INTRODUCTION

Efforts to establish international regulatory standards have increased in recent years, spurred by several agreements emerging from the Uruguay Round of trade negotiations in the mid-1990s.¹ and other similar trade agreements. An international regulatory standard is a regulatory requirement that originates as a result of international negotiations between the

¹ John M. Rounds Professor of Law, University of Kansas. This Article is based on a presentation that I made during the Spring Meeting of the American Bar Association Section of Administrative Law and Regulatory Practice on April 27, 2000. I appreciate the many useful comments and criticisms that I received from those in the audience. I am also indebted to John Head and to the members of the Globalization Faculty Seminar sponsored by the Hall Center for the Humanities, University of Kansas, for their comments and suggestions.

¹ The package of about twenty treaties, including the charter of the World Trade Organization (WTO), the updated General Agreement on Tariffs and Trade (GATT), and a new procedure for settling trade disputes was accepted by the United States in 1994, as reflected by enactment of the Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809 (1994).
United States and other countries or as the result of the actions of international institutions. Many regulatory agencies in the United States are involved in efforts to adopt international regulatory standards as domestic regulations.

The public has an important stake in the adoption of international standards. These standards can reduce trade barriers to the substantial benefit of American consumers and corporations. At the same time, the replacement of existing regulatory standards in the United States with international standards can weaken domestic regulatory protection of individuals and the environment.

Despite the public's stake in these issues, the government can make important decisions concerning the enforcement of international standards in the United States without effective public participation. This frustration of public accountability is easy to miss because the interrelationship between the creation of an international standard and its adoption in the United States is subtle and complicated. The aim of this Article is to explain this interrelationship and its impact on the administrative process in the United States.

Some federal agencies have taken tentative steps to solicit public input regarding the adoption and enforcement of international standards in this country. While these steps are noteworthy, it is beyond the scope of this Article to assess whether they are adequate to assure effective public input, a subject that I will address in a forthcoming article. The more limited goal of this Article is to alert readers to the problem of accountability created by the movement toward international standards.

This Article is organized according to the three ways in which international standards are implemented and enforced in the United States. Agencies adopt international standards through the process of harmonization, in response to the resolution of trade disputes by the World Trade Organization (WTO), or by making equivalency decisions. The following sections describe these processes at the international and domestic levels and explain why each process creates a problem of accountability.

I. HARMONIZATION

Harmonization involves the adoption of an international standard that adjusts the regulatory standards or procedures of two or more countries until they are the same. The United States can engage in bilateral or multilateral negotiations with other countries to create harmonized regulations, or domestic agencies can adopt standards created by international standard-setting organizations. This section describes the nature of these processes, their relationship with domestic decision making, and why that relationship poses a problem for citizen participation and public accountability.
A. The Harmonization Process

International agreements coming out of the Uruguay Round require harmonization of both food standards and technical standards. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) requires the United States to base its sanitary and phytosanitary regulations on international standards, guidelines, or recommendations, where they exist, except as otherwise provided in the SPS agreement. A sanitary or phytosanitary standard is any measure intended to protect animal or plant health life or human or animal life or health, including all relevant laws, regulations, requirements, and procedures. Similarly, the Agreement on Technical Barriers to Trade (TBT) obligates the United States to use international standards (or parts of a standard) as a basis for technical regulations, except where the standards or the relevant parts would be "an ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued." A "technical regulation" is one that estab-


3. According to the SPS, a sanitary or phytosanitary standard is:

Any measure applied: (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms; (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs; (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

SPS, supra note 2, at Annex A 1.a.

4. The SPS defines sanitary or phytosanitary measures to include:

[All relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labeling requirements directly related to food safety.


5. According to the TBT:

Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfillment of
lishes product characteristics or their related processes and production methods, such as labeling or production requirements.6

Consistent with these mandates, the National Technology Transfer and Advancement Act of 1995 promotes the use of voluntary standards,7 and Office of Management and Budget (OMB) Circular A-119 calls on all agencies to “use existing voluntary consensus standards, both domestic and international, in their regulatory and procurement activities as a means of carrying out policy objectives.”8 The 1997 Food and Drug Administration (FDA) Modernization Act encourages FDA to participate in international harmonization efforts.9

The effort to develop a harmonized system of chemical classification and labeling, known as the “globally harmonized system” (GHS), illustrates the negotiation component of the harmonization process.10 Interest in the GHS began in 1984 when the United States established an interagency policy on chemical labeling issues.11 In 1992, the United States entered into a series of agreements concerning a GHS with other countries in conjunction with the United Nations Conference on Environment and Development (UNCED) in 1992.12 The UNCED objective is: “A globally harmonized hazard classification and compatible labeling system, including material safety data sheets and easily understandable symbols, should be

the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems. Agreement on Technical Barriers to Trade, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, art. 2.4, LEGAL TEXTS—RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 121 (1999) [hereinafter TBT].

6. According to the TBT, a technical regulation is a “[d]ocument which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method.” See TBT, supra note 5, at Annex 11.


11. See id. at 15,952 (working to meet its long time goal of regulatory harmonization, the U.S. government implements an interagency policy on chemical labeling).

12. See id. (participating countries, including the United States, make progress toward international harmonization of chemical classification at UNCED).
available, if feasible, by the year 2000." In 1997, the government established an interagency working group, and its representatives have participated in numerous international meetings, which are still ongoing in four major international institutions (International Labor Organization, Organization for Economic Cooperation and Development, Inter-Organization Program for the Sound Management of Chemicals, and United Nation Committee of Experts on the Transport of Dangerous Goods).

