HARMONIZATION HANDBOOK

Accountable Governance in the Era of Globalization: the WTO, NAFTA, and International Harmonization of Standards

A Public Citizen Backgrounder
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ACCOUNTABLE GOVERNANCE IN THE ERA OF GLOBALIZATION: THE WTO, NAFTA, AND INTERNATIONAL HARMONIZATION OF STANDARDS

I. INTRODUCTION

Over the past two decades, new international trade and investment rules of unprecedented scope and power, coupled with massive changes in business practices and organization, have resulted in an astonishing transformation of economic and social policy around the world. This new arrangement is often labeled "economic globalization." However, in addition to its economic consequences, globalization has a major effect on domestic governance, and thus on public health, economic development, and social and environmental policy.

NAFTA and the WTO

Two major trade pacts intensified and politically and legally formalized the move toward globalization: the North American Free Trade Agreement (NAFTA), passed by Congress in 1993, and the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), passed in 1994. The GATT Uruguay Round established the World Trade Organization (WTO), a powerful new global commerce agency.

Together, NAFTA and the WTO constitute permanent institutional structures which are significant engines driving corporate economic globalization. Both pacts contain numerous provisions that go far beyond the usual purview of trade agreements, which traditionally focused on tariffs and quotas. NAFTA and the WTO include provisions governing the domestic public health, food safety, consumer, worker and environmental protection policies of member-countries. These are all issues which traditionally have been at the core of domestic policy-making.

Both NAFTA and the WTO establish comprehensive international rules constraining the domestic policy objectives member countries may pursue, and what policy tools member countries may use to obtain even the allowed objectives. A core provision of the WTO states: "Each Member shall ensure the conformity of its laws, regulations and administrative procedures with its obligations as provided in the annexed Agreements."[1]

NAFTA also contains provisions limiting certain national investment and economic development policies. For instance, NAFTA forbids governments from establishing or maintaining some investment preferences to promote development in impoverished or minority areas, as well as investment conditioned on non-commercial performance standards, such as environmental performance.[2]

Mechanisms of Harmonization

NAFTA and WTO provisions are based on certain underlying premises, among them: domestic health, safety, and environmental policies must be designed in the "least trade restrictive" manner and national laws and standards should be standardized internationally so as to maximize economic efficiency in cross-border trade. This process of global standardization has been dubbed "harmonization" by the corporations that favor it.

NAFTA and the WTO provide powerful incentives for governments to harmonize standards and regulations even when they are not legally required to do so by the pacts. NAFTA and the WTO also set constraints on member countries' domestic laws by naming certain international standards as the presumptively permissible ones, and by establishing binding international dispute resolution processes where non-conforming domestic laws can be challenged.

NAFTA and the WTO pressure member

governments to base their domestic standard-making on specified international standards and on international standard-setting techniques. One example is a requirement that countries "base their sanitary and phytosanitary measures (food standards) on international standards, guidelines or recommendations. . . ."[3] NAFTA contains similar requirements. NAFTA and the WTOpermit countries to have food safety measures that achieve a higher level of health protection than relevant international standards only in very limited circumstances.[4]

NAFTA and the WTO also direct countries to use a standard-setting technique called "risk assessment." Yet, some U.S. standards are based not on assessing a tolerable amount of risk ("risk assessment"), but in forbidding public exposure to a risk altogether. Such "zero tolerance" standards, while safer for consumers, are inherently problematic under NAFTA and WTO rules because they are not developed using the internationally-recognized risk assessment method of standard-setting under the pacts.

Both agreements also require countries to base their non-food technical standards on relevant international standards are not yet completed, but their completion is imminent.[5] As with food standards, under NAFTA the WTO only technical regulations conforming to international standards are presumed *not* to create unnecessary obstacles to trade.

Standards providing more protection to consumers or public health or local communities or the environment can be challenged as unfair barriers to trade before dispute resolution panels established by both NAFTA and the WTO to enforce their rules over non-conforming domestic policies. The acceptable reasons for exceeding international standards in non-food areas under the WTO are strictly limited to fundamental climactic, geographical or technical inappropriateness.[6] NAFTA's rules allowing exceptions that provide more protection than international standards are only slightly less restrictive.

Because domestic standards that do not conform to international standards must satisfy a battery of NAFTA or WTO tests in order to avoid being considered barriers to trade, the burden of proof falls on the country defending a stronger domestic health or environmental law. Thus, the pacts create

U.S. Regulations and Standards Covering These Topics Are Now Being Affected by Harmonization

- **Meat, Poultry, and Fish Inspection**
- **Pharmaceuticals**
- **Telecommunications**
- **Genetically-Modified Foods**
- **Auto Safety**
- **Cosmetics**
- **Electrical Safety**
- **Shellfish Inspection**
- **Hazardous Waste Transportation**
- **Medical Devices**
- **Pesticides**
- **Organic Foods**
- **Chemical Classification and Labeling**
- **Informational Labeling and Eco-Labeling**
- **Aviation Safety**
- **Endangered Species**
- **Electromagnetic Safety**
- **Veterinary Drugs**
- **Electronic Commerce**
- **Marine Recreational Craft**

international standards, even where such significant incentives for the U.S. to *avoid*

exceeding international standards. The threat of a costly NAFTA or WTO trade challenge may also chill innovative solutions to consumer and worker health and safety, environmental, labor rights, or other social or economic development problems.

Types of Harmonization

There are two primary types of harmonization promoted by NAFTA and the WTO: *global standard setting*, which takes place in international standard-setting institutions, and *equivalency agreements*, which are usually bi-lateral agreements between two nations. Mutual Recognition Agreements, bi-lateral or multi-lateral agreements between nations, can be a vehicle for both types of harmonization.

Global Standard Setting: NAFTA and the WTO name specific international standards, such as those established by the International Organization for Standardization (ISO) in Geneva and the Codex Alimentarius Commission (Codex) in Rome as presumptively complying with trade rules.[7] Both the ISO and Codex are dominated by industry. Indeed, ISO, which sets product and manufacturing process standards, is a private sector organization, funded by industry and largely comprised of industry representatives. Codex, which sets food standards under the auspices of several United Nations-related organizations, consists of governmental representatives, but operates with an important formal role for industry. Citizen input in both is essentially non-existent, as is meaningful participation by health or consumer groups.

Currently, the U.S. is involved in international harmonization in the areas of genetically modified foods, meat and poultry inspection, medical devices, pharmaceuticals, chemical classification and labeling, pesticide residue levels, veterinary drugs, and automobile and aviation safety regulations, (just to name a few areas). These activities are being conducted in a diverse array of international standards organizations, industry associations, and inter-governmental fora.

Equivalency: In addition to the adoption of uniform international standards, another mechanism of harmonization required by NAFTA and WTO rules are "equivalence determinations." Under the notion of "equivalence," significantly different - and possibly less protective - regulatory systems and standards in other countries can be declared "equivalent" to domestic regulatory systems. Once a foreign system is declared "equivalent," it must be treated as if it were a domestic system, even if it differs from the domestic system in significant ways. Equivalence determinations are designed to allow foreign goods produced under "equivalent" systems free passage into the U.S. market.

The U.S. is in the process of determining equivalency between the U.S. and European Union (EU) member states in the area of manufacturing practices for pharmaceuticals. The U.S. Department of Agriculture (USDA) has already approved 32 meat inspection systems around the world as equivalent to our own and participates in a wide-ranging equivalency agreement with the EU on veterinary practices and medicines.

NAFTA and WTO rules mandate equivalence determinations but do not provide procedural guidelines or factors to consider. The absence of such guidelines and factors has resulted in subjective comparisons. Under these NAFTA and WTO rules, it is difficult, if not impossible, to understand *how* countries, including the U.S., will fulfill the requirement to determine whether the regulatory systems of dozens of other countries are equivalent to their own.

Mutual Recognition Agreements: Another tool in the international harmonization kit is the Mutual Recognition Agreement (MRA). A MRA is a negotiated, reciprocal agreement between nations which allows one nation to rely on the other's "conformity assessment" system.

"Conformity assessment" means verification by a country that a product meets a required standard. Thus conformity assessment systems include product testing, quality systems audits, and the reporting required from such testing or audits. For example, an MRA the U.S. is currently engaged in would allow foreign drug regulatory authorities to conduct inspections of that country's drug manufacturers on behalf of the U.S. Food and Drug Administration (FDA) to ensure they meet the

requirements of U.S. law. The FDA will accept these inspection reports as if they had been produced by U.S. regulators.

The U.S. is currently participating in a MRA with the EU covering electromagnetic safety, telecommunications, marine recreational craft, electrical safety, medical devices, and pharmaceutical good manufacturing practices. Another MRA with Canada on molluscan shellfish regulation is in the works.

Industry documents are unabashed in describing that MRAs are intended by industry to be a vehicle for standards harmonization and equivalency, not just conformity assessment. The U.S.-EU MRA on pharmaceuticals, for example, necessitates the determination of equivalency between the nations involved regarding good manufacturing practices, which ensure the purity and quality of the final drug product.

Harmonization Upward or Downward?

Theoretically, international harmonization could occur at the lowest or highest levels of public health or environmental protection or somewhere in between. Unfortunately, the actual provisions in NAFTA and the WTO requiring harmonization or providing incentives for harmonization could result in the lowering of the best existing domestic public health, social, economic justice, natural resource conservation and environmental standards around the world.

For instance, under NAFTA and the WTO, international standards serve as a ceiling which countries cannot exceed rather than as a floor that all countries must meet. The agreements provide for the challenge of any domestic standards that go *beyond* international standards in providing greater citizen safeguards, but contain no provisions for challenging standards that fall below the named international standard. Thus, the provisions in NAFTA and the WTO promoting harmonization are likely to serve only as a one-way downward ratchet on domestic standards. Challenges of domestic standards that exceed international standards will be resolved in the binding dispute resolution system built into these agreements.

Dispute Resolution Process

While similar in some ways to a judicial proceeding, the dispute resolution systems in NAFTA and the WTO lack the procedural safeguards inherent in the U.S. judicial system. Cases are decided by tribunals comprised of three trade experts. Tribunalists are chosen on the basis of a list of qualifications that ensure that panelists will have a favorable view of current trade rules and the dominance of NAFTA and WTO rules over other domestic policies.[8] (For instance, to qualify for a WTO tribunal a person must have worked at the GATT or WTO or represented a country there, with very limited exceptions.)[9] Tribunalists are not required to disclose actual or potential conflicts of interest, nor are the tribunals required to follow other due process standards.

The dispute resolution process in both NAFTA and the WTO is secretive; documents are confidential; oral arguments are closed to observation or participation by any entities except national government representatives; and no outside appeal is available.[10] Nor is there any mechanism for nongovernmental entities or other outsiders to submit amicus briefs.[11] A recent WTO ruling announced that such submissions are not absolutely forbidden, but can only be accepted if they are submitted as part of an involved government's documents.[12] State, federal or local laws and regulations judged to be out of compliance with NAFTA or the WTO must be eliminated or changed, or the "winning" country can place trade sanctions on products from the country whose law is ruled against.

Expansive international rules strongly enforced through international dispute resolution bodies have significant implications for the laws and policies domestic governments may establish, as well as for the processes domestic governments use to make policy. Yet, while the WTO and NAFTA establish an entire system of international governance, the two agreements were designed to promote narrow economic goals, such as freeing investment flows from government policies seeking to shape economic development, and expanding the volume

of international trade.

Other valuable goals, such as the promotion of democratic accountability, just economic distribution, strong communities, and consumer, public health and environmental protection were not included. Indeed, the pacts contain provisions to limit countervailing policy goals to the extent they could impact trade and investment flows.

