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Title: Foreign Trade Standards Often Ignore Science, U.S. Group Says

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Burdensome national standards and technical regulations imposed by the European Union (EU) and other major U.S. trading partners are trade barriers that often ignore sound science, according to a new report by a leading U.S. trade association. "I don't think there is a real appreciation for the breadth of the application of unjust trade restrictions across a multitude of industries," Bill Reinsch, president of the National Foreign Trade Council (NFTC), said in a May 6 press release announcing the release of the report, "Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science."

NFTC gathered evidence of regulations and standards not based on sound science or subject to balanced risk assessment, those that are not based on or do not adhere to internationally agreed standards, and cases in which U.S. and foreign exporters are effectively prevented from fully participating in the regulatory drafting and review process.

"We're also seeing more and more attempts to dictate not how products perform but rather how they are made," Reisch said. "Both these approaches are clearly violations of the WTO [World Trade Organization] rules-based system."

Affected products include beef and poultry, fresh and processed fruits and nuts, food additives, vitamins and nutrients, wines, foods derived from biotechnology, aeronautics, automobiles, consumer electronics, computers, chemicals. Downstream industries affected include textiles, plastics and finished consumer goods, toiletries and cosmetics and household and industrial biocidal products, according to the release.

The report was released at a panel discussion featuring speakers from the Office of the U.S. Trade Representative, the European Community and Mexico.

The full report and an executive summary may be accessed at: www.nftc.org.

Following is the text of the report's executive summary:

National Foreign Trade Council, Inc. Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science

Executive Summary

May 2003 National Foreign Trade Council, Inc. NW Washington, DC www.nftc.org Executive

Summary

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 [World Trade Organization] 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 adhere to internationally agreed upon standards developed by international standardization bodies (such as the Codex Alimentarius concerning food safety and the International Program on Chemical Safety concerning global chemicals management), or otherwise do not recognize equivalent U.S. standards and/or regulations (i.e., equivalent sanitary and phytosanitary measures or TBT 'conformity assessment' rules); and 3) where U.S. and other non-EU based exporters are effectively prevented from participating fully in the regulatory drafting and review processes and do not receive adequate and timely notification of regulatory changes having a material impact on market access and manufacturing processes (i.e., the regulatory processes are not fully transparent and inclusive).

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

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

The utility of standards and regulations within a multilateral rules-based trading system can be measured, in large part, by their predictability, transparency and reference to objective principles of sound science. The WTO rules-based trading system is based on the notion that predictable and clearly defined international standards devised and adopted by recognized international bodies through consensus is the preferred platform from which to facilitate

increased cross-border and international trade flows. Global businesses are not well served in the absence of such standards, or in the event governments in which they operate decide not to abide by them, and choose instead to impose their own regulations and standards.

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

Many regulations and/or standards deny market access to a myriad of imported products in the name of serving a national objective, such as the preservation of health and safety, animal welfare and the environment, and more recently, the protection of consumer choice. However, they may actually be intended to protect ailing or otherwise noncompetitive industries. The numerous examples cited in this paper suggest a broad approach to governance that is both insular and presumptive of the existence of unacceptable hazard or risk, even in the face of scientific evidence to the contrary. And that approach has resulted in de facto product bans without a prior science-based risk assessment having been conducted, as called for by the Sanitary and Phytosanitary ('SPS') and the Technical Barriers to Trade ('TBT') Agreements.

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

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

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

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

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

There is also evidence that the EU is seeking, through promulgation of national and regional laws and regulations, to implement international obligations assumed under multilateral environmental agreements ('MEAs'), which it and its Member States (unlike the U.S.) have ratified. These articulate the broadest expression available of the precautionary principle as a

non-science based justification for enactment of regulations to protect human health and the environment. It is possible that, by resorting to such a broad application of the precautionary principle, the EU believes it can utilize the broader provisions of the GATT [General Agreement on Tariffs and Trade] and, which appear to be easier to satisfy than the more narrowly construed science-based risk assessment and international standardization rules of the SPS and TBT Agreements.

