

# UPDATING AMERICAN ADMINISTRATIVE LAW: WTO, INTERNATIONAL STANDARDS, DOMESTIC IMPLEMENTATION AND PUBLIC PARTICIPATION

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## INTRODUCTION

Since the inception of the General Agreement on Tariffs and Trade (GATT),<sup>1</sup> global trade negotiations have focused on improving market access through the systematic reduction of tariffs in various industries. However, by the 1980s it was becoming increasingly clear that concessions attained in GATT tariff negotiations could be nullified through the creative use of regulatory policy. In particular, business interests raised concerns about the use of competing regulatory policies as non-tariff trade barriers. Industry representatives complained that competing standards and multiple conformity-assessment procedures and bodies had the effect of artificially increasing the price of exports, thereby making it difficult to compete with locally produced goods. Recognizing this challenge to free trade, the Uruguay Round Agreements included two agreements designed to reduce regulatory barriers to trade. The Technical Barrier to Trade Agreement (TBT)<sup>2</sup> and the Sanitary and Phytosanitary Measures Agreement (SPS)<sup>3</sup> were designed to promote

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<sup>1</sup> General Agreement on Tariffs and Trade, Oct. 30, 1947, T.I.A.S. No. 1700, 55 U.N.T.S. 194.

<sup>2</sup> Agreement on Technical Barriers to Trade, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, Legal Instruments-Results of the Uruguay Round, 1868 U.N.T.S. 120 (1994) [hereinafter TBT Agreement].

<sup>3</sup> Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, Legal

global harmonization<sup>4</sup> of standards and regulatory procedures associated with these standards. The goal of these agreements was to eliminate arbitrary and discriminatory standards by insulating the development of such standards from domestic special interests more interested in protecting their market share than promoting legitimate public health and safety goals.<sup>5</sup>

Despite the fact that the SPS and TBT agreements were negotiated and implemented at the same time,<sup>6</sup> most of the harmonization work and public attention—at least where the United States is concerned—have centered on the SPS agreement.<sup>7</sup> Until recently, the U.S. government remained largely on the sidelines of the global battle over regulatory standards covered by the TBT agreement.<sup>8</sup> This passive

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Instruments—Results of the Uruguay Round, 1867 U.N.T.S. 493 (1994) [hereinafter SPS Agreement].

<sup>4</sup> While the word “harmonization” sometimes has a specific and distinct meaning within the literature of global administrative law, it is used in this Article to signify the process of reducing the costs associated with divergent regulatory standards. In that vein, this Article refers to activities such as mutual recognition and equivalence determination—both of which can result in the use of different, though similar processes—as being part of the harmonization enterprise.

<sup>5</sup> TBT Agreement, *supra* note 2, pmb.; SPS Agreement, *supra* note 3, pmb.

<sup>6</sup> Approval and Entry into Force of Uruguay Round Agreements, 19 U.S.C. § 3511 (2000).

<sup>7</sup> This is particularly so when one considers the harmonizing activities carried out directly by the federal government. Other than a few discrete actions undertaken by the National Institute of Standards and Technology [NIST] and the National Highway Traffic and Safety Administration [NHTSA], the majority of harmonization activities the U.S. government has directly participated in have been under the SPS agreement. *See, e.g.*, Trade Policy Staff Committee [TPSC]; Request for Comments on CITELE Multilateral Negotiations Regarding a Mutual Recognition Agreement for Telecommunications Equipment, 64 Fed. Reg. 1853 (Jan. 12, 1999); NHTSA: Rulemaking Procedures, 63 Fed. Reg. 26508 (May 13, 1998) (to be codified at 49 C.F.R. pt. 553) (reaffirming NHTSA’s position on harmonization activities). Furthermore, this phenomenon becomes obvious when looking through the Federal Register, where references to the SPS agreement outnumber references to the TBT agreement by a ratio of roughly five to one. One possible explanation for this phenomenon might be that in the United States, most top-down regulation occurs in the areas of food, animal, and plant health. Thus, most regulations covered under the TBT agreement remain within the province of voluntary, consensus-based standards often negotiated by industry members themselves.

While the government has not been very active in harmonization activities related to the TBT, business representatives have not been successful in this area either. For example, William Reinsch, the president of the National Foreign Trade Council, notes that while there are meetings and congresses aimed at promoting harmonization, they have had little, if any, practical impact on the development of a harmonized regulatory system. Telephone interview with William Reinsch, President of the Nat’l Foreign Trade Council, Inc. (Sept. 1, 2004).