Implications for Democracy

Under NAFTA and the WTO, international standards developed in industry-only standard-setting institutions that are closed to government or public participation or outside scrutiny or input have the same status as standards developed by wholly governmental institutions or quasi-governmental standard-setting institutions.

Standard-setting bodies recognized by NAFTA and the WTO operate with widely differing membership, decision-making structures, and rules about transparency. In many, members of the public or public interest groups have no standing, can be refused a seat at the table and denied access to documents. Yet, because of NAFTA and WTO requirements, the international standards set in these institutions have the same compelling implications for existing domestic standards and the ability of interested parties to have future standards developed.

In sharp contrast to the closed door process of many standard setting institutions, U.S., policy-making must be conducted "on the record," with a publicly accessible docket, under laws such as the federal Administrative Procedure Act. Public access to information and decision-making is also guaranteed in U.S. domestic law by the Freedom of Information Act, the Government in the Sunshine Act and the Federal Advisory Committee Act (FACA). FACA requires balanced representation on and open operations of government advisory committees.

For international harmonization of standards, however, agency adherence to the U.S. domestic procedures for notice, balance, openness, and public input has been spotty at best. U.S. federal agencies follow different procedures for involving the public in their international harmonization negotiations and make differing amounts of information available to the public at different stages. In a manner both subtle and powerful, recent international commercial agreements such as the WTO and NAFTA have redefined the relationships in policy-making between governments, industry, and the diffuse public interest.

The Origins of NAFTA and the WTO

NAFTA and the WTO's systematic prioritization of commerce over all other policy goals was possible because the negotiation and adoption of both NAFTA and the WTO largely foreclosed citizen and public interest group participation. The agreements were negotiated behind closed doors between unelected and largely unaccountable government agents, such as staff of the Office of the U.S. Trade Representative and U.S. Department of the Commerce.

Under uniquely constricting procedural rules called "Fast Track," Congress' role in the development of NAFTA and the WTO was also very limited. During negotiations of the pacts, consultation with Congress was minimal. Once completed, Congressional approval of the pacts and the thousands of pages of changes to U.S. law required to conform to the pacts' terms by a simple majority was required within 90 days. Uniquely, under Fast Track the Executive Branch writes trade agreement implementing legislation. Under Fast Track's uniquely restrictive procedural requirements, only 30 hours of Congressional debate is allowed and the vote must occur without any amendments to the lengthy implementing legislation. As a result, few Representatives were well-informed about the pacts' requirements.

Documents, draft texts and negotiations on NAFTA and the WTO were inaccessible to the public. Even Members of Congress were largely limited to information provided by negotiators. Actual draft texts were only available to Members of Congress at certain times and under certain conditions. Only staff with security clearance were allowed access to such documents at all.

At the same time, industry had extensive access to information and the opportunity to provide input into the negotiations through an official trade advisory committee system. The U.S. trade advisory system includes more than three dozen committees with over 800 industry representatives who have access to inside information and provide advice on most aspects of negotiation and implementation of trade agreements and policies.[13] During the negotiation of the WTO and NAFTA, a dozen labor representatives, but no health, consumer, or environmental representatives were included on these committees.

The constricted and one-sided access to information, the lack of a full public debate and the constraints placed by Fast Track on the normal democratic process, virtually guaranteed that these important trade pacts would be unbalanced and thus would cause significant problems when implemented.

II. MAJOR INTERNATIONAL STANDARD-SETTING BODIES

Numerous harmonization negotiations are currently underway. Both NAFTA and the WTO established new committees to develop uniform international standards and to promote harmonization of domestic food safety and technical standards, which include all non-food standards such as those pertaining to natural resources, product safety, or automobile pollution. NAFTA also established numerous committees to harmonize auto, truck and highway safety and hazardous transportation rules,[14] and both agreements set up harmonization committees for banking, insurance and other services sectors.

Under NAFTA and the WTO, specific international standard-setting bodies, such as the ISO and Codex, are given the task of setting presumptively-permissible global standards. NAFTA and WTO provisions obligate member countries to participate in harmonization talks in these fora.

It does not matter whether these negotiations take place in private, industry-funded standard-setting organizations like the ISO or quasi-governmental bodies like the Codex. NAFTA and the WTO do not mandate any procedural safeguards requiring openness or transparency. The sole criterion for NAFTA and WTO compliance is whether the standard is set in an international body. Below are two examples of these international standard-setting bodies.

A. The Codex Alimentarius Commission and Food Safety Standards

"Codex Alimentarius" is Latin for food law. The Codex Alimentarius Commission (Codex) in Rome is one of the international standard-setting bodies recognized by both NAFTA and the WTO for setting global food standards. It was established as a voluntary standard-setting body in 1962 by the World Health Organization and the U.N. Food and Agriculture Organization, primarily to facilitate international trade of food and agriculture products. Codex's initial mission was to boost trade by helping developing countries set food-related standards. Soon, numerous agribusiness, chemical, and food companies sought a role at Codex. Codex is officially comprised of government representatives, with active and formal assistance from official industry advisors, who serve as actual members on country delegations.[15]

Food industry giants, such as Hershey Foods, Nestle U.S.A., Kraft, General Foods, Coca Cola, and Pepsi, and trade groups, such as the Grocery Manufacturers of America and the National Food Processors Association, regularly attend international Codex meetings as part of the official U.S. delegation. These industries also have a central role in developing the U.S. positions taken to such meetings, including providing scientific data and scientists. A 1993 study showed that over four-fifths of the nongovernmental participants on all delegations to Codex committees represented industry, while only one percent represented public interest organizations.[16]

Until it was empowered by both NAFTA and the WTO as the presumptively-legal international food standard body, Codex published only voluntary

standards for the hygienic and nutritional quality of food, food additives, pesticide residues, contaminants, labeling, and methods of analysis and sampling. Despite its important new duties, Codex's mission is still to promote food trade. Codex has no public health mandate to which it must conform its decisions. It even lacks power to compel production of data from industry for standard-setting.

Codex holds meetings which are closed to the general public. Draft Codex standards are not made public until well into the process. In order to provide input, members of the public must persuade a governmental participant to present their positions.

Thanks to efforts by Public Citizen and others, internationally incorporated public interest organizations can now petition to attend Codex meetings as observers.[17] However, Codex's design is typical of international standard-setting bodies named in NAFTA and the WTO. Unlike U.S. standard-setting, where meaningful participation is possible thanks to a centralized process, Codex meetings are held around the world. Thus, effective participation in the creation of any individual standard requires an interested party to provide the proper scientific or policy expert for each of numerous working groups, committees, and experts' groups all of which meet regularly in different locations around the world.

This is in contrast to U.S. systems of accountable, democratic governance, where the role of government is to provide scientific expertise and accessible locations for obtaining comprehensive information and submitting policy input. Codex's design and processes ensure that even when nongovernmental organizations (NGOs) are admitted to meetings, meaningful public interest participation is all but impossible.

A significant number of Codex standards are weaker than food standards in the U.S., which by law must be established using public health considerations. For example, some Codex standards allow residues of pesticides that have been banned in the U.S.[18] Others allow higher residues than are permitted in the U.S. for pesticides such as heptachlor, aldrin, diazinon, lindane, permethrin, and benomyl.[19] In some cases, Codex standards allow residue levels that are five times higher than U.S. standards.[20] In addition, some Codex standards allow pesticide residues that are banned in certain U.S. states.[21]

Given that some of Codex's standards are lower than U.S. norms and that they now are empowered through NAFTA and the WTO, downward harmonization of U.S. food standards is a clear possibility. Alternatively, another country may simply challenge higher U.S. food standards using NAFTA or the WTO's dispute settlement process. To avoid such WTO challenges, for example, Japan preemptively lowered over 1500 of its domestic pesticide standards which provided greater public health protections than Codex standards.[22]

For more information on Codex, see the Codex Internet site at http://www.fao.org/waicent/faoinfo/ECONOMIC/esn/codex/default.htm, or the U.S. Codex Office Internet site at http://www.fsis.usda.gov/oa/Codex/index.htm.

B. International Organization for Standardization

The International Organization for Standardization (ISO) in Geneva is a private, industry standard-setting body. The ISO has been recognized by both NAFTA and the WTO as the presumptively-legal international standard setter for all non-food products.

When the ISO started in the 1950s, its goal was to standardize sizes for light bulbs, screws, batteries, and other consumer products to help industry expand markets. In the past decade, however, the ISO's areas of interest have expanded to include standards for environmental products, eco-labels, and humane fur trapping standards. The ISO is now nearing completion of additional standards, called the "ISO 14000 series," that focus on management practices, including providing a best "environmental practice" seal. To date, these proposals do not actually include requirements that environmental quality industry-set standards be measured with performance requirements.

The ISO's recent expansion into these new issues has begun to concern some environmental, animal welfare, and consumer groups who have tried to participate in the ISO process. Unfortunately, the ISO is designed in a manner that makes meaningful non-profit group participation impossible.

According to a report for the Brussels-based European Environment Bureau, the ISO's standards drafting committee is "made up principally of executives from large international corporations, national standards-setting firms and consulting firms."[23] The ISO "has belatedly invited delegates from governments and citizen's groups; but has used this invitation, and the limited participation that ensued, to claim an openness while ignoring their substantive input."[24] The report also notes, "Decision-making in ISO is by member associations and firms. Other participants, while they may be invited and are recorded as 'participants' in a 'consensual' decision-making process, do not have voting rights."[25]

One of the questions posed in this NGO report is whether ISO 14001 can become an international trade standard enforced by NAFTA and the WTO without operative participation from governments or NGOs? The report concludes that the answer is, "Yes," under current trade rules, these standards would have status regardless of the process by which they were set.[26]

For more information on the ISO and international standards, see the ISO Internet site at http://www.iso.ch, or the American National Standards Institute (ANSI), the U.S. member of ISO, at http://www.ansi.org.

Some International Harmonization Fora

Codex Alimentarius Commission	**Food Safety, Pesticides, GMOs**
Cosmetics Harmonization & International Cooperation	**Cosmetics**
Global Harmonization Task Force	**Medical Devices**
International Atomic Energy Agency	**Nuclear Materials**
International Civil Aviation Organization	**Aviation Safety**
International Conference on Harmonization	**Pharmaceuticals**
International Labor Organization	**Chemical Hazard Labeling**
International Organization for Standardization	**Products, Eco-Labels, Enviro. Services**
NAFTA Technical Working Groups	**Food Safety, Pesticides**
Organization for Economic Cooperation & Development	**GMOs, Chemical Classification**
United Nations Economic Commission for Europe	**Auto Safety**
Veterinary International Cooperation on Harmonization	**Veterinary Drugs**

III. WTO AND NAFTA TRIBUNALS ENFORCE INTERNATIONAL STANDARDS AND CONSTRICT DOMESTIC SOVEREIGNTY

Both NAFTA and the WTO require countries to base their environmental, food safety, public health, and worker safety standards on international standards.[27] And both agreements stand ready to enforce the international standard through their powerful dispute resolution systems.

Following is an example of a WTO case which illustrates the implications of the WTO's reliance on and enforcement of international standards. The so-called U.S.-EU "beef hormone" case, brought to the WTO by the U.S. in 1996, is still causing friction between the nations. The EU is currently paying punitive tariffs worth $116 million after losing this case in the WTO. Also discussed is a NAFTA dispute resolution case in which a Canadian corporation is challenging a California environmental law banning a certain type of reformulated gasoline produced by the company. NAFTA dispute resolution rules contain an extreme provision that allows companies to directly sue governments for cash compensation for regulations that affect a company's profits. This NAFTA case demonstrates how the dispute resolution system can chill the development of more health-protective sub-federal laws.

