of world trade talks”.

¹⁴² The EU provided notice of the proposed GMO food and feed authorization regulations under the TBT Agreement without also providing parallel notification under the SPS Agreement. This provoked the curiosity of the U.S. Government. “While the United States welcomes the notification to WTO members under the TBT Agreement, we question why a parallel notification was not also made to WTO members under the SPS Agreement. The United States would encourage the Commission to also evaluate the proposed regulation in light of the disciplines of the SPS Agreement”. “U.S. Comments to Proposal for a

justification or conducting any science-based risk assessment¹⁴³ showing an actual ascertainable risk of harm to human and animal health or to the environment posed by specific GMO food or feed products. To the contrary, the WHO reports that, “GM foods currently available on the international market have passed risk assessments and are *not* likely to present risks for human health. In addition, *no* effects on human health have been shown as a result of the consumption of such foods by the general population in countries where they have been approved” (emphasis added).¹⁴⁴ Absent evidence of any specific instance of harm, the EU has nevertheless proceeded to invoke the ‘precautionary principle’¹⁴⁵ pursuant to which it has established an administrative presumption of a general risk of harm to justify these measures.¹⁴⁶

Regulation of the European Parliament and of the Council on Genetically Modified Food and Feed, Re: WTO Notification G/TBT/N/EEC/6, (Dec. 6, 2001), at p. 3. An analysis of these measures would show that, both the EU legislation laying down a general prohibition of market placement of new GMOs without prior approval, and the individual Member State bans on GMOs approved prior to 1998, are arguably SPS measures. See: “GMOs in the WTO – The Dispute Between the U.S. and the EU: The EC GMOs Ban under WTO Law”, Institute of International Economic Law, Georgetown University Law Center, at: (http://www.law.georgetown.edu/iel/current/gmos/gmos_wto.html).

¹⁴³ The EU must conduct two different types of risk assessments; one for food/feed borne risks and another for pest/disease-related risks. The food/feed borne risk assessment must follow the rules set forth above. “The Panel in EC-Hormones held that, ‘an assessment of risks is, at least for risks to human life or health, a scientific examination of data and factual studies; it is not a policy exercise involving social value judgments made by political bodies.’” Joost Pauwelyn, “WTO Agreement on SPS Measures As Applied in the First Three SPS Disputes”, at p. 648, citing *EC-Hormones*, par. 186. As noted above, it requires an “evaluation of the potential for adverse effects on human or animal health”, which includes identification of the adverse effects, as well as, an evaluation of the potential occurrence of said effects. *Ibid*, at p. 645; “GMOs in the WTO – The Dispute Between the U.S. and the EU: The EC GMOs Ban under WTO Law”, Institute of International Economic Law, Georgetown University Law Center website; SPS Annex A(4), second definition. The EU must follow different rules when conducting a pest/disease-related risk assessment. Such an assessment requires: 1) an evaluation of the likelihood of entry, establishment or spread of a pest or disease and the associated potential biological and economic consequences (this requires an evaluation of the diseases to be prevented and the likelihood of entry); and 2) an evaluation of the likelihood of entry, establishment or spread of a pest or disease after the SPS measures will be applied (a comparison). Joost Pauwelyn, “WTO Agreement on SPS Measures As Applied in the First Three SPS Disputes”, at p. 645, citing par. 121 of the *Australia-Salmon* case; “GMOs in the WTO – The Dispute Between the U.S. and the EU: The EC GMOs Ban under WTO Law”, Institute of International Economic Law, Georgetown University Law Center website; SPS Annex A(4), first definition.

¹⁴⁴ “Fact Sheet: WHO Answers Questions About Biotechnology Foods”, U.S. Department of State, International Information Program, at p. 3.

¹⁴⁵ Paragraph 8 of Directive 2001/18/EC provides that, “The precautionary principle has been taken into account in the drafting of this Directive and must be taken into account when implementing it.”

¹⁴⁶ The EU is basing its use of the precautionary principle on the **uncertain possibility** of risk of harm. According to the WHO, there are three main *potential risks* being currently “debated [. They] are tendencies to provoke allergic reaction (allergenicity), gene transfer and outcrossing. With respect to the issue of ‘allergenicity’ which the EU claims is one of the primary bases for adoption of GMO labeling regulations, the WHO has reported that, “**NO allergic effects have been found relative to GM foods currently on the market** (emphasis added)”. “Fact Sheet: WHO Answers Questions About Biotechnology Foods”, U.S. Department of State, International Information Program, at p. 3. A different report prepared by the Food and Agriculture Organization (FAO) and World Health Organization (WHO) joint panel, also indicates that, while “allergenicity [has been] one of the most frequently asked questions in connection with the safety of genetically modified foods”, **no actual evidence has yet been presented that shows GM food to pose a greater risk of allergic reaction than conventional food**. For this reason, the panel concluded that, “...when assessing the safety of foods produced through genetic modification, the characteristics of GM food, with its “novel gene products (proteins) must be evaluated in light of their

b. *Criticisms of the GMO Moratorium and Authorization Rules*

In general, the enactment of the GMO authorization regulations (COM (2001) 425, intended to implement Directive 2001/18/EC) and the continued EU moratorium discriminates against and imposes upon U.S. and other non-EU exporters of bioengineered seed, food and feed products a disproportionate economic and evidentiary burden. Since the U.S. is currently “the leading developer and producer of agricultural biotech products” with the most to lose from the current global ‘chilling effect’ triggered by these EU actions¹⁴⁷, it is incumbent upon the U.S. Government also to take a lead role in arguing against them. Developing countries, as well, have much to lose if the EU is permitted to determine the biotech debate on a political rather than a scientific level.

Therefore, it cannot be overemphasized how the following arguments are equally relevant to exporters from other GM food exporting countries such as China, Argentina and Mexico that may eventually overtake the U.S. as lead exporter. And they may well aid future efforts of LDCs located in Asia and Africa that are aggressively pursuing at this time extensive agricultural biotechnology research in the hope of generating agricultural exports and a better national livelihood for their citizens.

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. Virtually every food or

similarities to known food and environmental allergens.” (emphasis added).; See: “Evaluation of Allergenicity of Genetically Modified Foods”, Report of a Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology, Food and Agriculture Organization (Jan 22-25, 2001), at pp. 3-5. Furthermore, with respect to the issue of ‘outcrossing’, the U.S. Agricultural Department has imposed increasingly stricter conditions on biotech companies engaged in the field-testing of pesticide and herbicide-resistant food crops, and on food crops used to make drugs, a practice known as ‘biopharming’. Such actions have been prompted by actual events, including the Monsanto, Starlink – Aventis, and Prodigene cases, rather than motivated by a presumed regulatory notion of harm. The WHO reports that several countries [including the U.S.] have adopted strategies to reduce mixing, including a clear separation of the fields within which GM crops and conventional crops are grown”. Ibid, at p. 3. The most recent Prodigene case involved a corn plant genetically modified by Prodigene Inc. to make a diarrhea drug that was to be tested on piglets. Some material from corn plants was accidentally mixed with 500,000 bushels of soybeans at a Nebraska elevator. For a discussion of the Prodigene case, See: Scott Kilman, “U.S. Rules for Crop Experiments To Make Drugs Are Tightened”, Wall Street Journal (3/7/03), at p. A5; See, also: Suzanne Goldenberg, “Alarm As GM Pig Vaccine Taints U.S. Crops”, The Guardian (Dec. 24, 2002), at: (<http://www.guardian.co.uk/gmdebate/Story/0,2763,865030,00.html>).

¹⁴⁷ In particular, the U.S. Government has argued that the moratorium and regulations both “concern mainly U.S. producers [of new species of GMOs as well as agricultural producers that use such GMOs], notwithstanding the pending EU market placement applications from exporters of other countries”. “U.S. Comments to Proposal for a Regulation of the European Parliament and of the Council on Genetically Modified Food and Feed, Re: WTO Notification G/TBT/N/EEC/6, (Dec. 6, 2001), at p. 2; “GMOs in the WTO – EC Ban Under WTO Law”, Institute of International Economic Law, Georgetown University Law Center website, at: (http://www.law.georgetown.edu/iel/current/gmos/gmos_wto.html).

feed carries some level of risk if not properly handled.”¹⁴⁸ The regulation may also be discriminatory and a disguised trade barrier, within the meaning of SPS Article 2.3, to the extent this standard differs, if at all, from any other applied by the EU to non-biotech food and feed safety standards or standards established for food additives or pesticide residues.¹⁴⁹

Furthermore, the regulatory provision that requires “applicants [to] supply a method for sampling and detection of each event in foods and feeds”, imposes undue administrative, economic and evidentiary burdens on U.S. exporters for several reasons. First, “reliable methods for quantifying biotech material within the low threshold levels established as tolerances by the EU are not yet available”.¹⁵⁰ Second, “detection methods and limits of detection vary depending on the degree of processing. In many cases, no trace of the event will be present in the final processed product. When the margin of error is so low, inconsistent test results will increase the level of uncertainty for shippers thereby discouraging trade for some and increasing liability for others... Experience has shown that a one percent threshold... cannot be reliably tested and consistently be met”.¹⁵¹ Third, U.S. operators required “to demonstrate that they have taken appropriate steps to avoid the adventitious presence of biotech material” may not be treated even-handedly with regard to same products by different Member States implementing the provision, in the absence of a harmonized EU procedure. As a result, exporters may be able to establish that they have been arbitrarily discriminated as prohibited by SPS Article 2.3.¹⁵²

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’). Both SPS Articles 2.3 and 5.5 prohibit this type of regulatory discrimination. 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, a test that appears within Article III of the GATT and Article 2.1 of the TBT Agreement. This concerns not only ‘like’ domestic vs. imported products, but also ‘like’ Country ‘A’ vs. Country ‘B’ imported products. “The central issue in an analysis of ‘likeness’ will be whether genetic modification through modern techniques generally renders GM products unlike their traditional counterparts... Traditional breeding techniques also aim at modifying an organism’s DNA, thereby creating species with desirable characteristics... All organisms have different DNA. Yet that will not render them ‘unlike’ for purpose of GATT Article III:4.”¹⁵³

¹⁴⁸ 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.

¹⁴⁹ 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.

¹⁵⁰ “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.

¹⁵¹ Ibid, at pp. 4-5.

¹⁵² Ibid, at p. 5.

¹⁵³ For an interesting discussion of this issue, see: “GMOs in the WTO – EC Ban Under WTO Law”, Institute of International Economic Law, Georgetown University Law Center website.

In addition, U.S. officials have 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, as called for by Article 7 and Annex B of the SPS Agreement.¹⁵⁴ 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.¹⁵⁵ As a result, these Member States are left to guess how the EU will evaluate such products in order to arrive at the appropriate level of sanitary and phytosanitary protection (effectively zero) required, and whether such decisions will be subject to other than science-based considerations. According to earlier U.S. comments on these regulations,

“The proposed regulation foresees that a new European Food Authority (EFA) will be required to undertake scientific risk assessments for both bioengineered foods and feed, yet final approval decisions will be taken by member states in committee, rather than by the EFA itself, whose opinion appears designed to be limited to scientific and technical considerations. The process allows the Commission to take into account unspecified ‘other legitimate factors’ and to propose a decision regarding approval inconsistent with the outcome of the risk assessment... This decision-making structure leaves substantial room for political interference of the type that has led to the current moratorium on agricultural biotech product approvals. In addition, the legislation sets a standard of ‘no risk’ as the basis for regulatory decision-making, which could ultimately block the authorization process since it is impossible to guarantee ‘no risk’ for any product, biotech or conventional... In short... the new proposal fails to address the core problem facing the European Union in biotechnology – individual member states will continue to be able to hold the approval

¹⁵⁴ SPS Article 7 provides that, “Members shall notify changes in their sanitary and phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B. Most importantly, these provisions require the EU to: 1) promptly publish such adopted regulations to enable interested Member States to become acquainted with them; 2) allow a reasonable interval between their publication and their entry into force, unless urgent circumstances demand otherwise, in order to provide producers in exporting Members time to adapt their products and methods of production; 3) ensure that one enquiry point exists to answer interested Member State questions and provide relevant documents regarding: a) the regulations adopted or proposed; b) approval, testing and control procedures required; c) risk assessment procedures employed and factors considered in determining the appropriate level of sanitary or phytosanitary protection; and 4) publish and provide notice to other Members of proposed regulations at an early stage, when amendments can still be introduced and comments taken into account, and allow a reasonable time for other Members to make comments in writing, to discuss these comments with the EU upon request, and to take other Members comments and the results of the discussions into account in the drafting of the regulations. This latter publication and notice requirement applies where an international standard, guideline or regulation does not exist or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation, and if the regulation may have a significant effect on trade. SPS Annex B, paragraphs 1, 2, 3 and 5.

¹⁵⁵ “Articles 7.8 and 20.8 [of the proposed regulations] state that ‘before the entry into application of this Regulation, the Commission shall publish a recommendation on the nature of the risk assessment to be undertaken by the [EU Food Safety] Authority for the purpose of preparing its opinion’. The United States believes this recommendation should be published in the proposed regulation to afford a meaningful opportunity for comment...” “U.S. Comments to Proposal for a Regulation of the European Parliament and of the Council on Genetically Modified Food and Feed, at pp. 5-6.

process hostage to political concerns with complete disregard for science and sound regulatory decision-making.”¹⁵⁶

The failure of the EU to provide harmonized risk assessment information is surprising, on the one hand, because it could amount to an arbitrary or unjustified discrimination against U.S. or other exporters (under SPS Article 2.3). This would occur if biotech food products having the same characteristics are assessed differently in terms of risk of harm by different Member States. It is also surprising given the recent issuance of draft international standards on this matter. On March 8, 2002, a task force of the Codex Alimentarius Commission issued a final draft of “Principles for the Risk Analysis of Foods Derived from Modern Biotechnology” (the ‘Draft Principles’). The Draft Principles provide a framework for evaluating the safety and nutritional aspects of biotech foods. They identify what is necessary at each of the three stages of risk analysis – risk assessment, risk management and risk communication. In particular, “they define the need for a pre-market safety assessment of all such foods on a case-by-case basis and would require authorities to manage the uncertainties identified in the safety assessment. The principles also provide guidance related to analytical methods and other tools to be used in risk management.”¹⁵⁷ Also, the principles permit the tracing of GM products as a risk management measure, for the purpose of facilitating withdrawal from the market when a risk to human health has been identified. And, they also “adopt detailed requirements for assessing the safety of GM plants, including tests for allergenicity.”¹⁵⁸

¹⁵⁶ Ibid, at p. 2. “The EFA may ask a ‘food assessment body’ or ‘feed assessment body’ in a member state to do a safety assessment or a ‘competent authority’ to carry out an environmental risk assessment. What criteria would be used by the EFA to determine if safety and/or environmental risk assessments were required beyond the initial information provided by the applicant? Could the EU provide more guidance as to the role that these bodies will play in individual regulatory decisions?” Ibid, at p. 4. In addition, these concerns apply to how Member States will apply ‘risk management principles. “It is clear that member states’ authorities apply different principles of risk management in regulating biotech products. Under this regulation, how will the Commission ensure that the risk management decisions of the individual member states are consistent and transparent? Will the regulation strengthen the Commission’s ability to enforce EU regulations currently being flouted by several member states?” Ibid, at p. 6.

¹⁵⁷ “Codex Issues Risk Analysis Guidelines for Biotech Foods”, American Seed Trade Association, E-News Update, (March 11, 2002), at p. 1. See, also: FAO/WHO news release at: http://www.fao.org/WAICENT/OIS/PRESS_NE/english/2002/3060-en.html

¹⁵⁸ This source further notes that, “The final work of the task force will be submitted to Codex at its next meeting in July 2003 in Rome for adoption.” Ibid. “*Risk assessment* includes a safety assessment which is designed to identify whether a hazard...or other safety concern is present, and if present, to gather information on its nature and severity. The safety assessment should include a comparison between the food derived from modern biotechnology and its conventional counterpart focusing on determination of similarities and differences...Risk assessment should apply to all relevant aspects of foods derived from modern biotechnology. The risk assessment approach for these foods is based on consideration of *science-based* multidisciplinary data and information taking into account the factors mentioned in the accompanying Guidelines...Data should be assessed using appropriate *science-based* risk assessment methods. Risk assessment should take into account all available scientific data and information derived from different testing procedures, provided that the procedures are *scientifically sound* and the parameters being measured are comparable (emphasis added).” Ibid, at p. 2. “*Risk management* measures for foods derived from modern biotechnology should be *proportional to the risk* [and] *based on the outcome of the risk assessment*...It should be recognized that, different risk management measures may be capable of achieving the same level of protection with regard to the management of risks associated with safety...impacts on human health...Risk managers should take into account the *uncertainties* identified in the risk assessment and implement appropriate measures to manage these uncertainties. Risk management

c. *Criticisms of the EU GMO Traceability and Labeling Rules*

It is arguable that, the EU's inclusion of general traceability and labeling rules within the GMO authorization regulations is intended to create a regulatory linkage (a condition precedent relationship) between GMO authorization of and the traceability and labeling of biotech products. In other words, in order to obtain GMO authorization, biotech products must be so labeled and their GM content thoroughly traced. Such a linkage would parallel the linkage established between the Member States' refusal to lift the moratorium and the enactment of new traceability and labeling regulations. However, 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, for authorization purposes, would not contribute further 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 (i.e., biotech products deemed as safe for human consumption as conventional products) are not likely to enhance consumer safety.

Furthermore, by embedding general traceability and labeling rules within the GMO authorization regulations the EU may be endeavoring to confuse their true purpose. This confusion would then be compounded if the EU were to articulate two different objectives for the same GMO authorization regime, namely, the protection of human or animal life or health, and the need to provide consumers with informed choices.¹⁵⁹ If it cannot be determined definitively that the SPS Agreement applies to the proposed GMO authorization regulations, it would permit the EU to take advantage of the more flexible tests within the TBT Agreement. These tests would provide the EU with a greater opportunity to justify all or part of the authorization regulation as legitimate and

measures may include, as appropriate, food labeling, conditions for market approvals and post-market monitoring. Post-market monitoring may be an appropriate risk management measure in specific circumstances... Specific tools may be needed to facilitate the implementation and enforcement of risk management measures... These may include... the tracing of products for the purpose of facilitating withdrawal from the market when a risk to human health has been identified or to support post-marketing monitoring (emphasis added)." Ibid, at pp. 2-3. "Effective risk communication is essential all stages of risk assessment and risk management... Risk communication should include transparent safety assessment and risk management decision-making processes. These processes should be fully documented at all stages and open to public scrutiny... and reports prepared on the safety assessments and other aspects of the decision-making process should be made available to all interested parties. Effective risk communication should include responsive [and interactive] consultation processes. The views of all interested parties should be sought and relevant food safety... issues that are raised during consultation should be addressed during the risk analysis process (emphasis added)." Ibid, at p. 3. "Draft Principles For the Risk Analysis of Foods Derived From Modern Biotechnology (At Step 8 of the Elaboration Procedure)", at: (http://www.codexalimentarius.net/biotech/en/ra_fbt.htm).

¹⁵⁹ "The regulations require applicants for authorization of biotech food [and feed] to provide studies or otherwise demonstrate that the food... does not mislead the consumer." "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. The labeling rules that would fulfill this objective would not be based on a scientific risk assessment.

necessary based on non-scientific factors.¹⁶⁰ This is probably why the EU notified WTO members of the proposed GMO authorization regulations and the proposed traceability and labeling regulations only under the TBT Agreement.¹⁶¹

The EU justifies its labeling requirements on the basis of consumer choice, and by extension, consumer protection. As the USTR noted, “The proposal indicates the objective of the ‘comprehensive’ *labeling* requirements are to respond to an overwhelming need for consumers to make individual choices, thereby fostering increased public confidence and acceptance of products of biotechnology.”¹⁶² 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.”¹⁶³ In other words, information should be provided “that assure[s] that products labeled [as] ‘non-GMO are in fact non-biotech’, and that products labeled as biotech are in fact biotech; this would prevent consumers from being misled.”¹⁶⁴ This is made more difficult because of the inability of exporters, especially those from developing countries, to detect adventitious amounts of GMO products, as required by the EU’s proposed labeling and traceability rules.

The labeling requirements as elaborated upon within the proposed traceability and labeling regulations provide an additional problem -- they are susceptible to fraud and misinformation, which only ‘truth in labeling’ can remedy.¹⁶⁵ “This proposed regulation would expand mandatory labeling of biotech food and feed to require the labeling of all food and feed products according to the biotech content of each ingredient, whether or not those ingredients are detectable in the end product, and even when test methods do not exist to confirm their presence.” U.S. officials have noted that, “in these cases it

¹⁶⁰ Given this latter objective, at least a portion of the regulation could conceivably be classified as a ‘consumer protection’ measure and possibly pass the ‘legitimate objectives test under the TBT and GATT Agreements. See: “GMOs in the WTO – EC Ban Under WTO Law”, Institute of International Economic Law, Georgetown University Law Center website. The first objective, by contrast, would clearly enable a portion of the regulation to be characterized as a sanitary and phytosanitary measure within the scope of the SPS Agreement.

¹⁶¹ This issue was identified in each of the two U.S. comment letters submitted to the EU. See: “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; “U.S. Comments to Proposal for a Regulation of the European Parliament and of the Council concerning Traceability and Labeling of Genetically Modified Organisms and Traceability of Food and Feed Products from Genetically Modified Organisms and Amending Directive 2001/18/EC, at p. 3. The EU’s mandatory labeling requirements have been criticized as disguised trade barrier, failing the

¹⁶² “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.

¹⁶³ Ibid.

¹⁶⁴ Ibid. Such information could refer to specific handling, usage, or safety, or could identify compositional distinctions. “U.S. Comments to Proposal for a Regulation of the European Parliament and of the Council concerning Traceability and Labeling of Genetically Modified Organisms and Traceability of Food and Feed Products from Genetically Modified Organisms and Amending Directive 2001/18/EC, at p. 2.

¹⁶⁵ According to Assistant USTR, Agriculture, James Murphy, it is important that the labeling scheme result in ‘truthful’ not ‘frightening’ labeling, given how some EU retail chains have announced that they would not carry identifiable biotech foods in their stores. (Comments made by Mr. James Murphy, WITA Seminar).

[would] be impossible to verify, by testing, a claim that product ingredients are non-biotech. [As a result,] ...this regulation [would]...invite fraud and a further weakening of consumer confidence in EU food safety delivery systems.”¹⁶⁶

An additional labeling concern is discrimination. In this regard, it has been argued that it is preferable to impose no labeling requirement at all upon GMO food and feed, than it is to have labels that identify only biotech products.¹⁶⁷ Conversely, a labeling scheme that requires the identification and labeling of both biotech and nonbiotech products would be able to satisfy the EU’s stated objective of providing consumers with a choice, and consequently, would go a long way toward establishing ‘justification’. Currently, within the EU, there is no similar labeling required for non-biotech products. Presumably, this is because non-biotech labeling would likely disclose the presence of potentially harmful chemicals within such products, and thus inflame environmental and consumer groups against the EU chemical and biotech industries.¹⁶⁸

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, in whole or in part, a measure defined as a sanitary or phytosanitary measure under the WTO, i.e., one applied, among other things, ‘to protect human or animal life or health...from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs.’”¹⁶⁹

However, these regulations present their own difficulty. In light of the EU’s determination that GMO products are as safe or even safer than conventional products¹⁷⁰, it would appear that they would not provide any added ‘margin of safety’. In addition, the documentation requirements imposed on GMO producers and downstream users pursuant to the proposed traceability regulations, are not subject to reliable testing and verification, and are therefore susceptible to fraud.¹⁷¹ Furthermore, there exists a less costly, administratively burdensome and trade-restrictive measure that the EU could have adopted to accomplish its objective, namely the U.S. trace-back system.

¹⁶⁶ “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.

¹⁶⁷ Comments made by Mr. Craig Thorn, DTB Associates, WITA Seminar.

¹⁶⁸ According to Mr. Tony Vanderhaegen of the European Commission, many biotech companies in the EU still produce pesticides and chemicals that are harmful to human health and the environment. He suggested that the industry wait until the second or third generation of GMO products before it attempts to educate the public about GMOs, for it lacks the credibility to do so at the present time. (Notes taken from comments made by Mr. Vanderhaegen, WITA Seminar).

¹⁶⁹ “U.S. Comments to Proposal for a Regulation of the European Parliament and of the Council concerning Traceability and Labeling of Genetically Modified Organisms and Traceability of Food and Feed Products from Genetically Modified Organisms and Amending Directive 2001/18/EC, at p. 3.

¹⁷⁰ The EU has acknowledged this in a recent report entitled “A Review of Reports: EC-Sponsored Research of Genetically Modified Organisms”. Ibid.

¹⁷¹ Ibid, at p. 2.

“U.S. experience shows that ‘trace-back’ systems for human health or food safety, and traceability systems for consumer information, lead to significantly different approaches and policy decisions. The trace-back system used in the United States is part of a food safety system. [It] was developed largely by the private sector to recall food in response to a public health or food safety concern. In the United States, lot numbers, batch codes and/or processing plant indicators appear on virtually all processed food packages to satisfy the various business needs of food producers and for trace-back purposes. Such measures are also widespread in Europe. This less burdensome and less costly system has worked effectively for years and enjoys a high level of public confidence.”¹⁷²

Given all of the above, the ‘necessity’ of the proposed traceability regulations as an SPS measure, would be in doubt.

6. *The EU’s Application of the Precautionary Principle is Beyond the Scope of the SPS Agreement*

It is also arguable that the four-year EU and Member State moratorium on pre-1998 GMO approvals and their refusal to authorize new biotech products until after traceability and labeling regulations have been enacted, does *not* qualify as a ‘temporary provisional’ measure within the meaning of SPS Article 5.7. While this article generally permits WTO Members to take precautionary actions when they do not possess sufficient relevant scientific evidence of a product’s safety, the EU and its Member States must satisfy certain tests to invoke this safeguard provision.

“WTO case law has determined that a WTO Member must demonstrate that: 1) the provision is imposed in respect of a situation where relevant scientific evidence is insufficient; 2) the provision is adopted on the basis of available pertinent information; 3) the Member affirmatively seeks to obtain the additional information necessary for a more objective assessment of risk; AND 4) the Member reviews the measure within a reasonable period of time... Whenever one of these four conditions is not met, the measure will be found to be inconsistent with the SPS Agreement.”¹⁷³

Even if the EU is able to satisfy these requirements, it must be remembered that the safeguard provided by Article 5.7 has been considered by the WTO Appellate Body to be only a limited permissible application of the ‘precautionary principle’. “The ‘precautionary principle’ (other than that expressed in SPS Article 5.7 on provisional measures) does not override the obligation to base SPS measures on a risk assessment.”¹⁷⁴

If the EU relies on a broader interpretation of the precautionary principle it will likely be operating beyond the bounds of WTO law. In such instance, it will need to establish that the precautionary principle is a principle of customary international environmental law. According to the WTO Appellate Body in the EC-Hormones case, “[the precautionary principle is regarded by some as having crystallized into a general principle of customary international *environmental* law. Whether it has been widely accepted by Members as a

¹⁷² Ibid.

¹⁷³ Joost Pauwelyn, “WTO Agreement on SPS Measures As Applied in the First Three SPS Disputes”, at pp. 649-50, citing the Appellate Body Report in the Japan –Varietals case.

¹⁷⁴ Ibid, at p. 651, citing the Appellate Body Report in the EC-Hormones case.

principle of *general or customary* international law appears less clear... We note that... the precautionary principle, at least outside the field of international environmental law, still awaits authoritative formulation.”¹⁷⁵

The EU appears to have embraced the broadest possible interpretation of the ‘precautionary principle’ with respect to its treatment of GMOs and the bioengineered food and feed products derived from them. It has utilized the precautionary principle as a risk assessment tool to justify the establishment of an administrative presumption that identifies a general hazard potentially posed by bioengineered foods both to human health and the environment without scientific proof of any actual harm. It has also used the precautionary principle to identify a legitimate public objective, namely the eradication of that potential hazard, which is premised on such political considerations as, as consumers’ ‘right to know’ and consumer distrust for European institutions of science and government. Furthermore, the EU has employed the precautionary principle as a risk management tool to justify the creation and imposition of a regulatory framework deemed ‘necessary’ to fulfill that objective. This framework manages the assessed threat by controlling the authorization to use GMOs and bioengineered food and feed products within the EU, and by regulating their subsequent introduction into the EU marketplace through imposition of onerous tracing and labeling rules. Lastly, the EU utilizes the precautionary principle as a risk communication tool to justify to EU consumers through the media all that it has done on their behalf, namely its exercise of precaution in order to protect them. Hence, it can be argued that, the ‘precautionary principle’ is being used as a self-justifying principle.

7. *The EU's Broad Interpretation of the Precautionary Principle is Consistent With the Expression of That Principle Within the Cartagena Protocol on Biosafety ('Biosafety Protocol')¹⁷⁶, a Multilateral Environmental Agreement*

The EU’s approach of identifying, assessing and addressing the perceived hazards to human health and the environment posed by GMOs and the food products derived from them appears consistent with the approach taken by the Cartagena Protocol on Biosafety (‘Biosafety Protocol’), a multilateral environmental agreement. The relationship between these two approaches is evidenced within the Preamble to the EU’s ‘Directive On the Deliberate Release into the Environment of Genetically Modified Organisms’. That Directive specifically requires the European Commission to “take into account

¹⁷⁵ Ibid.

¹⁷⁶ The following provisions of the Biosafety Protocol make reference to the precautionary principle: Preamble of the Biosafety Protocol states: “Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development...”; Article 1 provides, “In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development...”; Article 10(6) provides, “Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question...in order to minimize such potential adverse effects.”

international experience in this field, ...international trade commitments and...the requirements of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity...[and], as soon as possible...in the context of the ratification of the Protocol, to submit the appropriate proposals for its implementation.”¹⁷⁷ The EU and six of its Member States are Parties to both the Convention and the Protocol.¹⁷⁸

a. *The Biosafety Protocol Summarized*

Although it has not yet entered into force¹⁷⁹, the Biosafety Protocol is already having an impact on the way countries are handling biotech products awaiting shipment across their borders. “The Biosafety Protocol has emerged as a blueprint for an international regulatory regime that has the potential to minimize the risks to environmental biodiversity from the transboundary movement of products of biotechnology...[and] to standardize the application of the principles of risk analysis.”¹⁸⁰

“The Biosafety Protocol addresses the safe transfer, handling and use of living modified organisms LMOs – (a subset of GMOs) that may have an adverse effect on biodiversity. It takes into account risks to human health, with a specific focus on transboundary movements.”¹⁸¹ These LMOs include “animals, plants, seeds, crops, and raw foods that have been produced through bioengineering. Human pharmaceutical products produced through bioengineering are excluded from this agreement if they are ‘addressed’ by other international agreements or bodies.”¹⁸² Agricultural and other products that fall within the scope of the Protocol are divided into “three classes: 1) those intended for release into the environment; 2) those for food, feed, and processing; and 3) those in transit and for contained use.”¹⁸³

The Protocol imposes strict and burdensome requirements upon both exporters and importing countries with respect to biotech products ‘intended to be introduced into the environment’, such as seeds, trees, plants and live fish. “An Advanced Informed Agreement (‘AIA’) procedure requires advance notice by the exporter to the importing country before the first shipment into the country. The required paperwork includes

¹⁷⁷ 2001/18/EC, Preamble par. 13.