SANITARY AND PHYTOSANITARY MEASURES CONSTITUTING DISGUISED TRADE BARRIERS

An interesting pattern that seems to have emerged recently in the agricultural products sector is the promulgation of measures to regulate and manage the use of advanced technologies in the food chain. Examples of this include hormones used to promote beef production, chlorine and other antimicrobial treatments used to safeguard poultry production, the in-line pulp wash process used in the production of fruit juices, bioenzymes and other micro-organisms used in the wine fermentation process, and genetically modified seed, feed and food used in the production of grains, flours, and produce.

Beef in the EU

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

Poultry in the EU and Japan

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

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

Fresh Produce and Processed Fruits and Nuts in Korea and Japan

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

Furthermore, burdensome quarantine restrictions imposed by Japan on U.S. apple exports in order to prevent transmission of fireblight bacteria serve to limit market access and reduce

competitiveness of U.S. apples in Japan. The scientific evidence derived from joint research conducted by U.S. and Japanese government scientists "does not support Japan's assertion that mature, symptomless apples can transmit said bacteria."

Additives, Vitamins and Nutrients in Japan and Other Countries

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

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

Wines in the EU

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

Genetically Modified Food Products in the EU

The refusal by the EU and its Member States to admit biotech food and feed products into their markets has arguably resulted in one of the most volatile trade disputes in a long while. This practice continues even though the European Commission has acknowledged the potential benefits offered by this technology.

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

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

Canada, Argentina and Mexico have also been adversely affected.

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

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

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

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

GMO Traceability and Labeling

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

The labeling component of the proposed regulations would require that all food and feed which consist of, contain or are produced from GMOs be labeled as such. One of the more problematic aspects of the labeling regulations is that they would "extend the current labeling provisions to all genetically modified food or feed, irrespective of the detectability of

genetically modified DNA [deoxyribonucleic acid] or protein" (emphasis added). This issue would seem to go right to the heart of the 'like products' test within the 'national treatment' clauses of the SPS, TBT and GATT Agreements.

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

The GMO Moratorium and Proposed Regulations Are Disguised Trade Barriers

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

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

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

The regulations' requirement that "biotech food and feed must not present a risk for animal health, human health or the environment imposes an insurmountable evidentiary burden upon exporters of such products. As the U.S. Government has noted, "this level of assurance is wholly unobtainable for any food or feed product, regardless of production method, as the absence of risk can never be proven." The regulation may also be discriminatory and a disguised trade barrier to the extent this standard differs from any other applied by the EU to non-biotech food and feed safety standards or standards established for food additives or pesticide residues. 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 exporters. A related concern is that, biotech food products will be distinguished from conventional food products having essentially

the same physical and DNA characteristics, based on their differing processing and production methods ('PPMs'). Aside from the potential issue surrounding the imposition of different levels of protection on equivalent levels of risk, there remains the broader obligation to accord 'like-kind' products similar treatment.

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

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

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

GMOs and the Precautionary Principle

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

A careful examination of the Protocol also indicates that, it creates "a precedent for genetically modified crops to be treated differently from hybridized crops, even when there is no scientific evidence that they represent a threat to anything. As such, these crops are being judged on the basis of the process used to produce them rather than on the level of risk represented by the product itself. Given the Biosafety Protocol's inclination towards precaution, it is not

surprising that the EU has chosen an approach to assessing and managing hazards that approximates the Protocol's approach to risk analysis. This approach favors processes over products and non-science over science, and as a result is in conflict with the hard fought scientific and objective principles contained within the WTO Agreements, which seek to establish a stable, clear, predictable and consistent regulatory approach.

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

New EU GMO Legislation and the Developing World

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

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

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Chemicals in the EU

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

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

transport), construction, automotive, paper and printing products, and final consumption products.

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

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

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

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

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

At least one industry comment letter received from a prominent U.S. trade association, the American Chemistry Council ('ACC'), has stated that its members have been denied the

opportunity to effectively participate in the drafting and review process involving the promulgation of regulations to implement the proposed Chemical White Paper. 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. 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".