For more information on WTO agreements, the WTO dispute resolution system, and WTO cases, see http://www.wto.org. For more information on NAFTA agreements, see http://www.sice.oas.org/default.asp. For more information on pending NAFTA cases, see the International Center for Settlement of Investment Disputes (ICSID) site at http://www.worldbank.org/icsid/cases/pending.htm.

A. WTO Enforces International Standards in Beef Hormone Case

Since 1988, the European Union (EU) has banned the sale of beef from cattle treated with artificial growth hormones. The EU ban applies in a non-discriminatory fashion to both domestic and foreign beef producers.[28] Exposure to the artificial hormones themselves have been linked to cancer and premature pubescence in girls,[29] although the risk to humans of artificial hormone residues in the meat they consume is uncertain.

On the basis of the known risks of direct exposure and the public's demand for a ban on meat from cattle treated with artificial hormones, the EU adopted a "zero risk" standard. Rather than trying to assess a tolerable amount of an indeterminable risk or waiting for negative human health effects to accrue over time, the EU chose to eliminate public exposure to the risk altogether. The EU made this policy choice after prolonged and effective consumer campaigns in numerous EU countries.

The U.S. beef and biotechnology industries have long opposed this EU policy,[30] and in 1996 the U.S. challenged the EU ban in the WTO.[31] In 1997, a WTO dispute panel ruled that the EU ban was illegal under the WTO's food rules, contained in the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), in part because the EU ban was not based on international standards.[32] At that time, Codex rules allowed use of the artificial hormones and set residue levels for five of the six hormones at issue.

A key argument centered around the meaning of the term "based on international standards," a requirement in the SPS Agreement. The dispute panel ruled that "based on" meant "complied with," which essentially meant that all domestic standards had to be the same as international standards. Since the EU ban covered five hormones for which Codex had set maximum residue levels, the dispute panel ruled that the EU measures were not "based on" international standards. And since the EU measures were not based on international standards, under WTO rules they would be considered illegal trade barriers unless the EU could bear the burden of proving that its measures met a long set of tests set forth in the WTO text, including that the ban was "scientifically justified."

The dispute panel ruled, "Since in this dispute we have already found that there exist international

standards and that the EC measures at issue are not based on these standards, we find that the burden of justifying the measures in dispute under Article 3.3 . . . rests on the European Communities."[33] Article 3.3 of the SPS Agreement requires domestic standards that provide more consumer protection than international standards, among other conditions, to be based on a scientific risk assessment.[34] The dispute panel concluded that the EU had not done a proper risk assessment and ruled the ban on hormones an illegal barrier to trade.[35]

The EU appealed this decision to the WTO Appellate Body. Although the Appellate Body softened the harsh tone of the language in the dispute panel's opinion, it still upheld the panel's final decision and ordered the EU to begin importing U.S. artificial hormone-treated beef by May 13, 1999.[36]

However, the EU refused to import the hormone-treated beef and commissioned the EU Scientific Committee on Veterinary Matters Related to Public Health to study the health effects of the hormones.[37] The U.S. petitioned the WTO dispute panel for permission to impose sanctions on $202 million of EU exports, but the panel lowered that figure to $116.8 million.[38]

The EU scientific committee found that one of the six artificial growth hormones used by U.S. cattlemen, 17 beta oestradiol, may cause cancer. The European Commission then issued a statement declaring, "The Commission agreed that there can no longer be any question of lifting the ban on hormone-treated beef since the risk assessment has identified risks to health caused by hormones."[39]

As of June 2000, the EU has not lifted the ban on hormone-treated beef, and is paying millions of dollars worth of sanctions to the U.S. on a variety of products. Thus, U.S. consumers face higher prices on a variety of goods imported from Europe. The only relief U.S. consumers could obtain from these raised prices would come at the cost of EU consumers' exposure to artificial hormone residues in their beef.

B. NAFTA Rules Restrict California's State Sovereignty

When the U.S. Congress passed the North American Free Trade Agreement in 1993, consumer, environmental, and other groups condemned the agreement in part for provisions that empower corporations to demand compensation from NAFTA governments for costs incurred in complying with laws protective of the environment and public health. Specifically, NAFTA's Chapter 11 "Expropriation and Compensation" provisions allow private investors to sue NAFTA nations directly in international dispute tribunals for cash compensation for government actions judged by the tribunal to undermine an investor's future profitability. Chapter 11 guarantees foreign investors compensation from NAFTA nation governments for any government action "tantamount to" an "indirect expropriation."[40] These provisions have been widely criticized as establishing a broad "regulatory takings" mechanism.

The power of these provisions was most recently demonstrated when the Canadian corporation Methanex used them to sue the U.S. government for $970 million after California banned *methyl tertiary butyl ether* (MTBE). MTBE is a gasoline additive designed to reduce harmful air emissions. But the chemical also has been classified as a possible human carcinogen and has been found in water supplies in California, a state in which it was being used as a gas additive.

State environmental officials concluded that the groundwater contamination was being caused by leaks in gas storage tanks. On March 25, 1999, California, by order of the governor, required the removal of MTBE from gasoline sold in the state by December 31, 2002. California Governor Gray Davis declared that "on balance, there is significant risk to the environment from using MTBE in gasoline in California."[41]

Methanex, the company producing MTBE, claims that California's ban on MTBE violates NAFTA's Chapter 11 provisions by limiting the corporation's ability to sell MTBE. If a NAFTA tribunal finds the law to be a "regulatory taking," as claimed by Methanex, the U.S. government can be held liable for the corporation's lost profits.

U.S. scientists have associated the chemical with human neurotoxicological effects, such as dizziness, nausea, and headaches, and also consider it to be an animal carcinogen with the potential to cause human cancer.[42] The International Agency for Research on Cancer (IARC), a body under the World Health Organization, claims that not enough data exists to classify MTBE as a human carcinogen, even though it has listed MTBE as an animal carcinogen.[43] It is unclear whether Methanex is using the IARC data in its argument since in NAFTA Chapter 11 challenges the briefs of the parties are not publicly available.

The U.S. Environmental Protection Agency (EPA) has classified MTBE as a "possible" human carcinogen and is considering banning or limiting the use of MTBE in gasoline.[44] The EPA has also determined that "[l]ow levels of MTBE can render drinking water supplies unpotable due to its offensive taste and odor."[45]

The California ban is based on a 1998 University of California-Davis report which found, "There are significant risks and costs associated with water contamination due to the use of MTBE."[46] The report noted, "MTBE is highly soluble in water and will transfer readily to groundwater from gasoline leaking from underground storage tanks, pipelines and other components of the gasoline distribution system."[47] The report also found that the use of MTBE gas in motor boats results in contamination of surface water. The report concluded, "We are placing our limited water resources at risk by using MTBE."[48]

Methanex claims that MTBE provides cleaner air.[49] However, the U.C.-Davis report found that "there is no significant additional air quality benefit to the use of oxygenates such as MTBE in reformulated gasoline . . . ."[50] The report also found no economic benefit from the use of MTBE. In comparing the costs of gas with MTBE added to gas with ethanol and gas without any oxygenate added, the report concluded that MTBE gas "has the highest net annual cost due primarily to the costs of treating contaminated water supplies, higher fuel prices, and lower fuel efficiency."[51]

Critics have accused Methanex of using NAFTA to override the priorities and judgements of the Governor, State Senate, and people of California.[52] Ironically, the state of California will not even have a voice in the NAFTA case because NAFTA rules permit only the corporation and the federal government of the country being sued to be represented.[53] While the case is still pending, it is being watched closely by many members of the U.S. Congress, including those who supported NAFTA, as a test of NAFTA's ability to undermine the democratic process and the resulting public health and environmental legislation.

For more information on MTBE and its effects, see the University of California at Davis MTBE report on the Internet at http://tsrtp.ucdavis.edu.mtberpt.

IV. INTERNATIONAL HARMONIZATION POSES CHALLENGES TO DEMOCRATIC RULEMAKING AND CITIZEN PARTICIPATION

In sharp contrast to the functioning of most international standard setting bodies, U.S. law requires that the public be notified and offered an opportunity to comment on regulatory proposals. Agency rulemaking must be conducted "on the record" under the Administrative Procedure Act (APA),[54] which includes a process for advance notice about proposed regulations, opportunities for public comment, and open review of draft regulations. The APA also requires an agency, when issuing a final rule, to describe in writing how and why it made its decisions and on what basis it rejected other options.

Public access to information about and participation in agency decision-making is facilitated by the Freedom of Information Act (FOIA),[55] which permits individual citizens to get copies of government documents; the Government in the Sunshine Act,[56] which ensures that important

agency meetings are publicly noticed; and the Federal Advisory Committee Act (FACA),[57] which requires balanced representation on—and open operations of—government advisory committees. These laws provide opportunities for the public to monitor and participate in domestic policy-making. Public notices of policy-making initiatives are listed in the *Federal Register*, which is easily accessible at many public libraries and on the Internet.

The open government laws described above are key aspects of our U.S. policy-making procedures and guarantee that U.S. citizens have a voice in the development of rules and regulations that may intimately impact their lives. However, with the international harmonization of environmental, health, safety, and other regulatory standards, these four laws are being inadequately applied or stretched to accommodate activities that were not even contemplated when the laws were developed. The result is a greatly reduced level of citizen and public interest group involvement in the process.

In February 1998, the USDA published a procedure for accepting public comment on its activities in the Codex. This USDA policy is worth examining for its casual treatment of public input. The procedure was outlined in a *Federal Register* notice and request for comments.[58] The notice described the duties of the U.S. delegate to the Codex and outlined the procedures delegate would follow in developing U.S. positions on Codex matters, how the delegate would involve the public in the development of those positions and select members to be part of the U.S. delegations to important Codex meetings.

Per the requirements of the Uruguay Round Agreements Act[59] (the implementing legislation for U.S. participation in WTO agreements), the USDA procedure states that the U.S. delegate to the Codex will post in the *Federal Register* an annual notice listing: a) each standard under consideration or planned for consideration; b) a description of the standard; c) whether or not the U.S. plans to participate in the consideration; d) the agenda for the U.S. participation; and e) the federal agency responsible for representing the U.S. in the development of the standard.

The USDA procedure also commits the agency to providing the public an opportunity for comment on the Codex standards under consideration or planned for consideration. The procedure states that the U.S. delegate will "take into account" all comments received but "will not be bound to agree with any comment."

This proposed procedure has a variety of significant flaws. First, the proposal lacks a statement of the overall goals or principles to guide the U.S. Codex delegation in their activities. Such principles should include a commitment that the U.S. will participate only in upward harmonization, and that transparency and public involvement in the process are required.

Second, the USDA's proposal for obtaining public input is far too casual to ensure meaningful participation. The proposal states that "the U. S. delegate may solicit comments as deemed appropriate." Yet there is a complicated multi-step process for the finalization of Codex standards. Public comment may be needed at each stage, yet the proposal includes no requirements to seek such systematic input. In addition, leaving the solicitation for comments up to the discretion of the U.S. Codex delegate is inappropriate. Different delegates may have different views about when and which Codex papers should be offered for comment.

Third, the vague statement that USDA will "take into account" comments received, coupled with the fact that the Codex delegation rarely, if ever, responds to public comments in writing, compounds the problem. The APA seeks to force agencies to put their reasoning on the record so that consumers and other interested parties can evaluate and comment on agency decision-making. As in the domestic arena, in the international context, the agency must request comments at each decision point and respond on the record, making clear to all the parameters of their negotiation position. This process would ensure that the U.S. public can have input into the governments negotiating position before U.S. negotiators go overseas, and that the U.S. Codex delegation can be held accountable for their actions overseas by those who will live with the results.