<sup>8</sup> Press Release, Dep’t of Commerce, A Call to Action to Strengthen U.S. Competitiveness: Initiative to Enhance Commerce Dep’t Standards Activities (Mar. 19, 2003), *available at* [http://www.commerce.gov/opa/press/Secretary\\_Evans/2003\\_Releases/March/19\\_Standards.htm](http://www.commerce.gov/opa/press/Secretary_Evans/2003_Releases/March/19_Standards.htm) (“There is a sense from industry that the U.S. Government, specifically Commerce, could do more to reduce the barriers to export markets caused by foreign governments’ adverse policies on standards and technical regulatory requirements.”).

attitude has evolved, however, as the Department of Commerce, prodded by industry concerns about the use of regulatory policy to erect trade barriers, established the “standards initiative.”<sup>9</sup> After soliciting comments from businesses on the use of standards as barriers to market entry,<sup>10</sup> the Department of Commerce (DOC) issued a report noting that the standards initiative was a response to “intensifying global competition,” which has pushed harmonization activities to the forefront of business concerns.<sup>11</sup> The report, which was designed to serve as the basis of DOC policy,<sup>12</sup> presents a series of recommendations, including a more assertive role for the U.S. government in negotiating international standards and promoting an active harmonization agenda.<sup>13</sup>

This agenda is likely to differ in scope depending on the area under consideration. Harmonization may be accomplished through the implementation of common substantive regulatory standards.<sup>14</sup> Alternatively, in areas where an agreement on a common standard is difficult to attain or where the standard has high political salience, regulators may choose to focus on conformity assessment procedures.<sup>15</sup> Regardless of its underlying policy goal, harmonization may be accomplished through a variety of mechanisms. Ranging from relatively formal and legally binding international standards to relatively informal regulatory equivalence determinations—the menu of harmonization mechanisms for U.S. regulators, it seems, is limited only by their imaginations.

The most formal harmonization activity involves the development of international standards. These standards are usually developed by international organizations and adopted domestically by

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<sup>9</sup> *Id.* (introducing the standards initiative and outlining its goals in eight broad strokes).

<sup>10</sup> Request for Technical Input on Standards Issues and Foreign Markets, 68 Fed. Reg. 55287, 55287 (Sept. 24, 2003).

<sup>11</sup> Press Release, Nat’l Inst. of Tech. and Sci., Evans Releases Report on Reducing Standards-Related Barriers to U.S. Exports Through Enhanced Dep’t of Commerce Standards Activities (May 18, 2004), *available at* [http://www.nist.gov/public\\_affairs/releases/standards\\_related\\_barriers.htm](http://www.nist.gov/public_affairs/releases/standards_related_barriers.htm).

<sup>12</sup> DEP’T OF COMMERCE, STANDARDS AND COMPETITIVENESS—COORDINATING FOR RESULTS: REMOVING STANDARDS-RELATED TRADE BARRIERS THROUGH EFFECTIVE COLLABORATION I (2004), *available at* <http://www.ita.doc.gov/td/standards/Final%20Site/Standards%20and%20Competitiveness.pdf>.

<sup>13</sup> *Id.* at 15-22.

<sup>14</sup> *Id.* at 12.

<sup>15</sup> *Id.* at 13.

individual member states.<sup>16</sup> A less formal mechanism of harmonization is the mutual recognition agreement (MRA). MRAs, which are negotiated either bilaterally or among a small group of trading partners, allow “respective regulatory authorities to accept, in whole or in part, the regulatory” decisions of the trading partners without adopting a common regulatory standard.<sup>17</sup> The scope of an MRA can vary from recognizing conformity assessment or testing procedures to accepting the substantive regulatory standards of the trading partner.<sup>18</sup> A third means through which regulators can choose to harmonize is the use of equivalency determinations.<sup>19</sup> Unlike international standards or MRAs, equivalency determinations are especially informal as they do not require any formal agreement and can be implemented directly through executive action.<sup>20</sup> In making an equivalency determination, one state recognizes the regulatory procedures and institutions (such as conformity assessment bodies) or substantive standards of a trading partner as equivalent in terms of the public policy protection they offer.<sup>21</sup> Over time, such determinations may harden into more formal agreements and ultimately into MRAs.<sup>22</sup> In implementing its active harmonization agenda under the

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<sup>16</sup> These international organizations are often composed of member states whose delegates negotiate the applicable standards. Some international standard-setting organizations, however, are private bodies—for example, the International Standards Organization—where industry representatives collaborate to decide on the applicable standards. Since the SPS agreement, which is the primary subject of this Article, delegates standard-setting activities to three intergovernmental organizations, this Article focuses heavily on the work of state driven international standard-setting organizations. The public participation problems discussed in this Article, however, are equally applicable to private standard-setting bodies. While these problems and possible solutions to them will be noted as appropriate, additional research is necessary to fully understand the scope of the public participation problem in private standard setting organizations.