¹⁷⁸ These EU Member States include, Luxembourg, Austria, Sweden, Spain, The Netherlands and Denmark.

¹⁷⁹ The Biosafety Protocol will “enter into force on the ninetieth day after the deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.” Without counting the European Community’s ratification of the Protocol, there are, as of this writing, 44 out of the 50 ratifications.

¹⁸⁰ Grant E. Isaac, Martin Phillipson & William A. Kerr, “International Regulation of Trade in the Products of Biotechnology”, Estey Centre for Law and Economics in International Trade”, Saskatoon, CN (Nov. 2001), at p. 2.

¹⁸¹ Jacek Plazinski, “Implications of International Agreements On Agricultural Biotechnology Products for Trading Nations”, Department of Agriculture, Fisheries and Forestry – Australia, APEC ATC WG SubGroup on Research, Development and Extension of Agricultural Biotechnology and JIRCAS Joint Symposium and Workshop on Agricultural Biotechnology, Bangkok, Thailand (Sept. 3-12, 2001), at p. 6.

¹⁸² Frances B. Smith, “The Biosafety Protocol: The Real Losers Are Developing Countries”, James V. DeLong, Editor, National Legal Center For the Public Interest, (2000), at p. 18.

¹⁸³ Ibid.

detailed descriptions of the product's origin, biotechnological techniques used in its production, its characteristics, intended uses, risk assessment reports, and methods for safe handling, storage, transport and use. The regulatory status within the exporting country must also be explained.”¹⁸⁴ Given the costs and administrative burdens involved with this procedure, developing countries are very likely to be adversely impacted. “With increased transaction costs and built-in delays for trade in seeds and plants, exporters will have strong incentives to focus on high-value crops and large-scale importers and to ignore the smaller and less valuable third world markets...[this] may prevent poorer [developing] countries from using seeds that would produce higher-yielding, pest-resistant or enhanced-nutrient food.”¹⁸⁵

The AIA procedure does not apply to “bulk shipments of LMOs intended for use as food or feed or for processing. However, the producing nation must inform the parties of the existence of the product by notifying the Biosafety Clearing House, and [must] provide a risk assessment of the product, prepared in accordance with the annex to the Protocol.”¹⁸⁶ When reviewing such a risk assessment, the Protocol provides that, “a party [an importer] may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.”¹⁸⁷ This language would seem to permit an importer who is also a Party to the Protocol to ban bioengineered products if it already bans their domestic production. And, as indicated specifically by the Protocol, such a ban would not be precluded by a ‘lack of scientific certainty due to insufficient relevant scientific information’.¹⁸⁸ Consequently, based solely on the terms of the Protocol, and without regard to SPS Article 5.7, the EU moratorium on U.S. bioengineered food and feed products would not constitute a discriminatory trade practice per se.

b. *The Relationship of the Biosafety Protocol to the SPS Agreement*

One commentator has noted that, a “preliminary legal analysis [would] indicate that this aspect of the Protocol,...which draws on the precautionary approach endorsed at the 1992 Earth Summit in Rio de Janeiro, is compatible with existing WTO rights and obligations that allow governments to take provisional sanitary or phytosanitary measures in cases of insufficient scientific information as part of a science-based decision making process.”¹⁸⁹ Another commentator, however, has noted that a more careful examination of this

¹⁸⁴ Ibid. “After receiving this information, the importing country must officially authorize the shipment and must take measures to evaluate and control risks.” Ibid.

¹⁸⁵ Ibid. By implication, the EU’s regulatory approach to GMOs, which effectively implements the Biosafety Protocol’s AIA procedure, will adversely affect developing countries.

¹⁸⁶ Ibid, at pp. 18-19.

¹⁸⁷ Ibid, at p. 19.

¹⁸⁸ Ibid. “The precautionary principle as used in the Protocol states that even when there is a lack of scientific evidence that products produced through biotechnology are likely to cause harm, a country can take action to ban the import of those products. The Protocol invokes the precautionary principle in its Preamble and several other specific references and thus enshrines it as a key principle in the agreement.” Frances B. Smith, “The Biosafety Protocol: The Real Losers Are Developing Countries”.

¹⁸⁹ Jacek Plazinski, “Implications of International Agreements On Agricultural Biotechnology Products for Trading Nations”, at p. 7.

provision would indicate 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.”¹⁹⁰ Adherence to the Protocol’s provisions, therefore, would seem to provide ammunition to “governments around the world [that are] under pressure from their constituencies to manage trade in agricultural commodities for maximum competitive advantage by using the provisions of the SPS Agreement”¹⁹¹ in aggressive fashion. It is these countries that would not likely hesitate to use the provisions of the Biosafety Protocol [to expansively interpret SPS Article 5.7] in order to restrict trade and market access for domestic purposes.¹⁹²

c. *How the Biosafety Protocol Would Adversely Impact WTO Members*

From an institutional perspective, the Biosafety Protocol reflects “a broader set of interests than the narrow trade-liberalization interests underpinning the WTO.”¹⁹³ In fact, a comparison of the two will reveal that “the specific regulatory regime the Protocol proposes is in direct and significant conflict with the general principles of the regulatory regime for international trade in goods and services embodied in the WTO.”¹⁹⁴

“The WTO deals with biotech products on a *product* basis... The focus is on the *application* of the techniques and procedures of modern biotechnology (i.e., the outcomes) rather than on the *use* of biotechnology (i.e., the process) per se. According to such an approach, some applications may yield products that can be considered substantially equivalent to or ‘like’ conventional products because the *end use* is the same, despite the fact that different production and processing methods may have been used in their creation... The WTO trade rules adopt a commercial approval structure such that a biotech product, once approved, is approved everywhere and every time. This is in direct contrast to the *regulatory* approach under the [Biosafety Protocol], which has adopted a *process- or technology-based* focus. For the [Protocol], it is the *use* of modern biotechnology per se that incurs regulatory oversight regardless of any determinations of substantial equivalence or like products. Essentially, this means that biotech products under the

¹⁹⁰ Frances B. Smith, “The Biosafety Protocol: The Real Losers Are Developing Countries”, at pp. 19-20.

¹⁹¹ Jacek Plazinski, “Implications of International Agreements On Agricultural Biotechnology Products for Trading Nations”, at p. 9.

¹⁹² Ibid.

¹⁹³ Grant E. Isaac, Martin Phillipson & William A. Kerr, “International Regulation of Trade in the Products of Biotechnology”, at p. 4.

¹⁹⁴ Ibid, at p. 2-3. It is the possibility of a conflict such as this formally arising at the WTO level (i.e., through the WTO Dispute Settlement Mechanism) that is currently being discussed at the Doha Round trade negotiations. While no MEA has been challenged at the WTO, to date, there remains a concern that the relationship between existing WTO rules and specific trade obligations set out in MEAs, such as the Biosafety Protocol, is not clear. Clarification is also thought to be lacking with respect to how that relationship will impact WTO Members that are and are not Parties to an MEA. According to the Bush Administration, the members of the Committee on Trade and Environment have had difficulty agreeing on the scope of the relationship to be discussed. Some argue that the negotiations should focus narrowly on specific trade obligations, while others argue that negotiations should refer to trade obligations in the abstract. President’s Trade Policy Agenda, at pp. 29-30.

[Protocol] are considered to be in a *perpetual state of novelty* and there is no granting of ‘like products’ status (emphasis added).”¹⁹⁵

The implications of this distinction are significant. Since the approvals process called for by the Protocol “is ‘transactions-based’ (i.e., a risk assessment is performed on a case-by-case basis) ...[rather than products-based,] there is no granting of ‘national treatment’ or ‘most favored nation’ status under the [Protocol]”.¹⁹⁶

Furthermore, the nature of the risk analysis that must be performed under each regime is very different.

“The [WTO regime emphasizes its] links to various scientific organizations. [As a result,] the idea of scientific justification is limited to natural science determinations of hazard or risk. When the issue is environmental safety, only environmental biodiversity risks are considered not human health risks. Further, socio-economic risks are not part of the risk assessment process. At the risk management stage, science essentially *makes* the regulatory decision and the goal is to reduce and/or prevent actual risks only...In contrast, risk assessments under the [Biosafety Protocol] broaden the definition of science to include both natural science and social science. The result is to extend the idea of risk beyond environmental biodiversity risk and to include also risk to human health as well as socio-economic risk. Accordingly, at the risk management stage, science *informs* but does not *decide* regulatory matters where the goal is not only to reduce and prevent actual risks but to also manage risk perceptions, regardless of the scientific justification for those perceptions. In short, the [Protocol] regulatory regime may be characterized as blurring the distinction between science and other legitimate factors (socio-economic considerations) in the Risk Analysis Framework.”¹⁹⁷

Moreover, the parties and interests that each regime is designed to protect are diametrically opposed. The WTO’s economic model proceeds from the assumption that “consumers always win from a liberal trade regime, and that trade barriers are welfare reducing. [This implies] that it is only producer interests that will ask for protection from their government – never consumers (or other groups in society such as environmentalists). [It goes to] the heart of the WTO’s narrow focus on applications – or end products –of biotechnology, rather than on process or on the technology used.”¹⁹⁸ By contrast, the conceptual underpinnings of the Biosafety Protocol assume that consumers always win when biodiversity and, by extension, human health are promoted and protected against the risks posed by commercial biotech products. This suggests that it is society (including consumers and civil society) that seeks government protection from unfettered imports, not producers. It also means that the focus of the Protocol is on process rather than product. As previously discussed, this distinction is important, because if consumers perceive they have lost as a result of unfettered imports, then liberalized trade, which ignores the issue of process, may no longer be perceived as good for consumers.¹⁹⁹ Arguably, it is the threat of this perception and the Protocol’s focus

¹⁹⁵ Ibid, at pp. 4-5.

¹⁹⁶ Ibid, at p. 5.

¹⁹⁷ Ibid, at pp. 5-6.

¹⁹⁸ Ibid, at p. 11. In effect, the WTO presumes that, “if differences in processes [technologies] could be used to justify an exemption to the national treatment and nondiscrimination principles, and thus, to put trade barriers in place, the regulatory regime would be wide open to protectionist interests...” Ibid.

¹⁹⁹ Ibid, at p. 11-12.

that has motivated the EU to seize upon consumer concerns about biotechnology as a partial justification for its moratorium and proposed regulatory measures.²⁰⁰

To some degree, the concerns EU consumers have expressed with regard to biotech products inversely relate to “the quantity and quality of the information that is available pertaining to biotechnology.”²⁰¹ It therefore follows that, in the absence of such information [or the communication of such information, EU] “consumers [will] value the products of biotechnology less than they value those produced with conventional methods.”²⁰² Although “the WTO tries to compensate for this information problem by recourse to [sound] science and scientific consensus [international science-based organizations], its assumption that consumers (or environmentalists) trust the science upon which [such] consensus is based and the scientists themselves”, is now being severely challenged within Europe. The Biosafety Protocol is appealing to the EU, precisely because its underlying principles offer countries a political safe harbor from this dilemma; it aims “to prevent a market failure resulting from an unanticipated environmental hazard” and to address the consumer information gap by “allow[ing] countries a bias towards precaution.”²⁰³

Given the Biosafety Protocol’s inclination towards precaution, it is not surprising that the EU has chosen an approach to assessing and managing hazards to human health and the environment that approximates the Protocol’s approach to risk analysis. In the case of both biotech products and products made from chemicals or other potentially harmful substances, the perceived risks and lack of definite information available about processes have generated consumer concerns that have induced EU regulatory actions, such as labeling²⁰⁴ and traceability requirements. These actions have been undertaken despite producer concerns that they are adverse to liberalized trade. The approach chosen by the EU favors processes over products and non-science over science, and as a result, threatens not only European commercial interests, but also non-EU commercial export interests as well.

As previously discussed, this approach is contrary to and in conflict with the hard fought scientific and objective principles contained within the WTO Agreements. Those principles seek to establish a stable, clear, predictable and consistent regulatory approach. “The traditional trade approach attempts to disentangle trade barriers erected because of safety reasons from [trade barriers] erected for non-safety reasons. The former, [(safety

²⁰⁰ It is also arguably the reason behind the EU’s request that “certain WTO sub-Agreements be re-opened for negotiation to take account of consumer concerns.” Ibid.

²⁰¹ Ibid, at p. 12.

²⁰² Ibid.

²⁰³ Ibid, at p. 13.

²⁰⁴ “In the case of non-safety concerns, the WTO only allows labeling restrictions on the basis of products being not alike...The WTO does not allow the process used to be the reason a product would be considered not ‘like’ another product. It ignores the possibility that consumers may suffer a loss simply on how a product is made...[Thus,] if the Biosafety Protocol allows the imposition of a trade barrier either in the face of a scientific consensus or on the basis of process then it will be considered distortionary at the WTO and the trade barriers could be struck down if challenged through the dispute settlement mechanism.” Ibid, at pp. 12-13.

measures),] are subject to a scientific justification for the safety measure. In the event of such a justification, it is legitimate for a country to impose a unilateral safety barrier to particular imported products. [By contrast,] the latter, (non-safety measures), are subject to the traditional trade principle of non-discrimination.”²⁰⁵

Under WTO law, therefore, GM corn and GM soy arguably are just as much ‘products’ as are conventional corn and soy. Consequently, to the extent they pose what is deemed to be an unacceptable health or environmental hazard, the EU hold-up of pending GMO authorization applications and its imposition of new GMO authorization regulations must be justified by a science-based risk assessment performed on each risk presented by each particular product. And to the extent the lifting of the EU moratorium on GM products already authorized is contingent upon GM labeling and traceability regulations being enacted, the EU, is obliged to enforce this barrier equally across similar or ‘like’ products, irrespective of how they are processed, both domestic and foreign.²⁰⁶

The problem is that the EU has refused to accept this outcome. For example, it continues to contravene WTO law by relying upon the notion of consumer protection, as advanced through the Biosafety Protocol, to justify its GM food labeling regulations. In effect, it has conveyed to the WTO SPS Committee that its determination of whether GMO food products are or are not ‘like’ similar conventional food products will, in part, be based on consumer perceptions.

“...available empirical evidence shows that consumers’ choice may depend on a specific process and production method having been used or not used which may affect or modify the properties of a product, even if such DNA modification cannot be currently identified. Because there is solid evidence that for European consumers foods and food ingredients produced from GMOs are different from those produced from conventional organisms, even where the food in question has little difference from other conventional foods, it would be unacceptable to deprive consumers of the information they clearly wish to have.”²⁰⁷

²⁰⁵ Ibid, at p. 5. “The WTO has gone to great lengths to avoid dealing with the problems of social protectionism, but all that has happened is that the ‘social protectionists’ have sought to attain the right to ban non-safety process grounds through other regulatory regimes. The result has been the emergence of regimes that are in conflict with the international trading system – such as the Biosafety Protocol!” Ibid, at p. 19. In addressing social protectionist issues, the WTO Committee on Trade and the Environment [(‘CTE’)] has recommended “a market-oriented, *voluntary* program, such as an eco-label or a humane-label. The rationale is as follows. If consumer demand for the ability to avoid a certain process or production method in favor of alternative methods is truly strong, then the first-best policy is to encourage those firms employing the alternative methods to use a voluntary label to identify their products in the marketplace and capture this demand... The CTE argues that shifting the solution of this trade policy problem from a regulatory measure (a mandatory strategy) to a *voluntary, market-oriented measure* is the most effective method for dealing with the non-safety process concerns that consumers may have in a manner congruent with the international system (emphasis added).” Ibid, at p. 19, citing World Trade Organization (1999) Trade and the Environment: Special Studies 4. Geneva.

²⁰⁶ Ibid, at p. 6. WTO jurisprudence identifies several factors that must be considered when determining whether products are ‘like’ products. The are, namely: 1) physical characteristics; 2) end-uses; 3) substitutability /consumer taste; and 4) tariff classifications.

²⁰⁷ WTO-Doc. G/SPS/GEN/337, p. 19, cited in “GMOs in the WTO – EC Ban Under WTO Law”, Institute of International Economic Law, Georgetown University Law Center website.

The EU has also endeavored to modify WTO law through its participation in the Codex Alimentarius Commission. There, it seeks to incorporate the Protocol's expression of the precautionary principle into the Codex's risk assessment rules.

"Besides the ambiguities about how trade disputes would be resolved when the Protocol butts up against the WTO agreements, there is no guarantee that the WTO and Codex policies relating to the use of scientific principles in resolving trade disputes relating to food safety and human health will remain sacrosanct. The WTO...has increased attention focused on its activities, with some vocal critics calling for linkages of trade with other issues, including environmental and human rights issues. Codex, partly because of its own enhanced role in the WTO, is also facing greater pressure to move away from standard-setting based on scientific principles toward a precautionary approach. Much of the pressure on Codex is coming from the EU..."²⁰⁸

Furthermore, the EU document entitled, "Communication on the Precautionary Principle",²⁰⁹ expressly references the Biosafety Protocol as an important part of the legal framework (including other multilateral environmental agreements) on which the precautionary principle rests. The communiqué also notes "how the WTO Agreement's Preamble 'highlights the ever closer links between international trade and environmental protection,' [and] how the WTO Appellate Body has interpreted those standards in trade disputes so that the precautionary principle is 'reflected'. [It then asserts] that there [must] be a consistent approach so that the precautionary principle, as a general principle, [is] taken into account in the WTO SPS and TBT agreements."²¹⁰

Thus, the EU's efforts to incorporate the risk analysis rules of the Biosafety Protocol within the SPS and TBT Agreements indicate a broader objective, namely the sanctification of the precautionary principle throughout WTO legal jurisprudence. This would, in effect, elevate the status of the precautionary principle, as enshrined in recent multilateral environmental agreements²¹¹, from a limited (provisional) WTO exception to a 'norm' of customary international law equal in importance to general principles of international trade 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."²¹²

8. *The Adverse Impact of the GMO Moratorium Upon Developing Country Formulation of Scientific and Economic Policies*

USTR Robert Zoellick has pointed out that the confusion over biotechnology generated by the U.S.-EU GMO food dispute is now having devastating effects in already famine-stricken developing countries in Southern Africa. Some of these countries had refused to accept U.S. food aid that might contain products derived from biotechnology out of

²⁰⁸ Frances B. Smith, "The Biosafety Protocol: The Real Losers Are Developing Countries", at pp. 22-23.

²⁰⁹ Commission of the European Communities, Communication From the Commission on the Precautionary Principle (Brussels: Feb. 2000).

²¹⁰ Frances B. Smith, "The Biosafety Protocol: The Real Losers Are Developing Countries", at p. 23.

²¹¹ Ibid, at p. 19. Other examples of such regimes include the Basel Convention on the Transboundary Movement of Hazardous Waste, the Montreal Protocol on Substances That Deplete the Ozone Layer, and the International Convention on Climate Change and the Kyoto Protocol which implements it.

²¹² Frances B. Smith, "The Biosafety Protocol: The Real Losers Are Developing Countries", at p. 25.

concern that these products are not ‘safe’.²¹³ Others, according to Assistant USTR Chris Padilla, had hesitated to accept U.S. food aid that may contain biotech products, for fear that their own food exports would later be judged unacceptable for EU consumption”.²¹⁴ While a few African countries have since reconsidered their rejection of U.S. food aid and the merits of agricultural biotechnology²¹⁵, other countries continue to ban bioengineered seed and food.²¹⁶ Whether or not the EU intended for its treatment of U.S. biotech food to worsen the effects of the current African famine,²¹⁷ the much larger issue that must be emphasized is the degree to which the EU attitude toward agricultural biotechnology will influence the formulation of future scientific and economic policy by developing country governments. It is for this reason, that the USTR must be especially vigilant in containing this EU political practice.

a. *The GMO Moratorium Has Contributed to Developing Country Political Opposition to GM Food Around the World*

EU refusals to accept GM ‘tainted’ agricultural exports have encouraged many anti-GM food movements around the world²¹⁸ and have led many other developing country

²¹³ Berta Gomez, “U.S. Seeks Partners for WTO Challenge to EU Biotech Moratorium -- But USTR Zoellick Offers No Timetable for Filing Case”, U.S. Department of State International Information Programs, (March 5, 2003), at: <http://usinfo.state.gov/topical/econ/wto/03030501.htm>).

²¹⁴ Ibid.

²¹⁵ After initially rejecting U.S. food aid containing GMO maize, it was reported on July 31, 2002, that the U.S. and Zimbabwe had finally reached an agreement “to supply emergency food to the famine-stricken southern African nation.” Charles Cobb, Jr. “U.S. Zimbabwe Emergency Food Dispute Settled”, allAfrica.com, (July 31, 2002), at: (<http://www.allafrica.com/stories/printable/200208010010.html>). Pursuant to that agreement, “the government of Zimbabwe accepted U.S. GM maize with the proviso either that it come in ‘milled’ or that, once it arrives in the country, it be milled. By milling corn, it can no longer be planted. Consequently, the GMO grains not consumed in the food chain cannot end up being planted and ‘released into the environment’ with potentially negative consequences. In addition to Zimbabwe, Malawi and Mozambique have accepted ‘milled’ GM food relief. “Regional GM Food Schism Delays Food Aid to Africa”, Reuters (Oct. 1, 2002), at: (<http://www.planetark.org>).

²¹⁶ In addition to Zambia, which “has completely outlawed GM relief”, Lesotho and Swaziland, as of October 2002, had not accepted U.S. food aid. “Regional GM Food Schism Delays Food Aid to Africa”, Reuters. And in Gambia, which recently decided to receive American food aid containing GM grains to avert an acute food shortage, popular rejection of GM food is on the rise. “No GM Foods Please”, The Independent (Banjul), Editorial (Mar. 14, 2003), at: (<http://www.allAfrica.com>).

²¹⁷ U.S. Undersecretary of Commerce Tim Hauser, during a recent Washington area seminar, focused on how biotech fears triggered by EU attitudes are bound to affect developing countries around the world. “Other countries, too, are potentially affected. In Afghanistan, 4 million people depend on food aid. North Korea has 20% or more of its food need met through international food aid. The inability to obtain food can lead to mass migration, conflict, and regional instability. The political calculations of the EU have led to starvation. The EU must act quickly to dispel fears that acceptance of food aid will endanger African agricultural exports to the EU.” (Comments made by Mr. Hauser at a recent Congressional Economic Leadership Institute Seminar, on 3/5/03, (hereinafter referred to as “CELI Seminar”)).

²¹⁸ “Consumers in the United Arab Emirates are now “calling for the enforcement of a new law to label genetically modified food, following the example of other countries. They believe that this will protect their right to decide whether to buy the GM food, and enhance their confidence in local traders...’Citizens in the European Union, Japan, Australia, and many other countries have the right to know if the food they buy has been genetically engineered. We should have the same right here.” “United Arab Emirates: Call for GM Labels on Food”, Gulf News, (Mar. 31, 2003), cited on the ‘Campaign to Label Genetically Engineered

governments either to officially reject the importation of GM seed and food products²¹⁹ or to condition their acceptance upon the satisfaction of rigorous labeling or other

Foods News Center website. Furthermore, in December 2002, a Hindu newspaper reported that “a public forum held in Hyderabad, India, demanded [that India conduct] an outright ban on genetic engineering.” The forum, which was “attended by farmers, scientific researchers and environmental activists from a number of South Asian countries, released a declaration stating categorically that there is no place for transgenic crops in Asia or for that matter anywhere else in the world. It praised the African continent’s ‘brave’ refusal to accept GM crops.” “Public Forum Calls for Ban on Genetic Engineering”, Justfood.com News, (Dec. 5, 2002), at: (<http://www.justfood.com>), reported on Norfolk Genetic Information Network. Moreover, the EU response to GMO food and feed products has triggered popular protests against the planting of biotech crops in Brazil. These protests have worsened during the past few years as Brazilian farmers have increasingly smuggled into Brazil GM soy seeds produced in Argentina. Because of these protests, Brazil had not, until recently, ‘officially introduced’ GM soybeans into its food production system. This permitted Brazil to claim that its soybean exports were largely free of genetic modification. “Brazil GM Soy Move Sparks Green Fury, Farmer Doubt”, Reuters (March 31, 2003), cited at: The Campaign to Label Genetically Engineered Foods Newscenter website. Furthermore, in December 2002, it was reported that the Chief of the Department of Agriculture and Forestry of Aichi Prefecture, Japan, “will stop the research cooperation with Monsanto that has continued since 1996 to develop a Roundup herbicide tolerant rice strain in Japan. The Prefecture had also decided not to commercialize the herbicide tolerant rice strain considering Japanese consumer opposition.” This decision came about despite the fact that, “the Roundup tolerant gene was injected into a rice strain that was developed by the research center using ordinary breeding techniques and was a recommended strain of the prefecture for farmers by its good taste. Japanese consumers [had] opposed the development because rice is their main food... The decision by Aichi Prefecture may influence and act as a brake to other GM research by institutes and companies in Japan.” Masaharu Kawata, “Monsanto Failed Halfway in Developing Herbicide Tolerant Rice in Japan”, GMO Information Service Japan, (Dec. 5, 2002), at (<http://www.nucc.cc.nagoya-u.ac.jp>), reported by Norfolk Genetic Information Network. In addition, opposition in the EU to GMO products has prompted China, which after the United States has the most advanced biotechnology programs in the world, to place a moratorium on biotech food crops that had already been approved for commercialization. David Barboza, “Development of Biotech Crops is Booming in Asia”, The New York Times, (Feb. 21, 2003).

²¹⁹ Since the EU’s rejection in 1999 of Thai ‘Golden Rice’ enriched with betacarotene to produce Vitamin A which prevents disease, Saudi Arabia has followed Denmark in banning Thai canned tuna packed in oil from glyphosate resistant soybeans shipped from the U.S. “Thailand is a big importer of U.S. soy products. In 1999, Thailand imported over \$178 million worth of U.S. bulk beans and soymeal. The bans will likely lead to a reduced Thai demand for U.S. GMO soy. The tuna bans have serious implications for Thailand. Some exporters have had to recall products... In one case, the Saudis rejected a U.S. \$2.6 million dollar shipment from a major Thai tuna packer because of GMO soy oil contamination.” “GMO Soy Oil Headache for Thai Exports”, Cropchoice.com News, (Mar. 28, 2003), at: (<http://www.choicecrop.com>). The report notes that “other Middle Eastern countries may follow Saudi Arabia’s lead. Furthermore, in December 2002, it was reported that the Chief of the Department of Agriculture and Forestry of Aichi Prefecture, Japan, “will stop the research cooperation with Monsanto that has continued since 1996 to develop a Roundup herbicide tolerant rice strain in Japan. The Prefecture had also decided not to commercialize the herbicide tolerant rice strain considering Japanese consumer opposition.” This decision came about despite the fact that, “the Roundup tolerant gene was injected into a rice strain that was developed by the research center using ordinary breeding techniques and was a recommended strain of the prefecture for farmers by its good taste. Japanese consumers [had] opposed the development because rice is their main food... The decision by Aichi Prefecture may influence and act as a brake to other GM research by institutes and companies in Japan.” Masaharu Kawata, “Monsanto Failed Halfway in Developing Herbicide Tolerant Rice in Japan”, GMO Information Service Japan, (Dec. 5, 2002), at (<http://www.nucc.cc.nagoya-u.ac.jp>), reported by Norfolk Genetic Information Network. In addition, opposition in the EU to GMO products has prompted China, which after the United States has the most advanced biotechnology programs in the world, to place a moratorium on biotech food crops that had already been approved for commercialization. David Barboza, “Development of Biotech Crops is Booming in Asia”, The New York Times, (Feb. 21, 2003).

provisional requirements.²²⁰ Their increasing number and geographic distribution suggest that EU efforts to influence the global biotech food debate on a political rather than a scientific level have been somewhat fruitful.

b. *New GMO Legislation Will Deny Developing Countries the Opportunity to Actively Participate in the Global Economy*

The newly revised EU GMO regulatory regime will have a deleterious impact on developing country agricultural trade and economic growth. The GMO authorization rules would effectively block, until a costly, time consuming and technically challenging risk assessment establishing product 'safety' is performed, several different types of developing country trade in seed and food products. It would block trade in: 1) indigenously produced GM seed; 2) GM food products, whether derived from GM seed indigenously produced or purchased from other countries, (e.g., U.S., Argentina); 3) conventional food products, if packed or otherwise processed with oils or other substances derived from GM seed; and 4) genetically manipulated produce (molecular farming), including tomatoes, potatoes and bananas.

The consequences are significant. Economically speaking, the trade loss resulting from an EU ban would deprive developing countries of sorely needed revenues from which to finance their balance of payment obligations and infrastructure development.²²¹ Also, it would reduce the number of currently available jobs and prospects for future employment, especially within least developed countries lacking a manufacturing infrastructure. This is especially critical on the African continent, where it has been reported that, "Over 70% of Africans are involved in agriculture".²²² In such countries

²²⁰ In August 2002, it was reported that South Korea was proposing additional regulations to regulate biotech food products, "The regulations on labeling have already impacted U.S. exports of food grade corn, and to a lesser extent, food grade soybeans to Korea. This is essentially now a 'non-biotech' market, as retailers avoid placing 'GMO' labeled products on store shelves, fearing consumer reaction." "FAS: Korea Now 'Essentially a Non-Biotech Market'", Cropchoice.com News, (Aug. 8, 2002), at: (<http://www.cropchoice.com>). Although Brazil's official stance strengthened its position in European markets, it had all but allowed Argentina to control the South American biotech export market. Recognizing the importance of biotechnology to the future of Brazilian agricultural exports, however, the Brazilian Government recently, during March 2003, published a 'provisional' measure allowing GM soybeans to be sold in Brazil until the end of January 2004. Brazil GM Soy Move Sparks Green Fury, Farmer Doubt", Reuters (March 31, 2003), cited at: The Campaign to Label Genetically Engineered Foods Newscenter website.

²²¹ This is one of the objectives of the African Growth and Opportunity Act (AGOA), a U.S. initiated framework for shaping future U.S.-Africa economic relations. Passed on May 23, 2000, it seeks to promote global economic development through international trade. "AGOA is a primary means to support a U.S. policy objective of further integrating African nations into the global economy. The underlying premise is that Africa's poverty and marginalization are the result of Africa being left out of globalization..." "US Politics and Free Trade: Trade Policy Options for Africa", Consumer Unity and Trust Society of the African Resource Center, No. 1, (2001) at pp. 1 and 3.

²²² Reported in a Joint AfricaBio – Europa Bio Press Release entitled, "Africa Needs Biotechnology Tools to Aid in Sustainable Development and Disease Control", Brussels (June 21, 2001). The economic significance of agriculture to Africa was previously highlighted in a June 1, 2000 London Financial Times article entitled, "Africa's Plight in the International Economic System". The article, citing a then recent World Bank report, wrote that, "no single measure to assist Africa's battle to recover...its share of world [agricultural] commodity trade...would provide a greater incentive, and have a greater impact, than

agriculture is a necessity due to technical capacity, local capital and foreign direct investment limitations.