Fourth, the USDA's Codex public participation proposal says that U.S. government positions should

be "based on sound science and take into account U.S. statutes, regulations and policy." This statement suggests that the U.S. Codex delegation does not feel *bound* by U.S. law or policy in Codex negotiations. Therefore it is not surprising that at a July 1999 Codex meeting, the U.S. Codex delegation failed to block the development of a Codex standard on pesticides that does not take into account the specific effects of pesticides on children, as required by U.S. law.[60]

The fact that the U.S. Codex delegation acceded to the development of an international pesticide standard that could put the higher, pro-child health U.S. standard at risk if challenged as a trade barrier in the WTO raises troubling questions about the parameters in which the U.S. negotiators work. Many consumer advocates believe that, at a minimum, in harmonization negotiations U.S. law should be a negotiating floor which U.S. negotiators may improve upon, but are forbidden to fall below.

Finally, the proposal does not provide any guarantee that a Codex delegation will provide balanced representation of government, industry, and consumers. Unless they are part of the U.S. delegation, public interest groups can only attend as observers, cannot vote and have no formal role in policy formation. In addition, to be qualified simply to observe, an organization must be incorporated internationally, adding an undesired level of complexity and expense to the operations of public interest organizations seeking merely to observe.

The USDA's Codex procedure explicitly rules out the possibility of funding for public interest delegates or observers who, for example, might not be able to afford regular flights to Chiba, Japan, where Codex discussions of genetically modified foods have taken place. As a consequence, while industry is well-represented at Codex meetings around the world, consumer representatives are rarely invited or able to attend.

Recently, the U.S. delegate to the Codex has started to post many Codex documents on its web-page[61] and has held more frequent public meetings. However, much more must be done to ensure that concerned citizens and public interest groups have meaningful, substantive input into the formation of U.S. positions to the Codex and in the Codex itself.

For more information on upcoming Codex meetings, see the FSIS Codex Internet site at http://www.fsis.usda.gov/OA/codex/meeting.htm.

V. WHEN HARMONIZATION IS INAPPROPRIATE

While voluntary harmonization can be useful for setting uniform product standards (i.e. standardizing the size of computer disks and credit cards), unlimited harmonization is conceptually troublesome for several reasons.

First, a core notion underlying harmonization is that a uniform global standard that is appropriate for numerous different cultures and suitable to the world's variety of social norms can always be established. Yet, standard setting is based on numerous, diverse considerations, not the least of which is the extent to which people (generally people in a particular country or subfederal region) choose to be exposed to a particular risk. As well, setting relevant standards requires consideration of objective data that will differ with geographic and cultural circumstance. For instance, setting an allowable limit for pesticide residues on a commodity such as rice requires consideration of actual intake levels for consumers -- which would vary enormously between consumers in the U.S., Asia, and Latin America.

Second, harmonization moves decision-making away from accessible, accountable state and national governance fora to international bodies that are largely inaccessible to citizens and generally operate without accountability to those who must live with their decisions. Yet, standard-setting requires not only scientific knowledge, but also subjective policy decisions about the level of risk a society is willing to accept. The corrosive effect on democratic accountability of shifting decision-making to

inaccessible venues almost guarantees some level of industry capture, and thus increases the possibility of the development of weaker standards.

The Transatlantic Consumer Dialogue (TACD) has considered these issues in developing policies and procedures for dealing with harmonization. The TACD consists of 65 U.S. and European consumer groups representing some 600 million consumers. The TACD was formed in 1998 to formalize U.S. and EU consumer group cooperation and input to the U.S. and EU governments on a range of international commerce and other issues.

In February 2000, the TACD developed a paper entitled "Principles of Harmonization" that lists the group's recommendations for when and how governments should participate in international harmonization activities. The paper recommends that: (1) standards that do not have a health and safety component should be the primary candidates for international harmonization; (2) international standards should be used as a floor rather than a ceiling for consumer and environmental protection; (3) governments should only recognize or be involved in international harmonization activities negotiated in open, accountable, democratic fora with clear avenues for public input and transparent methods of rulemaking and record keeping; and (4) governments should reject the notion of "functional equivalence," which allows governments to recognize different, and often less protective, standards of other nations as equal to their own.

The TACD paper also recommended that the Precautionary Principle should be incorporated more broadly in the international standards-setting process. The Precautionary Principle is the legal principle that acknowledges that science does not always provide the evidence necessary to avert environmental or public health threats in a timely manner, and encourages regulators to err on the side of safety when faced with uncertain scientific evidence or great potential risks to public health.

The recent debates over the safety and long term effects of genetically modified organisms (GMOs) and foods illustrate the importance of setting a definition of precaution that allows nations to move slowly and cautiously when regulating products like GMOs whose long term effects on the environment and public health remain unclear.

The use of the Precautionary Principle is a controversial issue between the U.S. and EU especially with regard to the regulation of genetically modified foods. The EU favors adding the Principle to Codex rules, while the U.S. argues that countries will use the Principle to restrict food imports based on non-scientific factors.

The Codex debate over the Precautionary Principle is not an academic one. Unless and until major changes are made to international agreements like NAFTA and the WTO, the definition and scope of the Precautionary Principle, agreed to in international standard-setting bodies, may be the most effective tool to defend precautionary public health, product safety, and environmental standards from successful challenges as unfair barriers to trade.

VI. EXAMPLES OF HARMONIZATION'S POTENTIAL IMPACT

Harmonization is now under way on a wide range of standards, regulations, and regulatory systems - from meat and poultry inspection to automobile safety and pesticide regulations. Following are several examples of cases now under consideration for harmonization, with potential implications for an array of domestic standards.

A. Company Meat Inspection Equivalent to Government Meat Inspection?

On June 1, 1999, the USDA's Food Safety and Inspection Service (FSIS) announced that it had determined Australia's new Meat Safety Enhancement Program (MSEP) to be equivalent to the U.S. government's system.[62] Under Australia's new program, Australian meat processors' own employees will perform inspections, with the oversight of government inspectors. In comparison, U.S. law requires government inspectors to examine each animal carcass.[63]

The MSEP was first introduced in Australia in 1997. The first year it was in place, according to the Australian Department of Health, salmonella poisonings in Australia increased twenty percent from the previous year, from 5,819 cases to 7,004.[64] In 1998, the number of salmonella poisonings jumped again, to 7,700 cases.[65] In 1999, the number of poisonings dropped to 7,182, but that is still a twenty-three percent increase in the number of salmonella poisonings in the first three years of the company inspection program.[66]

The same Australian system found equivalent by the USDA was rejected by the European Commission (EC). After inspecting Australian meat establishments in April, 1998, the EC's Health & Consumer Protection Directorate General (DG 24) found that "veterinary supervision was generally weak; [and] no initiatives were taken for correction of deficiencies."[67] After another such inspection in November 1999, DG 24 officials concluded, "In many instances, the Australian quality assurance systems permit establishment employees to act as if they were officers of the competent authority. This is in breach of the requirement that inspectors should enjoy a status which guarantees their impartiality. The level of official supervision and control is reduced to a level below that required by the EC legislation and must therefore be considered inadequate."[68]

Company-inspected meat, if produced in the U.S., would be condemned under the applicable U.S. law, the Wholesome Meat Act.[69] That law requires beef and other meat from animals to be examined by federal inspectors for safety. However, because MSEP has been declared equivalent to USDA inspection, U.S. consumers will have no way to distinguish between Australian meat imports produced under a highly-privatized inspection system and domestic meat inspected by U.S. government employees. Both products will bear the USDA's seal of approval.

For more information on the FSIS equivalence process, see the report from the USDA's Office of Inspector General, located on the Internet at http://www.usda.gov/oig/auditrpt/full_fsis.pdf.The FSIS Internet site is at http://www.fsis.usda.gov.

B. NAFTA & Commercial Truck Standards

The transportation annex to NAFTA's Agreement on Technical Barriers to Trade set up numerous harmonization committees and set time lines by which North American transportation standards must be harmonized.[70] A working group organized under the U.S. Department of Transportation (DOT) with numerous industry members, but no public safety representation, has been developing the U.S. positions to be taken to on-going international NAFTA transportation harmonization negotiations. Given the unbalanced representation of the working group, it would not be surprising if the new standards are less protective of public safety and the environment than current U.S. standards.

For instance, the maximum weight for commercial trucks traveling on U.S. interstate is generally 80,000 pounds. In Mexico, the maximum weight is 171,000 pounds.[71] Furthermore, according to data from Citizens for Reliable and Safe Highways (CRASH), U.S. trucks on average are 4.5 years old, while Mexican trucks average 15 years, and U.S. trucks are required to have front brakes and Anti-Lock Braking Systems, while Mexican trucks are not required to have either.[72] All NAFTA borders were to have been opened by December 17, 1995, to commercial trucks meeting the new harmonized standards. However, the DOT denied access to the U.S. market to Mexican truckers because of systematic, well-documented safety problems.

A December 28, 1998, DOT audit of the Federal Highway Administration's motor carrier safety program for commercial trucks at U.S. borders concluded that "far too few trucks are being inspected, and that too few inspected trucks comply with U.S. standards."[73] At one border crossing in El Paso, Texas, where an average of 1,300 trucks cross each day, there is only one inspector, who is able to inspect only 10 to 14 trucks each day.[74]

Nevertheless, of the fraction of Mexican trucks that were inspected, 44 percent were forced out of service due to serious safety violations. In contrast, only 25 percent of U.S. trucks were forced out of service during the same time period.[75]

Given the role played by organizations such as the American Trucking Association, which has advocated weakening existing U.S. standards, the prospect of harmonized standards which meet the higher U.S. standards is unlikely. Meanwhile, communities on both sides of the U.S.-Mexican border oppose the opening of the border due to environmental and public health threats posed by the additional dangerous trucks. However, because of the lack of public input, transparency and accountability, these community concerns have no role in the harmonization process, where uniformity is the only goal.

For more information on NAFTA and commercial trucks, see the Teamsters' Internet site at http://www.teamster.org. The DOT audit report is at http://www.oig.dot.gov/audits/tr1999034.html.

C. Equivalence Language Undermines USDA Organic Rule

On December 16, 1997, the USDA issued a proposed rule to establish national standards for organically-grown foods, to be called the National Organic Program.[76] The USDA proposal allowed foods produced with genetically-modified organisms, grown with sewage sludge, and exposed to irradiation to be labeled as "organic."

Organic farmers, food cooperatives, and consumers immediately condemned the rule, flooding the USDA with over 275,000 comments, the most USDA has ever received in response to a proposed rule. This citizen outcry was effective and the USDA issued a new draft of the proposed rule on March 13, 2000, deleting the offending provisions and addressing many suggestions raised.[77]

Almost completely unnoticed in both proposals, however, was a small section permitting imported foods to be labeled organic if produced in foreign countries whose organic standards are determined "equivalent" to USDA's.

Under the WTO's notion of "equivalence," significantly different - possibly less protective - regulatory systems and standards in other countries can be declared "equivalent" to a domestic regulatory system. Once a foreign system is declared "equivalent," goods meeting its standards must be treated as if they met domestic standards, even if there are significant differences between the two systems. The goal of the WTO's equivalence rules is to ensure that goods produced under equivalent systems are allowed free passage into each other's markets.

Under the proposed organic food regulation, USDA will permit foreign certifying agents to approve foods as "organic" if the foreign government authority that accredited the certifying agent "acted under an equivalency agreement with the United States." In explaining this language, the USDA says it will give "positive consideration to accepting as equivalent the technical regulations of other countries even if those regulations differ from our own, provided such regulations fulfil the objectives of this proposed program."

Neither the WTO rules nor the USDA's proposed regulation lay out the guidelines to be followed or the factors to be weighed when determining equivalence. Lacking such precise criteria, the organic proposal means that the equivalency decision will be a subjective judgement on the part of a few government officials.