Several agencies participate in the interagency working group, and when the negotiations are complete, they are likely to impact a number of important domestic safety and environmental laws and regulations. Agencies in the interagency working group include the Department of State, Environmental Protection Agency (EPA), Department of Transportation (DOT), Occupational Safety and Health Administration (OSHA), Consumer Product Safety Commission (CPSC), FDA, Department of Commerce, Department of Agriculture (USDA), and U.S. Trade Representative (USTR). The GHS negotiations seek to harmonize the methods by which countries classify chemicals according to their degree of danger that they pose to the public, disseminate information about hazardous chemicals, and establish appropriate safe handling procedures for hazardous chemicals, rules for labels, placards, and material safety data sheets. Standard-setting organizations constitute the other component of the international harmonization process. The International Organization for Standardization (ISO), one such organization, is a private sector, industry-funded organization that produces technical standards. When the ISO started in the 1950s, its goal was to standardize sizes for light bulbs, screws, batteries, and other consumer products to help business expand markets. More recently, the ISO’s areas of interest include standards for environmental products, eco-

13. Id.
14. See id. at 15,952.
16. See id. (naming federal agencies participating in the development of a harmonized chemical classification system).
labels, and humane fur trapping standards. The ISO has also developed a series of standards, such as the ISO 14,000 series, which focuses on management practices, including providing a best environmental practice seal.\textsuperscript{20} The Codex Alimentarius (Codex), established as a voluntary standard setting organization by the World Health Organization (WHO) and the United Nations (U.N.) Food and Agricultural Organization,\textsuperscript{21} produces international standards to facilitate the world trade in foods.\textsuperscript{22}

\section*{B. ACCOUNTABILITY}

The public has an important stake in harmonization because of its economic potential.\textsuperscript{23} Regulations in a foreign country can constitute a barrier to entry for U.S. companies. In addition, because the United States is a country with high levels of consumer and environmental protection, domestic companies can be disadvantaged in open competition with firms operating in jurisdictions with less rigorous (and less costly) regulation.\textsuperscript{24} Finally, substantial differences among countries concerning production processes and methods can distort competition and create incentives for industrial relocation from the United States to foreign countries.

The public has an important stake in harmonization for a second reason. Harmonization can impact the stringency of regulatory protection available in the United States. Theoretically, harmonization can occur at the lowest or highest level of public health, worker safety, or environmental protection, or somewhere in between. Public interest groups and others, therefore, have an interest in determining whether a particular harmonization initiative raises, lowers, or does not change the regulatory protection that is currently available, and in seeking to favor or oppose a change in regulatory protection that they favor or do not favor.

The nature of the harmonization process, however, can limit meaningful

\begin{itemize}
  \item \textsuperscript{23} See Daniel C. Esty & Damien Geradin, Market Access, Competitiveness and Harmonization: Environmental Protection in Regional Trade Agreements, 21 Harv. Envtl. L. Rev. 265, 268-73 (1997) (describing market access and competitiveness problems addressed by harmonization).
  \item \textsuperscript{24} See id. at 271 (arguing differential environmental requirements raise competitiveness problems).
\end{itemize}
public participation in harmonization decision making. Once the United States has negotiated a harmonized standard, domestic regulatory agencies, such as EPA and OSHA, will comply with the rulemaking procedures of the Administrative Procedure Act (APA), including notice and the opportunity to comment on a proposed regulation.25 In the harmonization context, however, literal compliance with the APA procedures may be ineffective in achieving meaningful citizen participation in the development of the harmonized regulation. The APA does not require an agency to seek public input in advance of agreeing to a harmonized standard.26 After such an agreement exists, there is an international commitment by the United States to adopt the harmonized regulation, which creates a substantial disincentive to change or amend the international standard during rulemaking. Consider the GHS, described earlier. EPA or OSHA, having spent years negotiating and finally agreeing to a harmonized standard, is likely to be predisposed to adopt that standard.

An agency, of course, may be stubborn about amending a rule that it has proposed in its "Notice of Proposed Rulemaking" when the proposed rule does not concern a harmonization activity. Harmonization activity, however, is different because there may be additional costs to the agency (and the United States) of changing a significant harmonization-related rule. Because an important change in the harmonized standard could violate the harmonization deal, the United States might have to renegotiate the deal with its foreign partners. This disincentive does not exist regarding rules that do not involve international harmonization agreements. After a harmonized standard is promulgated by an agency, a citizen or group would likely have a difficult time proving a proposed rule was a fait accompli because of an international agreement to implement a harmonization regulation. Nevertheless, the potential that the harmonization process may limit the effectiveness of public input is of concern because of the value of public input to agency decision making.