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

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

EU Chemicals Policy and the Developing World

Since many commodity products are formulated, manufactured and/or assembled in overseas developing country factories, developing country exporters of such products and their upstream producers are likely to bear the brunt of these EU regulations, though in most instances, they lack the technical capacity to satisfy them. If they are now compelled to undertake the rigorous testing, registration, and downstream risk assessment obligations imposed by the EU Chemicals White Paper, the cost advantages they had secured in order to compete effectively with the developed world would no longer be available. This would severely set back their economic advancement.

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

Cosmetics in the EU

The EU Commission and the EU Parliament have recently enacted two amendments to the EU Cosmetics Directive 76/768/EEC, both of which are contained within new Directive 2003/15/EC. One proposed amendment imposes a ban on the manufacture and sale of existing and new cosmetic products if their ingredients or the final formulation of the products themselves were tested on animals for safety purposes, where OECD-approved alternatives to

animal testing exist. The other proposed amendment bans the use in cosmetics of substances that cause cancer or pose reproductive mutagenic hazards. The amendments are to take effect no later than 2009. Interestingly, with regard to both these amendments, the EU and non-EU cosmetics industries are united in their opposition. As a result, these two amendments illustrate that even when a trade restrictive measure is not discriminatory against foreign producers, it stifles innovation and reduces consumer choice.

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

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. Furthermore, it does not appear that the views of stakeholders have been taken at all into account. Consequently, it is arguable that the legislative process was neither transparent nor inclusive for these stakeholders who were effectively denied an opportunity to participate in the process of drafting the regulations.

As for the use of chemicals in cosmetics, "(t)he general principle of the directive is that cosmetics must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use." While the directive would impose an outright ban on the use of CMR [carcinogenic, mutagenic and reprotoxic] category 1 and category 2 substances in the manufacture of cosmetics, it may allow the use of category 3 substances if a full risk assessment establishes the safety of such substances.

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

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

Biocidal Products in the EU

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

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. 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.

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

It would appear that the [BPD] legislation contains many of the same problems posed by other EU legislation. There seems to be a presumption of a hazard to human health and environment posed by biocidal products without any real evidence of actual harm. This presumption is most likely premised on the precautionary principle and on the perceived need to keep consumers informed, a nonsafety concern. Also, the labeling provision distinguishes between products based on process and production methods rather than on the basis of product characteristics and performance. Furthermore, the information sharing rules would likely threaten intellectual property. The comparative assessment provision and animal testing waiver provision are troubling because they would once again impose distinctions on products not based on end-use but rather on process. Overall, the EU could have chosen a less-trade restrictive alternative to protect human health and the environment from possible harm caused by biocidal products. The U.S. EPA approach provides such a model, but, there is no evidence that the EU sought reference to any equivalent national standards; nor does it appear that the EU considered any international standards or guidelines based on scientific method.

Lastly, it is arguable that the BCD [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 countries. Since the Earth Summit at Rio de Janeiro in 1992, biotechnology has been publicly recognized as a necessary part of the vision for Sustainable development. To the extent that the BCD [BPD??] would discourage or otherwise preclude developing country exports from entering the EU marketplace and thereby deter developing country research and development efforts in industrial biotechnology, it would discriminate against such such countries and their businesses in contravention of the TBT Agreement and the WTO Ministerial Declaration.

CONCLUSION

The EU has invoked the precautionary principle, a non-scientific touchstone, to justify its identification and assessment of such risks as well as its enactment of technical measures to

manage and eliminate them. By so doing, it has effectively banned U.S. and other non-EU exports of products deemed hazardous, stifled scientific and industrial innovation and advancement and, in the process, has ignored a basic reality, namely that a certain amount of risk is unavoidable in every day life. The EU continues to incorporate the precautionary principle into trade agreements both at the multilateral and bilateral levels, and this dual-level strategy has prompted the U.S. government to take a competing approach that advances sound science, risk analysis and transparency. As the two largest global economies anchoring the WTO rules-based system, it is incumbent upon the U.S. and the EU to try to harmonize the many differences among the WTO membership into a unified, workable and fluid mechanism that facilitates rather than impedes the flow of international trade. Ultimately, it will be important to reconcile these different approaches if the cause of trade liberalization is to advance.

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