The USDA record so far in making these judgement calls has been spotty. In 1999, the USDA declared the controversial and highly privatized meat inspection system in Australia as equivalent to that of the U.S. even though the European Union and other nations rejected the Australian plan as unsafe. In the same year, the USDA reaffirmed a Brazilian meat inspection system as equivalent to our own, even though at the time many Brazilian meat inspectors were hired and paid by the meat processing companies themselves rather than the government, as required by U.S. law.

The equivalence provisions are particularly troubling in this context. The USDA organic proposal consists of 150 pages of standards and requirements U.S. food producers must meet before their products can be labeled "organic." Many concerned Americans had a hand in shaping the proposed U.S. rules. Yet, the proposal's loophole permitting vague equivalency determinations as to what foreign foods

meet the precise organic standards threatens to undermine much of the proposal's progress.

The purpose of the 1990 Organic Foods Production Act, the law requiring USDA to develop the National Organic Program, was to assure "consumers that organically produced products meet a consistent standard."[78] If USDA recognizes foreign systems with different organic accreditation standards or production requirements as "equivalent," this Congressional goal will be undermined.

Given many people are not aware of the equivalence concept, this undermining element of the proposal could slip through. Those who are aware have demanded that the USDA strike the equivalence language and affirm that no equivalence determination will be made regarding core production requirements. These steps are needed to ensure that all food sold in the U.S., including imports, meet the requirements of our democratically-achieved organic food rule. This is the only way U.S. consumers can be assured that "organic" means organic for both imported and domestic foods.

For more information on organic agriculture, see the Organic Trade Association's Internet site at http://www.ota.com, or the USDA's Internet site at http://www.ers.usda.gov/whatsnew/issues/organic.

D. CHIC - Industry Pursues Cosmetics Harmonization Behind Closed Doors

The U.S. Food and Drug Administration (FDA)is developing a new global harmonization body, tentatively called CHIC (Cosmetic Harmonization and International Cooperation). Countries currently involved in CHIC discussions include the U.S., EU, Canada, and Japan.

CHIC had its initial meeting in Brussels in April, 1999. On the invitation list was the U.S.-based Cosmetics, Toiletry and Fragrance Association (CTFA), whose members include such multinational giants as Proctor and Gamble, Almay, Elizabeth Arden, Clinique, and Colgate. Also invited was COLIPA, the European cosmetics trade association, which includes companies like Gilette, L'Oreal, Avon, and Johnson & Johnson.

The record of this meeting includes an interesting exchange between regulators and industry about the need to include consumers and consumer representatives in the discussion. U.S. federal regulators asked industry representatives if they were including consumers in industry harmonization discussions, and the industry representatives responded by saying that it really was the regulators' job to deal with consumers. This conversation concluded with the assurance that "the needs of consumers were amongst the highest priority of all parties."[79]

Yet, no consumers or consumer groups were even invited to this meeting. Only after learning of these activities in obscure industry documents have consumer groups been able to know to demand to be involved in the discussions.

Not surprisingly, CHIC's tentative agenda tracks industry demands. For example, industry wants to replace the U.S. common-language labeling system, required by the Fair Packaging and Labeling Act,[80] with an EU labeling system that is in Latin. Under the EU system, U.S. consumers, many of whom may suffer from serious allergies, would see the Latin "persicum" instead of "peach" on cosmetics labels.

U.S. industry also wants to adopt the EU definition of "cosmetic," which would switch some products currently regulated in the U.S. as "over-the-counter drugs" to the less-regulated "cosmetics" category. In addition, U.S. industry wants the FDA to adopt the EU system of regulating color additives. The EU has approved more color additives for use in cosmetics than the FDA has. Some of these EU-approved additives are banned in the U.S.

If consumers were the driving force in this discussion, the emphasis would assuredly be different. For example, EU regulations require cosmetic labels to contain batch numbers and expiration dates and cosmetic companies to keep a full dossier of information on each product, including scientific evidence demonstrating efficacy. U.S. rules do not. Thus, the potential for upward

harmonization of U.S. standards in this area is significant. It will be an interesting experiment to see if consumer groups can turn the conversation around to promote upward harmonization of important cosmetic safety regulations.

For more information on CHIC, see the FDA's Office of Cosmetics and Colors Internet site at http://vm.cfsan.fda.gov/~dms/cos-intl.html.

E. The GHTF - Weakening Medical Device Regulations

The Global Harmonization Task Force (GHTF) was established in 1992 to harmonize medical device regulatory systems and facilitate trade. It is comprised of government health officials and industry representatives from Australia, Canada, the European Union, Japan, and the U.S. Consumer groups are excluded.

On August 5, 1999, the Food and Drug Administration, which participates in the GHTF, published a draft document prepared by the GHTF - "Proposal for Reporting of Use Errors with Medical Devices" - to serve as a reference for industry on adverse event reporting.[81] Under current regulations, the FDA requires medical device manufacturers to report to the agency information "that reasonably suggests that a device marketed by the manufacturer: (1) May have caused or contributed to a death or serious injury; or (2) Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur."[82]

The phrase "cause or contribute" is defined under the regulations as an event that may occur as a result of six different factors, one of which is "user error."[83] Thus, user errors that lead to malfunctions that could cause or contribute to a death or serious injury if the malfunction were to recur must be reported under current FDA regulations.

The GHTF proposal, which applies only to user errors (renamed "use errors" in the proposal), is a significant departure from FDA regulations. Under the GHTF proposal, "Adverse events involving use error, where there is no death or serious injury, should not be reported."[84] This proposal thus would continue to require manufacturers to report use errors that cause death or serious injury, but not use errors that lead to malfunctions that could cause or contribute to death or serious injury if the malfunction recurred.

Requiring manufacturers to report incidents in this second category is critical. The entire purpose of the device reporting requirements is to prevent future adverse events. Yet, under the GHTF proposal, important adverse events deemed by the manufacturer to be due to "use error" could continue to accumulate and not be reported to the FDA until deaths or serious injuries resulted. The GHTF proposal does not even deign to provide a justification for this radical departure from current practices.

If finalized and adopted by the FDA, the GHTF proposal would significantly weaken current FDA standards and fray the safety net for U.S. patients. Fortunately, the GHTF is reconsidering the proposal after Public Citizen's Health Research Group intervened and wrote a letter to the FDA protesting the proposal.[85]

For more information on the GHTF, see the GHTF Internet site at http://www.ghtf.org.

F. Harmonizing Standards for Carcinogenic Pesticide Residues in Food

Because Codex standards are named in both NAFTA and the WTO as the presumptively legal food standards for international commerce, any domestic standard which provides greater restrictions on pesticide residues could face a trade challenge.

Yet Codex still allows DDT residues in milk, meat and grains. Until Public Citizen publicized Codex's DDT standards in 1993, Codex also allowed DDT residues on fruits and vegetables. In 1993, Public Citizen joined with the scientists of the Environmental Working Group to study the relative strength of U.S. and Codex standards. Until this study was conducted, the only information

comparing U.S. and Codex standards was a Government Accounting Office study noting that in 55 percent of cases compared, U.S. standards provided more consumer protection than Codex standards.[86]

Codex lists specific levels of allowable pesticide residues and allowable additives such as colors, flavors and preservatives for specific foods. The Environmental Working Group's scientists found that of the 3,285 pesticide/crop combinations for which Codex has standards, 1,539 are barred by the U.S. Similarly, the U.S. has rules banning residues of 40 pesticides for which Codex provides 569 different standards. Eight of these barred active pesticide ingredients allowed by Codex are rated as highly hazardous by the World Health Organization. Yet, Codex provides for 116 food tolerances for such pesticide residues.[87] As the report emphasized, any decline in guaranteed public health protections that downward food standard harmonization could cause would be disproportionately borne by poor consumers who do not have the extra income to "choose" safer food by buying organic produce.

On April 7, 2000, EPA published a Notice (which is the EPA's version of a Proposed Rule), in which the agency proposed to amend its tolerances for the pesticide "avermectin" (or "abamectin") to harmonize them with Codex tolerances.[88] EPA originally set avermectin tolerances for tomatoes and bell peppers at .01 parts per million (ppm) and for head lettuce and celery at .05 ppm.[89]

However, on September 7, 1999, EPA doubled its avermectin tolerance for all peppers to .02 ppm in order to harmonize with the Codex tolerance.[90] Based on information submitted by Novartis Crop Protection, Inc., the manufacturer of avermectin, EPA is proposing to lump tomatoes, peppers, and other "fruiting" vegetables into one category with a tolerance of .02 ppm; and head lettuce, celery, and other "leafy" vegetables into one category with a tolerance of .10 ppm.[91] This will effectively double EPA's current tolerances for tomatoes, head lettuce, and celery.

For more information on Codex, see the Codex Internet site at http://www.fao.org/waicent/faoinfo/ECONOMIC/esn/codex/default.htm.

G. The U.S.-EU Mutual Recognition Agreement

On May 18, 1998, the U.S. and the European Commission signed a Mutual Recognition Agreement affecting trade in billions of dollars worth of products between the U.S. and European Union member nations.[92] An MRA is a reciprocal agreement between countries requiring them to treat each other's "conformity assessment" procedures as if they were their own. "Conformity assessment" means verification by a country that a product meets a required standard. Thus conformity assessment systems include product testing, quality systems audits, and reporting of analysis of such tests and audits.

The 1998 U.S.-EU MRA consists of a general framework (the "umbrella agreement") and six sectoral annexes covering telecommunications, electromagnetic compatibility, electrical safety, recreational craft safety, medical devices, and pharmaceutical good manufacturing practices (GMPs). Good manufacturing practices ensure the purity and the quality of the finalized drug product.

The purpose of the pharmaceutical GMP Annex is to permit European drug regulatory authorities to conduct GMP inspections in their nations on behalf of the FDA. To achieve this, the FDA will examine the pharmaceutical GMP regulatory systems of each of the 15 EU nations and determine whether each is equivalent to the U.S. regulatory system. Once the FDA declares a nation's GMPs equivalent, nations will be able to export drugs to the U.S. without having to submit them for inspection by the FDA.

The FDA began assessing the equivalence of EU member nations in October 1999 and expects to finish by August 2001. The General Accounting Office has estimated that the FDA will require at least $10 million including 125 full-time employees to implement this aspect of the MRA.[93]

The GMP Annex defines "equivalence" as involving "systems [that] are sufficiently comparable to assure that the process of inspection and the ensuing inspection reports will provide adequate information to determine whether respective statutory and

regulatory requirements of the authorities have been fulfilled. Equivalence does not require that the respective regulatory systems have identical procedures."[94]

While the FDA has stressed that the MRA does not mean that standards would be harmonized, at a December 8, 1999 meeting on the topic, one FDA official stated, "There is certainly no prohibition against certain harmonizations taking place. I think it's just a natural outcome of the process."[95]

Consumer groups are concerned about the MRA for a variety of reasons. The FDA has indicated that it will not solicit public comment before making each equivalence determination and that the governing body which will determine equivalence will operate behind closed doors. (This stands in stark contrast to the FDA's procedure on the equivalency of food systems which allows for early notice and comment on a tentative declaration of equivalence.) In addition, consumers will have no access to the correspondence, comparative memos and documents that led to the equivalence decision until after a positive declaration of equivalence is made. If the FDA rejects an equivalence decision, documents will remain sealed.

Moreover, U.S. consumer groups have expressed concern about whether documents currently available to the U.S. public under the Freedom of Information Act (FOIA) would remain so once the FDA turns over its inspection duties to foreign regulators. Few EU countries have a law similar to FOIA, and not all EU countries publish recall information like the U.S. does. FDA officials have even indicated that the agency might use the "national security information" exemption[96] to FOIA if it needed to keep certain business information confidential.

For more information on the U.S.-EU MRA, see the MRA Internet site at http://www.fda.gov/cdrh/mra/index.html.