The inability to use biotechnology to facilitate growth of agricultural exports would thus deny African countries a more affordable and less capital-intensive way to recover their lost trade in agricultural commodities.²²³ According to one commentator, “low-income developing countries that wish to employ an agriculture-led export growth strategy will be faced with the choice between adopting modern biotechnology in agriculture or maintaining the possibility of GM-free food exporting to the EU. In view of the tremendous importance of productivity increases in agriculture in low-income developing countries for both the rural and urban poor, it is hard to believe that any low-income developing country would refrain from utilizing appropriate modern biotechnology in agriculture within reasonable biosafety limits.”²²⁴ Similarly, the International Society of African Scientists emphasized that, “agricultural biotechnology represents a major opportunity to enhance the production of food crops, cash crops, and other agricultural commodities in Africa, the Caribbean and other developing nations... The production and marketability of important cash crops must be promoted to enable African farmers to raise their standards of living.”²²⁵

Furthermore, it has been argued that, additional jobs and technological opportunities would be lost if developing countries rich in biodiversity and prior scientific knowledge in agriculture are discouraged from creating a self-sustaining agricultural biotech industry for future generations. Dr. John Mugabe, an African scientist who recognized this possibility, encouraged the African Delegations at the Biosafety Protocol negotiations during the late 1990’s “to push for provisions that would strengthen African countries’ biotechnology capabilities”.²²⁶ In effect, new EU GMO regulation that effectively blocks developing country agricultural exports and discourages GMO research and field trials would likely contribute to developing country poverty, which would then likely result in an increased rate of disease, environmental degradation and mortality.

reducing... agricultural subsidies and *opening up this market for African [agricultural] products* (emphasis added).”

²²³ According to Dr. Wafula, previously “African farmers were besieged by high costs of farm inputs and high crop and animal losses due to diseases and pests, providing the rationale for the use of biological technologies, including genetic manipulation, to address these problems.” Catherine Mgendei, “Local Scientists Snub the West in Biotech War – ‘Need for Biotechnology in Africa is Very Clear’”, Africa News Service (Oct. 21, 1999), at: (http://www.agbioworld.org/biotech_info/topics/agbiotech/local_scientists.htm)

²²⁴ Per Pinstrip-Andersen, “Agricultural Biotechnology, Trade, and the Developing Countries”, AgBioForum – Vol. 2, No. 3&4 – 1999, at pp. 216-217.

²²⁵ “Position Statement On Agricultural Biotechnology Applications in Africa and the Caribbean”, International Society of African Scientists, October 5, 2001 Technical Conference, at pp. 1-2, at: (<http://www.monsantoafrica.com/reports/ISAS/ISAS.html>). One of the ISAS’s recommendations was to “promote internationally accepted standards for trade involving bioengineered foods, including considerations for potential implications on export crops from Africa and the Caribbean such as bananas, coffee, tea, cocoa, etc.” Ibid., at p. 2.

²²⁶ Dr. Mugabe was quoted as saying that, “Africa has comparative advantages in biotechnology. These include its enormous genetic diversity and prior scientific knowledge in agriculture. Biotechnology offers new opportunities to transform rural agriculture without undermining local ecologies and socioeconomic landscapes.” Ibid.

c. *New GMO Legislation Will Adversely Impact Developing Country Scientific Research Efforts Aimed at Improving Human Health, Environment and Poverty Alleviation, Thereby Undermining Their Prospects for Sustainable Economic Growth*

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 countries dependent on imports of food products and of materials necessary for agricultural, fish, and livestock production, the developing countries face a dilemma of reliance on foreign exports and legitimate concern for potential adverse impacts on health and environment...In the long term, it is imperative for developing countries to develop and strengthen their indigenous capabilities in biotechnology...As parties to multilateral negotiations on GMOs, labeling and safety issues, the developing countries will seek to obtain increased market access for their products and technical assistance in the monitoring of imports and/or development of their own biotechnology capacity.”²²⁷

The link between health, environment and economic growth was noted by the United Nations, in its “Human Development Report 2001”. The report, published by the United Nations Development Program, predicted that “Opposition in richer countries to genetically modified crops may set back the ability of the poorest nations to feed growing populations.” The report stated that, “The current debate in Europe and the United States over genetically modified crops mostly ignores the concerns and needs of the developing world...Western consumers who do not face food shortages or nutritional deficiencies or work in the fields are more likely to focus on food safety and the potential loss of biodiversity...”²²⁸

It is well known that bioengineered crops can increase yields per acre, require less intensive land use, and reduce the use of pesticides, and thereby contribute to sustainable development.²²⁹ As noted by another African scientist, Dr. John Wafula, of the Kenya Agricultural Research Institute (KARI), “The use of high-yielding, disease-resistant and pest-resistant crops would have a direct bearing on improved food security, poverty alleviation, and environmental conservation in Africa.”²³⁰ According to Dr. Wafula, “Biotechnology in Africa hinges on averting mass starvation and alleviating rampant

²²⁷ A.H. Zakri, “International Standards for Risk Assessment and Risk Management of Biotechnology”, International Center for Trade and Sustainable Development, Workshop on Biotechnology, Biosafety and Trade: Issues for Developing Countries” (July 18-20, 2001), at: (<http://www.ictsd.org>). If incentives for biotech research were eliminated because the European markets would not be available, it would effectively deny developing countries the right to choose for themselves whether biotechnology is appropriate. See: Joseph M. Gopo, “Biosafety and Trade Issues for Developing Countries”, at p. 5.

²²⁸ See: Barbara Crossette, “Move to Curb Biotech Crops Ignores Poor, U.N. Finds”, New York Times, (July 8, 2001).

²²⁹ See: “Africa Needs Biotechnology Tools to Aid in Sustainable Development and Disease Control”, a Joint AfricaBio – Europa Bio Press Release, at p. 1.

²³⁰ Catherine Mgendi, “Local Scientists Snub the West in Biotech War – “Need for Biotechnology in Africa is Very Clear”.

poverty.”²³¹ Agricultural biotechnology can improve nutrition and combat diseases such as Vitamin A deficiency and anemia.²³² And “agricultural biotechnology, because it can require less capital for small farmers to expend on synthetic pesticides, herbicides, and fertilizers, and because of demonstrated higher yields for many staple crops, can aid farmers in producing food beyond subsistence levels.”²³³ In sum, agricultural biotechnology for many of these nations “may mean the difference between survival and starvation for many millions of people.”²³⁴

According to one developing country scientist, “One of the most promising areas of transgenic plants is the area of ‘Molecular Farming’. Molecular Farming [...] is used to produce transgenic plants for high value products...such as Tomato, Potato, Tobacco and Banana to produce recombinant vaccines, special chemicals, pharmaceuticals, enzymes, autoimmune antigens, new generation antibiotics...The geopolitical resource distribution shows that 83% of these economic plants come from the south.”²³⁵ Bananas are a staple diet in large parts of sub-Saharan Africa. KARI developed a technique of tissue-culturing bananas to ensure seedlings are free of harmful fungi and bacteria and thus a useful way of increasing productivity. Dr. Wafula refers to projects like these as key to agricultural development in Africa. And agricultural biotechnology projects for small-scale cotton farmers in South Africa show that this technology has a role to play in ‘sustainable agriculture’.²³⁶

Two recent announcements underscore the growing recognition by African governments of the biodiversity within their borders and the importance of agricultural biotechnology to their future prosperity and survival. On March 24, 2003, at a biotech forum organized

²³¹ According to Dr. Wafula, “...with a population expected to triple over the next 25 years and an agricultural sector that has maintained a downward trend, Africa would have to seek refuge from biotechnology to fast-forward the production of large amounts of food in order to meet the needs of its peoples...as a result of maintaining a low profile in food production, Africa has the lowest per capita food availability in the world.” Ibid.

²³² Frances B. Smith, “The Biosafety Protocol: The Real Losers Are Developing Countries”, at p. 32.

²³³ Ibid, at p. 34.

²³⁴ Frances B. Smith, “The Biosafety Protocol: The Real Losers Are Developing Countries”, at p. 34. It has been estimated that “more than 800 million people around the world are considered to be *food insecure*. The Food and Agriculture Organization of the United Nations had estimated back in 2001, that 254 million people were chronically under nourished in Asia. In the absence of the Green Revolution, the agricultural technology of the 1940’s could not have met the food demand for today’s population. Similarly, it is difficult to assume that the food requirement of the people of 2020 will be sustained by the technology of today. Therefore, advancement of agriculture through biotechnology is expected to play a major role in farm production. While major food biotechnology research initiatives have been seen in the developed world...many developing countries have also invested in this area with a view to find succor from hunger in a cost-effective manner (emphasis added).” Atul Kausik, “Addressing Developing Countries’ Concerns Related to Biotechnology and Biosafety in the WTO”, International Center for Trade and Sustainable Development, Workshop on Biotechnology, Biosafety and Trade: Issues for Developing Countries” (July 18-20, 2001), at: (<http://www.ictsd.org>).

²³⁵ Joseph M. Gopo, “Biosafety and Trade Issues for Developing Countries”, International Center for Trade and Sustainable Development, International Center for Trade and Sustainable Development, Workshop on Biotechnology, Biosafety and Trade: Issues for Developing Countries” (July 18-20, 2001), at: (<http://www.ictsd.org>). Dr. Gopo is Director, Biotechnology Research Institute, Harare, Zimbabwe.

²³⁶ “Africa Needs Biotechnology Tools to Aid in Sustainable Development and Disease Control”, a Joint AfricaBio – Europa Bio Press Release, at p. 1.

in Nairobi, Kenya by the United Nations Industrial and Development Organization ('UNIDO'), the Kenyan Agriculture Minister, Kipruto arap Kirwa, declared that the government of Kenya "is ready to embrace the use of biotechnology to boost food production and reduce post-harvest losses."²³⁷ Although biotechnology in Kenya remains relatively underdeveloped, Kirwa noted that, the Government had realized its potential in solving food crises. "Over 2 million Kenyans depend on food relief throughout the year and the figure rises to 5 million people during the dry seasons."²³⁸ It was notable, furthermore, that the Ugandan State Minister for Agriculture, Kibirige Sebunya, was among the guest speakers at the forum, attended by 15 African countries and 20 regional organizations, whose purpose was to promote the use of biotechnology in developing countries.²³⁹

In Uganda, "scientists are already working with the Uganda National Agricultural Research Organization ('NARO') to insert genes that will enhance banana tolerance to plant diseases like banana weevils, which destroy the trees' stems and roots."²⁴⁰ NARO is one organization that might benefit from a new initiative recently announced by the Rockefeller Foundation, called the 'African Agricultural Technology Foundation ('AATF').²⁴¹ Rockefeller Foundation president, Dr. Gordon Conway, has characterized the AATF as an African-led initiative, intended to assist African scientists in "identifying areas of research or patented technology that can help boost food crop production to feed Africa's millions of chronically hungry citizens."²⁴² Under the AATF, "banana growers, who now must replant part of a tree to prepare next year's crop could use disease-free banana plantlets created by a biotechnology method called tissue culture. If applied

²³⁷ "Government Ready to Apply Biotech, Says Minister", The East African Standard (Nairobi), (March 24, 2003), at: (<http://www.allAfrica.com>).

²³⁸ Ibid.

²³⁹ Ibid.

²⁴⁰ Milly Kalyabe, "Uganda: Banana Farming to Access Biotechnology", New Vision (Kampala), (March 19, 2003), at: (<http://www.allAfrica.com>). NARO's mission is to improve the welfare of the people of Uganda by increasing the productivity and utilization of crop, livestock, fisheries and forestry resources through enhancement of *sound scientific knowledge base*, generation, adaptation and transfer of improved technologies while conserving the natural resource base. The objective is to significantly contribute to the national development challenges of modernizing agriculture, ensuring food security, alleviating hunger and eradicating poverty." (emphasis added). See: (<http://www.naro.go.ug/about/aboutnaro.htm>).

²⁴¹ The new initiative was announced on March 12, 2003 at a keynote address at the Woodrow Wilson International Center of Scholars in Washington. The foundation is being funded in part by the U.S. Agency for International Development (USAID) and its counterpart in Great Britain, and plans to negotiate with Western companies for assistance in developing patent licenses and new strains of plant varieties for small subsistence farmers on the continent. Charles W. Covey, "New Foundation May Help Solve Africa's Chronic Hunger Problem – Africa-based Foundation Will Offer African Solutions to African Problems", U.S. Department of State, International Information Programs, (March 14, 2003), at p. 1, at: (<http://www.usinfo.state.gov>).

²⁴² Cooperation on agricultural development, Conway noted, is a key area where Africa, the United States and Europe can move together. "Unjamming the logjam on ...Africa's food security is a priority put forth by the Africans themselves." He warned, however, "they can't make it happen on their own." Ibid. According to Conway, "The more information that is out there about genomics, genetic structures and how you use genetic structures, the more everybody can benefit -- both the public and private sector," he said. This is why companies are now sharing their information about the rice genome, he added. "It turns out that the rice genome tells you a lot about the wheat genome, which tells you a lot about the maize genome. So the more that is out there -- the better it is."

successfully in Africa, the scheme could increase the production of bananas, a staple food in many areas, by some 75%, providing food for farmers and their families and possibly generating extra income from the sale of excess production.”²⁴³ The AATF will be officially launched in Nairobi, Kenya sometime during September 2003.

In order to facilitate such research, the Rockefeller Foundation indicated that the AATF would enter into licensing agreements to access proprietary technologies royalty-free, then ‘sub-license’ them to institutions in Africa for further research and even issue commercial licenses for production and distribution. “The AATF will transfer material and knowledge, offering its partners access to advanced agricultural technologies that are privately owned by companies and other research institutions on a royalty-free basis”.²⁴⁴ Among the companies joining to assist the AATF are Monsanto, Dupont, Pioneer and Dow Agro. According to Dr. Gordon, “Many of these companies hold patented bits of technology on new strains of crops, which -- if pooled by the group -- might lead to breakthroughs, which could enhance Africa's food security situation.”²⁴⁵

Consumer and environmentalist objections notwithstanding, agricultural biotechnology and its potential to stimulate future developing country economic growth has captivated the interest of an increasing number of Asian governments that are now aggressively establishing biotech research and development institutions.²⁴⁶ Like their African colleagues currently engaged in biotech research, Asian countries have come to view agricultural biotechnology as a ticket into the world trading system. The New York Times recently reported that, according to representatives of the Asia-Pacific Economic Cooperation Group (‘APEC’),

“Spending on biotech research and development is booming throughout Asia. The three most populous countries in Asia – China, India, and Indonesia – are already planting millions of acres of genetically modified cotton. Several other large Asian countries, including Japan, Thailand and the Philippines and Malaysia, are earmarking billions of dollars for private and government-sponsored research on biotech crops. Given that there are already 145 million acres planted with genetically modified crops worldwide, mostly in North America and South America, these developments in Asia can pave the way for bioengineered crops to dominate the world’s food supply.”²⁴⁷

The Times report notes that, “in the absence of any solid evidence that genetically modified crops are harmful to humans, scientists in Asia are experimenting on everything from modified corn, potatoes and papaya to biotech mustard and chili peppers.”²⁴⁸ According to the Times, the Philippines Government “has allowed the marketing of foods

²⁴³ Ibid.

²⁴⁴ Ibid; Milly Kalyabe, “Uganda: Banana Farming to Access Biotechnology”, at p. 1.

²⁴⁵ Charles W. Covey, “New Foundation May Help Solve Africa’s Chronic Hunger Problem – Africa-based Foundation Will Offer African Solutions to African Problems”, at p. 2.

²⁴⁶ David Barboza, “Development of Biotech Crops Is Booming in Asia”, The New York Times, (Feb. 21, 2003). “Aware of food safety concerns, especially among Europeans, most governments in Asia plan to move cautiously before approving the use of genetically modified food crops.” Ibid.

²⁴⁷ Ibid. “Critics of GM crops say these moves in Asia could leave consumers around the world with little choice but to accept them. Ibid.

²⁴⁸ Ibid.

made with biotech corn, a first for Asia. The Philippines is also the sight of the International Rice Institute, which is working to use biotechnology to develop ‘golden rice’, a variety fortified with Vitamin A.”²⁴⁹ In addition, the Chinese Government “has over 20,000 people employed in government-led research at about 200 labs. Government spending on biotech research has tripled in recent years and could top \$1.5 billion for the five years ending in 2005, making China second only to the United States in this area.”²⁵⁰ Furthermore, it was reported that, “Malaysia is creating a biotech hub outside Kuala Lumpur that it calls ‘biovalley’. Indonesia is setting up its own industrial park called ‘bioisland’”...[And,] India and Indonesia are beginning to release their first biotechnology products...a variety of insect-resistant biotech cotton that drastically reduces the need for pesticides...India is conducting biotech research at most of its major universities.”²⁵¹ Even “South Korea expects to spend over \$300 million a year on biotech research.”²⁵²

The likely impact that these nations’ collective actions will have upon the future makeup of the world food supply should not be underestimated. As more Asian countries engage in this ‘race’ to produce the most competitive agricultural products, the developed world, whether it likes it or not, will be compelled to come to terms with the increasing GM composition of the food it consumes. “Most of these countries must embrace biotechnology or risk seeing their crops lose value in a rapidly changing marketplace that promises a new breed of super crops.”²⁵³ And “If they don’t employ biotechnology, they’re going to be left behind...”²⁵⁴ This development has been heralded as significant because, “this is not only a *region* where most of the population growth is, it’s a *region* where most of the food growth is (emphasis added).”²⁵⁵ Once again, the troublesome issue is that the EU’s regulatory actions are grounded in politics rather than science, and would effectively quarantine biotech foods, thereby denying developing countries an invaluable social and economic opportunity.

d. *New GMO Legislation Will Severely Strain Developing Country Technical Capacity by Establishing Without Justification Food Safety Standards Unnecessarily More Stringent than Harmonized Standards Currently Being Formulated By Codex*

Furthermore, the GMO authorization, traceability and labeling rules would impose additional costs and administrative burdens upon developing countries that already lack

²⁴⁹ Ibid.

²⁵⁰ Ibid.

²⁵¹ Ibid. “In both China and India, where small farmers work under the harshest conditions and often suffer the affects of pesticide spraying, biotech crops have mainly been seen as beneficial.” Ibid.

²⁵² Ibid.

²⁵³ David Barboza, “Development of Biotech Crops Is Booming in Asia”, The New York Times, (Feb. 21, 2003).

²⁵⁴ Ibid, quoting Dr. Cho Kyun Rha, Professor of Biomaterial Sciences, at MIT.

²⁵⁵ Ibid, quoting Nicholas Kalaitzandonakes, a professor of agribusiness at the University of Missouri at Columbia. However, Dr. James Rissler of the Union of Concerned Scientists is concerned that, “these countries do not have the regulatory infrastructure to assess the risks”.

the institutional and technical capacity to adhere to more workable international standards on food safety. In light of developing countries' low technical capacity, the low EU threshold for adventitious GMO presence would effectively constitute a barrier to trade. It is not inconceivable that developing countries would be required to conduct a risk assessment on many conventional seeds and food products perceived by the EU to be contaminated with GMOs. "Developing countries often lack the technical capacity to test, inspect, or study the safety of imported [and also exported] products and therefore are unable to exercise their potential range of options related to the SPS Agreement."²⁵⁶

The technical, administrative and economic burdens that will be borne by developing country governments, let alone their farmers and biotech companies, as the result of the EU's new GMO regulatory regime would only worsen their ability to satisfy international food safety standards. A recent report issued jointly by the World Health Organization and the World Trade Organization has noted how many developing countries remain unable to satisfy *existing* international food standards on additives and toxins without international assistance.

"Many developing countries have found that for their exports to meet international food safety and quality standards, they need to invest substantially in both physical and institutional infrastructure. Article 9 of the SPS Agreement requires developing countries to be provided with technical assistance to do this, but there is still a big gap between what is needed and what is provided. In addition, many of the LDCs lack the data as well as the capacity and technical expertise to fully participate in Codex standard-setting processes as well as other fora relevant to food safety and/or quality issues. (WHO, ISO). The funding for developing countries' participation in Codex work is also a problem. Both the WHO and FAO, among other groups, are providing more technical assistance to alleviate this problem. Pursuant to a resolution passed by the World Health Assembly in 2000 (WHA 53.15), WHO is also stepping up efforts to support 'capacity-building' in developing countries for critical food safety activities."²⁵⁷

The issue highlighted by this report (the difficulties that developing countries face in implementing the TBT and SPS Agreements) was previously pointed out following the "first triennial review of the WTO TBT Agreement and subsequently mentioned by developing countries in their preparations for the Seattle Ministerial."²⁵⁸ "Whether this [difficulty] is due to lack of hard infrastructure, shortages of trained staff, or an excess of other, more pressing, policy priorities on the docket, the implementation of SPS and TBT obligations has been slow. Financial constraints and the need for technical assistance are often named as major impediments."²⁵⁹

The Codex Alimentarius recently announced the development of a framework for risk assessment in the area of biotechnology, intended to facilitate the development of harmonized GMO standards. However, until such standards have been agreed upon by

²⁵⁶ A.H. Zakri, "International Standards for Risk Assessment and Risk Management of Biotechnology", International Center for Trade and Sustainable Development, Workshop on Biotechnology, Biosafety and Trade: Issues for Developing Countries" (July 18-20, 2001), at: (<http://www.ictsd.org>).

²⁵⁷ "WTO Agreements & Public Health, A Joint Study by the WHO and the WTO Secretariat" (2002), at par. 119.

²⁵⁸ Gary Hufbauer, Barbara Kotschwar and John Wilson, "Trade Policy, Standards, and Development in Central America" (2000), at pp. 32.

²⁵⁹ Ibid.

consensus, national or regional regulatory regimes will continue to govern the disposition of GMO food. The general absence of harmonized food safety standards for non-GMO foods has itself resulted in a “fragmented system of [domestic] unilateral actions...that run counter to general WTO principles and [increase] transaction costs for exporters and global consumers.”²⁶⁰ As one recent World Bank study has revealed,

“Developing countries are most directly affected by a fragmented system in which firms meet differing standards for multiple export markets...Since regulatory requirements and product standards are substantially different across countries, typically between developed and developing countries, trade disputes in a non-harmonized system are inevitable...Food safety measures may have different implications in terms of the welfare effects in different countries depending on the differences in risk perceptions, available market information, the incidence of risk production and traditional methods of food processing and preparation.”²⁶¹

This same World Bank Study concluded that, the adoption of an international food safety standard based on current Codex guidelines would result in a greater increase in trade among countries, including developing countries than if the current divergent national standards remain in place.²⁶² It found that harmonization of food safety standards at a level more stringent than one suggested by international standards (such as the EU GMO regulatory regime) can severely limit developing country exports.²⁶³ Consequently, the report recommended that the goal of the developed world should be to engage in “an initiative to encourage international standards, along with mechanisms to directly assist developing countries in raising standards to international levels.”²⁶⁴ These findings were corroborated by another World Bank Study, which “estimated that new harmonized European standards on aflatoxin (a substance which affects products such as peanuts, corn, and other agricultural products), could cost African exporters \$700 million each year, as opposed to adoption of an international standard.”²⁶⁵

²⁶⁰ John S. Wilson and Tsunehiro Otsuki, “Global Trade and Food Safety: Winners and Losers in a Fragmented System”, Development Research Group, The World Bank (October 2001), at p. 2.

²⁶¹ The benefits of food safety regulation are reductions in risks of morbidity and mortality associated with the consumption of contaminated food. The costs of food safety regulation include the cost of production, the compliance cost, the administrative cost borne by the taxpayers and the deadweight loss associated with taxation. Ibid, at p. 5.

²⁶² Ibid.

²⁶³ Ibid, at p. 19.

²⁶⁴ Ibid, at p. 20. “One example of [these] widely different approaches to standards and food safety is the new EU maximum allowable level of aflatoxins in cereals, dried and preserved fruits and nut imports.” This regulation, which was implemented during 2002, has been alleged to have no scientific basis. It has generated concern among exporting countries, many of them developing countries (Argentina, Australia, Brazil, Canada, Colombia, India, Indonesia, Malaysia, Mexico, the Philippines, Senegal, South Africa, Thailand, Turkey and Uruguay, as well as the U.S.) Developing countries, in particular, are being adversely impacted by these regulations, given their continued reliance on agricultural exports. “This includes some of the least developed exporters of cereals, fruits and nuts in Africa, Asia and the Western Hemisphere”.. John S. Wilson and Tsunehiro Otsuki, “Global Trade and Food Safety: Winners and Losers in a Fragmented System”, Development Research Group, The World Bank (October 2001), at p. 3, and fn 1; USITC Report at pp.xx and 1.

²⁶⁵ Gary Hufbauer, Barbara Kotschwar and John Wilson, “Trade Policy, Standards, and Development in Central America” (2000), at pp. 32. Ibid. at pp. 18-19.

The current difficulties experienced by Central American countries endeavoring to satisfy *existing* international food safety standards further demonstrates the need, not only to provide developing countries with technical assistance, but also to avoid imposing upon them unnecessary *additional* technical burdens.

“Most countries in Central America, which have accepted the TBT Agreement as part of the Uruguay Round trade negotiations, are relatively new to certification and accreditation activities, and all have expressed a need for modernization and improvement for standards infrastructure. One of the more important challenges in the region is upgrading of legal metrology systems – the infrastructure that supports accurate measurements for weight, size and other product characteristics, that need to be exactly calibrated. This infrastructure tends to be relatively expensive.”²⁶⁶

Central American countries, likewise, have found it difficult to satisfy requirements imposed by national eco-labeling and other so-called environmental measures that, prior to the GMO debate, had previously targeted developing countries diversifying from agricultural to manufactured exports. It is now these same countries “that have a particular stake in the outcome of debates” over regulations governing the testing, production and sale of high tech GM food and feed products,²⁶⁷ not to mention the placement of those standards within free trade agreements.

The difficulties Central American countries have experienced satisfying international standards may encourage such countries to take a regional approach. In fact, one study recommends that Central American countries take a regional approach to standardization to reduce the costs of setting up national accreditation, testing and metrology infrastructure. This study also suggests that Central American countries actively participate in regional standardization bodies and actively contribute to the development and maintenance of regional standards.²⁶⁸

In sum, the EU GMO directive and regulations work contrary to current WTO efforts to ensure that developing countries derive measurable benefits from global commerce.

“In an effort to address the problem of effective participation by developing countries in the standard-setting process, an interagency cooperation and coordination mechanism, involving the WTO, the FAO, WHO, OIE (the world animal health organization) and the World Bank, was established to identify ways of facilitating developing country participation in standard-setting activities and addressing their technical assistance needs. These organizations, in a joint statement delivered at the Doha Ministerial Conference, affirmed their commitment to ‘enhance developing countries’ capacity to participate effectively in the development and application of international standards and to take full advantage of trade opportunities.’”²⁶⁹

²⁶⁶ Ibid, at p. 12.

²⁶⁷ Ibid, at pp. 32-33. Biotechnology has spurred a number of new standards-related issues”, including questions about standards for selling GM food products and developing country uses of traditional knowledge products.

²⁶⁸ Ibid, at pp. 34-35.

²⁶⁹ “WTO Agreements & Public Health, A Joint Study by the WHO and the WTO Secretariat”, at par. 120.

IV. NON-FOOD REGULATIONS CONSTITUTING DISGUISED TRADE BARRIERS

A. Introduction

Although the biotechnology trade dispute between the EU and the U.S. has received the most international media attention it is still not the most costly. The industries and products impacted by the bioengineered food product moratorium and regulations reflect only the tip of the proverbial iceberg. Many more nonagricultural products lie below the surface of international trade flows to face disguised trade barriers. Most of these products are created within industry sectors that develop or otherwise employ high technology.

The nature and degree of regulation imposed within the EU, especially with respect to industries reliant upon science and high technology applications, such as GM seed and food products, electronics, automobiles, chemicals, pharmaceuticals, cosmetics and biocidal products is overwhelming to say the least. However, just like the bioengineered products effectively banned by the EU, they are evaluated not by how and where they are used (performance) but rather by their intrinsic properties (processes and production methods) and by the deemed dangers, both known and unknown, that are associated with them. Similarly, the decisions made by the EU to address these potential 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. Unfortunately, this regulatory practice reflects a pattern which is proliferating across industry lines and geographic borders at an alarming rate.

A threshold question that must be answered before a non-food measure that does not fall under the provisions of the SPS Agreement can be challenged under the TBT Agreement is whether it can be characterized as a ‘technical regulation’. This involves determining whether the measure 1) “[applies] to an identifiable product or group of products; 2) lays down one or more characteristics of the product; and 3) specifies that compliance with the product characteristics must be mandatory”.²⁷⁰ However, voluntary ‘standards’ have also been deemed to be within the scope of the TBT Agreement, as they are often used as a basis for or alternative to technical regulations.²⁷¹

²⁷⁰ Paragraph 1 of Annex I of the TBT Agreement defines the term ‘technical regulation’ as any “document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking, or labeling requirements as they apply to a product, process or production method”. See, also: Gregory Shaffer and Victor Mosoti, “EC Sardines: A New Model for Collaboration in Dispute Settlement?”, cited in Bridges, Comment, at: (<http://www.ictsd.org>); These authors discussed the WTO Appellate Body’s ruling in EC-Trade Description of Sardines (‘EC Sardines’) (WT/DS231/AB/R). It was the first time that the Appellate Body held a WTO Member to be in violation of its obligations under the TBT Agreement. The quoted passage appeared in paragraph 176.

²⁷¹ Paragraph 2 of Annex I of the TBT Agreement defines the term ‘standard’ as any “document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may

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

B. EU Aviation Hushkits

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.

The hushkits regulation was based on EU-established design (process) standards rather than upon international (performance) standards created by the ICAO, and effectively discriminated against aircraft that did not satisfy the EU standards. It disproportionately impacted U.S. manufacturers and airlines by limiting registration and use within the EU of certain aircraft that had been modified and re-certificated to meet only the International Civil Aviation Organization’s (ICAO) most stringent noise certification standards.²⁷² These were essentially re-certificated aircraft that were equipped with “hushkit” noise reduction devices or “re-engined” with engines of a certain design.²⁷³ Because of the one-sided impact of the regulation, it also appeared that U.S. aviation industry interests had not been equitably represented and taken into account during the EU legislative process. For these reasons the hushkits regulation was deemed by the U.S. government as a technical barrier to trade.

The hushkits regulation was eventually repealed by the EU on March 13, 2002²⁷⁴ and replaced with an international framework called the ‘Balanced Approach’.²⁷⁵ According

also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method”. The Explanatory note accompanying this definition provides that, “This Agreement deals only with technical regulations, standards, and conformity assessment procedures related to products or processes and production methods. Standards as defined by ISO/IEC Guide 2 may be mandatory or voluntary. For the purpose of this Agreement standards are defined as voluntary and technical regulations as mandatory documents. Standards prepared by the international standardization community are based on consensus. This Agreement covers also documents that are not based on consensus”.

²⁷² NTE Report at p. 118.

²⁷³ “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).

²⁷⁴ On March 13, 2002, the European Parliament voted to repeal EU legislation on aircraft noise that would have required the EU, by April 1, 2002, to ban flights into European airports of older airlines retrofitted with noise suppression equipment (‘hushkits’) used on many older American jets. The repeal of the hushkit legislation formed part of a broad EU directive intended to give greater emphasis to controlling overall noise nuisance from airports rather than focusing on individual aircraft types. Arthur Rogers, “EU Parliament Votes Bill to End Dispute Over Aircraft Noise; Focus Shifts to Airports”, March 21, 2002, *International Trade Reporter*, Vol. 19, No. 12, BNA, Inc.