The harmonization process also makes it more difficult to promote


26. As a practical matter, agencies may find it difficult to voluntarily comply with the APA at the initiation of a harmonization effort. Under the APA, an agency is required to include "either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b)(3) (1994 & Supp. V 1999). Most agencies, however, publish the text of the proposed rule when commencing rulemaking, and some enabling statutes expressly require that an agency do so. See Jeffrey S. Lubbers, A Guide To Federal Agency Rulemaking 183 (3d ed. 1998). When an agency commences a harmonization activity, however, there is no text of a proposed rule to propose. Moreover, it may harm the agency's ability to negotiate effectively if it published what it expected to be the outcome of the negotiations.
meaningful citizen participation. Agencies generally do not publish notices of their intention to enter into negotiations concerning a harmonized regulation, or their continued participation in such a process, as part of their regulatory agenda, except for the FDA and the USDA. These agencies fall under a statutory requirement that the public be informed about international "sanitary or phytosanitary standards under consideration or planned for consideration . . ." 27 Additional agencies issue periodic notices of such participation, 28 but these may not present a full picture of an agency's harmonization activity. Moreover, unlike the regulatory agenda, such notices do not conveniently provide the public with one source document to find out about an agency's harmonization activity.

The harmonization process also differs because many harmonization activities occur out of the United States, or at a site other than Washington, D.C. in the United States. For example, numerous working groups that meet in Europe and elsewhere are undertaking the GHS effort. With a domestic regulation, citizen groups usually have the opportunity to monitor the rulemaking process, both before and after a rule is proposed, to the extent that there is public information available through formal or informal channels. This capacity may be lessened in the harmonization process to the extent that some public meetings are held at distant locations from Washington, D.C. and to the extent that public documents may be available in other countries, but not in the United States.

The distant location raises another issue. Regulated entities, or their trade associations, may have the wherewithal to participate in harmonization activities, even if they are located abroad or in other locations distant from Washington, D.C., whereas other citizen groups often lack this capacity. Of course, such differences in resources are common in the domestic regulatory process. However, the foreign location of harmonization activity may make any such imbalance greater.

The frustration of public participation in the development of harmonized standards is unfortunate because the benefits of public participation are widely recognized. 29 Members of the public are often in a position to furnish valuable information or insights to an agency at a low cost to an agency. Michael Asimow has remarked on this:

Rules adopted with public participation are likely to be more effective and less costly to administer than rules written without such participation. They contain fewer mistakes. They are more likely to deal with unexpected and unique applications of ex-

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28. See infra notes 90-98 and accompanying text.
ceptional situations, and are more politically acceptable to the persons who must live with them.30

Public participation also provides legitimacy to the rulemaking process. Agencies occupy an awkward position in our democratic system because unelected officials have the power to adopt legally binding rules. In many cases, it is the "agency, not Congress, [that] will make the policy decisions significant to a regulatory program."31 Public participation reduces the undemocratic character of such rule making by creating a surrogate for the political process.32 For example, “[i]t provides a channel that allows interested persons to exercise political power by indicating mass opposition to a proposed rule."33 Public participation also enhances the legitimacy of rule making by enhancing the capacity of Congress and the president to oversee the rulemaking process.34 By indicating constructive proposals for change, or even their total opposition, members of the public alert political overseers concerning the wisdom of proposed policies.35

Recognizing these benefits, some agencies have taken steps not required by the APA to obtain more meaningful citizen input concerning harmonization activity. These initiatives have taken various forms. Agencies, such as the National Highway Traffic Safety Administration (NHTSA), have sought public comment on pending harmonization activities.36 The USTR and the Department of Commerce have also experimented with various limited means of securing public input and guidance, although these activities have been in a different context.37 Some agencies have held public

30. Id.
33. Asimow, supra note 29, at 708.
35. See id. at 244-46 (asserting administrative law is designed to assist elected politicians control vague legislative mandates).
37. See, e.g., Trade Policy Staff Committee; Request for Comments on CITEL Multilateral Negotiations Regarding a Mutual Recognition Agreement for Telecommunications Equipment, 64 Fed. Reg. 1853, 1854 (Jan. 12, 1999) (announcing request for public com-
meetings to receive input on their harmonization activity. The Department of State, for example, held a public meeting concerning the effort to develop a GHS, described earlier. Some agencies, such as the Federal Aviation Administration (FAA), have involved their advisory committees in developing harmonization proposals and positions, which invite public participation through the provisions of the Federal Advisory Committee Act (FACA).

The American Bar Association (ABA) has recognized the need for special efforts to improve citizen input. The ABA has recommended agencies use special procedures concerning "significant agency efforts to harmonize domestic and foreign regulations through international negotiations that may require new regulations or the amendment of existing regulations." The ABA has recommended "the President seek to ensure effective public participation by encouraging federal agencies to . . . list at an appropriate time significant proposed and ongoing harmonization activities in their annual regulatory agendas or equally widely available medium" and by "preparing impact statements already required by statute or executive order as near as is practical to the time of the agency's consideration of a decision to engage in negotiation of significant harmonization . . ." The ABA has asked agencies to take three steps to seek effective public participation in harmonization efforts. First, agencies should "invite[e] the public periodi-


42. Id. ¶ (1).
cally to comment on new and ongoing significant harmonization activities and to attend public meetings concerning such activities[,]” second, “refer[,] significant harmonization issues to advisory committees where appropriate and possible[,]” and third, “establish[,] a public docket of documents and studies available under the Freedom of Information Act (FOIA) pertaining to each significant harmonization activity.”

Evaluating the adequacy of these steps is beyond the scope of this Article, but it can be noted that the ABA’s recommendations fall short of guaranteeing any procedural rights. The ABA asks only that the President “encourage[,]” federal agencies to notify the public about harmonization initiatives and to complete impact statements during the period in which negotiations are occurring. Likewise, the ABA recommends agencies seek greater public input, but it does not recommend such steps be mandatory. The ABA’s tentative position may encourage agency experimentation, which could yield additional information concerning the best way to address the procedural problems created by the harmonization process. Agency compliance, however, may be spotty and uneven, thereby perpetuating the problems identified earlier.