H. When Are Pasteurized and Non-Pasteurized Milk Equivalent?

From 1977 through 1991, ultra-high temperature ("UHT") milk was exported from Quebec to Puerto Rico. Under pressure from the Food and Drug Administration for its lax hygiene standards regarding milk, in 1990 Puerto Rico adopted the Pasteurized Milk Ordinance and joined the National Conference on Interstate Milk Shipments (NCIMS) which subjects the milk industry to strict sanitation standards, practices and inspection. The UHT milk did not comply with these new rules. Quebec refused either to participate in the NCIMS or to contract with a northern U.S. state to conduct the required milk inspections and certifications. Thus, Puerto Rico banned imports of UHT milk at the end of 1991.

Canada then demanded a study to assess the "equivalence" of pasteurized and non-pasteurized UHT milk under the U.S.-Canada Free Trade Agreement which contains provisions similar to NAFTA's. The two countries could not agree on the parameters of the study, and Canada filed a formal trade challenge. In June 1993, the panel concluded that Puerto Rico had not violated any specific terms of the U.S.-Canada Free Trade Agreement. However, the panel ruled against the United Stated anyway, deciding that the prohibition on UHT imports "nullified and impaired" benefits Canada reasonably expected would accrue to it under the trade agreement.[97]

The panel specifically concluded that, in light of the pact's equivalency provisions, Canada had a reasonable expectation that a product, like UHT milk, which had been sold in the U.S. for some time, would not be excluded from the market because of adoption of a new U.S. standard if it could be shown that the product was being produced under standards having the same effect as the new U.S. standard.[98]

Puerto Rico was allowed to keep out UHT milk while negotiations continued over how to resolve the issue. However, in 1996, Puerto Rico was required to accept imports of Canadian UHT milk.[99] In fact, after implementing the trade ruling, Puerto Rico accepted so much Canadian UHT milk that on March 17, 1997, a Puerto Rican milk producer filed antidumping petitions with the U.S. Department of Commerce and the U.S. International Trade Commission against Canadian producers of UHT milk.[100] The petition claims Canadian producers sold

UHT milk in Puerto Rico for less than fair market value and requests an Antidumping Order against imports of Canadian UHT milk.[101]

I. Auto Safety Standards Go Global

The National Highway Traffic Safety Administration (NHTSA) has signed onto a 1998 Global Auto Agreement that will create a new (as yet unnamed) international institution for setting the WTO-legal standards for automobiles and auto safety standards in Geneva. The 1998 Agreement will go into force as soon as it is signed by eight countries, likely in the summer of 2000.[102] Auto safety experts in the U.S. have lobbied against the agreement citing the lack of specific consumer benefits ascribed to harmonization, the democracy deficit that ensues when U.S. standards are negotiated overseas and concerns about the drain on NHTSA's scarce resources.

The global auto body empowered by the 1998 Agreement will be unlike most standard setting organizations. The body will operate by consensus, and each nation *must* attempt to adopt *each* approved standard into domestic law. (In contrast, while Codex standards have standing under the WTO, and thus can be used to challenge higher domestic standards, they are technically "voluntary" and do not have to be adopted domestically by the nations involved.)

Critical reductions in safety can result from changes in technical details of U.S. safety standards. NHTSA's early experience with international harmonization has not been good. In 1995, NHTSA adopted an EU standard that would allow brake status to be checked by a manual push button rather than requiring automatic brake status checks[103] and NHTSA allowed European parts maintenance and replacement practices for headlamps that are less economical and less effective at illuminating U.S. road signs.[104]

However, in 1999, NHTSA rejected two industry proposed "equivalency" determinations.[105] Unlike other federal agencies, when NHTSA determines equivalency, it is not looking at a broad definition of equivalency between regulatory agencies, but a very specific determination of equivalency proposed by industry on a specific standard.

For example, NHTSA rejected an American Automobile Manufacturers Association request to amend two federal motor vehicle safety standards, one on windshield wiping and washing and another on windshield defrosting and defogging, and to determine corresponding EU standards "functionally equivalent." NHTSA made its decision after determining that the EU standards would result in sizeable reduction in the area cleared by the wipers and the defoggers, reducing visibility and providing less safety. However NHTSA did say it believes a harmonized standard is possible and it will continue to work on the issue with EU colleagues.

In an April 2000 meeting, NHTSA officials conceded to auto safety experts that the standards set in the new Geneva-based harmonization body would qualify as the presumptively-legal WTO standards, and that other standards the U.S. might develop outside this forum could be challenged as technical barriers to trade in the WTO dispute resolution system. In fact, NHTSA said it pushed for the agreement because it did not want to see a similar European auto standard setting body, which operates under the auspices of the United Nations Economic Commission for Europe, to set the official WTO-legal standards. Ironically, the European group will still continue to meet and promulgate harmonized standards for the EU.

While the proposal for a new global auto body poses many challenges for public interest groups and U.S. consumers who will find it hard to attend meetings in Geneva and track the progress of any standard, the same situation presents industry with an interesting array of new options. The dual venues for auto standards create an interesting situation where industry could try to play one forum off of the other, or forum shop for the more amenable institution. If, for example, the U.S. blocks the development of a global auto standard under the 1998 Agreement that NHTSA believes would unacceptably lower existing U.S. standards, industry could try and get the same standards passed in the European auto standards body, thus placing the higher U.S. standard at risk for a WTO challenge as a technical barrier to trade.

For more information on auto safety standards harmonization, see the United Nations' Economic Commission for Europe (UNECE) Internet site at http://www.unece.org/trans/main/welcwp29.htm. For more information on harmonization of other types of transportation safety standards, see http://www.unece.org/trans/Welcome.html.

J. Creating a Global System for Chemical Classifications and Labeling

The Organization of Economic Cooperation and Development (OECD), the International Labor Organization (ILO), the United Nations (U.N.) and no less than ten U.S. federal agencies have been involved in a decade long effort to create a Globally Harmonized System (GHS) for chemical classification and labeling. The definition of "chemicals" for the negotiations includes pesticides, pharmaceuticals and consumer products. This international harmonization effort will result in a system that will have profound effects on U.S. regulations regarding worker, consumer and environmental protections, the transportation of hazardous materials, and community right-to-know laws.

Four different international agencies have a piece of the GHS pie. The OECD has primary responsibility, through a series of expert committees, for classifying acute health hazards (such as irritation, sensitization and acute toxicity), chronic health hazards (such as carcinogenicity and reproductive toxicity) and environmental hazards. The U.N. Committee on the Transport of Dangerous Goods, which already has a set of international rules governing the transportation of hazardous materials, is charged with developing further rules on transportation and physical hazards, including flammability and reactivity (explosion hazard). The ILO is responsible for information systems, including rules regarding labeling and material safety data sheets.

Overall coordination of the entire harmonized system is provided by the Inter-organization Programme for the Sound Management of Chemicals (IOMC) which includes representatives from the four relevant chemical classifications and transportation systems, the U.S., the EU, Canada and the U.N. transportation system. U.S. OSHA currently chairs the IOMC. Once completed, the GHS will be permanently housed at the United Nations Economic and Social Council.

While gains in efficiency and worker safety could accrue from a GHS on chemicals and while diligent union representatives have worked hard to monitor the negotiations and to promote upward harmonization, critics cite three concerns.

First, many important battles have been fought in ten years of negotiations, and many more years of negotiations are still planned. By the time the GHS is implemented in the U.S. (likely via half a dozen large *Federal Register* notices posted by the federal agencies involved), crucial issues will already have been decided. These issues include the definition of "acute toxicity," rules governing mixtures and alloys, and whether those preferring the worker-protective "hazard-based" labeling will prevail over those preferring a "risk-based" labeling system, which provides a lesser level of worker protection,. The ability of public interest organizations, labor unions, or public health officials to impact those decisions so late in the game will be minimal.

Second, once in place and adopted by many nations and thousands of manufacturers, the system will be extraordinarily difficult to modify. As currently constituted, it is not clear how the GHS will incorporate change as new science presents new evidence of hazard. In addition, the negotiators have yet to decide how to handle corporate "trade secret" claims, raising the fear that chemical suppliers will be able to claim business confidentiality with regard to certain information, and thus nullifying the information requirements at the core of the agreement.

Finally, labor representatives involved in the GHS lost a battle to turn the results of harmonization talks into a binding international convention. This means that there will be no capacity to sanction countries for violating the standards or having lower standards.

However, the dispute resolution system of the WTO will stand ready to enforce the GHS as the presumptively-legal international standard. Should

any nation adopt worker safety protections that exceed those in the GHS, they could be subject to challenge as an unfair barrier to trade in the WTO.

For more information on the GHS, see http://www.epa.gov/oppfead1/harmonization.

K. The ICH - Weakening U.S. Carcinogenicity Testing Standards

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) was created by industry and regulatory authorities to harmonize requirements for the production and registration of pharmaceuticals in the U.S., EU, and Japan. The ICH is comprised of three governmental bodies - the European Commission, Japanese Ministry of Health and Welfare, and U.S. Center for Drug and Biologics Evaluation and Research (an office of the FDA) - and three pharmaceutical industry trade associations - the European Federation of Pharmaceutical Industries Association, Japanese Pharmaceutical Manufacturers Association, and Pharmaceutical Research and Manufacturers of America. Again, consumer groups are excluded.

In 1996, the FDA proposed changes to the guidelines for testing the potential carcinogenicity of pharmaceuticals. These proposed changes are now under active consideration.[106] The purpose of these proposed changes was to harmonize U.S. standards with those promoted by the ICH.

Previously, the U.S. required companies to test new drugs on two species, typically mice and rats. Testing on two animal species offers more assurance in assessing the risk to humans than testing on only one species. The most accurate predictor of carcinogenicity is the rat-mouse combination. For instance, for 65 substances, tests in rats alone have failed to produce evidence of carcinogenicity, while additional tests on mice have yielded clear evidence. Yet, the proposal for a harmonized testing standard allows pharmaceutical companies to drop mice tests and substitute short-term tests for a second species test, even though short-term tests are less indicative than the longer-term animal studies.[107]

The U.S. also has a role in lowering other nations' standards by pushing U.S. policy into international standards. For example, the U.S. is trying to push its use of placebos in clinical trials onto other countries through the ICH.

On September 24, 1999, the FDA published a Draft Guidance on Choice of Control Group in Clinical Trials ("The Guidance"), which was prepared by the ICH.[108] About ICH guidelines, the FDA says, "Although [ICH] guideline[s do] not create or confer any rights for or on any person and [do] not operate to bind FDA, [they do] represent the agency's current thinking."[109]

The Guidance attacks active-controlled trials, in which a new drug's effects are compared to the effects of drugs that have already been approved and are on the market, and advocates the use of placebo-controlled trials, in which a new drug's effects are compared to the effects of a placebo. In an active-controlled trial the test group is given the new drug and the control group is given a drug that has been approved as safe and effective. In a placebo-controlled trial, the test group is given the new drug, but the control group is merely given a placebo.

Experts have criticized the FDA's reliance on placebo-controlled trials as uninformative and unethical. For example, in a letter to the FDA protesting the Guidance, Public Citizen's Health Research Group stated, "Most patients and physicians have little need for information addressing whether a new drug for a disease for which there already is an effective therapy is better than nothing; they would like to know whether the new drug is better than the existing drug."[110]

Furthermore, the letter continues, "The Guidance is a transparent attempt to legitimize evasions of the clear requirements of the Declaration of Helsinki, which requires that 'in any medical study, every patient - including those of a control group, if any - should be assured of the best proven diagnostic and therapeutic method."[111] The letter concludes, "While this may make things easier for regulatory bodies, which can approve drugs simply on the basis

of superiority to placebo, and to the pharmaceutical industry, which can more easily prove a new drug superior to placebo than approximately equivalent to a known effective treatment, patients will often not receive optimal medical treatment during the trial."[112]

By controlling ICH discussions, and excluding consumer groups from these discussions, the pharmaceutical industry's goal seems clear: paving the way for new drug approvals worldwide with as little testing as possible.