²⁷⁵ 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

to Rockwell Schnabel, U.S. Ambassador to the European Union, “We worked this issue hard, and the EU has now adopted a framework for management of aircraft noise that is compatible with multilateral standards”.²⁷⁶

A review of the underlying ICAO Resolution upon which the new EU Directive will be based is instructive, because it reflects the type of balanced, transparent and scientifically objective international standards-based regulatory approach envisioned by the WTO agreements and advocated by the U.S. The resolution

“Recognized that solutions to noise problems need to be tailored to the specific characteristics of the airport concerned, which calls for an ‘airport-by-airport’ approach, and that similar solutions could be applied if similar noise problems are identified at [an] airport”. [In particular, it] “urged states to: 1) adopt a ‘*balanced approach*’ to noise management, taking full account of ICAO guidance, relevant legal obligations, existing agreements, current laws and established policies, when addressing noise problems at their international airports; 2) institute or oversee a ‘*transparent*’ process when considering measures to alleviate noise, including *assessment of the noise problem* at the airport concerned based on ‘*objective measurable criteria*’ and other relevant factors, evaluation of the *likely ‘costs and benefits’ of the various measures* with the goal to achieve maximum environmental benefit most cost effectively; and 3) provide for the dissemination of the results through *consultation with stakeholders* and dispute resolution” (emphasis added).²⁷⁷

C. EU End-of-Life Initiatives

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.²⁷⁸ They include: 1) Directive on Waste from Electrical and Electronic Equipment (WEEE)²⁷⁹ which focuses

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.

²⁷⁶ Ambassador Schabel’s Speech to the American Chamber of Commerce in Budapest, “U.S. - European Union Relations: Implications for the Candidate Countries” (6/7/02).²⁷⁶

²⁷⁷ See: Initiative for Noise Control Engineering (INCE) Europe, discussion of this EU Directive at: (<http://www.inceurope.org/Aircraftnoise.htm>)

²⁷⁸ Dave Bell, “Europe Targets Environmental Impacts of Electrical and Electronic Equipment”, ChipCenter.com, (Feb. 20, 2002) at: (<http://www.chipcenter.com/eeexpert/1goldberg2/dbell021.html>).

²⁷⁹ 2000/0158 (COD), now 2002/96/EC of the European Parliament and of the Council, dated January 27, 2003. This Directive was adopted by the European Parliament on December 18, 2002, after more than three years of intense debate between the EU institutions with input from various EU stakeholders along the way. It recently went into effect on February 13, 2003, its official date of publication within the Official Journal of the European Union. However, the governments in the individual EU Member States must still adopt the Directive and “it is essential that ...[they] respect the delicate balance engineered through the last round of EU negotiations when turning the Directive into national law and practice”. “End-of-Life Domestic Electrical Equipment: Europe Sets Major Challenge for Domestic Appliance Industry – CECED Urges Prudent Implementation of Electro-scrap Rules”, CECED Press Release, Dec. 18, 2002, at p.1.

on the take back and recycling of discarded equipment; 2) Directive on Restrictions on the Use of Hazardous Substances (RoHS)²⁸⁰ which focuses on restricting the use of certain hazardous substances such as lead, mercury, cadmium, and certain flame retardants; and 3) Directive on the Impact on the Environment of Electrical and Electronic Equipment (EEE) which focuses on mandating environmental design requirements for electrical and electronic equipment sold in the EU.²⁸¹ On February 13, 2003, both the WEEE and RoHS Directives became EU law. Member states have 18 months to transpose the legislation into national law.²⁸²

1. *The WEEE Directive*

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.²⁸³ 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”.²⁸⁴ It is very broad in scope and applies to a number of product categories including large and small household appliances, IT and telecom equipment, consumer equipment, lighting equipment, electrical and electronic tools (other than large stationary industrial tools), toys, leisure and sports equipment, medical devices (with the exception of all implanted and infected products), monitoring and control instruments and automatic dispensers.²⁸⁵ In addition, the Directive also applies to “‘components’ (e.g., circuit boards, transistors), ‘sub-assemblies’ (e.g., the shelves in a refrigerator) and ‘consumables’ (i.e., short-term replaceable or disposable parts like batteries) that are part of the [subject] ‘product’ at the time of discarding.”²⁸⁶ However, it does not apply to ‘components of components’ that are part of another type of equipment that does not fall within the scope of the Directive.²⁸⁷

As noted, the WEEE Directive applies to virtually all types of electronic products placed on the European Community market, as well as to the producers of those brand name products. The selling technique utilized, furthermore, is irrelevant for these purposes. In other words, the directive would apply not only to ‘brick and mortar’ local sellers, but

²⁸⁰ 2000/0159 (COD), now 2002/95/EC of the European Parliament of the Council, dated January 27, 2003. Like the WEEE Directive, the RoHS Directive went into effect on February 13, 2003, the date the directive was published in the Official Journal of the European Union.

²⁸¹ Ibid.

²⁸² “EU Directives – RoHS and WEEE Now EU Law”, Reported by ERA Technology Ltd., at: ()

²⁸³ It aims at “the prevention of waste [from] electrical and electronic equipment” and “minimizing the risks and impacts to the environment associated with the treatment and disposal of waste electrical and electronic equipment.” 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.

²⁸⁴ 2002/96/EC, Preamble par. 12. The U.S. EPA has also characterized these two directives as ‘product stewardship’ initiatives. See: “U.S. Environmental Protection Agency, Product Stewardship, International Initiatives for Electronics”, at : (<http://www.epa.gov>).

²⁸⁵ 2002/96/EC, Annex IA; Annex IB.

²⁸⁶ Squire Sanders, at p. 2.; 2002/96/EC, Annex I.

²⁸⁷ Ibid; 2002/96/EC, Art. 2.1.

also to long distance and electronic sellers such as mail order and internet catalogues. And the directive would also apply to importers²⁸⁸, as well as, to resellers (wholesale distributors) of such products if they market products under their own brands that were originally manufactured by other companies.²⁸⁹ However, suppliers or manufacturers of individual components, subassemblies or consumables would not be considered producers for purposes of this directive.²⁹⁰

One burdensome WEEE provision that has particularly incensed American businesses is that relating to the financing (costs) of the collection, treatment, recovery and disposal of WEEE from private households. The directive requires producers to bear such costs, from the designated collection points onwards.²⁹¹ Producers are required furthermore, to share proportionately with all other producers then existing on the market, the costs of financing historical waste from products put on the market before February 13, 2003 (date the Directive entered into force).²⁹² Producers will, however, be permitted to voluntarily show users (consumers), by means of identification on a point-of-sale price tag, the cost of collecting, treating and disposing of the historical waste in an environmentally sound manner. In this way, the cost of managing the historical waste (products sold before September 2005) as reflected in this 'transparent visible fee' can be temporarily passed through, in the form of higher prices, to consumers. This will be possible until 2011 for most products and until 2013 for larger household appliances with longer life cycles.²⁹³ With respect to users other than private households (business users), the directive permits producers to call upon users to participate in bearing the costs associated with historical waste.²⁹⁴ The WEEE Directive, furthermore, imposes annual target thresholds that must be satisfied within each Member State for the separate collection of WEEE from private households and for the treatment and recovery/reuse/recycling of WEE so collected.²⁹⁵

²⁸⁸ Manufacturers within the EU and 'importers' have the same status under this directive. CECED Press Release, Dec. 18, 2002, at p. 4.; 2002/96/EC, Preamble, pars. 12 and 13; Art. 3(i).

²⁸⁹ "Where companies market products under their own brand which were originally manufactured by other companies, the definition of 'producer' applies to the companies marketing the products rather than to the original manufacturers". Ibid.

²⁹⁰ Ibid.

²⁹¹ Ibid, at p. 3. "The main principles of the proposal include the requirement of setting up collection points, the possibility for consumers to return their equipment free of charge and the involvement of distributors in the collection system". Ibid.

²⁹² Ibid. A compromise was reached on October 11, 2002, whereby "producers will be held individually responsible for the waste arising from their *new* products." In effect, "each manufacturer [will be] legally and financially responsible for the recycling of the products that it puts onto the market." 2003 NTE Report at p. 117.

²⁹³ Ibid; CECED Press Release, Dec. 18, 2002, at p.3.

²⁹⁴ Producers and business users are even encouraged to conclude agreements stipulating other financing methods of 'cost sharing'. Ibid; "What is the WEEE Directive", by the Joint Procurement Policy and Strategy Group for UK Higher Education, (January 29, 2003) at: (http://www.jpmsg.ac.uk/guidances/weee_overview.htm). The JPMSG, which is an organization devoted to developing and promoting good procurement practices in higher education institutions, surmises that manufacturers and suppliers are likely to increase prices to cover the costs of complying with the WEEE Directive. They estimate that this will add approximately 1-3% to the cost of equipment, though it could be even greater for equipment containing certain components (e.g., cathode lamps).

²⁹⁵ 2002/96/EC, Arts. 5, 6 and 7.

Another element of the directive that is controversial to American exporters (and related EU importers) concerns the financing of orphan waste, namely WEEE coming from producers that are no longer present on the market or which can no longer be identified. The directive requires producers to provide for appropriate financial guarantees for the recycling of *its own products* sold after September 2005. The guarantee can assume the form of recycling insurance, a locked bank account or a ‘participation’ to a financing scheme. In the event an importer in the EU is unable to provide such a guarantee, an additional duty would be imposed on products originating from non-EU Member States.²⁹⁶

Based on the above, it is arguable that the onerous requirements imposed by the WEEE Directive are disguised trade barriers. While it may be agreed that the facilitation of waste reduction to protect the environment from discarded waste is a legitimate public objective, the measure adopted to achieve that objective is neither ‘necessary’ nor ‘the least trade-restrictive’ alternative available within the meaning of the TBT Agreement.

2. *The RoHS Directive*

The RoHS Directive bans the use of certain hazardous substances in electrical and electronic equipment that could potentially cause significant environmental problems during the waste management phase. Its stated objective is “to contribute to the protection of human health and the environmentally sound recovery and disposal of waste electrical and electronic equipment”.²⁹⁷ This directive applies to the same ‘products’ covered by the Directive on WEEE, with the exception of medical devices and monitoring and control instruments; it also applies to electric light bulbs and luminaires in households to which the WEEE Directive does not apply.²⁹⁸ The hazardous substances identified by this directive include heavy metals such as lead, mercury, cadmium and hexavalent chromium, as well as, brominated flame retardants, such as polybrominated biphenyls (PBB) and/or polybrominated diphenyl ethers (PBDE).²⁹⁹ The Directive

²⁹⁶ Ibid; CECED Press Release, Dec. 18, 2002, at p.3. The ‘guarantee scheme’ was championed by EU industry in order to address what was perceived to be a ‘free-rider’ problem -- companies that undercut established players and withdraw from the market before their products become waste. Member States are charged with the responsibility of ensuring that such guarantees are received.

²⁹⁷ 2002/95/EC, Art. 1. “The need for EU action was justified by the European Commission on the basis of: 1) the rapid growth of waste electrical and electronic equipment; 2) the hazardous content of waste electrical and electronic equipment; and 3) the lack of harmonized European legislation, perceived as hampering the effectiveness of national recycling policies, leading to substantial disparities in the financial burden for economic operators across EU countries and causing trade distortions between EU Member States.” “EU Proposals Regarding Electrical and Electronic Equipment, Environmental Update”, Squire Sanders, Legal Counsel Worldwide (May 2002), at p.1.

²⁹⁸ Squire and Sanders, at p. 4; 2002/95/EC, Art. 2.1. This directive, however, does not apply to spare parts for the ‘repair’ or to the ‘re-use’ of electrical and electronic equipment put on the market before July 1, 2006 (the ‘phase-in’ period). 2002/95/EC, Art. 2.3.

²⁹⁹ Ibid; Dave Bell, “Europe Targets Environmental Impacts of Electrical and Electronic Equipment” at p. 1. The Directive, furthermore, gives producers a clear guarantee that no individual Member State will be able to introduce separate bans or restrictions on any other substance than those specified. “What Does the Emerging European Legislation On WEEE and RoHS Mean For Brominated Flame Retardants?”, Bromine Science and Environmental Forum (June 18, 2002); 2002/95/EC, Art. 4.1 provides that, “National measures

applies to the same producers as does the WEEE Directive; however, it 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.³⁰⁰

As with the WEEE Directive, while the U.S. has supported the RoHS Directive's underlying objective, it has been critical of the procedural process pursuant to which the directive was drafted and adopted. "The United States has expressed concerns that these directives lacked transparency in their development..." and consequently failed to take into account important stakeholder interests.³⁰¹ Furthermore, these proposals would, in part, ban certain materials and impose comprehensive collection and recycling requirements for end-of-life equipment on a *retroactive* basis, and would thereby discriminate against 'like' products based on how they were processed. Furthermore, trade would be damaged to the extent no viable alternatives to the banned products could be developed.³⁰²

Prior European industry concerns with these directives are particularly enlightening because they are based on the declaration contained in par. 8 of the Preamble to the RoHS Directive.³⁰³ That paragraph provides, in part, that, "The measures provided for in this Directive take into account existing 'international' guidelines and recommendations and *are based on an assessment of available scientific and technical information...* (emphasis added)"³⁰⁴ However, an early discussion paper on these directives circulated by the EU Committee had previously determined that the Commission had not actually carried out a targeted risk assessment on any of the 'hazardous' substances used in EEE products PRIOR to proposing the RoHS Directive, and it opined that such failure would likely violate international trade law. "An EU substance ban not supported by appropriate risk assessment [based on science] is contrary to international trade law, as it would create a technical barrier to the trade of electronic

restricting or prohibiting the use of these substances in electrical and electronic equipment which were adopted in line with Community legislation before the adoption of this Directive may be maintained until 1 July 2006."

³⁰⁰ "EU Directives – RoHS and WEEE Now EU Law", Reported by ERA Technology Ltd.; 2002/95/EC, Art. 4(3). This requirement will support ongoing efforts to substitute these substances by less harmful substances, in line with the directive on end-of-life vehicles (presumably, autos). The substitution of pbb and pbde, however, must not lead to a lowering of the fire safety standards. Accordingly, the directive provides for exemptions from the substitution requirement if such substitution is not possible. Ibid; "Commission Tackles Growing Problem of Electrical and Electronic Waste", Brussels, 13 June 2000, at: (<http://www.europa.eu>).

³⁰¹ 2003 NTE Report at p. 117. ; 2002 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).

³⁰² 2003 NTE Report, Ibid; 2002 NTE Report at p. 116.

³⁰³ See: European Brominated Flame Retardant Industry Panel Comment Letter in Response to the RoHS Directive, (December 14, 2000).

³⁰⁴ It also states that, "The measures are necessary to achieve the chosen level of protection of human and animal health and the environment, having regard to the risks which the absence of measures would be likely to create in the Community. The measures should be kept under review, and if necessary, adjusted to take account of *available technical and scientific information.*" (emphasis added) 2002/95/EC, Preamble, par.8.

and electrical equipment without the requisite demonstration of justification.”³⁰⁵ Efforts made by three of Europe’s largest semiconductor manufacturers (Infineon, Philips and STMicroelectronics) 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.³⁰⁶ If the EU had indeed encouraged this industry response, believing that there was “a lack of international standards and methodologies for assessing the quality and reliability of alternative solder alloys and soldering processes”, it would seem to conflict with its express declaration in paragraph 8 of the Preamble.

This declaration was highlighted and elaborated upon by the European Brominated Flame 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 proposal to phase-out all three of the PBDE flame retardants...provides the most extreme example of this move away from ‘scientific risk assessment’ in that for two of the PBDE flame retardants -- octaBDE and decaBDE - preliminary risk assessment conclusions dating from August 1999 identify no need for any risk reduction measures...The Commission’s proposal is backed up by erroneous statements and references to outdated scientific studies...”³⁰⁷

³⁰⁵ “Initial Discussion Paper on the Proposed WEEE and RoHS Directives”, EU Committee Comments, (October 5, 2000) at: (<http://www.eucommittee.be/pop/pop2000/Env/env47.htm>). The Committee, in support of its position, cites a June 2000 report issued by the European Commission’s Scientific Committee that, “criticiz[ed] a lead ban proposed by Denmark for the failure to perform a risk assessment and base that ban on science”. Ibid.

³⁰⁶ Lead is used in solder for printed-circuit-board assemblies, and is used exclusively in semiconductor packaging. Its electrical, mechanical and thermal properties and low cost have contributed to its extensive use worldwide. The EU is concerned with the hypothetical risk that IF and WHEN such EEE devices are discarded in landfills, rainwater accumulating over time would dissolve the metal and possibly contaminate the soil and groundwater. See: Dave Bell, “Top European Manufacturers Moving Forward on Lead-Free Technologies – Infineon, Philips and STMicroelectronics Cooperate on New Standards”, (Sept. 28, 2001) Chipcenter.com, at: (<http://www.chipcenter.com/eexpert/lgoldberg2/dbell016.html>). Prior to this effort, Matsushita, a major Japanese electronics manufacturer, announced that it would begin using no-lead solder in its consumer products. Telephones, VCR’s, kitchen appliances, and other short-life products with close exposure to the general public were to be the first to be affected. This followed a similar initiative launched by Hitachi almost a year earlier. Bill Trumble, “Getting Started On Going Lead-Free”, (Jan. 6, 2000) Chipcenter.com at: (http://www.chipcenter.com/eexpert/lgoldberg2/lgoldberg_green001.html).

³⁰⁷ The comment letter goes on further to note that, “[t]he Commission has also ignored recent data from the leading German analytical laboratory GfA which demonstrates there is NO risk from dioxin exposure during recycling of plastics containing PBDEs...The proposal also ignores a recent study of TV sets by the Swedish National Testing Institute, which demonstrated that, compared to a traditional TV set flame-retarded with decaBDE, TV sets without flame retardants emitted on average vastly greater levels of dioxins and polyaromatic hydrocarbons over their life cycle...[And] the Commission proposal ignores the fact that the final risk assessment studies on the PBDE flame retardants will be completed at the end of this year (2000), well in advance of final adoption of its proposal.” European Brominated Flame Retardant Industry Panel Comments to the RoHS Directive (12/14/00).

A similar criticism of the integrity of the risk assessments being performed to implement the European Risk Assessment Program for Existing Chemicals (Council Regulation 793/93)³⁰⁸, in connection with the 'EU eco-label scheme', was also made by the Chemical Industries Association (CIA) of the United Kingdom.³⁰⁹ CIA argued against Member State proposals for a regulatory "'hurdle' or limit of 0.1 per cent for active chlorinated compounds allowed in the ingredients of qualifying eco-label products over and above general controls on toxicity and chemical content". It cited test data provided by "Euro Chlor, a sector group of the European Chemical Industries Council...on the chlorine-based compound sodium hypochlorite, which is the active ingredient in machine dishwasher detergents and other household products (e.g., surface and sanitary cleaning agents). The test data showed that "active chlorine compounds such as this rapidly break down during use and in sewers into harmless salts and oxygen."³¹⁰ This is scientific fact accepted by the Oslo and Paris Conventions for the Prevention of Marine Pollution (OSPARCOM)". CIA mentioned also that an extensive scientific dossier on the environmental impact of the chlorine-based compound sodium hypochlorite, prepared by the European Soap, Detergent and Maintenance Products Industry Association (AISE), showed "no scientific evidence of adverse environmental impact from domestic cleaning and hygiene products containing sodium hypochlorite". Notwithstanding the lack of scientific evidence of harm presented, however, this compound continued to undergo an extensive evaluation under the EU's priority substance regime. As a result, the CIA proclaimed that, "The setting of criteria on political rather than scientific principles devalues the EU eco-labeling scheme and damages industry confidence in the regulatory process".

³⁰⁸ Council Regulation (EEC) No 793/93 dates back to 1993 when the European Community developed a "List of Priority Substances" which it eventually used to formulate a regulatory approach to the management of chemicals perceived to be harmful to human health "EEC 793/93 envisages a system of evaluation and control of the risks of existing substances and stipulates that in order to undertake the risk evaluation of existing substances it is appropriate to identify priority substances requiring attention. Consequently EEC No 793/93 requires the Commission [to] draw up lists of priority substances taking into account certain factors..." Referenced in the Preamble of Commission Regulation (EC) No 2364/2000 (Oct. 25, 2000), "Concerning the Fourth List of Priority Substances as Foreseen Under Council Regulation (EEC) No 793/93. There were three previous 'priority substances' lists. See: Commission Regulation (EC) No 1179/94 (OJ L 131, 26.5 1994, p. 3); (EC) No 2268/95 (OJ L 231, 28.9 1995, p. 18); (EC) No 143/97 (OJ L 25, 28.1 1997, p.13). Commission Regulation (EC) No 1488/94 (OJ L 161, 29.6.1994, p. 3) outlines the principles for the assessment of risks to man and the environment of existing substances in accordance with Regulation (EEC) No. 793/93.

³⁰⁹ "CIA is the UK chemical industry's leading trade organization, representing about 200 companies on 700 sites, including the five chlorine-producers and numerous chlorine using companies which make up the chlorine sector group. It notes that the chlorine sector, which underpins 60 percent of the EU chemical industry, is concerned about evolution of the EU scheme with potential discrimination against products that incorporate or use chlor-alkali derivatives in their manufacture". Chemical Industries Association, UK, paper on "Eco-Labeling" (1999), at p. 1, at: (<http://www.chlorine.org.uk>).

³¹⁰ CIA noted that "although some 'trace' chlorinated by-products are initially formed, these are generally volatile or water-soluble and biodegradable. They parallel those present in chlorinated drinking water and most, if not all, will also occur *naturally* in the environment. In respect of dishwasher detergents and other household cleaning products, the quantities released to the environment are less than those from tap water". Ibid, at p. 2.

The failure of the EU Commission to perform a scientific risk assessment on the targeted substances and to investigate whether substitutes would have less of an environmental impact, was also highlighted in a recent industry comment letter submitted to the U.S. Commerce Department by the American Electronics Association (AeA).³¹¹ The comment letter, furthermore, brought to light another problem with the RoHS Directive, namely that, “the EU did not notify its trading partners, as required by the TBT Agreement, until the proposal was sent to Parliament and Council for co-decision. Consequently our members were effectively denied access to the RoHS [regulatory] development process.”³¹²

The European Commission also expressed its reservation about the legality of the RoHS Directive under international trade law for other reasons.

“[It] may infringe the GATT’s prohibition of quantitative restrictions under Art. XI and the [TBT] Agreement under Art. 2.2, as the measure creates unnecessary obstacles to international trade. The substance restrictions proposed in this Directive are not necessary, because there exists other less restrictive alternatives such as the existing Landfill Directive and the Incineration Directive. It is important to note that alternatives to banned substances may not be technically feasible to use in EEE products or could possibly be more harmful for the environment.”³¹³

Two of the Commission’s concerns noted above were further elaborated upon by a Belgian law firm, which analyzed the WEEE Directive before it was procedurally separated from the RoHS Directive.³¹⁴ First, the law firm opined that, “the many scientific studies carried out [by the OECD] on the substances to be phased-out...fell short [of] constituting the valid risk assessment [necessary] to justify an EU ban of those substances...”, and thus, the ban was neither necessary to fulfill a legitimate objective nor proportional to the objectives pursued by the policy underlying it, as required by the GATT and TBT Agreements.³¹⁵ According to the legal opinion, “the studies mentioned [in the Explanatory Memorandum to the WEEE Directive] are not specifically devoted to the analysis of the risk posed by these substances as present in the waste stream.

³¹¹ This comment letter was submitted in response to a “Request for Comments on Non-Tariff Trade Barriers (NTBs)”, issued jointly by the U.S. Department of Commerce, Office of Multilateral Affairs and the USTR, to the Industry Sector and Functional Advisory Committees (ISACs and IFACs). This communication was intended to solicit industry comments about non-agricultural, non-tariff trade barriers that could be incorporated into the U.S. negotiating position on modalities at the Doha Round negotiations.

³¹² AeA Issue Paper on Non-Tariff Barriers (NTBs), “EU Restrictions on the Use of Certain Hazardous Substances in Electrical and Electronic Equipment” (January 2003).

³¹³ “Initial Discussion Paper on the Proposed WEEE and RoHS Directives”, EU Committee Comments, (October 5, 2000).

³¹⁴ 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).

³¹⁵ “Article 2.2 of the TBT Agreement requires that account is taken of ‘the risks non-fulfillment would create’ when adopting a technical regulation that affects trade. To assess these risks, one has to take into consideration all available scientific evidence and technical information, related processing technology and the intended end-uses of the products. As assessment of the ‘risks of nonfulfillment’ would require a systematic evaluation of the environmental, health and safety risks and/or advantages of possible substitutes. Since the DG XI failed to provide this evidence, the substance bans therefore appear disproportionate in relation to the objectives of the WEEE Directive.” Ibid, at p. 15.

Furthermore, DG XI has not found a single scientific study focusing primarily on risks posed by these substances as found in electrical or electronic waste...”^{316*}

Second, the law firm concluded that the lack of a valid risk assessment

“Provided no evidence that it had exhausted all alternatives available to it before resorting to a total import ban – arguably the most restrictive measure³¹⁷...and no evidence of efforts to encourage international cooperation on the matter. On the contrary, OECD countries have not implemented substance bans to deal with potential problems posed by electronic waste, and OECD studies on this matter do not encourage the adoption of such measures. Therefore, the substance bans do not appear to be ‘necessary’ in relation to the ...directive’s policy goals and do not satisfy the requirements for the application of the [GATT] Article XX(b) exception [to GATT Art. III, or the requirements of TBT Art. 2.2]”.³¹⁸

3. *The EEE and EuE Directives*

a. *The EEE Directive*

The European Union previously developed a proposed (draft) directive that would comprehensively regulate the product design of electrical and electronic equipment (EEE), with the objective of minimizing potentially harmful effects on the environment. The proposed directive was described by the European Commission as a ‘New Approach’ Directive.

“The New Approach is intended to regulate hazards associated with products, with a view to harmonizing requirements at EU level in order to ensure the free circulation of goods. Hence, where the environmental effects are associated with the manufacture, intended use, and/or end-of-life of a product, and specific environmental requirements for products need to be introduced, then the application of the ‘New Approach’ becomes relevant...[In fact,] several ‘New Approach’

³¹⁶ “DG XI seeks support in the OECD Risk Reduction Monograph No.1. [However, t]his report does not constitute a risk assessment on the risks posed by lead in the waste stream, and there is little in the study to justify the phasing out of lead in electronics ...According to the OECD study, ‘lead is one of the most recycled non-ferrous metals in the world’, and ‘post-consumer product scrap constitutes more than 80 percent of the scrap supply for recycling’...[*] However, according to the OECD [as concerns the possibility of lead contamination of drinking water], ‘since elemental lead and lead compounds are stable, *health concerns are minimal for a properly managed landfill* with runoff and leachate controls.’ As for incineration, lead emissions from lead-containing materials could constitute the potential health risk. However, the OECD opines that ‘lead emissions from combustible and non-combustible components of municipal solid waste can be controlled with 99 percent or greater efficiency’...No OECD country has banned the use of lead in electronics as a means to counteract a ‘potential’ risk arising from the disposal of electronic goods” (emphasis added). Furthermore, in all of the European countries reviewed, the average concentration of lead and lead discharges to air, water and soil has decreased in recent years.” Ibid, at pp. 8-9.

³¹⁷ “The OECD has found that controlled landfill sites and incinerators reduce the risks posed by heavy metals to the point where health concerns are negligible. It would thus appear that available less trade-restrictive measures would include enforcement of technical requirements for landfill sites and incineration plants, and selective landfill bans. Indeed, the EC has recently adopted a Directive on Landfill (Council Directive 1999/31/EC, 4/26/99, O.J.L 4/16/99) and is currently in the process of promulgating a Directive on Waste Incineration (COM 1999 330 Final 7/12/99), which will supplement existing European rules on waste disposal”. Ibid, at p.11.

³¹⁸ Ibid, at pp.11-12 and 15.

directives may be applied to the same product, depending upon the relevant hazards which are associated with it”.³¹⁹

According to the EU Commission,

“EEE is an integrated approach, which encompasses all aspects relating to the environment in the design of electrical and electronic equipment. The overall environmental impact of product design will be evaluated and optimized taking into account the entire product lifecycle... Although the scope of the EEE proposal is complementary to that of the WEEE Directive, it is also much wider, since it does not focus specifically on waste management issues but rather on the overall environmental impact of a product. There is no distinction made between products intended for home or professional use. [The] use of [certain ‘hazardous’ chemical] substances in EEE will be regulated by the RoHS Directive”.³²⁰

The EEE Directive would hold manufacturers responsible for carrying out a conformity assessment procedure and issuing a Written Declaration of Conformity. This would require manufacturers to assess the magnitude of environmentally relevant inputs and outputs and, to the extent possible, their related environmental impacts.³²¹ The assessment can be performed pursuant either to an internal design control procedure or an environmental assurance procedure.³²² 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.³²³ However, manufacturers of EEE components that are placed independently on the EU markets for end-users or consumers are fully

³¹⁹ Under the ‘New Approach’, the legislator does not lay down detailed requirements for each and every manufactured good. Rather, the regulator defines basic or essential requirements that manufacturers shall apply for the protection of ‘public interest’ – to protect against ‘risks’ to public health or safety, consumers, or as in the case of the EEE Directive, the environment. The private sector then determines how to best meet these requirements, either individually or collectively, through particular technical specifications or by publicly approved technical standardization mechanisms and bodies. Manufacturers are legally responsible for ensuring that all products placed on the market comply with the provisions of these directives. According to the Commission, this type of legislation now covers approximately twenty hazard areas. See: “A New Approach to the Environment”, The European Commission, Background Document Relating to EEE Directive Proposal, at:

(http://www.europa.eu.int/comm/enterprise/electr_equipment/eee/background.htm).

³²⁰ “A New Approach to the Environment”, The European Commission, Background Document Relating to EEE Directive Proposal.

³²¹ “This assessment would include definition of all significant material and energy inputs and outputs through the product life cycle. The life cycle should include inputs and outputs associated with raw material (e.g., steel) acquisition, product manufacture (e.g., television manufacture), distribution and installation (e.g., transport) use (e.g., energy consumer during anticipated life) and the end of life option (e.g., recycling). The environmental impacts of the inputs and outputs should then be characterized.” “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).

³²² Proposed Directive of the Parliament and of the Council On the Impact on the Environment of Electrical and Electronic Equipment (EEE), Art. 7, Annex III, and Annex IV. (February 2001) (“Proposed EEE Directive”).

³²³ Proposed EEE Directive, Art.3.

subject to the compliance measures.³²⁴ Electronics and electrical equipment that have been awarded an EC Eco-Label “shall be presumed to fulfill the basic requirements insofar as the Eco-Label covers them”. The language of this provision, however, has been deemed ambiguous at best, given the lack of guidance concerning which precise elements of the basic requirements are covered by the presumption.³²⁵ This presumption is intended mostly for consumer products, such as washing machines and computers.