The ABA’s recommendation is limited to significant agency efforts to harmonize domestic and foreign regulations through international negotiations. Similar problems of public participation and accountability exist, however, regarding agency adoption of standards issued by international standard-setting organizations. First, although the United States has not made a direct commitment to adopt such a standard, there is a qualified commitment to do so. As noted earlier, GATT provides that member countries “shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist,” with some exceptions. Second, the other problems associated with the negotiation of standards can also arise concerning the creation of standards by international organizations. When representatives of the United States participate in the development of a standard by an international standard-setting organization, the public is denied the opportunity to influence the contribution of the United States, unless an agency gives prior notice of its participation. The activities of international standard-setting organizations generally occur outside of the United States, making their activities more difficult to monitor for interested parties. Finally, there are problems unique to this harmonization pathway. As will be discussed in greater de-

43. Id. ¶ (2).
44. Id. ¶ (1).
45. See id. ¶ (2)(a) (stating federal agencies should consider public views concerning harmonization activities).
46. SPS, supra note 2, at art. 3.1.
tail in the next section, the lack of public participation in international standard-setting organizations may bias the standards that are adopted.

II. WTO ADJUDICATION

Besides the harmonization process, the WTO dispute resolution process can be the impetus for domestic adoption of international standards. The SPS and TBT establish certain restraints on the type of domestic regulations WTO member countries can enforce, and these agreements authorize the WTO's dispute resolution process to determine if member countries are in compliance with those obligations. WTO members are obligated to amend domestic regulations that the dispute resolution process has determined to violate the WTO agreement or potentially pay sanctions to the winning government. This section describes the nature of this process, its relationship with domestic decision making, and why that relationship poses a problem for citizen participation and public accountability.

A. WTO Dispute Resolution

Both the SPS and the TBT contain restrictions on the type of regulations that the United States and other WTO members can enforce. The SPS requires WTO member countries to "avoid arbitrary or unjustifiable distinctions" in the level of regulatory protection "if such distinctions result in discrimination or a disguised restriction on international trade." Therefore, member countries "shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility." A member country violates this requirement when there is another level of protection that will achieve an "appropriate" level of protection that "is significantly less restrictive to trade." To decide on the "appropriate" level of protection, member countries must use risk assessment, and they must take into account a number of factors, including available scientific evidence. Member countries must also take into account "relevant economic factors," including "the relative cost-

47. Id. at art. 5.5.
48. Id. at art. 5.6.
49. Id. at art. 5.6 n.3.
50. See id. at art. 5.1 (declaring members must ensure their SPS measures consider risk assessment techniques relevant to international organizations).
51. See id. at art. 5.2 (stating members must "take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment").
effectiveness of alternative approaches to limiting risks."52

The TBT prohibits procedures used to assess whether products confirm with domestic regulations from being "prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade."53 This means that such procedures cannot "be more strict or be applied more strictly than is necessary to give the importing Member adequate confidence that products conform with the applicable technical regulations or standards, taking account of the risks non-conformity would create."54

The United States and other WTO members are also prohibited from enforcing regulations that result in higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines, or recommendations. The SPS provides member countries "shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided" in the SPS agreement.55 The SPS permits a country to enforce a more stringent standard if there is a scientific justification for a more protective level of the regulation or if the regulation can be justified as consistent with the restrictions described in the previous paragraph.56 Similarly, the TBT requires countries base their technical regulations on relevant international standards "except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment [sic] of the legitimate objectives pursued."57

Conversely, the SPS provides a safe harbor for countries that base their regulations on international standards. If a sanitary or phytosanitary standard "conform[s] to international standards, guidelines or recommendations, the standard will be deemed . . . necessary to protect human, animal or plant life or health, and it is presumed to be consistent with the relevant provisions of [the SPS and of] GATT 1994."58

A WTO member country can request the Dispute Settlement Body

52. SPS, supra note 2, at art 5.3. Members are required to take into account the "potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks." Id.
53. TBT, supra note 5, at art. 5.1.2.
54. Id. at art. 5.1.2.
55. SPS, supra note 2, at art. 3.1.
56. See id. at art. 3.3 (stating when members may "introduce or maintain" a more stringent SPS standard).
57. TBT, supra note 5, at art. 2.4.
58. SPS art. 3.2 (stating standards that are higher than or comport with international standards are consistent with Agreement).
(DSB) to establish a dispute resolution panel to adjudicate another country’s compliance with its trade-related obligations.\textsuperscript{59} Specifically, the panel is authorized “to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law.”\textsuperscript{60} “In other words, the basic prescription is to uphold the rules.”\textsuperscript{61}