For more information on the ICH, see the ICH Internet site at http://www.ifpma.org/ich1.html.

L. U.S. Weakens GMO Regulations in International Negotiations

On January 29, 2000, in Montreal, Canada, representatives from 131 nations, including the U.S., agreed to a biosafety protocol that establishes rules for international trade in genetically-modified organisms (GMOs). The agreement, referred to as the "Cartagena Biosafety Protocol" because the first such negotiations took place in Cartagena, Columbia in 1999, will not take effect until at least fifty nations ratify it.

The agreement's conclusion was heralded by both industry and citizen activists, highlighting the ambiguity of the pact's language and the varying interpretations of its significance. Activists lauded the Protocol as the first international agreement to set binding global regulations on a global industry and as promoting the Precautionary Principle, which states that nations should take protective action when faced with uncertain risks or inconclusive scientific evidence. Notably the Protocol does not use the words "Precautionary Principle." Rather it outlines the steps nations may take in a "precautionary approach" to regulating GMOs. Industry promoted the Protocol as being of limited scope and subject to World Trade Organization (WTO) rules.

These negotiations took place in the context of an intensifying fight between the U.S. and EU over GMO regulation and trade. The EU, in response to consumers' concerns over GMOs' possible health and environmental risks, has restricted the domestic use of genetically-modified seeds and import and sale of products made with GMOs. Other nations, following the EU's lead, have required pre-market testing and labeling of GMOs and foods made with GMOs.[113] In contrast, GMO products do not require any special testing or approval in the U.S. U.S. consumers are not even informed of the presence of GMOs in their food given U.S. law does not require GMO labeling.

The U.S. was unable to participate officially in the Biosafety Protocol negotiations because it never ratified the 1992 Convention on Biological Diversity, which is the basis for the biosafety talks. However, the U.S. was able to influence the negotiations significantly as a vocal observer and through other nations, like Canada and Australia, that have ratified the Convention on Biological Diversity. These countries' aims for international trade in GMOs parallel the U.S.'s. The U.S. is the largest exporter of GM foods, but both Canada and Australia export billions of dollars worth of GM foods as well.

In February 1999, the "Miami Group" - consisting of the major food exporting countries Canada, Australia, Argentina, Uruguay, Chile, and the U.S. - blocked the adoption of a biosafety protocol during negotiations in Cartagena by refusing to allow commodities, like soybeans and corn, to be included in the agreement.[114] According to a statement from the European Commission, "This would in practice mean excluding 99 percent of the genetically modified organisms that the protocol is supposed to cover."[115] An estimated fifty percent of the U.S. soybean crop and thirty-three percent of the U.S. corn crop is grown with GM seeds.[116]

The U.S. finally stopped blocking the protocol in Montreal, but only after obtaining several concessions. Most significantly, the U.S. obtained language that obscures the Protocol's legal standing relative to the WTO's Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The U.S. wanted the Protocol to be subject to the SPS Agreement because these WTO rules prohibit nations from maintaining food safety regulations, including those governing GMOs, that are not based on scientific findings of specific human

health risks. This effectively eviscerates use of the Precautionary Principle. The SPS Agreement also does not allow nations to consider other legitimate factors, such as environmental implications and consumer opinions, in setting standards.

According to U.S. Department of Agriculture officials, the U.S. got what it wanted. At the Transatlantic Consumer Dialogue conference in Washington, D.C., February 2000, Bernice Slutsky of the USDA's Foreign Agricultural Service, informed a consumer group audience that the U.S. believes that the Protocol does not change nations' WTO rights and obligations.

Deciding whether the Protocol is subject to WTO rules will be a difficult and politically-charged process. Such a decision may be forced if a nation's laws regulating trade in GMOs are ever challenged at the WTO. Significantly, however, if a nation does challenge another nation's GMO regulations in a WTO tribunal, it is WTO trade bureaucrats, not the environmental, food safety, and consumer experts or groups that helped to shape the Biosafety Protocol, who will be making that critical decision.

The Biosafety Protocol is available on the Internet at http://www.biodiv.org/biosafe/protocol.

CONCLUSION

Reforming the practices of international institutions like NAFTA and the WTO, if ever possible, is a long-term goal. Providing consumer, environmental, health and other broad public interest balance in even the quasi-governmental harmonization agencies, like Codex, is limited by the structures of these organizations. Yet, the current trade-related proposals for harmonization and equivalence and organizations such as ISO and Codex will have far-reaching implications not only for strong substantive U.S. standards, but also on the process of open, accountable standard-setting in the U.S.. Clearly, the latter raises major issues about maintaining democratic and accountable governance in the era of globalization that to date have been overshadowed by focus on globalization's economic effects.

At a minimum, U.S. regulators must fully apply the due process and participation requirements of existing U.S. laws, such as the Administrative Procedure Act, Freedom of Information Act, and Federal Advisory Committee Act, to all international harmonization activities. Development of U.S. positions taken to harmonization talks and consideration of any other proposals coming out of such negotiations must be through the on-the-record system of notice-and-comment rulemaking, as required by the APA. To date, adherence to these existing legal requirements has been spotty, at best.

NOTES

1. Agreement Establishing the WTO, Article XXIV-12 in Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, GATT Doc. MTN/FA (Dec. 15, 1993), 33 I.L.M. 9 (1994).

2. Also, the Agreement on Government Procurement, one of several plurilateral agreements completed in conjunction with the GATT Uruguay Round, forbids procurement set-asides aimed at providing beneficial terms for minority or small businesses. (Agreement on Government Procurement, in Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, GATT Doc. MTN/FA (Dec. 15, 1993), 33 I.L.M. 9 (1994), Article XVI-1.) Such procurement set-asides exist in current U.S. law and the European Union has similar provisions to promote development in economically distressed regions.

3. Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) ¶ 9, in Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, GATT Doc. MTN/FA (Dec. 15, 1993), 33 I.L.M. 9 (1994).

4. *See, e.g., id.* at ¶¶ 11, 16-23. Even where a higher level of protection is permissible, the standard, on its face and as applied, must comply with all of the other WTO requirements to pass muster under WTO.

5. Agreement on Technical Barriers to Trade (TBT Agreement) ¶¶ 2.4, 5.4. in Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, GATT Doc. MTN/FA (Dec. 15, 1993), 33 I.L.M. 9, (1994); Agreement on Technical Barriers to Trade, ¶ 905-1, North American Free Trade Agreement, Dec. 17, 1992.

6. TBT Agreement, Arts. 2-4, in Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, GATT Doc. MTN/FA (Dec. 15, 1993), 33 I.L.M. 9 (1994).

7. Codex is a quasi-governmental commission based in Rome that sets food standards through a process involving a large role for industry, but little involvement of public health or consumer interests. Codex is discussed at length later in this handbook.

8. For instance, the WTO requires one of the following professional backgrounds to qualify for its roster of potential tribunalists: having served on or presented a case to the GATT panel, having represented a government at GATT, having worked in the Secretariat of GATT, having served as a senior trade policy official of a GATT Member, or having taught or published articles on international trade law or policy. (Agreement Establishing the WTO, Art. 8-1, Understanding on Rules and Procedures Governing the Settlement of Disputes, in Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, GATT Doc. MTN/FA (Dec. 15, 1993), 33 I.L.M. 9 (1994)). Thus, the world's leading expert on air quality regardless of numerous advanced degrees, publications, and high-level experience, would not be qualified under WTO rules to sit on a WTO case judging a country's air standards.

9. WTO, Understanding on Rules and Procedures Governing the Settlement of Disputes, Art. 8.1.

10. The WTO's Dispute Settlement Understanding specifically mandates that all dispute panel activities and documents are confidential. *See* WTO, Understanding on Rules and Procedures Governing the Settlement of Disputes, Art. 14 and App. 3, Paras. 2 and 3. NAFTA's Rules of Procedure state that the dispute "panel's hearings, deliberations and initial report, and all written submissions to and communications with the panel shall be confidential." North American Free Trade Agreement, Art. 2012.1(b).

11. In mid-1996, Public Citizen and the Sierra Club Legal Defense and Education Fund sent an unsolicited amicus submission to the WTO in support of the European ban of certain artificial hormones in beef. The U.S. had filed a WTO case against the European hormone ban. The ban is supported by U.S. consumer groups and is considered a cutting-edge public health measure. Thus, the case has significant public health and democratic governance implications. Not only was the amicus submission rejected, but the WTO staff actually mailed the large package containing the brief back to the United States from Geneva. Attached was a sharp-toned note about the WTO's policy of not accepting outside submissions. The WTO dispute resolution staff had not returned a past unsolicited amicus submission the two groups made on an earlier WTO case with major environmental implications. Top WTO officials were concerned that failing to return the next submission might create expectations that outside submissions were appropriate or allowed. The WTO dispute panel eventually ruled the artificial hormone ban an illegal trade barrier.

12. WTO, "United States - Import Prohibition of Certain Shrimp and Shrimp Products," Report of the Appellate Body, Oct. 12, 1998, at 35-36.

13. This elaborate trade advisory committee system is established at the 1974 Trade Acts (19 U.S.C. § 2155).

14. Agreement on Technical Barriers to Trade, Land Transportation Subcommittee, Annex 913.5.9-1, North American Free Trade Agreement, Dec. 17,1992**.**

15. *See* 56 Fed. Reg. 29050-51 (Jun. 25, 1991), describing the formal role of industry advisors to Codex.

16. National Food Alliance, *Cracking the Codex: An Analysis of Who Sets World Food Standards* (1993) at 1. As a result, some multinational food corporations like Nestle, with representatives on numerous nations' delegations, are represented by a dozen delegates, while poor countries are generally unable to send more than one official government representative to Codex's major Rome and Australia sessions.

17. Public Citizen efforts in 1992 convinced the U.S. Environmental Protection Agency (EPA) to add some contacts at U.S. consumer and environmental groups to the list of industries getting notice of certain U.S. Codex activities. As well, several other environmental and consumer groups have convinced individuals at some federal agencies to allow them into U.S. Codex delegations, joining the team of U.S. industry advisors. However, such groups must pay their own way to attend. Industry has been willing and able to fly teams of scientists, policy experts and lawyers to

the numerous different Codex subcommittees now in operation at locations around the world on each standard for each such international standard-setting body. However, after trying to participate in these fora, most environmental and consumer groups concluded they would be wasting limited resources to task numerous staff to a process without clear operating rules or accountability, even if they had the resources to do so. Many groups have concluded a more strategic and practical arena for participation is at the levels of domestic development of positions to be taken to Codex and domestic implementation of proposed Codex standards. As well, many consumer and environmental groups have concluded that it is not worth participating in organizations, such as Codex, only to squabble over international standards providing health protections similar to U.S. domestic standards in the 1960s.

18. General Accounting Office, *International Food Safety: Comparison of U.S. Codex Pesticide Standards* (Aug. 1991).

19. Ritchie, "GATT, Agriculture and the Environment: The Double Zero Plan," 20 *The Ecologist* 214, 216-17 (Nov./Dec. 1990) (Pl. Ex. 16).

20. *Id.; see also*, General Accounting Office, *International Food Safety: Comparison of U.S. & Codex Pesticide Standards* (Aug. 1991) at 4 (Pl. Ex. 17).

21. *See, e.g.*, Md. Agric. Code Ann. § 5-210.5 (1989) (heptachlor); Minn. Stat. § 18B.115 (1990) (same).