It was anticipated that the EEE Directive would apply to a number of product categories, including “office machinery and computers; telecommunications equipment; electronic components; electric domestic appliances; instruments, watches and clocks; consumer electronics; lighting equipment; insulated wire and cable; batteries and accumulators; electricity distribution and control apparatus; games and toys; electric motors, generators and transformers; and electrical equipment for engines and vehicles”.³²⁶

In light of the broad scope of this proposed directive, “U.S. industry was concerned that it ha[d] the potential to interfere with design flexibility, delay new product development and introduction, and impose extensive [and duplicative] administrative [costs and] burdens...[and that]...European standards and regulatory development processes are not sufficiently transparent and open to non-EU stakeholder input.”³²⁷ The ‘New Approach’ has already been characterized by some within the EU as an illegal and illegitimate legislative delegation to private standardization bodies, as construed under the EC Treaty.³²⁸ 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. Although the ‘New Approach’ mandates that directive standards be based on sound scientific knowledge, fit for purpose, mutually consistent and rapidly modifiable to keep pace with technological innovation, there can be no such assurance if European standardization bodies are assigned the task of framing standards to implement the directives.³²⁹

³²⁴ Ibid; *A New Approach to the Environment*, The European Commission, Background Document Relating to EEE Directive Proposal.

³²⁵ Proposed EEE Directive, Art. 8.3; “Legality of the Draft Directive on the Impact on Environment of Electrical and Electronic Equipment”, by Rod Hunter, Candido Garcia Molyneux and Marta Lopez Torres, Hunton & Williams (January 2001) at pp. 7-8.

³²⁶ Proposed EEE Directive, Annex I.

³²⁷ 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). This view has been echoed by the National Electric Manufacturer’s Association (NEMA) in a recent comment letter submitted to the USTR. “

³²⁸ According to one Belgian law firm opinion letter, “the delegation to standard bodies to draft harmonized standards under the draft EEE Directive would not be legitimate because: 1) the EC legislature may not delegate harmonization power that it does not possess; and 2) the ambiguity of the basic requirements and the necessity of making ‘political’ choices in balancing conflicting environmental objectives would result in assumption by standards bodies of legislative powers that belong to the EC institutions and may not be delegated to private bodies”. See: “Legality of the Draft Directive on the Impact on Environment of Electrical and Electronic Equipment”, Rod Hunter, Candido Garcia Molyneux and Marta Lopez Torres, Hunton & Williams.

³²⁹ “A New Approach to the Environment”, The European Commission, Background Document Relating to EEE Directive Proposal. This view was echoed in a recent comment letter submitted to the U.S. Department of Commerce by the National Electric Manufacturer’s Association (NEMA). “The EU

Similar international trade concerns were expressed in a comment letter jointly prepared and submitted by the American Electronics Association (AeA), the Electronics Industries Alliance (EIA), the National Electrical Manufacturer's Association (NEMA) and the Semiconductor Industry Association (SIA), four leading U.S. associations in the electrical and electronics industries.³³⁰ 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.³³¹ As a result, a company's design decisions would not be immune from questioning by individual Member States which are unable to clearly determine whether the product has satisfied the directive's compliance / conformity requirements; nor could a company be assured that its product would receive uniform treatment from all Member States.³³² Second, it alleged that because the supply chain in the electrical and electronics industry is worldwide³³³, the design choices made by European standardization bodies would have 'extra-territorial' environmental and

continues to seek 'New Approach Directives' such as those relating to *Chemicals and Environmentally-Friendly-End-Use-Equipment (EuE)* that would have significant impact on NEMA members' products. The chemicals proposal, while nominally not about our sector, features important implications and reporting requirements for downstream users... The EU is increasingly establishing regulations that lack technical justification and whose burdens of implementation are not proportionate to intended consumer or environmental benefits. Typically these regulations are developed with procedures that are not transparent to all stakeholders, including the U.S. electrical manufacturing industry and other trading partners. Further, stakeholders find they have no way to hold EU authorities 'accountable' for the regulations produced. In short, the EU's regulatory process fails to meet applicable international obligations as set forth in the [TBT Agreement]. On a related level, the important standards-setting bodies CEN and CENELEC are even more lacking in transparency and openness inasmuch as they absolutely deny access to participation by an U.S.-interested party. This is particularly significant when there is specific knowledge that the CEN/CENELEC standards resulting from 'New Approach' directives will be developed into requirements". Comment Letter, dated December 5, 2002, to U.S. Department of Commerce, Office of Trade and Economic Analysis, from National Electrical Manufacturer's Association, in response to federal register notice for public comments in preparation of the Annual National Trade Estimate Report on Foreign Trade Barriers (NTE), at p. 2.

³³⁰ AeA ("The American Electronics Association – representing more than 3,500 U.S.-based technology companies"); EIA (The Electronics Industries Alliance – a federation of associations and sectors, comprising over 2,100 members, representing 80% of the U.S. electronics industry"); NEMA ("The National Electrical Manufacturer's Association – the largest trade association representing the interests of U.S. electrical industry manufacturers"); SIA ("The Semiconductor Industry Association – the leading trade association representing the U.S. computer chip industry"). 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).

³³¹ "The broad list of requirements seemingly covers the impact of every conceivable aspect of product design, manufacture, use and disposal, encompassing the product supply chain up through the harvesting of the raw materials... [As a result,] [t]he results of the standardization process may not produce clear, measurable standards that Member States could use to determine compliance." Ibid.

³³² "This may result in a situation where Member State authorities question a company's design decisions. That could be detrimental to innovation and free movement of goods through the EU. Moreover, what may be considered to be environmentally beneficial in one Member State for purposes of compliance may be different in another Member State due to differing priorities and circumstances". Ibid.

³³³ The raw materials and components that comprise a product on the EU Market are likely to come from many countries outside the EU.

economic impacts on non-EU countries and industries that had not previously participated in the underlying EU standardization process.³³⁴

The joint letter, furthermore, emphasized the potential “trade-distorting and anti-competitive impacts” that could result from the standardization process called for by the EEE Directive. It said that the process, which was intended to “fill in the regulatory and compliance details which companies have to follow, did not include all stakeholders”.³³⁵ 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. Interests from within the region typically dominate regional standards bodies. Therefore... international rather than regional standards development organizations (SDOs) should produce voluntary guidelines to address the environmental impacts of product design.”³³⁶

b. *The EuE Directive*

The EEE Directive (and a sister directive, the EER Directive -The Directive on Energy Efficiency Requirements for End-Use Equipment³³⁷) will soon be replaced with a new proposal, the EuE Directive (Eco-Design of End-Use Equipment).³³⁸ 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”.³³⁹

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

³³⁴ Ibid.

³³⁵ Ibid.

³³⁶ Ibid.

³³⁷ 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.

³³⁸ 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 EUE 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).

³³⁹ 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.

“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”.³⁴⁰

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).³⁴¹

4. *The End-of-Life Vehicle Directive*

Another EU directive that is, in many ways, the precursor to the WEEE, RoHS and EEE regimes is the Directive of End-of-Life Vehicles (ELV Directive).³⁴² The objective of this directive is to encourage vehicle producers to prevent and reduce the use of potentially hazardous substances in the production of vehicles³⁴³ in order to prevent their release into the environment, facilitate recycling and avoid the disposal of hazardous waste.³⁴⁴ These substances include heavy metals such as lead, mercury, cadmium, hexavalent and

³⁴⁰ “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>)

³⁴¹ 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.

³⁴² 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). Member States were required to implement the directive no later than April 21, 2002. Ibid, at Art. 10.

³⁴³ The term ‘vehicle’ means any passenger or commercial vehicle, including three wheel vehicles (which are excluded from collection and treatment obligations) but excluding motor tricycles, motorcycles, and ‘special-purpose’ vehicles (which is excluded from recycling obligations). Ibid, at Art. 2(1); Art. 3(4) and (5). A ‘producer’ is defined as any “vehicle manufacturer or the professional importer of a vehicle into a Member State”. Ibid, at Art. 2(3).

³⁴⁴ Ibid, at Preamble, par. 11; Arts. 1 and 2(11).

chromium, as well as, all plastics, including PVC.³⁴⁵ The directive covers all new vehicles and end-of-life vehicles³⁴⁶, as well as their components and materials, and it precludes the use of heavy metals in vehicle materials and components after July 1, 2003.³⁴⁷

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.³⁴⁸ 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.³⁴⁹ The directive, furthermore, places the financial burden of collecting end-of-life vehicles from consumers almost entirely upon vehicle manufacturers and importers.³⁵⁰ However, the regulatory and financial burden of meeting the reuse and recovery/recycling targets and information reports imposed by the directive are to be borne by all ‘economic operators’ collectively.³⁵¹

Once again, 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’ alternative 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.

5. *The Green Paper on Integrated Product Policy*

In addition to the regulations discussed above, the EU has issued the Green Paper on Integrated Product Policy (IPP)³⁵² The IPP is intended to cover all product systems and their environmental effects, taking a lifecycle perspective as the lead principle.³⁵³ 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,

³⁴⁵ Ibid, at Preamble, par.11.

³⁴⁶ An ‘end-of-life-vehicle’ is a vehicle which is ‘waste’. Ibid, at Art. 2(2).

³⁴⁷ Ibid, at Art. 4(2)(a); Annex II.

³⁴⁸ Ibid, at Arts. 2(2), 3(1), 4(1)(c).

³⁴⁹ Ibid, at Art. 8

³⁵⁰ Ibid, at Preamble, par. 7 and Art. 5(4). “Member States shall take the necessary measures to ensure that ‘producers’ meet all, or a significant part of, the costs of the implementation of this measure

³⁵¹ Ibid, at Art. 7(2) and Art. 9. The term ‘economic operator’ is defined to include “producers, distributors, collectors, motor vehicle insurance companies, dismantlers, shredders, recoverers, recyclers and other treatment operators of end-of-life vehicles, including their components and materials”. Art. 2(10).

³⁵² Green Paper on Integrated Product Policy COM(2001) 68 final (Feb.7, 2001). (“Green Paper”).

³⁵³ “In principle, all products and services are included in the scope of this policy...In practice, action might address all or only certain products, selected on the basis of discussions with stakeholders because of their importance and their scope for improvement. [A]lthough services are not the primary focus of IPP[,]...services may play an important role in partly or entirely replacing products (e.g., car sharing; voice mail instead of answering machines; dematerialization potential for the ‘new economy’).” Ibid, at p. 5.

from the mining of raw materials to production, distribution, use, and waste management.”³⁵⁴ The overriding objective is to use the “synergies of environmental improvement and business development ...to contribute to the goals of [s]ustainable [d]evelopment...as called for in the 1992 Rio Declaration on Environment and Development”.³⁵⁵

The IPP reflects an extension of the concepts of producer responsibility³⁵⁶ and product stewardship that have been integrated into the Directive of End-of-Life Vehicles, the WEEE and RoHS Directives and the proposed EEE Directive.³⁵⁷ As expressed by the Green Paper, “This concept should be extended to further areas of Community and Member State legislation whenever the integration of environmental concerns into the product design can be usefully achieved in this way.”³⁵⁸

The IPP presumes that “once a product is put on the market, there is relatively little that can be done to improve its environmental characteristics” or to ensure that consumers use the product in an environmentally friendly manner. For these reasons, “the [IPP] approach will focus on the ‘eco-design’ of products and the creation of [consumer] information and incentives for an efficient take-up and use of greener products”.³⁵⁹

Among the several forms available for communicating environmental information to consumers, the Green Paper calls for generating consumer demand for such products by providing consumers with the ‘power of choice’ mostly through ‘eco-labeling’.³⁶⁰

“Clarity on label types promotes comparability and may promote progression from one label type to another...Eco-labels, whether at a national or EU level, are a reference of environmental excellence among products on the market, while guaranteeing a minimal good quality (‘fitness for use’). As such, they 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...There are cases where the eco-label standard later became a general product standard. Therefore, their scope should be extended to cover as many products as possible.”³⁶¹

³⁵⁴ Ibid, at p.3.

³⁵⁵ Ibid.

³⁵⁶ As discussed above, “the concept of producer responsibility relates to the integration of costs occurring once the product has been sold into the price of new products. This [is meant to] encourage prevention at the design stage and allows consumers to bring back end-of-life products free of charge.” Ibid, at p. 11.

³⁵⁷ These directives are commonly based on ‘New Approach’ legislation for promoting eco-design. Green Paper, at pp. 19-21.

³⁵⁸ Green Paper at p. 11. “Member States should financially support the development of environmentally friendly products through state aid [subsidies or]...deposit-refund systems could be further investigated”.

³⁵⁹ “IPP focuses on those decision points which strongly influence the lifecycle environmental impacts of products and which offer potential for improvement, notably eco-design of products, informed consumer choice, the polluter pays principle in product prices. It also promotes instruments and tools which target the whole life cycle of products”. Ibid, at p. 5.

³⁶⁰ “...The power of consumer choice stimulates the potential for market-driven continuous environmental improvement of products...Consumers must have easy access to understandable, relevant, credible information either through labeling on the product or from another readily accessible source (e.g., consumer and environmental NGOs, websites, public authorities)...” Ibid, at pp. 12-13.

³⁶¹ Ibid, at p. 13.

One problem with the IPP is that it reflects a political rather than a scientific determination that the burdensome and costly eco-design requirements are necessary to ensure a clean environment and that eco-labeling is the only and least trade-restrictive alternative available to educate consumers about the relative merits of eco-designed products. Another problem 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.³⁶² This problem was noted by the EU Committee of the American Chamber of Commerce in its IPP comment letter to the EU Commission.³⁶³

The IPP is intended not only for “locally established companies but for all businesses operating and trading within the Community³⁶⁴...[including]...non-European companies”³⁶⁵. What is most troublesome about this initiative is the almost certain extra-territorial impact it will have, particularly upon developing countries with which the EU has or intends to enter into trade agreements and the SMEs that operate within them. “Experiences gained on the European market may later be transferred to the global level, including developing countries”.³⁶⁶ 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. That the Green Paper makes reference to ISO design and labeling standards as a basis for eco-design and labels³⁶⁷ could only add complications, especially if the distinction between lifecycle assessments and ‘risk’ assessments is not recognized. The EU Committee of the American Chamber of Commerce highlighted this problem in its IPP comment letter to the EU Commission.

“While applying the ISO requirements helps [to conduct a lifecycle assessment which] can bring

³⁶² See: fn 145.

³⁶³ “The EU Committee supports the arrangement of stakeholder debates, since it is of utmost importance that all voices be heard in this issue. Expert workshops on IPP related subjects may also provide the Commission with essential information about the more technical aspects related to IPP. *But, the Commission has a great responsibility for securing input from a wide range of stakeholders. Unfortunately, our members have not had many chances for input in the workshops as many have applied unsuccessfully. Also, the outcome of the debates and of further written comments have to be properly processed into EU policy* (emphasis added)”. “Position Paper on Integrated Product Policy (IPP): Ideas and Comments on the Commission’s Green Paper”, The EU Committee of the American Chamber of Commerce in Belgium, June 29, 2001, at p.2.

³⁶⁴ “A Community IPP can only be successful if it takes up and integrates the experience gained from local and national initiatives and extends this to general business and government practice.” Ibid, at p. 4.

³⁶⁵ “In particular for businesses operating across Member State borders and non-European companies, a Community framework offers greater consistence of the European market”. Ibid, at p. 7.

³⁶⁶ Ibid. “SMEs will profit from an easier access to information and tools on how to reduce the environmental impacts of products. There will also be a special focus on the product chain as a support for SMEs to bring about environmental improvements”. Ibid.

³⁶⁷ “ISO has already developed a framework of distinct types of environmental labeling, differing in degree of life cycle thinking and methodology, inter alia. This is an important and useful base for systems notably eco-labels. Product information on the product through 3rd party verified product labels (Type I ISO), like the European eco-label, is available for a range of product categories.” Ibid, at p. 13.

useful information for assessing the overall environmental performance of a product or a type of product, they cannot guarantee a ‘scientific’ outcome of the results...The [lifecycle] assessment procedure usually contains elements of subjective evaluations and there is a remaining uncertainty associated with all LCA steps. This is why LCA can be used as a very valuable tool *to support* the decision making, but it can never be the only basis for deciding on the environmental performance of a product...Considerations on product/ingredient bans must take into account *scientifically sound risk assessments*, other realistic management options, and the sustainability aspects of the current and other options (emphasis added).”³⁶⁸

Other concerns were identified by the European Brands Association (Association Des Industries De Marque -AIM) in a comment letter submitted in response to the original IPP proposal.

“The Prescriptive standards for ‘green’ products entail practical difficulties, including avoiding undesirable [economic, social and environmental] side effects and *ensuring compatibility with international trade obligations*...For branded goods manufacturers, in particular, mandatory prescriptive standards would impose design constraints and inhibit innovation -- the very innovation that often leads to environmental, social and economic improvement...Environmental product assessment is an immensely complex issue and needs to be hugely oversimplified for communication with the consumer...*The award of an eco-label to a product...does not guarantee that the environmental impact of the product will actually be less than that of products which do not have the eco-label.* The contribution of eco-labels for fast-moving consumer goods to solving global environmental problems seems negligible. ***And, in specific cases, they are regarded by countries outside the EU as creating a ‘technical barrier to trade’ under the WTO agreements*** [In addition] *the [sharing of information called for among supply chain manufacturers] may cause disclosure of potentially sensitive business information [about manufacturing processes]* (emphasis added).”³⁶⁹

D. The EU Chemicals White Paper

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”).³⁷⁰ It is but another example of a ‘hazard-based’ rather than a ‘risk-based’ regulatory approach, “which is an evolution of the current EU system of classifying chemicals according to their intrinsic properties” rather than performance characteristics.³⁷¹ The proposal seeks

³⁶⁸ The EU Committee of the American Chamber of Commerce, at pp. 1 and 3. At least one European legal commentator has also identified the importance of this distinction, though she recommended a different solution. “...A lifecycle analysis in the classical sense or the simplified lifecycle analysis suggested by the Commission would be single-minded and flawed. Instead, products should be designed and assessed also to take into account suspected and long-term environmental consequences (e.g., *the precautionary principle*, not mentioned in the draft Green Paper, should be applied). Moreover, a truly integrated approach would also involve an assessment of product quality and *health and safety considerations, again short and long-term and presumed effects* (emphasis added)”. Ursula Schliessner, “Integrated Product Policy: Where is the EU Heading?” 86 European Environmental Law Review (March 2001).

³⁶⁹ Association Des Industries De Marque (European Brands Assoc.) AIM Position Paper on Integrated Product Policy (July 2000), at pp. 4-5.

³⁷⁰ COM (2001) 88 Final (Feb. 27, 2001). A White Paper is traditionally used by the EC to launch new policy initiatives. It contains concrete suggestions for the future, where appropriate for changing existing legislation or introducing new legislation. As such, a White Paper creates no legal obligations”. (See: <http://www.europe.eu>).

³⁷¹ “Executive Summary: Trade Implications of the EU White Paper ‘Strategy For a Future Chemicals Policy’, Powell, Goldstein, Frazer & Murphy, LLP, (April 9, 2002), at p. 12.

to establish a single system for assessing *existing* and new chemical substances called ‘REACH’ (Registration, Evaluation, and Authorization of Chemicals).

1. *The Proposed EU Chemicals Strategy*

Under the REACH system, the burden for testing chemicals and carrying out risk assessments will shift from government to companies and importers. Companies and importers will be held responsible for making this information available to a central database, and these data requirements will also be extended to downstream users of chemicals. As the result of this new strategy, U.S. business will bear the administrative burden of registering substances and the high cost and limited timeframe of conducting testing. U.S. industry intellectual property rights may also be compromised to the extent they are linked to the release of test data. Furthermore, U.S. chemical manufacturers as well as downstream users of such products may be subject to bans of certain chemical substances that “could [constitute] obstacles to trade and innovation, possibly distorting global markets for thousands of products”. These possible bans would be based on the ‘precautionary principle’.³⁷², a highly debated concept that the EU is attempting, through practice, to establish as a norm of customary international law.

The REACH proposal would require some 30,000 chemicals now in use³⁷³ to be immediately registered with EU authorities. According to Tom Reilly, chairman of the American Chemistry Council, “This [proposal] would paralyze trade”... We are seriously concerned... This legislation is of great concern to the world community.” U.S. industry argues that the extensive testing required under the legislation would cost between \$1.85 billion and \$7.7 billion, with chemical manufacturers bearing the bulk of the burden. Similarly, Eggert Boscherau, chairman of the European chemical manufacturers association (CEFIC) indicated that the German chemical association has done a study estimating that the new EU system could lower German gross domestic product by more than 2 percent and jeopardize some 3 million jobs. “It would clearly create an unnecessary obstacle to free international trade”, he said.³⁷⁴ A separate CEFIC study that analyzed the impacts of the EU chemicals policy, concluded, in part, that: “[1)] roughly

³⁷² See: “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); NTE Report, at p. 115.

³⁷³ One law firm has characterized this as a “situation where the chemical products in question have been on the market for at least 21 years and often much longer.” Legal Opinion of Crowell & Moring, on the White Paper, Strategy for a future Chemicals Policy (‘The White Paper’), (Nov. 7, 2002), at p. 2, fn 3.

³⁷⁴ Gary G. Yerkey, “Chemical Makers Say New EU Plan May Violate Trade Organization Rules”, BNA International Environmental Daily, 11/13/02. In addition, the Federation of German Industries (BDI), representing all manufacturing industry in Germany, has published a study, prepared by consultants at Arthur D. Little (ADL) of the impact on the German Economy of the proposed chemicals policy. It concluded generally that considerable production and job losses in German industry – not just in the chemical industry – would result. “Under a relatively benign scenario, a production loss of 1.4% is forecast for the overall German manufacturing sector, as well as a loss of 150,000 jobs. At the other extreme, there would be a production loss of 20.2% and job losses of 2.3 million. The middle scenario projects production losses of 7.7% and job losses of 900,000.” Patricia Short, “EU Chemical Rules Hard Hit for Germany”, Chemical and Engineering News, (Nov. 25, 2002), at: <http://pubs.acs.org/cen/topstory/8047/print/8047notw8.html>.

20% of the total EU chemical industry will carry over 80% of the costs of testing and administration; [2]) the main companies affected are small and medium-sized in the fine and specialty chemicals sector; [3]) 20-40% of substances produced in quantities in the range 1-100 tonnes per year are at risk; and [4]) the costs imposed by REACH will add to the costs of key pharmaceutical and other essential products...”³⁷⁵

While it is unknown which particular substances³⁷⁶ or uses of substances the EU will decide not to authorize, it is believed, following a review of the ‘CMR’ (Carcinogen, Mutagen and Reproductive Toxin) list, that the following EU chemical markets will be severely impacted”: adhesives and sealants;³⁷⁷ dyes;³⁷⁸ electronics;³⁷⁹ laboratory (analytical) reagents;³⁸⁰ photographic chemicals;³⁸¹ colored pigments;³⁸² plastics additives;³⁸³ and rubber manufacturing chemicals.³⁸⁴

2. *Significance to Industry*

In order to determine the magnitude of the impact that the EU Chemicals White Paper could possibly have on U.S. industry, one need first consider the dynamics of the U.S. chemicals industry itself. As revealed in a 1996 report, the U.S. Department of Commerce found that,

“The U.S. chemical industry is vital to the U.S. economy; it produces 1.9 percent of U.S. gross domestic product and is the nation’s number one exporter. It supplies more than \$1 out of every \$10 of U.S. exports and consistently runs large international trade surpluses. It is a high tech, research and development (R&D) oriented industry that is awarded about one out of every eight U.S. patents...Most importantly, chemicals is a ‘keystone’ industry – one critical to the global

³⁷⁵ “Barometer of Competitiveness 2002: Business Impact of New Chemicals Policy”, CEFIC, at pp.1-2.

³⁷⁶ Single chemical substances as well as formulations of agents and preparations are affected.

³⁷⁷ ‘Adhesives and sealants’ include: epoxies and polyurethanes; modified acrylics; anaerobics; crylates; radiation-curable adhesives; intermediates used in the production of polyurethanes, acrylics, and acrylates; and end-use industries such as transportation and construction.

³⁷⁸ ‘Dyes’ include: azo dyes; chemicals used in the making of dyes; and end-use industries such as textiles, paper and leather.

³⁷⁹ Chemicals used in the electronic sector include: cleaners; developers; dopants; capsulents; etchants; photoresists; specialty polymers; plating solutions; strippers; arsenic compounds used for doping purposes. Downstream users of these chemicals include: computers; telecommunications equipment; automotive devices; and medical devices.

³⁸⁰ Laboratory (Analytical) Reagents include chemicals used to detect, measure, examine or analyze other substances or mixtures (Merck is the leading producer of laboratory reagents in EU). End-use industries include universities, hospitals and government.

³⁸¹

³⁸² ‘Colored Pigments’ include chemicals used to make major classes of inorganic (chromium and cadmium-based) and organic (azo) pigments (azo pigments are most important class of organic pigments). Downstream end-users of azo pigments include printing inks and paints and coatings.

³⁸³ ‘Plastics Additives’ include: plasticizers, which are largest category of additives -- used in PVC more than any other polymer; and certain plastic additives (phthalates and brominated flame retardants), which have prompted environmental concerns. Phthalates are the most important plastic additive, while brominated flame retardants are next most important.

³⁸⁴ ‘Rubber Manufacturing Chemicals’ include: synthetic rubber; accelerators; activators; anti-oxidants; stabilizers; and vulcanizing agents. Major ‘downstream’ products include tires and mechanical goods.

competitiveness of other U.S. industries. Because so many modern products depend on chemicals, the international competitiveness of other U.S. industries requires a high-tech, globally competitive U.S. chemical industry that can supply new products at prices that give U.S. producers an edge".³⁸⁵

The report, now somewhat dated, describes the U.S. chemicals industry as it then existed, as consisting of "some 9,125 corporations whose primary business is the development, manufacturing, and marketing of industrial chemicals, pharmaceuticals, and other chemical products.

The *industrial chemicals segment* consists of some 1,725 corporations, whose primary business is the manufacturing and marketing of alkalis and chlorine, inorganic pigments, industrial gases, and other industrial inorganic chemicals; plastic resins, synthetic rubber, and man-made fibers; and petrochemicals and other industrial organic chemicals. The *pharmaceuticals segment* consists of some 1,225 corporations, whose primary business is the development, manufacturing and marketing of medicinal chemicals and botanicals; in vitro and other diagnostic substances to diagnose or monitor the state of human or veterinary health; bacteria and virus vaccines, toxoids, serums, plasmas, and other biological products for human and veterinary health; and vitamins and other pharmaceutical preparations for both human and veterinary use. The '*other chemical products*' segment consists of some 6, 175 corporations, whose primary business is the manufacturing and marketing of: soaps and detergents; surfactants; specialty cleaning, polishing, and sanitary preparations; perfumes, cosmetics, and other toilet preparations; paints, varnishes, enamels and other allied products; fertilizers, pesticides and other agricultural chemicals; and adhesives and sealants, explosives, printing ink, and other specialty chemicals and chemical preparations".³⁸⁶

The U.S. chemicals industry was identified in 2002 as a \$454 billion a year industry, and it is now broken down into four different segments: basic chemicals, specialty chemicals, life sciences and consumer products.³⁸⁷

The EU chemical industry breaks down, similarly, into four sectors: base chemicals, which include petrochemicals, plastics and synthetic rubber, man-made fibers, other basic inorganics, industrial gases and fertilizers; specialty and fine chemicals, including paints and inks, crop protection; pharmaceuticals; and consumer chemicals, such as perfumes and cosmetics and soaps and detergents.³⁸⁸

³⁸⁵ Dr. Allen J. Lenz and Dr. John Lafrance, "Meeting the Challenge: U.S. Industry Faces the 21st Century - The Chemical Industry, Executive Summary", U.S. Department of Commerce, Office of Technology Policy (January 1996), at p. 1. See: (<http://www.ta.doc.gov/reports/chemicals/chemical.htm>). The report seeks to identify the most important of the many interacting factors that will determine the future competitiveness of U.S.-based chemicals R&D and production.

³⁸⁶ Ibid, at p. 2.

³⁸⁷ News Release, "2002 Guide to the Business of Chemistry Published", American Chemistry Council, (August 16, 2002), quoting Kevin Swift, chief economist and senior director of ACC's Industry Dynamics and Statistics group, at: (<http://www.americanchemistry.com>).

³⁸⁸ "Barometer of Competitiveness 2002: Business Impact of New Chemicals Policy", CEFIC, at p.3.

“The global trade in chemicals is worth more than \$1,000 billion annually (one trillion). The largest exporter nations for chemicals are: United States - \$94.2 billion; Germany - \$83.2 billion; France and Belgium – each about \$50 billion; and Japan - \$40 billion.”³⁸⁹

The number of ‘downstream’ industries potentially impacted by the White Paper is staggering. It can range 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. As far as the EU is concerned, CEFIC has determined that the EU chemicals industry supplies the following downstream sectors of the economy: textiles and clothing, including leathers; agriculture; metals, mechanical and electrical engineering (including electrical goods, office machines, industrial machinery and metal products); services and administration (including lodging and catering services, inland transport services, maritime and transport services, auxiliary transport services and other market services, and non-market services; construction; automotive; paper and printing products; final consumption products, including chemicals used in photographic development; and ‘other’.³⁹⁰

The U.S. is not the only state that recognizes the extreme importance of the chemical industry to its global competitiveness, and the vital role of science and technology in driving national economic growth. The chemical industry is very important, as well, to the European Union, both in terms of commerce and scientific R&D investment. It “is Europe’s third largest manufacturing industry, with a turnover of 519 billion euro in 2001...It is a value adding industry focused on innovation and growth in global markets delivering one of the largest trade surpluses of any manufacturing industry (65 billion euro per annum)”.³⁹¹ In support of high tech industries such as this, the European Union recently launched its sixth five-year Framework Program for Research and Technological Development (FP6). Unlike the previous FP5 (1998-2002), which “focused on fostering practical technology applications and commercialization”,³⁹² “FP6 seeks to strengthen research networks across Europe by enhancing research facilities’ infrastructures, and by promoting basic research partnerships between individual scientists, laboratories and research organizations in different countries.”³⁹³ In real terms, FP6 will focus on projects that involve more participants and have a longer duration and larger budget than did the

³⁸⁹ Martin Jones, “The Global Chemical and Plastics Industry – How Environmental Standards Are Being Used As a Non-Tariff Trade Barrier”, PACIA (The Plastics and Chemicals Industries Association), Delivered at the Monash Conference Center in Melbourne, Australia, (July 5, 2002), at: ([http://www.pacia.org.au/Media/speech9-Apec5July02\(MJ\).html](http://www.pacia.org.au/Media/speech9-Apec5July02(MJ).html)).

³⁹⁰ Ibid, at p.2. See, also: “Business Impact Study – Sectoral Fact Sheets”, CEFIC (December 2002).

³⁹¹ “EU Chemicals Policy Review – The View of European Mid-Sized and SME Chemical Manufacturers”, CEFIC, (Nov. 28, 2002) at p.1.

³⁹² “International Science and Technology: Policies, Programs and Investment”, Office of Technology Policy, U.S. Department of Commerce, Technology Administration, (December 2000), at p.39. FP5 was a multinational research program intended to network centers of excellence, develop a European approach to large research infrastructure, and undertake measures to promote spin-offs from research (patents, venture capital) and researcher mobility. Ibid.