There is a process of negotiation and penalties to secure compliance with panel decisions. The DSB must accept the report (i.e., results) of a panel, or of an appellate body if there is an appeal,\textsuperscript{62} unless there is a consensus of the member countries of the WTO not to adopt the report.\textsuperscript{63} Barring this unlikely event, the DSB makes recommendations aimed at achieving a satisfactory settlement of the dispute that is consistent with the applicable trade-related agreement.\textsuperscript{64} Thus, if a panel has ruled that a regulation is inconsistent with an agreement, the DSB will attempt to convince the violating country to withdraw the regulation.\textsuperscript{65} If the offending country refuses to amend its regulation, it must agree to compensation agreeable to the complaining party.\textsuperscript{66} If there is no agreement concerning satisfactory compensation, the DSB can authorize suspension of concessions or other obligations.\textsuperscript{67} In essence, the DSB as a last resort can authorize the complain-

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\textsuperscript{59} See SPS, supra note 2. See also Understanding on Rules and Procedures Governing the Settlement of Disputes, art. 3.2, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, art. 4.3, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 1, 33 I.L.M. 1226 (1994) [hereinafter DSU] (allowing a Member to request the establishment of a panel if another Member does not respond to request for consultations); see also id. art. 6.1 (explaining the latest a complaining party can request panel is at DSB meeting following first appearance of request).

\textsuperscript{60} Id. at art. 3.2.


\textsuperscript{62} See DSU, supra note 59, at Annex 2 art. 17.14 (stating in appellate review procedures, appellate body report will be adopted by DSB unless it decides not to adopt it).

\textsuperscript{63} See id. at art. 16.4 (stating panel report will be adopted within sixty days of circulation unless party appeals or DSB decides not to adopt report).

\textsuperscript{64} See id. at art. 3.4 (explaining DSB in essence should act in accordance with agreement in its rulings).

\textsuperscript{65} See ARUP, supra note 61, at 52 (arguing being charged with implementation of panel report, DSB primary goal should be to withdraw regulations inconsistent with agreement).

\textsuperscript{66} See DSU, supra note 59, at Annex 2, art. 22.2 (stating if offending party does not amend violating regulation, it must enter into negotiations aimed at reaching mutually acceptable compensation).

\textsuperscript{67} See id. (describing options available to members after regular dispute mechanisms have failed).
B. Accountability

The public has an important stake in the WTO dispute resolution process and how the United States responds to adverse decisions. Consumers in the United States may benefit if WTO decisions eliminate trade barriers, but a WTO decision can also lead to a reduction in the level of regulatory protection of people or the environment in the United States. Indeed, unlike harmonization, which can lead to increased regulatory protection or the same level of protection, the WTO process works only to dilute existing levels of protection. Although a country can be sued on the ground that a domestic regulation is too stringent, it cannot be sued on the ground that a regulation is too weak.

Despite the public’s stake in the outcome of WTO disputes, the public may have little opportunity to offer input. Public participation in the United States may be frustrated because any amended rule that an agency proposes in order to comply with a WTO result effectively may be a fait accomplis. The limitation of public participation in the United States is compounded by the lack of public participation in the WTO dispute resolution process and in the process used by international standard-setting organizations to create international standards.

The problem with public participation in the United States arises because an agency may be under considerable political pressure to comply with an adverse WTO ruling. If an agency proposes an amended rule that will comply with an adverse WTO ruling, it is technically free to reject the regulation after receiving public comments in the rule making process. However, as noted earlier, the United States is obligated as a member of the WTO to negotiate a satisfactory resolution of an adverse WTO ruling with the country that brought the complaint. If the United States fails to do so, the WTO can authorize the complaining country to subject this country to trade penalties. This disincentive does not exist when an agency decides to change a proposed rule that does not concern a WTO adjudication on the basis of comments received during rulemaking. In other words, WTO adjudication may effectively preclude effective citizen participation at the APA stage because of the necessity to comply with the WTO ruling.

The United States, of course, may decide not to comply with the WTO ruling, or it may attempt to negotiate a solution that preserves the regulation that has been struck down. Presumably the State Department, the Department of Commerce, and the president, as well as the agency whose

68. See ARUP, supra note 61, at 2 (noting such actions should start under the authority of same agreement as the infringement).
regulation was the subject of the WTO decision, will determine how the
United States will proceed. If, however, the president ultimately deter-
mines that the United States will comply with the WTO decision, it is diffi-
cult to see how the agency at this point can decide not to change the regu-
lation. Any decision by the president to abide by the WTO ruling, or reach
a settlement with the complaining country that requires amendment of a
regulation, can occur without any public input. The APA imposes no obli-
gation on the president, or any agency, to seek public comment on how the
United States should respond to an adverse WTO ruling.

This potential lack of effective public participation is compounded by
the lack of accountability, transparency, and citizen participation in WTO
adjudication. WTO dispute panels operate in secret, documents are re-
stricted to countries in dispute, citizen participation is absent, and no out-
side appeal is available. The dispute resolution procedures provide that
panel deliberation “shall be confidential” and that “[o]pinions expressed in
the panel report by individual panelists shall be anonymous.”69 “Any
Member having a substantial interest in a matter before a panel[,]” referred
to as a “third party,” is entitled to receive the submissions of the parties, if
it notifies the panel of its interest.70 Such member countries are also enti-
tled “to be heard by the panel and to make written submissions to the
panel.”71 All parties to a dispute are entitled to comment on the “descrip-
tive (factual and argument) sections” of a draft report of the panel,72 but
only the two parties to a dispute may appeal the panel’s decision to an Ap-
PELLate Body.73 Members, who are third parties, may file written comments
and the Appellate Panel “may” give them an opportunity to be heard.74