22. Mika Iba, Network for Safe and Secure Food, interview with Mary Bottari, Public Citizen's Global Trade Watch, Jun. 15, 2000.

23. Benchmark Environmental Consulting, *ISO 14001: An Uncommon Perspective - Five Public Policy Questions for Proponents of the ISO 14000 Series* (Nov. 1995), at 13.

24. *Id.* at 11.

25. *Id.* at 12.

26. *Id.* at 11.

27. *See* SPS Agreement, in Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, GATT Doc. MTN/FA (Dec. 15, 1993), 33 I.L.M. 9 (1994), Art. 3.2; and North American Free Trade Agreement, Arts. 713 and 905.

28. *See* European Economic Council Directive 88/146/EEC.

29. *See, e.g.*, "Brie and Hormones," *The Economist*, Jan. 7, 1989, at 22; Samuel S. Epstein, "The Chemical Jungle," *International Journal of Health Services* (1990) at 278; A.L. Fisher, *et al.*, "Estrogenic Action of Some DDT Analogues," 81 *Proc. Soc. Expt'l Med.* 439-441; and W.H. Bulger & D. Kupfer, "Estrogenic Activity of Pesticides and Other Xenobiotics on the Uterus and Male Reproductive Tract," in J.A. Thomas, *et al.*, Eds., *Endocrine Technology* (1985) at 1-33.

30. *See, e.g.*, National Cattlemen's Beef Association, "Government Must Retaliate If EU Continues to Ban American Beef," Press Release, May 10, 1999: George Swan, NCBA President, said, "Ten years of false accusations. Ten years of lost markets for U.S. cattlemen and lost opportunities for European consumers. . . ."

31. WTO, European Communities - Measures Affecting Meat and Meat Products (Hormones) (WT/DS26), Complaint by the U.S..

32. WTO, European Communities - Measures Affecting Meat and Meat Products (Hormones) (WT/DS26/R/USA), Report of the Panel, Aug. 18, 1997, at Para. 8.88.

33. *Id.*

34. SPS Agreement, in Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, GATT Doc. MTN/FA (Dec. 15, 1993), 33 I.L.M. 9 (1994), Art. 3.3.

35. WTO, European Communities - Measures Affecting Meat and Meat Products (Hormones) (WT/DS26/R/USA), Report of the Panel, Aug. 18, 1997, at Para. 8.159.

36. *See* WTO, European Communities, Measures Affecting Meat and Meat Products (Hormones) (WT/DS26/AB), Report of the Appellate Body, Apr. 16, 1998.

37. "EU says it will not lift ban on hormone-treated beef, cites scientific committee's findings that growth hormone may cause cancer; JECFA finds growth hormone use safe," *World Food Chemical News*, May 12, 1999, at 1.

38. "U.S. issues final sanctions list in beef-hormone dispute with EU," *World Food Chemical News*, Jul. 21, 1999, at 1.

39. "EU says it will not lift ban on hormone-treated beef, cites scientific committee's findings that growth hormone may cause cancer; JECFA finds growth hormone use safe," *World Food Chemical News*, May 12, 1999, at 1.

40. North American Free Trade Agreement, Art. 1110 (Expropriation and Compensation).

41. California Executive Order D-5-99, Mar. 25, 1999.

42. Arturo Keller, *et al.*, Health & Environmental Assessment of MTBE, Vol. 1, Summary & Recommendations, Nov. 1998, available at http://tsrtp.ucdavis.edu.mtberpt, at 23-24.

43. 65 Fed. Reg. 16093, 16098 (Mar. 24, 2000).

44. *Id.*

45. *Id.* at 16093.

46. University of California at Davis Report: MTBE Fact Sheet, Nov. 12, 1998, at 1. Available at http://tsrtp.ucdavis.edu/mtberpt, and on file with Public Citizen.

47. *Id.*

48. *Id.*

49. *See* Bullet Point Background on Methanex's NAFTA Claim and MTBE, at 1. Available at www.methanex.com, and on file with Public Citizen.

50. U.C. at Davis Report: MTBE Fact Sheet, Nov. 12, 1998, at 1.

51. *Id.*

52. *See* Robert Collier and Glen Martin, "Canadian Firm Sues California Over MTBE," *San Francisco Chronicle*, Jun. 18, 1999.

53. *See* Dennis Pfaff, "NAFTA Challenge to California," *Daily Journal*, Jul. 22, 1999.

54. 5 U.S.C. § 551, *et seq.*

55.5 U.S.C. § 552.

56. 5 U.S.C. § 552b

57. *See* 5 U.S.C. § 562, *et seq.*

58. 63 Fed. Reg. 7118 (Feb. 12, 1998)

59. Pub. L. 103-465.

60. See Center for Science in the Public Interest. "Representatives Tell White House 'Modify Trade Agreements to Improve Food Safety,'" Press Release, Jul. 26, 1999, on file with Public Citizen.

61. The U.S. delegate to the Codex web site is at http://www.fsis.usda.gov/oa/codex.

62. *See* Clif Wiens, "FSIS finds Australian meat inspections system equivalent," *World Food Chemical News*, Jun. 9, 1999, at 7.

63. 21 U.S.C. § 451 (poultry) and § 604 (meat).

64. *See* Communicable Diseases Network - Australia New Zealand - National Notifiable Diseases Surveillance System, May 10, 2000, available at www.health.gov.au/pubhlth/cdi/nndss/year030.htm, and on file with Public Citizen.

65. *Id.*

66. The Australian Quarantine and Inspection Service claims some of the increased salmonella-poisoning cases are attributable to dairy and egg products and better reporting.

67. European Commission, Health & Consumer Protection Directorate-General, Australia Mission Report, Mar. 30-Apr. 2, 1998, available at www.europa.eu.int/comm/dg24/health/vi/reports/australia/index_en.html, and on file with Public Citizen.

68. European Commission, Health & Consumer Protection Directorate-General, Final Report of a Mission Carried out in Australia from 11 to 23 November 1999 Relating to the Production of Fresh Bovine Meat for Export to the European Union, at 36.

69. 21 U.S.C. § 601.

70. Agreement on Technical Barriers to Trade, Land Transportation Subcommittee, Annex 913.5.a-1, North American Free Trade Agreement, Dec. 17, 1992.

71. Data supplied by Citizens for Reliable and Safe Highways (CRASH), on file with Public Citizen.

72. *NAFTA: The Facts*, CRASH Document, on file with Public Citizen.

73. U.S. Department of Transportation, Office of Inspector General, "Audit Report: Motor Carrier Safety Program for Commercial Trucks at U.S. Borders," Dec. 28, 1998, report # TR-1999-034, at 1.

74. *See id.* at i.

75. *See id.* at iv.

76. 62 Fed. Reg. 65849 (Dec. 16, 1997).

77. 65 Fed. Reg. 13511 (Mar. 13, 2000).

78. 7 U.S.C. § 6501.

79. European Commission, DG III/E/3, "Cosmetic Products: Record of the Meeting, Cosmetics Harmonization and International Cooperation" (99/III/COS/52), Brussels, Apr. 7-8, 2000, at 4, on file with Public Citizen.

80. 39 U.S.C. § 1451.

81. 64 Fed. Reg. 42701 (Aug. 5, 1999).

82. 21 C.F.R. § 803.50(a).

83. 21 C.F.R. § 803.3(d).

84. Global Harmonization Task Force, Study Group 2, "Proposal for Reporting of Use Errors with Medical Devices," Apr. 21, 1999, at 2.

85. *See* "Stalemate on Use Error Reporting Stalls GHTF Adverse Events Effort," *FDA Week*, Feb. 18, 2000.

86. General Accounting Office, *International Food Safety: Comparison of U.S. Codex Pesticide Standards* (Aug. 1991).

87. P. GOLDMAN & R. WILES, TRADING AWAY U.S. FOOD SAFETY (1994).

88. 65 Fed. Reg. 18328 (Apr. 7, 2000).

89. 40 C.F.R. § 180.449 (Jul. 1, 1999).

90. 64 Fed. Reg. 48548 (Sep. 7, 1999).

91. 65 Fed. Reg. 18328 (Apr. 7, 2000).

92. *See* 63 Fed. Reg. 60121 (Nov. 6, 1998).

93. GAO/HEHS-99-143R, Mutual Recognition Agreement, Aug. 13, 1999, at 2, on file with Public Citizen.

94. Testimony of Sharon S. Holston, FDA's Deputy Commissioner for External Affairs, Before the U.S. House of Representatives Commerce Committee, Subcommittee on Oversight and Investigations, Oct. 2, 1998, at 14-15.

95. Joseph Famulare, Center for Drug Evaluation and Research, FDA, Dec. 8, 1999.

96. 5 U.S.C. § 552(b)(1).

97. Both the WTO and NAFTA also contain the "nullification and impairment" cause of action which allows a ruling against a country even if that country has not broken any specific rules, but has nullified or impaired a "reasonable expectation" the other country had about the agreement.

98. In re Puerto Rico Regulations on the Import, Distribution and Sale of UHT Milk from Quebec ¶ 5.60-.61 (Jun. 3, 1993).

99. *See* Canadian Food Inspection System Implementation Group, "Continuing Progress Toward a Canadian Food Inspection System: Recommendations and Report to Ministers," Jun. 1997, *available at* www.cfis.agr.ca/proge.txt.

100. *See* Adduci, Mastriani & Schaumberg, L.L.P., Trade Action Reports, Mar. 17, 1997, available at www.adduci.com/t031797.htm, and on file with Public Citizen.

101. *See id.*

102. As of May 2000, the U.S., Canada, Japan, France, the United Kingdom, and the European Commission are signatories. The Republic of South Africa, the Russian Federation, and the Republic of Korea, have initiated national procedures for signing on.

103. 60 Fed. Reg. 6411 (Feb. 2, 1995).

104. 60 Fed. Reg. 54833 (Oct. 26, 1995).

105. 64 Fed. Reg. 19106 (Apr. 19, 1999).

106. *See* 61 Fed. Reg. 43297 (Aug. 21, 1996).

107. Comment Letter from Sidney M. Wolfe, M.D., and Larry D. Sasich, Pharm.D., FASHP, to the U.S. Food and Drug Administration re: International Conference on Harmonization: Draft Guideline on Testing for Carcinogenicity of Pharmaceutical; Docket No.96D-0235, Nov. 1, 1996.

108. 64 Fed. Reg. 51767 (Sep. 24, 1999).

109. 61 Fed. Reg. 43299 (Aug. 21, 1996).

110. Peter Lurie, MD, MPH, Deputy Director of Public Citizen's Health Research Group, Letter to FDA on ICH Draft Guidance on Choice of Control Group in Clinical Trials, Dec. 23, 1999.

111. *Id.*

112. *Id.*

113. *See, e.g.*, Michiyo Nakamoto, "Japan set to demand testing of genetically modified products," *Financial Times*, Apr. 26, 2000; Michael Smith, Michela Wrong, and Nancy Dunne, "EU sets out plan for modified food labels," *Financial Times*, Oct. 22, 1999; "Health ministers agree to require labeling of genetically modified food in Australia, New Zealand," *World Food Chemical News*, Aug. 18, 1999, at 6; Michiyo Nakamoto, "Japan's food labels decision may fuel trade friction," *Financial Times*, Sep. 14, 1999.

114. Jeremy Lennard, "US Sabotages Biosafety Protocol," *Guardian* (London), Feb. 23, 1999.

115. "EU Accuses US, Others of 'Extreme' Positions That Will Block Biosafety Protocol," *International Environment Reporter*, Feb. 17, 1999, at 136.

116. Lucette Lagnado, "Group Sows Seeds of Revolt Against Genetically Altered Foods in U.S.," *The Wall Street Journal*, Oct. 12, 1999, at B1.