³⁹³ Dylan Brown, “The European Union’s Sixth Framework Program for Research and Technological Development (FP6)”, Global Tech Update, Office of Technology Policy, U.S. Department of Commerce, Technology Administration, (November 2002), at p. 2.

more narrowly targeted areas and featured projects of FP5.³⁹⁴ “These Integrated Projects are intended to have enough critical mass to lead to a real and lasting influence on Europe’s scientific and/or economic communities.”³⁹⁵

Evidence of the seriousness with which European industry views the risks posed to their global competitiveness appears within a comment letter prepared by Eurochambres, the Association of European Chambers of Commerce and Industry. 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).³⁹⁶

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 European Chemical Industry Council), the primary European chemical industry trade association, recognizes that the WTO rules prevent EU legislation from banning the import of lower cost substances or finished articles containing non-registered substances in order merely to maintain home country competitiveness.³⁹⁷

3.. *The Legal and Industry Case Against the Proposed EU Chemicals Strategy*

At least two legal papers evaluate whether the proposed system can be implemented consistent with the EU’s (and its Member States’) obligations under WTO trade rules. One such paper notes that, “The details of the [REACH] system have not yet been spelled out...But the White Paper framework contains elements that, if implemented in certain ways, risk putting the EU in violation of its WTO commitments”.³⁹⁸ That same paper

³⁹⁴ Ibid.

³⁹⁵ Ibid, at p.3. ‘Integrated Projects’ are large projects or clusters of several smaller projects.

³⁹⁶ Eurochambres, “European Business Position on the ‘White Paper on the Strategy for a future Chemicals Policy’” (Sept. 2001), at p.6.

³⁹⁷ “The chemical industry is truly global. The EU industry needs a level playing field with the rest of the world in order to compete. There is not support for amending legislation in the USA or Asia, who are our main competitors, to take a parallel approach to REACH. Therefore, REACH imposes a cost for chemicals testing and registration which our non-EU competitors will not have to bear. WTO rules and administrative practicalities prevent EU legislation from banning the import of finished articles containing non-registered substances...It is essential that a solution compatible with WTO rules be found to create a level playing field between EU producers of both substances and finished articles, and non-EU manufacturers of the same finished articles who are excluded from the requirements of the REACH system”. “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.

³⁹⁸ Ibid., citing “Executive Summary: Trade Implications of the EU White Paper ‘Strategy For a Future Chemicals Policy’”, a legal paper by law firm Powell, Goldstein, Frazer & Murphy, LLP, April 9, 2002.

recognizes the potential impact of REACH upon downstream users of chemicals and products made with chemicals, from pharmaceuticals to electronic consumer goods. The paper notes that downstream users are currently outside the scope of present EU chemical regulations, and are likely to face rising input costs and possibly supply and trade interruptions as a result of the REACH initiative.³⁹⁹

a. *The EU Chemicals Strategy is a Hazard-Based Regulatory Approach That Discriminates Against Otherwise 'Like' Products*

As these memoranda suggest, a legal analysis of the White Paper proposal should begin by focusing on the 'nature' of the EU's regulatory approach. Like many other EU directives that regulate the treatment of chemicals and products containing them, 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 risk⁴⁰⁰ based on the precautionary principle. The EU has deemed necessary the establishment of such a presumption, as it has for other related directives, for a number of reasons. 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 address systemic problems within the EU, primarily those of EU integration, rather than scientific evidence of actual risks or incidences of harm.⁴⁰¹

For example,

"The White Paper proposes that the most stringent data collection and regulatory review requirements, namely, those for 'authorization' of chemicals giving rise to 'very high concern' – will be triggered for all chemicals with certain characteristics. Substances 'with certain [assessed] hazardous properties' such as category 1 and 2 carcinogens, mutagens, or reprotoxins and

³⁹⁹ Ibid.

⁴⁰⁰ Legal Opinion of Crowell & Moring, examining certain international trade aspects of the proposal contained in the "White Paper, Strategy for a Future Chemicals Policy" ('White Paper'), (Nov. 7, 2002), at p. 6.

⁴⁰¹ According to the EC Commission, "There is a general lack of knowledge about the properties and the uses of existing substances. The risk assessment process is slow and resource-intensive and does not allow the system to work efficiently and effectively. The allocation of responsibilities is inappropriate because authorities are responsible for the assessment instead of enterprises which produce, import or use the substances. Furthermore, current legislation only requires the manufacturers and importers of substances to provide information, but not the downstream users (industrial users and formulators). Thus, information on uses of substances is difficult to obtain and information about the exposure arising from downstream uses is generally scarce....Without test results, however, it is almost impossible to provide such proof. Final risk assessments have therefore only been completed for a small number of substances...Current liability regimes ...based on the principle that those who cause damage should pay compensation for that damage...are insufficient to remedy the problems...Even if a causal connection can be established...between the cause and the resulting damage...compensations awarded by courts of EU Member States...have a limited deterrent effect..." COM (2001) 88 final, "Major Problems Identified By Review", at p.6.

persistent organic pollutants, will only be authorized for specific uses for which they are demonstrated [by industry] to be ‘safe’.”⁴⁰²

For all chemical substances, including those included in the high risk categories, the presumption of harm and the consequent testing, registration and data-sharing burden imposed on industry is based on the attainment of a volume threshold of production and/or importation within a specified, predetermined timeframe. Also, the evaluation of the dangers posed to human health and environment by all possible downstream uses of all such substances, formulations of substances and finished products containing such substances (products deemed likely to react with humans and the environment), including imports, also proceeds from this same presumption of harm.

According to these memoranda, these and other White Paper elements have the potential to violate the GATT Article III and TBT Article 2.1 national treatment clauses⁴⁰³. First, “by working from [administrative] presumptions rather than facts and by basing testing and timing requirements on volumes [and intrinsic chemical properties] rather than product [uses and performance] characteristics, [the White Paper] creates different and less favorable treatment of imported products”, especially for small importers or foreign producers.⁴⁰⁴ The fact that a small importer or foreign producer will be required to share proportionately in costs imposed for a higher threshold of testing that its individual volume-based activities had not triggered is likely to mitigate against any potential cost advantage that it otherwise might have exploited.⁴⁰⁵ To such extent, then, smaller importers or foreign producers would be disadvantaged to the benefit of larger EU producers.⁴⁰⁶

It has been argued, furthermore, that, “the inclusion of the downstream users in the testing process...[would not] involve a shift in the regulatory burden based...on the level of production or importation of ‘like’ product. [Rather, it would be] based...on the level of production or importation of an ‘input’ which is almost certainly not a ‘like’ product”.⁴⁰⁷ Consequently, finished ‘like’ products (e.g., toys, clothing and plastic

⁴⁰² Powell, Goldstein, Frazer & Murphy at p. 11.

⁴⁰³ TBT Art. 2.1 provides that, in respect of technical regulations, Members shall accord products imported from any other Member treatment no less favorable than that accorded the domestic ‘like’-products. It is generally assumed that this obligation is essentially the same as GATT Art. III:4, differing only in scope as it applies to technical barriers to trade. Legal Opinion of Crowell & Moring, *infra*.

⁴⁰⁴ Crowell & Moring, at p. 2.

⁴⁰⁵ For example, if a small importer ships a small volume (under 10 tons) of a chemical he alone would be eligible for the lowest corresponding threshold *in vitro* testing. If, however, within the same period, a larger European manufacturer markets a much larger quantity (over 1000 tons) of the same chemical product, the small importer would be subject to a higher threshold Level 2 testing and registration, along with a corresponding share of the testing costs. This would occur, even though it does not correspond to the importer’s individual activities. *Ibid*, at p. 3.

⁴⁰⁶ *Ibid*, at p. 4.

⁴⁰⁷ With respect to this issue, both legal opinions cite the Appellate Body’s report in European Communities – Asbestos. As one legal opinion letter notes, “It is true that the Appellate Body looked at certain health-related issues regarding asbestos in making a ‘like’ product determination, but it did NOT refer to the legislative aim (or purpose) [e.g., health objective of the measure]. The Appellate Body, rather, very much relied on the line of reasoning in previous WTO case law, [which] in turn, referred back to the traditional pre-aim and effects GATT case law. Those decisions employed a like product analysis based on

medical equipment) 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.⁴⁰⁸

The White Paper's presumption of risk, as evidenced by its dissimilar treatment of and discrimination between otherwise 'like' chemical substances and downstream products, rather than the activities and uses to which they are put, has implications far beyond the producers, importers and industrial downstream users. It also potentially affects the way the public perceives these 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.⁴⁰⁹ As noted by one legal opinion, this is tantamount to creating a "self-justifying" trade barrier" that can adversely and illegally "affect the competitive conditions of imports".⁴¹⁰

Another concern expressed by one of the legal opinion letters has to do with the White Paper's creation of a data-sharing obligation among chemical manufacturers, formulators, processors, and downstream industrial users, including importers. Under this mechanism, "generators of test data under the new system would be encouraged to share the data, and anyone who uses the data would be obligated to pay a 'fair and equitable contribution' to the generator of the data."⁴¹¹ Importers would not be exempt from this obligation; they too

physical characteristics, end-uses, consumer perception and consequent product substitutability and tariff classification". Ibid, at pp. 5-6. The other legal opinion also acknowledges that "the EU was allowed to ban products containing asbestos, while permitting the import and use of products containing substitute fibers, based on their different health risks." However, it also emphasizes that, "the WTO implicitly recognized that...**risk is a function of hazard and exposure**, when addressing not only the carcinogenicity of asbestos, a hazardous property, but also its *use* patterns (e.g., 'carcinogenic risk associated with inhalation') (emphasis added)". Powell, Goldstein, Frazer & Murphy, LLP at p. 12.

⁴⁰⁸ Crowell & Moring at p. 5. This opinion letter cites the example of wooden and plastic chairs with "identical physical characteristics, identical end-uses and similar consumer perceptions. As a result of the burden in the White Paper policy, however, the producer of the plastic chairs would be under an obligation to assess the exposure risk of the chemicals in the chairs. The producer of the wooden chairs would have no such burden...If the plastic chair manufacturer is an importer and the wooden chair producer is domestic, then there is less favorable treatment of the imported product, regardless of whether or not there are also importers of wooden chairs and domestic producers of plastic chairs...Similarly, there could be a significant regulatory distinction between two plastic chairs if one had a different chemical input that was at a different volume threshold than the other. The two plastic chair producers would then have different time tables and levels of testing obligations. Ibid, at p. 6; fn 18.

⁴⁰⁹ One of the stated objectives of the White Paper is to provide "consumers access to information on chemicals to enable them to make informed decisions about the substances that they use..." COM (2001) 88 final, 'Political Objectives of the Proposed Strategy', at p.7.

⁴¹⁰ "The panel in European Communities -- Trade Description of Sardines...specifically warned about government induced consumer distinctions. 'Thus through regulatory intervention, the European Communities consciously would have *created* expectations which are claimed to affect the competitive conditions of imports. If we were to accept a WTO member can *create* consumer expectations and thereafter find justification for the trade-restrictive measure which created these consumer expectations, we would be endorsing the permissibility of *self-justifying* regulatory barriers'" (emphasis added). See: Crowell & Moring, at p. 6, fn 20.

⁴¹¹ "Executive Summary: Trade Implications of the EU White Paper 'Strategy For a Future Chemicals Policy', Powell, Goldstein, Frazer & Murphy, LLP, (April 9, 2002), at p. 7.

would be obliged to assess the safety of their chemicals, to deliver information and to share the costs of testing.”⁴¹² This requirement could potentially be discriminatory 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... ‘TBT Article 5.1.1 requires that a conformity assessment procedure, such as the procedures contemplated for registering existing chemicals, must be prepared, adopted and applied so as to grant access for suppliers of imported products under conditions no less favorable than those accorded to suppliers of ‘like’ domestic products’”.⁴¹³

b. *The EU Chemicals Strategy Constitutes an Unnecessary Restriction on Trade, Denies Interested Stakeholders Participation in a Transparent Procedural Process and Imposes Obligations Not Based on International Standards*

Beyond discussing national treatment and discrimination arguments, these legal opinions and industry comments also focus on the Chemical White Paper’s potential violation of other TBT provisions. Such provisions include: TBT Art. 2.2, which precludes Member states from imposing unnecessary restrictions on trade;⁴¹⁴ TBT Art. 2.4, which requires Member states to use existing relevant international standards or the relevant parts of them as the basis for their technical regulations; TBT Art. 2.5, which requires Member states to justify how a proposed technical regulation that does not use international standards and that will significantly effect international trade pursues a legitimate state objective, is necessary to fulfilling that objective and constitutes the least trade-restrictive alternative available; TBT Art. 2.7, which requires Member states to give positive consideration to accepting as equivalent the technical regulations of other Members, even if these regulations differ from their own; and TBT Art. 2.9, which requires Member states to notify other Member states in writing, at an appropriately advanced stage, about proposed technical regulations that will significantly effect international trade, to afford those Members a reasonable opportunity to submit written comments and engage in discussions with officials about them, and to take these written comments and discussions into account when drafting such regulations.

c. *The Proposed EU Chemicals Strategy Constitutes an Unnecessary Restriction on Trade*

⁴¹² COM(2001) final 88 at p.9.

⁴¹³ Ibid, at p. 8, paraphrasing TBT Art. 5.1.1.

⁴¹⁴ GATT Art. III:4 provides that imported products shall be accorded treatment *to all laws and regulations* that is no less favorable than that accorded the domestic ‘like’ products. TBT Article 2.2 provides in pertinent part that “technical regulations shall not be more trade-restrictive than ‘*necessary*’ to fulfill a ‘*legitimate objective*’, taking into account the risk non-fulfillment would create”. One opinion letter highlights the similarities between the terminology utilized in TBT Art. 2.2 and that used in the GATT Art. XX exception to the ‘national treatment’ standard imposed by GATT Art. III. Ibid, at p. 7.

The question of whether a country has imposed a regulatory measure that does not fulfill a legitimate objective⁴¹⁵ and/or poses an unnecessary restriction on trade and thus violates the TBT Agreement, involves a legal analysis that borrows many analogous concepts from the existing body of GATT case law.⁴¹⁶

One White Paper objective noted by the Commission⁴¹⁷ that has been supported by European industry, is that of maintaining and enhancing the competitiveness of the EU Chemical industry. This position has been advanced in a paper submitted by Eurochambres (the European Chambers of Commerce and Industry)⁴¹⁸ which argued that lower cost imported chemicals and/or finished articles made from such chemicals should not be granted an exemption from the registration requirements, because to do so, would threaten the competitiveness of European industry.⁴¹⁹ According to one legal opinion letter, however, this position is not tenable. A policy in favor of

“...subjecting an article or polymer to health-based regulations purely for competitive reasons...clearly violates [TBT] Article 2.2 because the barrier to trade is not ‘necessary’, and it does not ‘fulfill a legitimate objective’...The exemption presently extends only to articles that do not release significant quantities of the chemical; [If] there is no release, there would seem to be no health-related basis for regulating them, suggesting that competitive concerns would be the principle motivation for eliminating the article and/or polymer exemptions. Under Article 2.2, protecting health is a legitimate regulatory objective, but interfering with foreign competitors is not”.⁴²⁰

Another objective of the White Paper previously mentioned concerns the need to provide consumers with information about chemical substances and related downstream products that have *a priori* been administratively determined to pose a hazard to human health or the environment. The goal is “to enable them to make informed decisions about the

⁴¹⁵ TBT Article 2.2 provides that the term ‘legitimate objectives’ are *inter alia*: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health or the environment”. The Appellate Body in the EC Sardines case has interpreted the use of the words *inter alia* to mean indicate a description of what the nature of SOME such objectives can be. The term is said to extend beyond the list of the objectives specifically mentioned in Article 2.2. See: EC Sardines, at par. 286.

⁴¹⁶ One legal opinion analyzes these similarities. It alleges that, “TBT Art. 2.2 uses terminology that tracks GATT Art. XX and seems similar to that provision in many respects. It is safe to assume that the term ‘necessary’ in Art. 2.2 would be given the same meaning as the term in Art. XX(a)(b) and (d)...GATT Art XX(b) permits measures that are ‘necessary’ to protect human, animal or plant life or health...In both cases, the critical question is whether the measure is ‘necessary’ to fulfill the policy objective...The analytical logic to be followed in interpreting the term ‘necessary’ is the same”. Ibid, at p.7. The opinion letter, furthermore, notes that under GATT Article XX the EC would need to establish that the “chemicals regime would not constitute either a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail OR a *disguised trade restriction on international trade*. “As the White Paper policy is inconsistent with GATT Article III: 4, it follows that it is inconsistent with Art. 2.1 of the TBT Agreement.” Ibid. “The analysis under Article XX of the GATT is basically similar to...Article 2.2 of the TBT Agreement, given that the interpretation of ‘necessary’ in TBT Article 2.2 is derived from the use of the term in GATT Article XX.” Ibid, at p. 9.

⁴¹⁷ COM (2001) 88 final, at par. 2.2 “Political Objectives of the Proposed Strategy”, at p. 7.

⁴¹⁸ See: Eurochambres, “European Business Position on the ‘White Paper on the Strategy for a Future Chemicals Policy’ (September 2001).

⁴¹⁹ Ibid, at p. 6.

⁴²⁰ Powell, Goldstein, Frazer & Murphy, LLP, (April 9, 2002), at p.15.

substances that they use”, and this goal is set forth in the portion of the White Paper entitled, “*Political Objectives of the Proposed Strategy*”: “The public has a right to access to information about the chemicals to which they are exposed. This will enable them to make *informed choices* and to avoid products containing *harmful* chemicals, so creating a pressure on industry to develop safer substitutes...(emphasis added).”⁴²¹ A similar objective has been expressed with regard to the EU eco-labeling scheme applicable to consumer products such as washing machines and computers. And, ‘the right of the public to know’ has been utilized by the EU as a justification for a number of sanitary and phytosanitary measures. These include, among others, the ban on hormone-injected beef products, and the mandatory labeling of certain ‘washed’ eggs and poultry. In addition, it has served both as the centerpiece of the EU’s proposed labeling and traceability regime for bioengineered food and feed products and as the linchpin to resolving the EU Member State’s imposition of a de facto moratorium on biotech food. In each of these cases, the EU has articulated a non-science-based objective to justify SPS and TBT restrictions currently referred to as the ‘Fourth Criterion’. Notwithstanding the EU’s proclamations, however, while consumer information is a worthy cause, it has not yet been deemed a ‘legitimate objective’ by the WTO.

The traditional legal approach to interpreting whether a Member state has imposed necessary measures “requires the country imposing the measure to ensure that the chosen measure entailed the least degree of inconsistency with other GATT provisions. At the very least, use of a reasonably available less [trade-]restrictive option [has been] required.”⁴²² Such an analysis would turn on the consideration of various possible measures, as viewed along a continuum of ‘indispensability’, ranging from ‘absolutely indispensable to achieving stated policy goals’ to ‘justifiable but dispensable because of the availability of other possible less trade restrictive measures’. This consideration would itself be based on “the weighing and balancing of a series of factors...[which] could include the importance of the common interests or values protected and the accompanying impact of the measure on imports”.⁴²³ In choosing between the different types of possible regulatory measures to employ, a state may not, however, rely on the excuse of administrative difficulty as justification for its failure to employ a measure that is arguably the least trade restrictive alternative available.⁴²⁴

With respect to the proposed Chemicals White Paper, “the EC Commissions’ desire to shift the regulatory burden on 30,000 chemicals of longstanding [presence] in the [EU] market [from the government to chemical producers], and to increase the burden on downstream users, does not align with the ‘indispensable’ measure end of the spectrum.

⁴²¹ COM (2001) 88 final at pp. 7 and 9.

⁴²² Ibid, at pp. 7-8. TBT Article 2.3 provides that, “Technical regulations shall NOT be maintained if the circumstances or objectives giving rise to their adoption no longer exist OR if the changed circumstances or objectives can be addressed in a LESS TRADE RESTRICTIVE MANNER” (emphasis added).

⁴²³ Ibid, at p.8, citing the Appellate Body’s decision in Korea - Measures Affecting Imports of Fresh, Chilled or Frozen Beef (WT/DS161, WT/DS169).

⁴²⁴ The opinion letter cited an unappealed portion of the panel’s decision in United States – Standards for Reformulated and Conventional Gasoline (WT/DS2) as support for this proposition. “...The panel...found that a less trade restrictive alternative did not cease to be reasonably available simply because the alternative involved administrative difficulties for a Member”. Ibid, at p. 9.

The White Paper's approach is not indispensable [and therefore, not 'necessary'] to achieving the stated policy goals, particularly in light of the potentially dramatic impact on imports".⁴²⁵ As indicated above, this conclusion would obtain under the broad provisions of the GATT as well as under the more specific provisions of the TBT Agreement.

This shifting of the related testing, registration and data sharing burdens is not necessary for several reasons. First, they appear to be based on a particular volume of a given substance or group of substances that is imported and/or manufactured by a class of producers collectively within a certain fixed time frame. They are not clearly based, as they should be, upon the individual activities of a particular manufacturer or importer with respect to a particular substance, or upon the level of risk to health or environment that those particular activities involving that particular chemical or group of chemicals presents.⁴²⁶ "There is no necessary correlation between volume and risk... The volume threshold simply serves as a surrogate for risk, but it is an arbitrary criterion, as higher volumes do not necessarily mean that actual exposures to the chemical are correspondingly high".⁴²⁷

In effect, the White paper articulates a preconceived notion that different volumes of chemicals relate correspondingly to preconceived notions of risk, irrespective of use, and bases its regulatory requirements on such presumption. Its

"Mandatory collection of a base set of data for all of the 30,000 existing chemicals... would have to be registered, *regardless of whether the data are really needed in view of the actual exposure and risk profile of the substance in question*. This base set requirement increases the cost of selling existing chemicals in the EU market, *and may well eliminate EU imports* of some low-volume, low-margin chemicals, even if those chemicals would be less hazardous than other competing chemicals"(emphasis added).⁴²⁸

⁴²⁵ Legal Opinion of Crowell & Moring, examining certain international trade aspects of the proposal contained in the "White Paper, Strategy for a Future Chemicals Policy" ('White Paper'), (Nov. 7, 2002), at pp. 8-9. The opinion letter, furthermore, identifies "at least two additional points worth noting. First there is no question that the country imposing the questioned measure has the burden of proof in establishing a defense under [GATT] Article XX. Second, there are further tests that must be satisfied in the *chapeau* of Article XX in order to successfully assert the defense. The *chapeau* contains three additional tests. The measure in question should not be a means of 'unjustifiable discrimination, a means of arbitrary discrimination nor a disguised restriction on international trade. However, in the context of evaluating the proposed EC Chemicals Policy where it is fairly clear that the 'necessary' test in Article XX(b) cannot be satisfied, it is not required to go further and examine the proposal in depth with respect to the *chapeau*...[O]ne only reaches the chapeau analysis if it has been first determined that a measure is consistent with one of the enumerated exceptions... In the present case, the White Paper policy fails the 'necessary' test of Article XX(b)..." Ibid, at p. 9.

⁴²⁶ "A set of *in vitro* tests will be required for substances produced or imported in quantities of 1a to 10 tonnes. Full base set testing (performance of a standardized set of tests) will be required for substances produced or imported in quantities between 10 and 100 tonnes." Powell, Goldstein, Frazer & Murphy, at p. 6. Production and imports between 100-1000 tons will require 'Level 1' testing and for those substances above 1000 tons, 'Level 2' testing will be required. Crowell & Moring at pp. 2-3.

⁴²⁷ Ibid, at p. 3., fn 5.

⁴²⁸ "Executive Summary: Trade Implications of the EU White Paper 'Strategy For a Future Chemicals Policy', Powell, Goldstein, Frazer & Murphy, LLP, (April 9, 2002), at pp. 6-7.

Furthermore, it argues that, “[while] the base set requirement does not discriminate on the basis of origin of the chemical...it may constitute an ‘unnecessary’ restriction on trade in violation of [TBT] Article 2.2... if there is no justification for it”.⁴²⁹

d. *The EU Chemicals Strategy Denies Interested Stakeholders Participation in a Transparent Procedural Process*

At least one industry comment letter received from a prominent U.S. trade association, the American Chemistry Council (‘ACC’), alleged that its members have been denied the opportunity to effectively participate in the drafting and review process of regulations to implement the proposed Chemical White Paper Strategy.⁴³⁰ The ACC argued that its members are entitled to a transparent, inclusive and accountable regulatory process within the meaning of TBT Article 2.9,⁴³¹ especially since the proposed regulations will have a significant effect on their trade flows with the EU.⁴³² This requires that the EU, at an early appropriate stage, provide them with a reasonable time period within which to prepare written comments, to engage in discussion about those comments with EU officials and to have their comments and the results of those discussions taken into account.⁴³³

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 2003.⁴³⁴ 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”.⁴³⁵ It reasoned that the “limited Internet review of the new regulations is designed to address only the ‘workability’ of the proposed approach, and may only

⁴²⁹ Ibid.

⁴³⁰ 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)”.

⁴³¹ That provision effectively provides that, “whenever a relevant international standard does not exist or the technical content of a proposed technical regulation is not in accordance with the technical content of relevant international standards, and if the technical regulation may have a significant effect on trade of other Members, Members shall” provide advance notice of the pending technical regulation, and “allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account” in crafting the new regulation.

⁴³² According to the ACC, the “potential impact [may be] well over \$500 million in U.S. chemical exports to Europe”. They “estimated that U.S. commercial interests would bear direct testing costs of some \$400 million under the new EU program, and the cumulative effects of the regulation, including indirect effects, will be many times that”. Ibid, at pp. 1-2.

⁴³³ TBT Art. 2.9.4.

⁴³⁴ “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.

⁴³⁵ Ibid.

provide highlights rather than the full details of the technical regulations being developed.”⁴³⁶ It is also concerned that this type of “limited review procedure could establish a precedent for future standard-setting actions by WTO members in general or by the EU in particular”.⁴³⁷

- e. *The EU Chemicals Strategy Imposes Obligations Not Based on Relevant International Standards or Equivalent Standards of other Member States*

A further argument that can be advanced against the Chemicals White Paper focuses on the EU’s failure, when formulating its proposed strategy, to take into account existing or imminent relevant international standards or the relevant parts thereof as a basis for such regime, as required by TBT Article 2.4.⁴³⁸ To be a relevant international standard, the international standard must bear upon, relate to or be pertinent to the technical regulation.⁴³⁹ If the international standard covers a number of similar products, including the product identified in the regulation, the international standard will be deemed to bear upon, relate to or be pertinent to the regulation in question.⁴⁴⁰

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 Chemical White Paper’s objectives in a less trade-restrictive manner, as required by TBT Article 2.7.⁴⁴¹ For example, the EU did not find suitable the voluntary industry standards encouraged by the U.S. chemicals program, as reflected in the Gore initiative referred to as the High Production Volume Challenge Program, which is a key element of the expanded Chemical Right-to-Know Program. The U.S. Environmental Protection Agency’s HPV program requires a voluntary

⁴³⁶ Ibid., at p.2

⁴³⁷ Ibid.

⁴³⁸ TBT Art. 2.4 provides that, “where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as basis for their technical regulations...” According to the Appellate Body, “The regulating [WTO] member...must [consider] all parts of a relevant international standard that relate to the subject matter of the challenged requirements...[that means]...the regulating member is not permitted to select only some of the relevant parts of an international standard”. *EC Sardines* Appellate Body Decision at par. 250. TBT Art 2.4 provides that WTO members need not use international standards as a basis for technical regulations “when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued...” Ibid, at par. 259. “...An ineffective means is a means which does not have the function of accomplishing the legitimate objective pursued, whereas an inappropriate means is a means which is not specially suitable for the fulfillment of the legitimate objective pursued....The question of effectiveness bears upon the results of the means employed, whereas the question of appropriateness relates more to the nature of the means employed.” Ibid, at par. 285.

⁴³⁹ *EC-Sardines*, at par. 229.

⁴⁴⁰ Ibid, at pars. 231-232.

⁴⁴¹ TBT Art. 2.7 requires Member states to give positive consideration to accepting as equivalent the technical regulations of other Members, even if these regulations differ from their own.

commitment by industry to complete the testing of high production volume chemicals by 2004.⁴⁴²

While the EU has recognized the existence of the U.S initiative, it has deemed it inadequate to fulfill its stated objective. According to the White Paper,

“There is a general lack of knowledge about the properties and uses of existing chemical substances...[which] amount to more than 99% of the total volume of all substances on the [EU] market...[and] the lack of data on existing chemicals is a global concern. For example, the US [has] recently launched initiatives. The US initiative aims to complete testing of 2,800 high production volume chemicals by 2004 (the Gore initiative). The initiative is regarded as the first approach to systematically obtain toxicological and eco-toxicological information about the most abundant existing chemicals on the US market. Studies on the dangerous properties of chemicals performed in the US will not have to be repeated in the Community and vice versa, since testing must be carried out using globally harmonized testing methodology. Accordingly, test results of the HPV/ICCA SIDS program of the OECD will be taken into account to reduce the number of tests to be performed in the EU.”⁴⁴³

f. *The EU Chemicals Strategy Reflects EU Attempts to Inject Nonscientific Principles Into the OECD*

⁴⁴² On April 21, 1998, Vice President Al Gore announced a major expansion of EPA’s chemical right-to-know program. The new initiative builds on EPA’s existing Toxics Release Inventory (1990 Inventory Update Rule under the Toxic Substances Control Act), a program that has helped communities and industry work together to achieve significant reductions in pollution for more than a decade”. “EPA to Expand Chemical Right-To-Know Program and Provide Public With Better Health Data”, EPA website, at: (<http://www.epa.gov/history/topics/earthday/09.htm>). HPV chemicals are defined as those manufactured or imported in quantities exceeding 1,000,000 pounds annually”. The complete list is available at: <http://www.epa.gov/opptintr/chemtest/hpv.htm>. “This program was developed to make publicly available a complete set of baseline health and environmental effects data on HPV chemicals. The data are to be collected for each chemical on EPA’s list of HPV chemicals. Testing will be necessary only when existing data are not adequate. The program will be generally be carried out in a manner consistent with the internationally recognized testing protocol, as developed by the OECD Screening Information Data Set (SIDS) program... SIDS represents an internationally agreed upon set of tests to screen chemicals and identify potential hazards...[The tests are intended] to ensure that the testing can be contributed to the international effort and, conversely, that international SIDS testing and assessments can be used to fulfill the Challenge Program’s requirements. The data generated through this program will be made available to the public, fulfilling the EPA’s commitment to the public’s right-to-know.” “Chemical Right to Know – High Production Volume Chemicals – Frequently Asked Questions”, U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics (March 1999), at pp. 1 and 3. The HPV program is voluntary. Companies that manufacture program chemicals are invited to sign-up and take responsibility for testing each of their chemicals voluntarily, although EPA promises issuance of mandatory testing requirements if voluntary testing does not fulfill its data needs. After the sign-up period closes, chemicals that are not volunteered are expected to be the subject of mandatory testing required by EPA during a final regulatory phase. See: “HPV Chemical Testing Initiative”, Bergson & Campbell, P.C. website at: (<http://www.lawbc.com/hvm/hpv5.htm>) (This law firm claims to specialize in chemical, medical device and diagnostic product approvals); “U.S. Environmental Protection Agency, High Production Volume (HPV) Challenge Program – Chemical Right to Know Frequently Asked Questions”, revised 12/14/99, at: (<http://www.epa.gov/chemrtk/hpvfaqs.htm>). Industry letters were sent during 1998-2000 to the EPA posing technical questions about the HPV Challenge Program. Copies of the letters and the EPA responses to them can be accessed on the EPA website, at: “High Production Volume (HPV) Challenge Program – Technical Letters & Responses”, at: (<http://www.epa.gov/chemtrk/techresp.htm>). The HPV initiative was developed with input from the American Chemistry Council.