Since procedural rights extend only to member countries, citizens and
citizen groups are excluded from participation. The only manner in which
citizen groups can seek to influence the WTO process is by amicus briefs.
Although the WTO originally prohibited such briefs, they are now ac-
ccepted, but only if they constitute part of a government’s formal submis-
sion in a case.75 This concession does not help public interest groups, how-

70. Id. at art. 10.2, 10.3 (elaborating rights of third parties and ability to make written
submissions).
71. Id. at art. 10.2.
72. Id. at art. 15.1 (outlining procedures of the interim review stage of disputes).
73. See id. at art. 17.4 (giving rules for appellate review and explaining third parties
can not appeal).
74. See id. at art. 4 (stating members who have substantial interest in dispute may be
included in the process).
75. See Lori Wallach & Michelle Sforza, Pub. Citizens Global Trade Watch, Whose
ever, if they oppose the position of their government.\textsuperscript{76}

The lack of citizen participation in WTO decision making may limit the perspective of dispute resolution panels. This possibility is heightened by the fact WTO adjudicators are trade lawyers, who may lack any expertise regarding environmental, health, and safety issues. According to the dispute resolution procedures:

Panels shall be composed of well-qualified governmental and/or non-governmental individuals, including persons who have served on or presented a case to a panel, served as a representative of a Member or of a contracting party to GATT 1947 or as a representative to the Council or Committee of any covered agreement or its predecessor agreement, or in the Secretariat, taught or published on international trade law or policy, or served as a senior trade policy official of a Member.\textsuperscript{77}

The results of WTO decisions concerning environmental, safety, and health regulations appear to support the critic’s concerns about potential bias. According to a study by Public Citizen of all WTO adjudicated cases as of July 1999, “[n]o democratically achieved environmental, health, food safety or environmental law challenged at the WTO has ever been upheld. All have been declared barriers to trade.”\textsuperscript{78} There has been one win for the environment since the Public Citizen study. A WTO panel upheld a French ban on asbestos.\textsuperscript{79}

Finally, the lack of effective public participation in the WTO is compounded by the lack of accountability, transparency, and citizen participation in international standard-setting organizations. As discussed earlier, the SPS and TBT obligate the United States to follow the standards of international organizations or defend any deviance. Thus, when international standard-setting organizations issue standards that are less stringent than similar regulations in the United States, it opens the door for other countries to challenge more stringent American regulations. Both the Codex and the ISO provide for some public representation, but the vast majority of standards established by these organizations were drafted behind closed doors, typically only with governmental and private industry at the table.

The Codex gives international nongovernmental organizations that briefs, now allowing amici to submit under certain criteria).

76. \textit{See id.} at 203 (arguing a government will not generally submit dissenting information by a public interest group to a WTO panelist).

77. DSU, \textit{supra} note 59, at Annex 2, art. 8.1; \textit{see also} WALLACH & SFORZA, \textit{supra} note 75, at 198 (noting panelists are restricted to persons with expertise in international trade law or policy).

78. WALLACH & SFORZA, \textit{supra} note 75, at 197.

qualify the status of "observers." Otherwise, Codex meetings are closed to the public, draft standards are not made available until well into the process, and the public may not provide input directly into the process. Despite the possibility of public participation, one estimate is that four-fifths of the nongovernmental participants in national delegations to Codex meetings represented industry, while only one percent represented public interest organizations.

The ISO standard setting process does include users (including consumers), along with producers, governments, and the scientific community, and the American National Standards Institute, which is the U. S. representative to the ISO. In practice, however, groups representing environmentalists and other citizen interests tend to be under-represented in these meetings.

80. According to the Codex rules, The following organizations are eligible for Observer Status: (a) international Non-Governmental Organizations in consultative status, specialized consultative status or liaison status with FAO; (b) International Non-Governmental Organizations having official relations with WHO; and International Non-Governmental Organizations that:

(a) are international in structure and scope of activity, and representative of the specialized field of interest in which they operate; (b) are concerned with matters covering a part or all of the Commission's field of activity; (c) have aims and purposes in conformity with the Statutes of the Codex Alimentarius Commission; and (d) have a permanent directing body, authorized representatives and systematic procedures and machinery for communicating with its membership in various countries. Its members shall exercise voting rights in relation to its policies or action or shall have other appropriate mechanisms to express their views.


83. See WALLACH & SFORZA, supra note 75, at 58 (stressing industry groups tend to set weaker standards than consumer oriented groups); Patti Goldman, The Democratization of the Development of United States Trade Policy, 27 CORNELL INT' L J. 631, 679 (1994) (discussing failure to incorporate public participation procedures into international standard-setting activities).
As noted earlier, one problem is the financial inability of public interest groups to participate in meetings held outside of the United States. Another problem is that the scope of ISO activity, which includes 2,100 working groups,\textsuperscript{84} overwhelms the capacity of citizen groups to participate or monitor ISO activities.

The relative lack of public participation in international standard-setting organizations raises an administrative law problem that dates back to the 1960s: the corporate dominance of decision making can lead to the capture of an organization by business interests. Even if actual capture is not a concern, administrative norms in the United States recognize the value of the input of all interested parties in producing sound and fair decisions.

III. EQUIVALENCY

Regulatory agencies in the United States adopt international standards in response to harmonization initiatives or to come into compliance with an adverse ruling by a WTO panel. Agencies also employ an equivalency process to adopt international standards. An equivalency decision is a judgment by an agency to substitute some aspect of foreign regulation for compliance with the corresponding aspect of domestic regulation. Thus, equivalency is different from harmonization because harmonization takes two differing standards and converts them into one. Equivalency, by comparison, treats some aspect of different regulatory systems as the same on the ground they produce the same results. The SPS and TBT obligate the United States to accept actions by foreign regulators if their decisions will meet domestic regulatory objectives. This section describes the nature of the equivalency process and why it poses a problem for citizen participation and public accountability.

A. The Equivalency Process

The United States is obligated to accept compliance with foreign regulation as equivalent to compliance with domestic regulation if a foreign country can establish that its actions are satisfactory to fulfill domestic regulatory objectives. The SPS requires the United States to accept the sanitary or phytosanitary measures of another country as equivalent to domestic regulations, even if the foreign measure differs from the domestic regulation, if the foreign country “objectively demonstrates” to the United States that its measures achieve the United States’ “appropriate level” of

sanitary or phytosanitary protection. The TBT requires the United States to give “positive consideration” to accepting as equivalent technical regulations of other countries provided this country is “satisfied that these regulations adequately fulfill the objectives of [its] own regulations.”

The equivalency process can be unilateral or bilateral. In a unilateral determination, a regulatory agency in the United States declares some aspect of a foreign regulatory system to be equivalent to the same aspect of domestic regulation at the request of that country. In a bilateral determination, the United States makes the same determination, and the foreign country also accepts some aspect of regulation in the United States as equivalent to its own regulatory process.

B. Accountability

Equivalency promotes trade by accepting compliance with foreign regulation as sufficient to import goods into the United States. Thus, an importer is spared the additional expense and difficulty of proving to regulatory authorities in the United States that its goods or services meet domestic regulatory requirements. Equivalency, however, raises three issues concerning domestic regulatory protection.

First, whereas harmonization produces domestic and foreign standards that are identical, equivalence produces regulatory protections for Americans that are “close enough.” The important issue for the public is how close is close enough? And this issue is ill-defined, at best. For example, definitions of equivalence in FDA documents vary greatly, ranging from “[resulting in] at least the same level of consumer protection” to “sufficiently comparable.” In some cases, the standard of closeness may be articulated in such definitions as the two mentioned above; in others, the standard must be articulated in the form of a list of criteria against which a system or procedure can be assessed. If the criteria are not sufficiently specific and rigorous or are not applied stringently, important statutory health, safety, and environmental protections will be undermined and their goals will not be met.

Second, equivalency shifts the location of regulatory decision making from this country to a foreign country. The problem of accountability arises because the implementation of product safety regulations by FDA or

85. SPS, supra note 2, at art. 4.
86. TBT, supra note 5, at art. 2.7.
88. Id.
89. See id. at 7.
other agencies is more transparent to consumers (or their representatives) than the implementation of equivalent regulations in foreign countries. Once the United States delegates to another country the responsibility for protecting American consumers, the implementation of regulation is outside the normal channels of political and legal accountability that exist in the United States. As a practical matter, this may make it virtually impossible for consumer organizations to monitor regulatory compliance.

Third, some equivalency determinations may make it less likely that U.S. agencies will change domestic protections. Authorities are not as likely to consider improving a standard if they run the risk of disrupting the equivalence determination upon which a regulatory cooperation arrangement with another country depends. Thus, equivalence could lock in a certain level of technological development and stifle the technological innovation that often follows standards improvements.

Although equivalency decisions raise important issues, agencies are not obligated to seek public involvement in many cases. Assuming that an agency has legal authority to make an equivalency decision, it would not have to resort to rule making unless the decision would contradict existing regulations. USDA and FDA are the only exceptions. In legislation implementing the Uruguay Round Agreements, Congress required FDA to obtain public comments for any equivalency determination concerning the sanitary or phytosanitary measure of a foreign country, and it prohibited FDA from adopting a final regulation “without taking into account the comments received.”90 Although the legislation refers specifically to FDA, USDA has determined it also falls under this legislative requirement.91 FDA has proposed a rule specifying how it would obtain public input into such decisions.92

Furthermore, if rule making is not necessary, an agency has two ways to make an equivalency decision without public input. The agency could

90. 19 U.S.C. § 2578(a)(b) (1994 & Supp. II 1996). If another statute requires FDA to promulgate a regulation to make this determination, the legislation requires, in addition to APA rulemaking procedures, that the notice of proposed rule making include the “basis for the determination that the sanitary or phytosanitary measure of a foreign country provides at least the same level of sanitary or phytosanitary protection as the comparable Federal sanitary or phytosanitary measure.” Id. If FDA is not required to promulgate an equivalency determination as a regulation, the legislation also requires, in addition to the procedures mentioned in the text, that FDA notify the public about a pending decision, inform the public of the basis for the determination that the sanitary or phytosanitary measure of a foreign country provides at least the same level of protection as the comparable federal sanitary or phytosanitary measure. See id.

91. Telephone Interview with Mary Botarri, Public Citizen (Sept. 14, 2001).

simply decline to bar products produced in foreign countries, or decline to seize such products, when they enter the United States. For example, USDA may accept as equivalent the inspection of beef done by a foreign country, and it would not inspect such meat upon its entry into the United States. As an exercise of prosecutorial discretion, the agency’s decision is not subject to any legal requirement that the public be involved. Alternatively, the agency can treat the equivalency decision as an adjudication. The APA would not obligate an agency to use any hearing procedures for equivalency decisions unless the agency’s statutory mandate required such decisions “to be determined on the record after opportunity for agency hearing.” Such a requirement is unlikely because agencies are operating statutory mandates passed by Congress long before the current interest in equivalency. The agency’s mandate is unlikely to specify hearing procedures for the same reason.