⁴⁴³ COM (2001) 88 final, par. 2.1 at p. 6 and par. 2.3 at p. 9..

Not having found the Gore initiative to constitute either a relevant international standard or an equivalent technical regulation, the EU looked beyond it to what it believes are harmonized chemicals management standards enacted by the Organization for Economic Cooperation and Development (OECD). The EU has held out the OECD as one of two international standards bodies involved in the development of global standards for chemicals. The other such body is the International Program on Chemical Safety (IPCS), which was created specifically to develop a ‘scientific basis’ for global chemicals management. “The chemical safety mandate of the IPCS was reaffirmed in 1992 by the UN’s Conference on the Environment and Development in Agenda 21, Chapter 9. In recognizing Codex Alimentarius as a standard-setting organization for foods, the WTO indirectly affirms the role of the IPCS, which performs the scientific work on chemical safety for Codex...”⁴⁴⁴

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.”⁴⁴⁵ Also, it has been alleged that the decisions of the OECD express a consensus that is neither indicative of U.S. views, nor reflective of the application of science-based principles⁴⁴⁶. These allegations rely on conclusions deduced from the structure and operation of the OECD. One such conclusion is that the OECD is a European-dominated ‘political and economic’ organization intent upon overwhelming U.S. economic competitiveness by 2010. Another such conclusion is that OECD decisions are being used to ‘usurp the mandates’ of more science-based international standardization organizations that specialize in chemicals management, such as the IPCS,

⁴⁴⁴ 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>).

⁴⁴⁵ “[The US] supports the OECD’s chemicals work, yet doesn’t endorse hazard-based assessments, a product of the OECD’s chemicals testing framework. Nor does the US support the precautionary principle, concept which OECD documents try to present as part of customary international law”. Ibid, at p. 2. The article cites the following papers: “Uncertainty and Precaution: Implications for Trade and the Environment”, OECD COM/ENV/TD (2000) 114/REV1 (May 4, 2001); “The Role of Precaution in Risk Assessment and Management: An American’s View”, John D. Graham, OMB, remarks prepared for “The U.S., Europe, Precaution and Risk Management: A Comparative Case Study Analysis of the Management of Risk in a Complex World”, (January 11-12, 2002); at: (http://www.whitehouse.gov/omb/inforeg/eu_speech.html).

⁴⁴⁶ The Appellate Body in the *EC-Sardines* case ruled that, under the TBT Agreement, countries must modify existing technical regulations to be based on international standards unless a legitimate objective cannot otherwise be met. Shaffer and Mosoti, at p.15. However, the Appellate Body also ruled that the TBT Agreement does not require international standards adopted by the international standardization community to be approved by consensus. “We uphold the panel’s conclusion...that the definition of a ‘standard’ in Annex 1.2 to the TBT Agreement does not require approval by consensus for standards approved by a recognized body of the international standardization community. We emphasize, however, that this conclusion is relevant only for purposes of the TBT Agreement. It is not intended to effect, in any way, the internal requirements that international standard-setting bodies may establish for themselves for the adoption of standards within their respective operations. In other words,...[this finding] should not be interpreted to mean that we believe an international standardization body should not require consensus for the adoption of its standards”. *EC-Sardines*, at par. 227.

or in food health and safety, such as Codex. It is within these latter organizations that science-based decision-making is the norm and where the U.S. possesses a stronger negotiating position.⁴⁴⁷

A likely consequence of the EU White Paper's adoption of the precautionary principle and the hazard-based assessment approach advocated by OECD standards is that "flawed tests developed by the OECD could label hormones in beef as 'endocrine-disrupting' substances, thereby requiring the denial of market access to such substances."⁴⁴⁸ Since "the science on endocrine disruptors is far from clear...and fails to show a proven risk, the banning of such substances would amount to technical barrier to trade" in violation of the TBT Agreement.⁴⁴⁹ That the standards developed by each of these international standardization bodies have not yet been harmonized is certainly a contributing factor to this ongoing dispute.⁴⁵⁰

The importance of ensuring the objectivity of science-based standards created by specialized and impartial international standardization bodies cannot be overstated. The ability of a country or group of countries to influence the development of these standards is critical to maintaining their global competitiveness. The current conflict between the EU and the U.S. is as much about their disagreement over which international bodies produce the highest technical and expert standards reflective of pure and unadulterated science and related applications, as it is about the place of non-scientific considerations within such standardization bodies. The ultimate prize is the securing of the 'heights', so to speak, namely global harmonization around the standards they champion. This divergence of opinion has influenced why and how States choose among these organizations, thereby impacting the relative global statures of the organizations themselves. And it has already begun to adversely interfere with global trade flows.

⁴⁴⁷ "The OECD is a Paris-based group of 30 industrialized nations that develops and suggests economic policy...The European Commission is a virtual member and active participant in its meetings. Of the OECD's 30 national members, 15 are EU Countries, and 6 are seeking to join the EU. The US contributes 25 percent of the OECD's annual budget. Although consensus is required for decisions, the US has a poor bargaining position due to European dominance and the EU's explicit goal to overwhelm U.S. economic competitiveness by 2010...EU bias in the OECD is, at times, blatant. OECD documents appear to be the work of the EU's legal counsel, in that they develop arguments against the trade position of the U.S. In supporting the EU's interests in such a broad range of areas, it has become necessary for the OECD to duplicate the work, and *usurp the mandates*, of several other global organizations and programs in which the U.S. has a stronger position – *such as the World Health Organization, the Food and Agriculture Organization, Codex Alimentarius, the United Nations Environmental Program and the International Program on Chemicals Safety*" (emphasis added). Ibid.

⁴⁴⁸ Ibid, at p.3.

⁴⁴⁹ "Chemical products must be subjected to OECD or equivalent tests to determine if they have potential cancer causing effects, affect the endocrine system, accumulate in the body, or are persistent or toxic in any way. A positive result indicates a hazard. There are numerous problems with this approach. The science on endocrine disruptors is far from clear. In natural systems, hormones affect the endocrine system. Under certain tests, endocrine disruptors may be inaccurately characterized as dangerous. Further, a National Academy of Sciences report recently stated that it lacked data showing that 'hormonally active compounds caused any adverse impacts on humans'. Ibid, at p.2., citing National Research Council, "Hormonally Active Agents in the Environment", Washington, D.C., National Academy Press, (2000).

⁴⁵⁰ This issue has been brought up for discussion by a number of trade associations, in their comment letters to the recent federal register notice on the TBT Agreement ***.

Annex 4⁴⁵¹ of the TBT Agreement reflects the WTO TBT Committee's recognition of this problem, as have a number of U.S. industry comments submitted to the USTR in response to its Third Triennial Review of the TBT Agreement.⁴⁵²

⁴⁵¹ Section C, paragraph 8 of Annex 4 provides that, "All relevant bodies of WTO Members should be provided with meaningful opportunities to contribute to the elaboration of an international standard so that the standard development process will not give privilege to, or favour the interests of, a particular supplier/s, country/ies or region/s. Consensus procedures should be established that seek to take into account the views of all parties concerned and to reconcile any conflicting arguments. Impartiality should be accorded throughout all the standards development process..." Section D, paragraph 10 provides that, "In order to serve the interests of the WTO membership in facilitating international trade and preventing unnecessary trade barriers, international standards need to be relevant and to effectively respond to regulatory and market needs, as well as scientific and technological developments in various countries. They should not distort the global market, have adverse effects on fair competition, or stifle innovation and technological development. In addition, they should not give preference to the characteristics or requirements of specific countries or regions when different needs or interests exist in other countries or regions. Whenever possible, international standards should be performance based rather than based on design or descriptive characteristics". Section E, paragraph 12 provides that, "In order to avoid the development of conflicting international standards, it is important that international standardizing bodies avoid duplication of, or overlap with, the work of other international standardizing bodies. In this respect, cooperation and coordination with other relevant international bodies is essential".

⁴⁵² The following are excerpts from several industry comment letters. 1) "The International Organization for Standardization (ISO) is recognized as the principal international standards-writing body for non-agricultural products. As such, ISO standards, in many instances, become the basis of the effort to harmonize product standards, conformity assessment, and mutual recognition of certification organizations throughout the world...The U.S. therefore needs to continue to be actively engaged in the ISO process and to facilitate the recognition of the standards we use domestically to ensure that they form the basis of new and/or revised ISO standards or are referenced by them...The TBT Agreement contains provisions that encourage countries to adopt international standards. However, this is repeatedly misinterpreted to apply only to ISO Standards, often putting U.S. products, developed under non-ISO specifications, at a disadvantage...Standards, regardless of their origin, should enjoy WTO recognition as long as they are developed in an open and transparent manner, and have achieved global consensus". Comment Letter dated February 28, 2003, to USTR from American Forest & Paper Association, in response to "Request for Comments on the Operation and Implementation of the WTO's Agreement on Technical Barriers to Trade", at p. 2. 2) "Due to differing regulatory environments, mutual recognition of standards and conformity assessment is often difficult and sometimes impossible to achieve. The *proliferation* of new regulations and supporting conformity programs may be an unavoidable by-product of the TBT Agreement, but there must be sufficient measures to ensure that these programs are fair and equitable for domestic manufacturers as well as those offshore, and that they are transparent and easily accessible...A general misunderstanding of the TBT's definition of international standards has given rise to a wide perception that this means only ISO standards are international standards. The WTO has exacerbated this situation by granting ISO observer status. Many countries, especially emerging nations, are entering into a policy of adopting only ISO standards and referencing them in regulations, to the exclusion of other established international standards. In some sectors, this practice will introduce confusion in the market by encouraging development of ISO standards when market relevant international standards already exist and support healthy international trade". Comment Letter dated February 2003 to USTR from ASME International, "Comments on Operation and Implementation of the WTO TBT Agreement", at p.1. 3) "The development of technically sound standards which promote trade and innovation while ensuring adequate levels of protection and safety can best be achieved on an industry and market sector basis...For some industrial or technology sectors, the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) are the preferred organizations within which to achieve one global standard for an aspect of a product or service...Many others rely on U.S.-based and non-U.S. standards organizations. Some sectors, such as information technology and telecommunications rely on a combination of ISO, IEC, ITU, regional, national, and global, independent bodies to meet their global needs. U.S. based standards organizations such as ASME, ASTM, IEEE and NFPA have for decades

- g. *The EU Has Utilized the Precautionary Principle as a Self-Justifying Standard to Identify and Assess Potential Risks the Eradication of Which is a Legitimate National Objective, and to Manage Those Perceived Risks by Regulating the Activities that May Give Rise to Them*

At least one legal opinion criticizing the EU Chemicals White Paper has posited that, the EU Commission's invocation of the precautionary principle⁴⁵³ can be considered a self-justifying regulatory trade barrier. "The EC asserts the so-called 'precautionary principle' as both the enforcement mechanism and the justification for the shift of the regulatory burden...The EC may attempt to rely on the precautionary principle...as a means of further interpreting the concepts of necessary and legitimate objectives [tests] of...[GATT Article XX(b) [and TBT Article 2.2]]".⁴⁵⁴ In other words, the precautionary

developed international standards used by industry and accepted by governments throughout the world because their documents are developed by processes in which the users have confidence...U.S. industry and U.S. based standards organizations have...long been involved in the development of ISO and IEC standards...Some U.S. based standards organizations, in response to the needs of their constituencies, are now working solely within ISO and IEC for the development of international safety and performance standards...Others have turned to ISO and IEC for the development of overall umbrella standards while mature markets continue to rely on their choices of specific technical standards. What needs to be recognized is that standards are driven by the market forces and technologies influencing a given sector, and by safe and compliant operating experiences in regulated sectors. As a result, the best path to effective standardization will vary. Having one global standard is an important goal; especially in view of the growing convergence of technologies and industrial sectors. Such a single global standard must be able to benefit trade, enable technological innovation, foster competition and establish common safety criteria for the affected sector(s). It is important that sectors are able to reach that goal through a coherent and consistent approach to standardization that is effective for that sector, an approach which adheres to basic principles of standards development and one which addresses the specific safety, health, environmental and market needs of that sector. The determination of international standards status, and thus favored treatment under the TBT Agreement, should be based on procedural elements of the standards development process and global relevance of the standards in question...With the heightened attention that ISO and IEC standards are being given by WTO members, it is important to recognize that the mere existence of an ISO or IEC standard does not mean that it is the relevant international standard or that such a standard indeed reflects international consensus and expertise. These standards, as well as those developed by other organizations, must meet the tests of real usage; they must be technically sound and useful to industries and governments on a global basis. The Annex 4 principle of 'effectiveness and relevance' applies irrespective of the standards organization". Comment Letter dated February 2003, to the USTR from American National Standards Institute (ANSI), "ANSI Paper on International Standards Development and Use", at p. 2-4. 4) "The [Annex 4] principles [for international standardization] laid to rest the assumption that credible standards needed to be developed in a certain body, or in a body with particular membership requirements. Annex 4 is a statement of clarification that should lead to greater implementation among the Members for one simple reason: it makes adherence achievable. It reinforces the rights of governments to choose standards that are most appropriate to their needs. This is useful in industrialized countries where technical regulations keep pace with advancements in technology..." Comment Letter dated February 25, 2003, to the USTR from ASTM, International, "Operation and Implementation of the World Trade Organization's Agreement on Technical Barriers to Trade", at p. 1

⁴⁵³ As defined by the White Paper itself, the precautionary principle is called for "[w]henver reliable scientific evidence is available [that shows] that a substance may have an adverse impact on human health and the environment but, there is still scientific uncertainty about precise nature of the magnitude of the potential damage. [In such case,] decision-making must be based on precaution in order to prevent damage to human health and the environment". COM (2001) 88 final, at p. 5.

⁴⁵⁴ Crowell & Moring, at p. 1.

principle is simultaneously being used to justify several things: 1) the establishment of a presumed hazard based on the intrinsic characteristics of individual chemical substances (or groups of chemical substances), without scientific proof of harm; 2) the assessment that certain chemical substances produced and/or imported at certain volume thresholds pose unacceptable risks of harm, without scientific proof of harm; and 3) the imposition of distinct regulatory treatment for otherwise ‘like’ chemical substances or products (or of similar treatment for otherwise dissimilar chemical substances and downstream products (intermediary and finished), without proof that such is necessary.⁴⁵⁵

Far from being a specimen of clarity as it relates to the WTO Agreements, however, this principle is yet also claimed by the European Commission to constitute customary international law.⁴⁵⁶ Despite conflicting interpretations over what the precautionary principle is supposed to be, its precise definition nevertheless remains elusive.⁴⁵⁷

Amid the obfuscation surrounding the precautionary principle and its application by European regulators to chemicals management, there seems to be at least one safe harbor of clarity and candor. It exists within a paper prepared by a former Swedish scientist who “over the past few decades...has been ‘deeply involved’ in the development of chemicals legislation in Sweden [...He] has seen how the concepts behind the legislation have been

⁴⁵⁵ “The proposed Chemicals Policy is built on **presumption** that all chemicals present a risk. It then requires that the producers prove the negative. This is not consistent with the EC’s own interpretation of the precautionary principle. As stated in the Communication of February 2000: ‘Recourse to the precautionary principle *presupposes* that potentially dangerous effects deriving from a phenomenon, product or process *have been identified*, and that scientific evaluation does not allow the risk to be determined with sufficient certainty.’” Ibid, at p. 14.

⁴⁵⁶ “The Commission asserts that the precautionary principle is an element of customary international law. As support, the Commission refers to several environmental agreements or Ministerial Declarations as evidence. [These include: 1)] *Communication from the Commission on the Precautionary Principle*, COM (2000)1, February 2, 2000, Annex II (‘Communication’) citing references in the Ministerial Declaration of the Second International conference on the Protection of the North Sea (1987); Ministerial Declaration at the Third International Conference on the Protection of the North Sea (1990); the so-called Rio Declaration from the UN Conference on the Environment and Development (1992); the Paris Convention for the protection of the marine environment of the north-east Atlantic (1992); and, the Protocol on Biosafety of 28 January 2000...The only broadly accepted reference is contained in Principle 15 of the Rio Declaration...[which] reads as follows: ‘In order to protect the environment, the precautionary approach shall be widely applied by all States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.’” Crowell & Moring, at p 10 and fns 35-36.

⁴⁵⁷ This confusion exists despite the principle’s recent affirmation by the Plan of Implementation, agreed to at the recent World Summit on Sustainable Development held in Johannesburg. “Section 103(f) of the Plan of Implementation provides, in relevant part, that signatories agree to: ‘Promote and improve science-based decision-making and reaffirm the precautionary approach as set out in principle 15 of the Rio Declaration...’” Crowell & Moring, at p. 10 and fn 37. And, the fact that much has been written about the precautionary principle, in the context of risks to the environment and a number of multilateral environmental agreements (‘MEAs’) have been executed to address activities that potentially give rise to those risks does not help much to further elucidate the concept. The risks referred to are namely those that materialize as a result of transboundary environmental harm to the ‘global commons’. They include, among others, ozone depletion, global climate change, and destruction of biodiversity. The MEAs referred to include among others, the Montreal Protocol, the Global Climate Change Convention and accompanying Kyoto Protocol, and the Biodiversity Convention and accompanying Cartagena Protocol.

exported throughout the western world [i.e., the EU]”.⁴⁵⁸ According to this scientist, “[despite] significant scientific progress in toxicology and risk assessment, the role of high quality science has gradually become less important in shaping national [and EU] policy priorities for chemicals control”.⁴⁵⁹ He warns that, the precautionary principle, as it applies to chemicals, has increasingly been shaped by and become largely a tool of politicians rather than true scientists⁴⁶⁰. And, he argues that the precautionary principle serves to justify actions taken more in response to government data of harm generated for

⁴⁵⁸ Robert Nilsson, “Misguided Precaution – Chemicals Control and the Precautionary Principle in Sweden” (2000). The author works at the Department of Genetic and Cellular Toxicology at Stockholm University.

⁴⁵⁹ Ibid, at p. 1.

⁴⁶⁰ The reduced role of science in chemicals control has largely been due to the growing influence of respected naturalists and environmental pressure groups in Sweden and Europe and their impact upon politicians and government science policies. “With respect to chemical risk, environmental pressure groups nowadays mostly preach a primitive ‘eco-fundamentalism’ based on ignorance of the scientific issues involved... While they have little or no training in the complex toxicological problems in which they are involved, they exert considerable political influence over government agency policies. “By controlling a block of MPs that can swing the votes in favor of either of the socialist block or the liberal/conservatives, the Swedish Green Party, like the German Green, exert a substantial political influence”. For this reason, politicians are often inclined “to play the environment card to secure support of marginal voters.” Ibid. In addition, Dr. Nilsson suggests that “the scientific community itself shares part of the responsibility for [the biased government policies concerning high volume chemicals]. In many cases, researchers with little knowledge of toxicology have acted far outside their own field of competence and provided fallacious interpretations of their results while shamelessly exploiting the news media to promote their own interests. Even when discounting such excesses, in order to secure continued funding with respect to certain ‘grant-dense’ areas like health risks from chemicals, professionals in medicine and epidemiology often tend to overextend interpretation of their own data. In a commentary in the famous U.S. journal *Science* (Taubes, G. 1995) ‘Epidemiology Faces its Limits’, *Science* 269, 164-169), one scientists affiliated with the prestigious U.S. National Institute Environmental Health Sciences bluntly stated that, ‘Investigators who find an effect get support, and investigators who don’t find an effect don’t get support. When times are tough it becomes extremely difficult for investigators to be objective.’” Ibid, at p. 3. Should scientists or other academics ‘step out’ to refute the science embraced by environmentalist groups that influence governmental policy they may be rebuked, disparaged, and possibly even discredited. This recently occurred to Professor (Dr.) Bjorn Lomborg, who teaches statistics at the University of Aarhus. He was recently director of the Danish Institute for Environmental Assessment, in which he reviews the effectiveness of government spending on environmental programs. Dr. Lomborg was ostracized for a recent book he had written in which he sharply refuted the dire pronouncements by environmentalists and scientists “who have long spoken of looming ecological and climatic catastrophes that have yet to materialize. The book, entitled ‘The Skeptical Environmentalist’, is a dense review of data on forests, climate change, food supplies, population growth and other issues. [While] it has not been a runaway best seller, it has been widely cited by conservative groups, commentators and elected officials who oppose strict environmental regulations... Many experts have said that environmental conditions, in most cases, are not nearly as good as Professor Lomborg portrays, them, but also not nearly as bad as some environmental groups and scientists have said... But, [the book] has been attacked as deeply flawed by many environmental scientists since its publication in English in 2001 by Cambridge University Press... The Danish Committees on Scientific Dishonesty, after a six-month review following several complaints filed by scientists, issued a 17 page report on January 7, 2003 concluding that the book displayed ‘systematic one-sidedness’. ‘Objectively speaking’, the committees found ‘the publication of the work under consideration is deemed to fall within the concept of scientific dishonesty’, as defined by Danish rules for scientific integrity. But because Dr. Lomborg was not found grossly negligent, he could not be found formally to have been scientifically dishonest the report said.” Andrew C. Revkin, “Environment and Science: Danes Rebuke a ‘Skeptic’, The New York Times (Jan. 8, 2003).

the political purpose of appeasing consumer concerns than hard scientific evidence of actual harm.⁴⁶¹

“Apart from its use as a justification for otherwise baseless bans or severe restrictions on the use of chemical products, the *precautionary principle* is used to justify the application of the so-called ‘substitution doctrine’...In the way...legislation has been implemented, almost any chemical product that fulfills certain criteria can be subjected to a ban or severe restriction, irrespective of the actual or projected level of risk...A number of excellent...substances were withdrawn on the basis of unsubstantiated claims that they were hazardous to health. They were subsequently replaced by considerably less efficient products, which were no doubt used in larger quantities in order to compensate for their inefficiency...Thus, bizarre consequences have resulted from the unfortunate combination of a reliance on the precautionary principle and the intrinsic properties (hazard) of a chemical. As Paracelsus pointed out in his treatise *Septem Defensiones*, written 1537-1538: any substance can elicit a toxicological response provided that the dose is sufficiently high when administered by an adequate route. (This is often paraphrased as ‘the dose makes the poison.’)...That there is, of course, no such thing as a ‘completely’ harmless chemical product except in the imagination of Swedish legislators and the eco-talibans of the green movement, is a frightening token of an absolute disregard for realities.” (emphasis added).⁴⁶²

4. *The Impact of the EU Chemicals Policy on Developing Countries*

At least one commentator has highlighted the enormous technical, administrative and financial burden that the proposed EU chemicals regime imposes on developing country exporters. Since many commodity products are formulated, manufactured and/or assembled in developing country factories, developing country exporters are likely to

⁴⁶¹ Ibid, at pp. 1-3. “In 1984 an extensive report of the Swedish Cancer Committee (SCC) was presented to the Government. The report’s conclusions were not what the politicians had expected and they were apparently disgusted...What activist politician wants to hear that in comparison with sunbathing, for example, industrial chemicals, pesticides, and air pollution are not significant causes of cancer? They, could of course, accept that smoking was bad, but obviously did not want to convey the message that diet was considered an important factor in avoiding cancer...and that bad genes also play a role. The SCC conclusions were practically identical with those presented...to the Office of Technology Assessment of the U.S. Congress in 1981. Politicians wanted to avoid such political mishaps in the future, so in 1996, when the Swedish Ministry of Environment was looking for specialists on chemical hazards to assist in drafting documentary support for new legislation...the job was conducted mainly by bureaucrats and politicians associated with the Ministry, assisted by some junior consulting firm employees with little knowledge of toxicology. A few scientific experts, diluted by a majority of laymen, were engaged to serve as hostages with little possibility of influencing the work. Whereas [this] report was translated into English and published by a major international scientific publishing company, the 1997 report from this ‘Chemical Committee’ called ‘A Sustainable Policy for Chemicals’, was a major disaster and received scathing criticism...*Today...politicians more or less openly admit that, rather than basing their policies on ‘real risk’, they are mostly guided by ‘risk perception’, a concept heavily tainted by a new kind of superstition. Instead of making an attempt to distinguish between what are significant and insignificant risks, our regulators tend to yield to media blackmail that will only accentuate the trend towards an increasing lack of rationality in risk management to the detriment of progress in modern society. Each time regulatory action is taken that is based solely, or mostly, on public ‘concern’ and where the actual risk is negligible, the mere fact that regulatory action is taken will strengthen the belief in its absolute justification. The layman critical of experts will exclaim: ‘You see, it was dangerous – we were right after all!’*” (emphasis added). Ibid.

⁴⁶² Ibid, at pp. 8-9.

bear the brunt of these EU regulations, though in most instances they lack the technical capacity to satisfy them.⁴⁶³

“Developing countries are major suppliers in the world market of commodity chemicals, plastic resins, products made from plastics such as toys, chemical fibers, and textiles and apparel made from chemical fibers. The new EU chemical regime envisioned by the White Paper may require a cutoff of their access to the EU market unless they develop the extensive data sets required, or pay the owner of an existing data set. The new barrier to market access will be all the higher if EU authorities refuse to recognize the tests performed by developing country laboratories or if an exporter lacks access to laboratory capacity. Developing country exporters will be particularly prejudiced if the new chemical regime micro-regulates uses, or reaches downstream articles, as discussed above.”⁴⁶⁴

Due to stark differences in technical capacity and the lack of similar regulations in either their domestic markets or non-EU export markets, developing country industries are simply not prepared or competent to meet these requirements. If they are now compelled to undertake the rigorous testing, registration, and downstream risk assessment obligations imposed by the proposed EU Chemicals strategy, the cost advantages they had long secured in order to compete effectively with the developed world would no longer be available, severely setting back their economic advancement.

The International Council of Chemical Associations has embraced the need identified by governments and civil society to “support developing countries in strengthening their capacity for the sound management of chemicals and hazardous wastes” pursuant to globally harmonized standards, consistent with the need to promote sustainable development (SD).⁴⁶⁵ The ICCA recognizes that such SD goals are best advanced by providing developing countries with technical and financial assistance.⁴⁶⁶ However, the ability of developing countries to achieve the goal of sustainable development will likely be compromised if they are compelled to satisfy burdensome and costly national regulations and/or standards that exceed international standards and constitute international trade barriers. In other words, the ICCA’s support of SD goals did not likely extend to rendering financial assistance to developing countries merely to ensure their compliance with the EU chemicals regulatory regime.

The WTO, in its Ministerial Declaration agreed to at the Doha Round, recognizes that

“International trade can play a major role in the promotion of economic development and the alleviation of poverty...and recognize[s] the need for all...peoples to benefit from the increased opportunities and welfare gains that the multilateral trading system generates. The majority of WTO Members are developing countries. We seek to place their needs and interests at the heart of the Work Programme adopted in this Declaration...we shall continue to make positive efforts designed to ensure that developing countries, and especially the least-developed among them,

⁴⁶³ As previously discussed, even U.S. importers of such finished products will be responsible for undertaking an assessment if they directly export those products to the EU.

⁴⁶⁴ Powell, Goldstein, Frazer & Murphy, LLP, at p. 17.

⁴⁶⁵ “A Golden Opportunity to Progress Sustainable Development”, ICCA at the Johannesburg Summit – Committed to Sustainable Development, (Jan. 10, 2003), at pp. 1-2, at: (<http://www.icca-at-wssd.org/index4.html>).

⁴⁶⁶ Ibid, at p. 2.

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” (emphasis added).⁴⁶⁷

The WTO’s TBT Agreement clearly suggests according developing countries ‘special and differential treatment’ in order to help them participate in the global economy. TBT Article 12 states that, “Members shall provide differential and more favorable treatment to developing country Members.” In the context of technical regulations and standards, more specific consideration must be given to developing country needs and capacities. As required by TBT Article 12.3, “in the preparation and application of technical regulations...[Members shall] take account of the special development, financial and trade needs of developing country Members, with a view to ensuring that [the regulations] do not create unnecessary obstacles to exports from developing country Members.”

Based on a cursory 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. While the international trade system affords the EU the opportunity to regulate trade in order to respond to actual health, safety and environmental risks, it does not grant them the unfettered right to act in an arbitrary manner that impedes rather than facilitates developing country trade.

E. The Amended EU Cosmetics Directive

The EU Commission and the EU Parliament have recently enacted two amendments to the EU Cosmetics Directive 76/768/EEC⁴⁶⁸, both of which are contained within new Directive 2003/15/EC.⁴⁶⁹ Examples of cosmetics include creams, lotions, gels, oils, soaps, shampoos, deodorants, perfumes, hair-dyes and sprays, make-up, shaving products, and sunbathing products.⁴⁷⁰ 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,

⁴⁶⁷ Ministerial Declaration of the World Trade Organization (WT/MIN(01)/DEC/W/1), Ministerial Conference Fourth Session, Doha, (Nov. 9-14, 2001), at par. 2.

⁴⁶⁸ Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products.

⁴⁶⁹ This agreement was reached on November 7, 2002. They are contained within EU Directive 2003/15/EC of the European Parliament and of the Council (Feb. 27, 2003). Official Journal of the European Union (Mar. 11, 2003).

⁴⁷⁰ “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>). 76/768/EEC defines the term cosmetics very broadly as “any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odor and/or protecting them or keeping them in good condition.”

where OECD-approved alternatives to animal testing exist.⁴⁷¹ The other proposed amendment bans the use in cosmetics of substances that cause cancer or pose reproductive mutagenic hazards.⁴⁷² The amendments are to take effect no later than 2009.⁴⁷³

1. *The Proposed EU Ban on Animal Testing and Related Product Labeling*

The proposed ban on animal testing would conflict directly with FDA rules requiring animal testing of certain cosmetics that are classified as over the counter drugs in the U.S, including anti-dandruff shampoos, sunscreens, and fluoride toothpaste.⁴⁷⁴ The Directive provides an ‘exceptional circumstances’ derogation from this rule “where serious concerns arise as regards the safety of an existing cosmetic ingredient. A derogation shall only be granted if the ingredient is in wide use and cannot be replaced by another ingredient able to perform a similar function, [or] if the specific human health problem is substantiated and the need to conduct animal tests is justified and supported by detailed research.”⁴⁷⁵ The directive also calls for the sharing of alternative testing information with non-EU companies in order to facilitate recognition of alternative testing methods developed in the EC.⁴⁷⁶

The European Cosmetics, Toiletry and Perfumery Association (‘COLIPA’)⁴⁷⁷ has argued essentially that the animal testing ban is unnecessary (i.e., that it serves no useful purpose). In particular, it has claimed that,

“Very few tests on animals are carried out specifically for the cosmetics industry...Moreover, research on animals conducted on cosmetic companies’ premises ceased years ago. Each company has developed its own knowledge, database and specific in vitro research methods in order to guarantee the global safety of finished products. Existing alternatives are broadly used. Without exception they allow the least tolerated substances to be eliminated and those that are best accepted to be identified for a specific use. Therefore, they have helped to significantly decrease the number of animals used in the safety assessment process. Although relatively few alternative methods have obtained international recognition and validation, there are a wide range of non-animal alternative tests that are used to screen substances, or combinations of substances, that may have mutagenic, carcinogenic or severe irritant potential....Unfortunately, the few remaining tests on animals are indispensable in specific cases. In order to guarantee consumer safety, the vast majority of regulators request animal testing when alternative methods do not exist or do not provide sufficient information to assess the correct level of risk.”⁴⁷⁸

⁴⁷¹ Ibid, new Article 4a (1).

⁴⁷² Ibid, new Article 4b.

⁴⁷³ Ibid, new Article 4b (2.2)

⁴⁷⁴ NTE Report at p. 115.

⁴⁷⁵ 2003/15/EC, new Article 4a (2.4).

⁴⁷⁶ Ibid, Preamble, par. 10.

⁴⁷⁷ COLIPA represents the interests of the cosmetic, toiletry and perfumery sectors which together comprises a 56.1 billion euro industry.

⁴⁷⁸ “Animal Testing Labeling: Information or Misinformation?, The EU Cosmetics Directive – Issues and Debates”, at: (<http://www.colipa.com>).

COLIPA has argued that imposition of the ban on existing cosmetics would 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. This means that there is no such thing as a ‘cruelty-free’ industry. All existing chemicals have been tested on animals and the use of any new chemical will be subject to animal testing until such time as all necessary validated alternatives are in place. This is the price to pay for consumer safety, and is a legal requirement under EU legislation for placing chemicals on the European market.”⁴⁷⁹

In addition, COLIPA has argued that the marketing ban would have a direct adverse impact on industry innovation.

“A marketing ban would make it illegal to use any new ingredient that had been tested on animals. As a direct result, innovation within the European cosmetics industry would come to an end. Without innovation, products such as decay-fighting toothpastes or sunscreen with UV filters would never have been developed...A successful industry plays a central role in generating and sustaining employment in addition to a healthy trade balance. By keeping ahead of international competition through the introduction of breakthrough products, industry is also continually generating new scientific expertise which ultimately leads to the discovery of new alternative testing methods.”⁴⁸⁰

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.⁴⁸¹ Furthermore, it does not appear that the views of stakeholders such as U.S. exporters and importers or the U.S. government have been taken into account. Consequently, it appears that the legislative process was neither transparent nor inclusive for these stakeholders, who were effectively denied an opportunity to participate in the process of developing the regulations. As previously discussed, the TBT Agreement requires that all interested stakeholders be afforded written notification, an opportunity to be heard (a transparent process) and accountability from the government that is promulgating regulations likely to have a significant and adverse impact on international trade.

The animal testing ban amendment, moreover, permits manufacturers, distributors, retailers, and importers to label their cosmetic products as ‘animal test free’. The consumer label can state “that no animal tests have been carried out by the manufacturer and its suppliers on the finished product, or its prototype, or any of the ingredients contained within it...only if the manufacturer and his suppliers have not carried out or

⁴⁷⁹ Ibid.

⁴⁸⁰ Ibid.

⁴⁸¹ Ibid. “Although [PPMs] are acknowledged as potentially constituting useful tools to combat pollution and protect the environment, there is a consensus to consider that their use should be subject to stringent conditions...There is a general agreement amongst WTO Members, including the European Union and its Member States, that the use of trade measures based on PPMs should only be permitted if they are supported by an agreement at the international level...There is not reason to believe that an EU marketing ban on products tested on animals would be analyzed differently [than the Shrimp/Turtle case (Decision WT/DS58/AB/R of Oct. 12, 1998)].” Ibid.

commissioned any animal tests...”⁴⁸² The voluntary labeling rule is intended to provide consumers with an informed choice. It will enable consumers “to know whether cosmetic products on the market have been tested on animals, so that they may choose to buy such products according to their own personal and ethical beliefs.”⁴⁸³ However, according to COLIPA, the voluntary labeling would mislead consumers and promote false and unsubstantiated claims⁴⁸⁴, despite the Preamble’s instruction to Member States to prevent against such practices.⁴⁸⁵ As COLIPA points out, “The criteria to which the Environment Committee wishes to subject the use of the voluntary claims would not fulfill the basic requirements that any legislation in this area should pursue i.e., the protection of companies against unfair competition and, more importantly for consumers, against misleading advertising.”⁴⁸⁶

2. *The Authorization and Banning of Chemicals Used to Produce Cosmetics*

As for the use of chemicals in cosmetics, the substances that would be banned under this proposed amendment include two phthalates – dibutyl phthalate (DBP) and di(2-ethylhexyl) phthalate (DEHP).⁴⁸⁷ Phthalates are used on cosmetic products as alcohol denaturants, film formers, plasticizers, solvents and fragrance ingredients.⁴⁸⁸ A third substance, butylbenzyl phthalate (BBzB), would soon be added to the list of banned substances, according to the directive, and industry officials say the action could affect lead acetate as well. According to one European Commission official, “these substances are on the list of CMR (carcinogenic, mutagenic and reprotoxic) substances that will now be banned through this directive.”⁴⁸⁹ “The general principle of the directive is that cosmetics must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use.”⁴⁹⁰

While the directive would impose an outright ban on the use of CMR category 1 and category 2 substances in the manufacture of cosmetics⁴⁹¹, it may allow the use of

⁴⁸² Ibid, new Article 4a (5).

⁴⁸³ “Animal Testing Labeling: Information or Misinformation?, The EU Cosmetics Directive – Issues and Debates”, at: (<http://www.colipa.com>).

⁴⁸⁴ Ibid.

⁴⁸⁵ 2003/15/EC, Preamble, par. 11.

⁴⁸⁶ “Animal Testing Labeling: Information or Misinformation?, The EU Cosmetics Directive – Issues and Debates”, at: (<http://www.colipa.com>).

⁴⁸⁷ Bengt Ljung, “EU Reaches Agreement to Impose Ban on Use of Toxics in Cosmetic Products”, International Environment Daily, (Nov. 27, 2002). These two substances are classified as ‘category 2’ substances on the CMR list, indicating they are ‘toxic to reproduction’.

⁴⁸⁸ “According to background documents released by the European Commission, at least six phthalates have been found in cosmetics in separate studies by U.S. environmental groups and Swedish health authorities, and eight of ten cosmetics examined in the two studies contained at least one phthalate. Ibid.

⁴⁸⁹ Ibid, quoting Per Haugaard, the European Commission’s industry affairs spokesman. These substances “are classified as category 1, 2 or 3 under an EU directive or classification and labeling of dangerous substances (Directive 67.548/EEC). Ibid.

⁴⁹⁰ Bengt Ljung, “EU Reaches Agreement to Impose Ban on Use of Toxics in Cosmetic Products”, International Environment Daily, (Nov. 27, 2002).

⁴⁹¹ “A category 1’classification means the substance is a proven hazard to humans, while a ‘category 2 listing means two independent animal tests have shown that the product is not ‘safe’ for use.” Ibid.

category 3 substances⁴⁹² if a full risk assessment establishes the ‘safety’ of such substances.⁴⁹³ The manufacturer would be required to perform a specific risk assessment for cosmetic products intended for use on children under three years of age and for products intended exclusively for use in external intimate hygiene.⁴⁹⁴

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.⁴⁹⁵ Consequently, it would appear that the same arguments advanced by the business and legal communities against the White Paper’s treatment of *existing* substances would also apply to this provision of the cosmetics directive as well.

3. *The Cosmetic Directive’s Ingredient Labeling Provisions*

The banned substances amendment to the cosmetic directive would require full ingredient identification and labeling of all cosmetic substances.⁴⁹⁶ This labeling mandate is intended to protect consumers who suffer from fragrance allergies (less than 0.1% of the EU population).⁴⁹⁷ According to CALIPO, “there are basically 26 fragrance ingredients that can cause allergic skin reactions, and the presence of one or more of these fragrance allergens is unavoidable in cosmetic products due to their widespread natural occurrence in plant extract (e.g., rose, lavender, camomile, ginger, cinnamon, narcissus and lemon).⁴⁹⁸ However, this rule would require listing non-allergens on the label as well.

CALIPO has argued that,

“This approach disregards the complexity of fragrance compounds” and that it is impractical to “list every single constituent of each cosmetic product...Fragrance compositions used in cosmetics

⁴⁹² “For substances identified as ‘category 3’, the hazard evidence is not as strong.” Ibid.

⁴⁹³ Ibid; 2003/15/EC, amended Article 7(a)(1)(d).

⁴⁹⁴ Amended Article 7(a)(1)(d).

⁴⁹⁵ On November 19, 2002, it was reported that scientific tests performed by the Cosmetic Ingredient Review (CIR) panel, reaffirmed that “phthalates are safe for use in cosmetic products in present practices of use and concentration.” It found “no evidence to suggest that consumer exposure to phthalates in cosmetics and personal care products poses a health risk.” The CIR panel is comprised of independent toxicologists and dermatologists, and is funded by the cosmetics industry with representatives from the Food and Drug Administration and the Consumer Federation of America as liaisons. Its decision followed a year-long review of existing and new evidence on three phthalates: di-methyl phthalate (DMP), di-ethyl phthalate (DEP) and di-butyl phthalate (DBP). See: “Panel Reaffirms Phthalates in Cosmetics Are ‘Safe For Use’”, Phthalate Information Center, American Chemistry Council website (Nov. 19, 2002), at: (<http://www.americanchemistry.com>)

⁴⁹⁶ Amended Article 6 (1)(g).

⁴⁹⁷ “Animal Testing Labeling: Information or Misinformation?, The EU Cosmetics Directive – Issues and Debates”.

⁴⁹⁸ Ibid.

are complex mixtures of hundreds of ingredients, which together give the compound its unique scent. Some of the ingredients are natural extracts which themselves contain hundreds of constituents. [For example,] in rose oil greater than 1,000 individual substances have been identified.”⁴⁹⁹

This argument is similar to that advanced about the impracticality of the White Paper’s chemicals registration requirement. It also imposes an undue administrative burden on manufacturers, distributors and importers that is unnecessary considering other less trade-restrictive alternatives. 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.⁵⁰⁰

F. The EU Biocidal Products Directive⁵⁰¹ -- An Attempt to Regulate and Manage, Rather Than Encourage Industrial Uses of Biotechnology:

1. The Promise of Industrial Biotechnology

The EU, in its report entitled, “Life Sciences and Biotechnology – A Strategy for Europe”, extols the benefits and opportunities that await the European Union should it be able to quickly develop an R&D base to exploit life sciences and biotechnology.

“Life sciences and biotechnology are widely recognized to be, after information technology, the next wave of the knowledge-based economy, creating new opportunities for our societies and economies...A revolution is taking place in the knowledge base of life sciences and biotechnology, opening up new applications in healthcare, agriculture and food production”, and environmental protection, as well as new scientific discoveries. This is happening globally. The common knowledge base relating to living organisms and ecosystems is producing new scientific disciplines such as genomics and bioinformatics and novel applications...These in turn offer the prospect of applications with profound impacts throughout our societies and economies, far beyond uses such as genetically modified plants. The expansion of the knowledge base is accompanied by an unprecedented speed in transformation of frontier scientific inventions into practical use and products and thus also represents a potential for new wealth creation; old industries are being regenerated and new enterprises are emerging.”⁵⁰²

As ‘enabling technologies’, the EU views life sciences and biotechnology as serving both private and public interests. Aside from use of ‘green’ biotechnology in agriculture (e.g., GM food, feed and seed), the EU envisions beneficial medical (health-related) uses of ‘red’ biotechnology for the production of plant-based drugs and facilitation of disease

⁴⁹⁹ Ibid.

⁵⁰⁰ Ibid.

⁵⁰¹ Directive 98/8/EC of the European Parliament and of the Council, Concerning the Placing of Biocidal Products on the Market, (Feb. 16, 1998) as reported in the Official Journal of the European Communities (April 24, 1998).

⁵⁰² “Life Sciences and Biotechnology – A Strategy for Europe”, Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions COM(2002) 27, at pp. 7-8.

management⁵⁰³. And the EU also foresees valuable uses of ‘white’ biotechnology (industrial biotechnology). The term ‘industrial biotechnology’ has been defined by the OECD as, “that set of technologies that come from adapting and modifying the biological organisms, processes, products, and systems found in nature for the purpose of producing goods and services.”⁵⁰⁴

The EU has identified the following potential for industrial biotechnology:

“Biotechnology has the potential as well as, to improved non-food uses of crops as sources of industrial feedstocks, or new materials such as biodegradable plastics. Plant-based materials can provide both molecular building blocks and more complex molecules for the manufacturing, energy and pharmaceutical industries. Modifications under development include alterations to carbohydrates, oils, fats and proteins, fibre and new polymer production...Biomass could contribute to alternative energy with both liquid and solid biofuels such as biodiesel and bioethanol, as well as to processes such as bio-desulphurisation...[It provides] new ways to protect and improve the environment [through] bioremediation of polluted air, soil, water and waste as well as [through] development of cleaner industrial products and processes, for example based on use of enzymes (biocatalysts).”⁵⁰⁵

The industrial uses to which biotechnology can be applied are manifold. According to one European industry executive, Dr. Stefan Marcinowski, Member of the Board of Executive Directors and Research Executive Director of BASF,

“‘White’ biotechnology aims to understand the metabolism of microorganisms and ultimately optimizes them for utilizing biotransformations on an industrial scale – often based on renewable raw materials. Today, white biotechnology is already the route of choice for the production of many amino acids, vitamins, antibiotics and steroids, for alcohol and lactic acid, or for high-fructose corn syrup and detergent enzymes...Because of the high efficiency of biological systems, biotransformations will play a key role in sustainable development. The technological advances for example in genomics will further enhance the industrial exploitation of enzyme reactions and fermentation. *The spectrum of applications for white biotechnology offers a huge economic potential in different industry sectors that range from chemicals and water treatment, to pulp and paper and energy* (emphasis added).”⁵⁰⁶

A recent OECD report, as well, identifies a number of affected industry sectors, including pharmaceuticals, fine chemicals, bulk (intermediate) chemicals, plastics, food and feed processing, natural fiber processing, textiles, pulp and paper, minerals and energy.⁵⁰⁷

⁵⁰³ Ibid, a pp. 10-11.

⁵⁰⁴ “The Application of Biotechnology to Industrial Sustainability”, Organization For Economic Cooperation and Development (OECD), Executive Summary at p. 10 (2001).

⁵⁰⁵ Ibid, at p. 11.

⁵⁰⁶ Dr. Stefan Marcinowski, “Biotechnology for Europe – An Industrial Overview on Potential Barriers and Needs”, EU Presidency Conference on Biotechnology, Copenhagen (Oct. 21, 2002).

⁵⁰⁷ “The Application of Biotechnology to Industrial Sustainability”, at pp. 12-15. The report cites actual industry case studies that show how governments and the private sector apply biotechnology in industrial development. Among the many conclusions drawn by the report are the following: 1) “Application of biotechnology in a wide range of industry sectors has invariably led to both economic and environmental benefits via processes that are less costly and more environmentally friendly than the conventional processes they replace; 2) The application of biotechnology to increase the eco-efficiency of industrial products and processes can provide a basis for moving a broad range of industries toward more sustainable production; and 3) The main driving forces for adoption of more efficient bioprocesses and bioproducts are

The EU predicts a global market of EUR 1.5 trillion by the year “2010 for industrial biotechnology in sustainable and environmental technology (only partly biotech)”, which includes a global market of EUR 90-120 billion for environmental technology alone.⁵⁰⁸

2. *EU Regulation of Industrial Biotechnology May Help EU Biotech Firms to Compete Against Those in the U.S.*

Despite the promise of industrial biotechnology, the European Commission clearly recognizes that there is a gap between Europe’s science capacity and its ability to convert that capacity into revenue generating innovative processes and products for market consumption. This gap is most apparent when the EU biotech market is compared with that of the U.S. In this regard, the Commission has found that,

“Total European investment in R&D is lagging behind the United States...[Although] there are now more dedicated biotechnology companies in Europe (1570) than in the United States (1273) [which] is an encouraging demonstration of entrepreneurial potential in Europe...the U.S. biotechnology industry started earlier, produces more than three times the revenues of the European industry, employs many more people (162,000 against around 60,000) is much more capitalized and, in particular, has many more products in the pipeline...Intellectual property rights were identified as a relevant factor [in analyzing why] EU industry currently lags behind that of the United States in the biotechnology sector.”⁵⁰⁹

It appears, however, that the EU does not intend to eliminate this gap through introduction of market incentives. Contrary to European industry pleas “to develop a reliable framework to attract more investment without compromising health or environmental safety”,⁵¹⁰ the EU has instead settled on another regulatory regime, namely the EU Biocidal Products Directive.⁵¹¹

3. *The EU Biocidal Products Directive (BPD) and Proposed Biocidal Products Regulation Summarized*

cost savings and improved product quality/performance. Environmental considerations were...an important but secondary driving force.” Ibid, at p. 16.

⁵⁰⁸ “Life Sciences and Biotechnology – A Strategy for Europe”, at p. 12.

⁵⁰⁹ Ibid, at pp. 14 -16.

⁵¹⁰ Ibid, at p. 8. According to one European industry official, “...While Europe continues to struggle with incomplete as well as not-yet-implemented regulatory schemes, other countries are moving ahead with approvals of innovative and beneficial biotech products beyond pharmaceuticals. The result of losing ground to other countries with regard to market approvals is a mounting number of trade conflicts between the EU and those nations.” Dr. Stefan Marciniowski, “Biotechnology for Europe – An Industrial Overview on Potential Barriers and Needs”, at pp. 7-8.

⁵¹¹ The EU Commission’s intention to regulate and manage industrial biotechnology finds support in the OECD report, which concludes, among other things, that “Successful biotechnology/ bioprocess development requires effective management of technology development by companies and use of tools that assess both the economic and environmental performance of technology during its development. There is a need for improved assessment tools that are easier to use and at earlier stages of the technology development process.” Ibid, at p. 16

The BPD entered into force on May 14, 1998. It covers any product that “is an ‘active substance’⁵¹², 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.”⁵¹³ The scope of the Directive is very broad, covering 23 different product types.⁵¹⁴ Biocidal products may be used as

“Disinfectants for home and industrial use; chemical preservatives for manufactured and natural products; and non-agricultural pesticides for use against insects, slugs and snails, rodents and other vertebrates. They also include a number of very specialized products such as embalming/taxidermist fluids and anti-fouling products [used on hulls of vessels]. While some biocidal products are sold directly to consumers, many such products are used only in industrial situations either during the processing of industrial products or to extend product performance while in use. [Biocidal products] have extended service life and subsequently reduced the wastage of a range of widely used products, including building timber, paint, adhesives, plastics, leather, paper and metal working fluids used in engineering [e.g., autos].”⁵¹⁵

Biocidal products are intended to have beneficial effects (e.g., disinfection of drinking water by killing bacteria and viruses in water) that are very important for the general public health and without which significant public health problems may occur.⁵¹⁶ “For specific applications there may be a range of active substances to choose from and the important step is then to know the undesired effects, if any, and then select the one causing the minimum adverse effect. In addition, there must be a range of actives on the market to allow change of substances to avoid resistance to an active.”⁵¹⁷ While biocidal products usually can be made and used without significant risk to the producer, user or the environment, they are nevertheless designed to kill or render harmless living organisms. Consequently, 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.⁵¹⁸ The objective of the BPD is therefore to ensure that biocidal products pose no unacceptable risk to humans, animals or the environment, and endeavors to facilitate this through the establishment of a single European market in biocidal products.⁵¹⁹ Many questions have been raised by industry

⁵¹² An ‘active’ substance is defined as “a substance or micro-organism including viruses or a fungus having general or specific action on or against harmful organisms.” Directive 98/8/EC, Article 1(d).

⁵¹³ Directive 98/8/EC, Article 2(1)(a).

⁵¹⁴ “Biocidal Products Directive (98/8/EC), at: (<http://europa.eu.int/comm/environment/biocides/>), the Europa website. The Directive will not apply to certain products already covered by other Community Legislation, such as plant protection products, medicines and cosmetics. Ibid. The website lists all 23 biocidal product types.

⁵¹⁵ “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).

⁵¹⁶ European Chemicals Bureau, “Overview of Biocidal Products Directive”, at: (<http://ecb.jrc.it/biocides/content1.htm>).

⁵¹⁷ Ibid.

⁵¹⁸ Ibid.

⁵¹⁹ Ibid, at p. 2. In the USA, industrial biocides have been regulated for many years by the U.S. Environmental Protection Agency (EPA), under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

stakeholders about the types of products covered by the directive. The EU recently prepared responses to those questions, of which there are many.⁵²⁰

The BPD concerns the authorization and placing on the market for use of biocidal products. It requires that all *new* biocidal products (both active substances and preparations containing one or more ‘actives’) 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, under two review regulations.⁵²¹ During this transitional period, when an active substance is reviewed and not yet included in one of the Annexes, Member States may continue to apply their national rules on biocidal products containing existing active substances until the Commission decides whether to include the particular substance in one of the directive’s annexes.⁵²² An evaluation of existing products by the Commission will be triggered once such data has been submitted or otherwise notified.

The first review regulation (2000/1896/EC) to implement the BPD came into force in September 2000.⁵²³ Its objective is threefold: “to collect the necessary data from producers and formulators in order to compile a formal EU list of existing active substances currently on the EU market; to develop a list of existing active substances which will be supported initially by limited data and ultimately by complete data; and to assign priorities for call-in [by product type] of supported substances.”⁵²⁴ The regulation sets forth procedures for companies to identify and notify the EU of *existing* active substances.⁵²⁵ The first product types that will be reviewed are wood preservatives and rodenticides. Companies that have already notified these substances must submit supporting documentation (a ‘dossier’) before March 28, 2004.⁵²⁶ “Companies are encouraged to make joint submissions when notifying and submitting full dossiers...”⁵²⁷

⁵²⁰ See: “Manual of Decisions For Implementation of Directive 98/8/EC Concerning the Placing on the Market of Biocidal Products”, Last Modified 1/23/03; “Guidance Document Agreed Between the Commission Services and the Competent Authorities of the Member States for the Biocidal Products Directive 98/8/EC”, Doc-Biocides-2002/04-rev1 (July 30, 2002).

⁵²¹ Mike Freemantle, Bryan Backhouse, “Global Implications of the European Biocidal Products Directive” (2001), at p. 1, at: (<http://ecb.jrc.it/biocides>).

⁵²² Biocidal Products Directive (98/8/EC), europa website.

⁵²³ The second review regulation has not yet been developed. “Four lists containing approximately 100 actives each, are expected in the second Review Regulation with deadlines for submission of the full data.” Mike Freemantle, Bryan Backhouse, “Global Implications of the European Biocidal Products Directive”, at p. 5.

⁵²⁴ Ibid. A distinction has been made between the type of information required for a notification and that required for a full dossier review. “Manual of Decisions For Implementation of Directive 98/8/EC Concerning the Placing on the Market of Biocidal Products”, at p. 4.

⁵²⁵ Only substances that were notified ‘acceptably’ before March 28, 2002 will be reviewed in the program. Biocidal Products Directive (98/8/EC), europa website

⁵²⁶ “Manual of Decisions For Implementation of Directive 98/8/EC Concerning the Placing on the Market of Biocidal Products”, Last Modified 1/23/03; “Guidance Document Agreed Between the Commission Services and the Competent Authorities of the Member States for the Biocidal Products Directive 98/8/EC”, at p. 3; Biocidal Products Directive (98/8/EC), europa website.

⁵²⁷ Ibid. “...They are also encouraged to explore waiving possibilities for toxicity studies involving vertebrate animals, using available information and arguments on the feasibility of testing and extent of exposure, especially for products where the uses are minor and essential.”

Once a reviewed active substance is included in one of the BPD Annexes (Annex I, IA or IB), applications for authorization to use biocidal products containing that active substance must be submitted in those Member States in which such biocidal products will be placed on the market.⁵²⁸ Market approvals will be granted based on the results of a full risk assessment for each claimed use of the product.⁵²⁹ The risk assessment must be prepared by the producer and formulator responsible for placing the product and its active substance(s) on the market. A comparative assessment will be required when an active substance, though ‘acceptable’ for listing, still causes concern. The substance’s inclusion in Annex I will be denied if there are less harmful suitable substitutes available for the same purpose.⁵³⁰

4. *The BPD Constitutes a Disguised Trade Barrier*

European industry is already criticizing the provisions of this directive as unworkable, in comparison to the approach taken by the U.S. EPA. Essentially, they characterize the BPD requirements for active substances as “very onerous”, and as “exceeding those required for an acceptable risk assessment”. “There is no tiered approach for toxicological studies and the core data set totally disregards likely exposure to the biocide. Other tools (such as realistic human and environmental exposure scenarios, emission models, leach tests, environmental fate methods, efficacy methods and environmental monitoring guidelines), which are urgently needed to make the BPD workable, have still not been developed for many of the product types.”⁵³¹ The U.S. tiered approach, by comparison, requires “toxicological studies based on an appropriate initial set and further conditional requirements related to exposure to the biocide. Assessment of human exposure is a USEPA requirement and, if low, can obviate the need for chronic studies.”⁵³²

In addition, the cost of compliance with the BDC is excessive. In particular, the cost of preparing the core data set required can be \$3,000-\$5,000 per active substance, which may be disproportionate relative to the type of biocide involved.⁵³³ In any event, it is alleged that the core data requirement itself exceeds the U.S. requirements for industrial biocides.⁵³⁴

Furthermore, it is claimed that biocidal product authorization under the BPD, which is based on a review of risk assessment data, can be refused on efficacy (i.e., effectiveness) grounds for all product types. The inclusion of such grounds, it is said, further complicates the assessment process, especially since appropriate efficacy tests have not

⁵²⁸ Ibid, at p. 3.

⁵²⁹ See: BPD Annex VI.

⁵³⁰ Biocidal Products Directive (98/8/EC), europa website.

⁵³¹ Mike Freemantle, Bryan Backhouse, “Global Implications of the European Biocidal Products Directive” (2001), at p. 3.

⁵³² Ibid, at p. 2.

⁵³³ Ibid, at p. 3.

⁵³⁴ Ibid.

yet been developed.⁵³⁵ More problematic, according to industry, is the concept of ‘comparative assessment’, where “two active substances, (both of which meet the approval criteria), can be compared and the ‘less safe’ one prevented from entering the market or withdrawn from sale. No satisfactory guidance is [currently] available on how to conduct such comparisons. There is no such scheme in the U.S.”⁵³⁶

Moreover, CEFIC has also argued that because the BPD directive is both unworkable and costly, it would stop all new product innovation and possibly result in existing products being pulled off the market by besieged companies. CEFIC has estimated that “60% or more of the existing active substances [as of the year 2000] and 10,000-20,000 of existing biocidal products marketed in the EU will be withdrawn as a result of the directive.”⁵³⁷

What has not yet been analyzed are the directive’s labeling provisions contained in Article 20. “Biocidal products shall be labeled, but shall not be misleading or give an exaggerated impression of the product. The label must show, among other things, the identity of every active substance and its concentration, the type of preparation, the uses for which the biocidal product is authorized, and particulars of likely direct or indirect adverse side effects.”⁵³⁸

Based on the arguments presented and a cursory review of the BPD, it appears that the BPD and accompanying regulations suffer from many of the same problems characteristic of 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 non-safety concern. Also, the labeling provision distinguishes between products based on process and production methods rather than on the basis of product characteristics and performance. It is perhaps also susceptible to misinformation given the volume of information that would be required to be included. Furthermore, the notification/ dossier information sharing rules would likely threaten intellectual property rights to the extent any proprietary information is disclosed in the process. 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 for 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.

5. *The BPD Authorization Regimen Effectively Blocks Market Access of Products and Processes that Can Benefit Developing Countries*

⁵³⁵ Ibid, at p. 4.

⁵³⁶ Ibid.

⁵³⁷ Ibid, at p. 5.

⁵³⁸ Article 20.3 .

Lastly, it is arguable that the BPD 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 country companies. 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.⁵³⁹ [That vision] has been identified as having three legs – economic, environmental and social.

“Industrial and environmental biotechnology has a proven track record across a range of industry sectors...In addition to direct progress toward the environmental component of Sustainable Development for developing nations, industrial and environmental biotechnology may also afford them much-needed economic opportunities (thereby achieving progress in all three aspects of Sustainable Development). For example, it may enable developing nations to move from exporting raw materials to exporting finished products (e.g., textiles and mining). This may also shift comparable advantage in economic terms to manufacturers in developing nations while lessening environmental impacts from transportation, etc...Applied to meet local, regional and national needs, [it] can play a significant role in addressing urgent global environmental problems...”⁵⁴⁰

To the extent that the BPD would discourage or otherwise preclude developing country businesses 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.

V. CONCLUSION

This White Paper has identified protectionist trade barriers cast in the form of national standards and regulations that aim to protect human health and safety, animal welfare and the environment. While many of these standards and regulations emanate from the European Union, they are proliferating rapidly throughout the world. Whether they are sanitary and phytosanitary measures or non-agriculture technical measures, these disguised trade barriers employ a common analytical framework that promotes and embraces a mindset of precaution, which presumes that a product is severely hazardous until proven ‘safe’ without scientific proof of any actual harm. The objective of this approach is to eliminate all potential risks associated with industrial and technological advancement. 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

⁵³⁹ Chapter 16 of Agenda 21 refers to its potential.

⁵⁴⁰ “Briefing Document: Critical Role of Industrial and Environmental Biotechnology for the World Summit on Sustainable Development, Johannesburg, South Africa, August-September 2002 , Biotechnology Industry Organization (‘BIO’) (June 6, 2002), BIO website; “Resolution Regarding Industrial and Environmental Biotechnology and the UN World Summit on Sustainable Development Johannesburg 2002”, BIO (June 11, 2002), Ibid.

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.

That this analytical framework is not WTO-consistent is made clear by EU regulatory procedures that deny foreign stakeholders an active role in the development of standards and regulations that significantly affect their commercial interests. In addition, the EU has repeatedly sought to elevate politics over science and to shield from public debate the merits of employing advanced technologies in daily life. At the international level, the EU has endeavored to promote political and economic organizations over international science-based organizations and to inject nonscientific principles into the standards created by science-based international standardization bodies. These practices have had an adverse impact on developing country attempts to participate effectively in the global trading system. They have not only inspired popular opposition to biotechnology and other advanced technologies (i.e., nanotechnology) on non-science grounds, but they have also blocked market access to developing country exports created with the use of such technologies and could thereby place a chilling effect on developing country research and development efforts.

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. Current EU practices have made this quite difficult, however. The EU continues to incorporate broad environmental principles such as the precautionary principle into trade agreements both at the multilateral and bilateral levels. This dual-level strategy has prompted the U.S. government to take a competing approach that advances sound science, risk analysis and transparency as it engages in negotiations over free trade agreements with individual nations and regions. Ultimately, it will be important to reconcile these different approaches if the cause of trade liberalization is to advance.