Although agencies could voluntarily seek public comment concerning proposed equivalency decisions, agencies have made equivalency decisions without public involvement. The Animal Plant and Health Inspection Service (APHIS) in the USDA, for example, announced the U.S.-E.U. veterinary equivalency agreement with a press release on July 20, 1999, but did not post notice of this agreement in the Federal Register. USDA did give public notice that it was considering declaring the Australian meat inspection system to be the equivalent of the U.S. system and it invited interested parties to a meeting. The agency, however, did not publish a proposed rule in the Federal Register, and the only rule it did publish was the final rule.

Recent developments at USDA suggest that an agency may not pay sufficient attention to consumer or environmental protection without public involvement and oversight. In a recent report, the Inspector General of the USDA found the Food Safety Inspection Service (FSIS) allowed a number

93. The decision is an adjudication because the agency is employing already existing legal criteria to the specific request it is determining. See 5 U.S.C. § 551(6)-(7) (1994) (defining adjudication as any process other than rule making). At a minimum, the agency would have to determine that equivalency was consistent with its statutory mandate.

94. 5 U.S.C. § 554(a) (1994 & Supp. V 1999). If a statutory mandate does not contain the language mandated by the APA, the APA has no procedural requirements concerning the adjudication.

95. Moreover, a court is unlikely to imply a hearing requirement. See City of W. Chicago v. U.S. Nuclear Regulatory Comm'n, 701 F.2d 632, 641 (7th Cir. 1983) (holding no formal hearing was required for NRC's interpretation of the regulation); see also Chem. Waste Mgmt., Inc. v. EPA, 873 F.2d 1477, 1482 (D.C. Cir. 1989) (ruling statutory ambiguity regarding hearing requirement will be left to agency).

96. Telephone Interview with Mary Botari, Public Citizen (Oct. 9, 1999).

97. See id.
of foreign countries to export meat and poultry into the United States although they failed to comply with conditions established by FSIS. Nineteen countries had failed to meet one condition and fifteen countries had failed to meet another condition.  

CONCLUSION

New international agreements coming out of the Uruguay Round obligate the United States to engage in harmonization, equivalency, and to abide by the WTO's dispute resolution procedures or be subject to potential trade sanctions. Agencies will make decisions regarding the scope of domestic regulatory protection in response to each of these international regulatory activities. Although such decisions have important ramifications for the American public, agencies are generally under no legal obligations to seek effective public input regarding these decisions.

The problem for effective public participation is that U. S. officials may make important decisions about harmonization, equivalency, or WTO dispute resolution before the APA or some other statute requires the government to involve the public. In some cases, there is no legal obligation to seek public input at any point in the decision making process. Some agencies voluntarily seek public participation before they make such decisions, but there is not yet any general pattern of such participation. Moreover, agencies are free to abandon this commitment, or to adhere to it only sporadically.

The ABA recommendation that agencies engage in voluntary efforts to obtain public participation in agency harmonization activities may cause more agencies to attempt to involve the public. The recommendation, however, does not apply in the context of WTO adjudications or equivalency decisions, although these activities can stymie effective citizen participation in the same manner as an agency's harmonization activities.

98. The IG found FSIS violated its own rules by permitting nineteen countries to export meat and poultry products to the United States even though the countries failed to certify that each of the establishments in their country continued to comply with FSIS food safety standards. Office of Inspector Gen., USDA, Food Safety Initiative: Meat and Poultry Products, Rep. 24099-3-HY (June 2000), section III, at ii-iii. In addition, fifteen of thirty-six countries that were certified to ship meat and poultry products to the United States had not submitted residue test plans to FSIS as they were required to do. See id. at iii. FSIS requires the submission of such plans to ensure that foreign countries maintain residue control standards equivalent to U.S. standards. Regulators use such controls to identify potential contaminants. See id. In addition, after FSIS or foreign inspectors declared seven establishments from four foreign countries as ineligible to export meat into the United States, FSIS permitted the companies to ship over four million pounds of meat into the United States. See id.
Agencies should therefore apply the procedures recommended by the ABA to these other activities.

The ABA recommendation focuses on transparency as a key procedural instrument to invoke more effective public participation. Agencies should regularly notify the public about planned and ongoing efforts to adopt international regulatory standards, and they should make all relevant documents available to the public, unless the information would not be available under the FOIA. The ABA recommendation also recognizes the value of public input. It recommends that agencies should invite the public periodically to comment on new and ongoing activities and to attend public meetings. Agencies should also rely on advisory committees to obtain additional input. As noted, agencies should engage in these procedures, whether they relate to harmonization or to WTO disputes and equivalency.

The ABA recommendation, however, asks the government voluntarily to undertake these activities. Whether such procedures should be, or are, required by the APA is a subject that I leave for a later article.

Public participation in agency decision making is an important procedural norm in the United States. The lack of effective public involvement in the development of international regulatory standards is therefore likely to decrease the legitimacy of this country's efforts to implement its obligations under the new international trade regime.