<sup>17</sup> Kalypso Nicolaïdis, *Globalization with Human Faces: Managed Mutual Recognition and the Free Movement of Professionals*, in *THE PRINCIPLE OF MUTUAL RECOGNITION IN THE EUROPEAN INTEGRATION PROCESS* 129, 133 (Fiorella Kostoris Pado Schioppa ed., 2005).

<sup>18</sup> Richard A. Merrill, *The Importance and Challenges of Mutual Recognition*, 29 *SETON HALL L. REV.* 736, 740-41, 751-54 (1998).

<sup>19</sup> *Id.* at 753.

<sup>20</sup> *Id.* at 753-54.

<sup>21</sup> *Id.* at 753 (explaining equivalency as one country telling another: “[w]hile our standards are not identical in text or in detail, we believe and agree that they provide equivalent public health protection. Accordingly, if the officials of country A affirm that a product meets country A’s standards, we will permit its entry . . .”).

<sup>22</sup> While this paragraph makes it seem that these mechanisms of harmonization are distinct and separate, “practice might often blur the distinction between the adoption of [a] common standard[] by . . . government regulators and mutual recognition arrangements and equivalence practices by such regulators.” Richard B. Stewart, *U.S. Administrative Law: A Model for Global Administrative Law?*, *LAW & CONTEMP. PROBS.*, Summer/Autumn 2005, at 63, 66.

TBT agreement, the U.S. government is likely to rely on some permutation of these three modes of harmonization.

A recent report issued by the Department of Commerce indicates that the U.S. government has come to realize the importance and advantages of global regulatory standards—even referring to them as “[t]he international language of commerce”<sup>23</sup>—and has decided to actively engage in harmonization activities on a global level.<sup>24</sup> As harmonization of standards becomes increasingly important, stakeholder attention to harmonization activities under the TBT agreement is likely to grow.<sup>25</sup> With tariff costs decreasing, the costs of redundant conformity assessment and regulatory compliance caused by multiple and somewhat different regulatory standards have emerged as the biggest barriers to free trade.<sup>26</sup> Harmonization has the potential to reduce, if not fully eliminate, these costs, and firms, which are “interested in reducing costs and getting new products to market” quickly, are likely to push for further harmonization.<sup>27</sup>

To date, the primary focus of the U.S. harmonization agenda has centered on activities occurring under the umbrella of the SPS agreement. As the United States prepares to enter the next battle in the war of harmonization, it is worthwhile to consider what impact these harmonization activities are likely to have on domestic standards and what problems, if any, will emerge. This Article reviews harmonization activities undertaken pursuant to the SPS agreement and their impact on U.S. regulatory policy, and analyzes one potential legitimacy problem that is likely to impact any future harmonization agenda—that of public participation.<sup>28</sup>

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<sup>23</sup> DEP’T OF COMMERCE, *supra* note 12, preface.

<sup>24</sup> *Id.* at 20-21.

<sup>25</sup> NAT’L FOREIGN TRADE COUNCIL, INC., VISION 2005: FREE TRADE AND BEYOND, RECOMMENDATIONS FOR THE DOHA DEVELOPMENT AGENDA 7 (2002), available at <http://www.nftc.org> (follow “NFTC Policy Activities” hyperlink; then follow “International Trade/NFTC Position &” hyperlink) (last visited Feb. 25, 2007) (noting that proliferation of regional trade agreements has resulted in 55 percent of world trade being duty free by 2002, and that this figure is likely to grow as more regional trade agreements are negotiated).

<sup>26</sup> Gregory Shaffer, *Reconciling Trade and Regulatory Goals: The Prospects and Limits of New Approaches to Transatlantic Governance through Mutual Recognition and Safe Harbor Agreements*, 9 COLUM. J. EUR. L. 29, 30 (2002).

<sup>27</sup> *Id.* at 51. It is important, however, to note that domestic producers are not the only ones who might benefit from harmonization. Domestic consumers are also likely to benefit, since reduced regulatory compliance costs are likely to lead to lower consumer prices.

<sup>28</sup> It is important to note here that legitimacy can mean different things at different times. This Article is concerned with the legitimacy deficit created by the inability of domestic stakeholders to take part in the international harmonization process envisioned by the SPS and TBT

Presently stakeholder participation rights are insufficient, both domestically and in the international arena.<sup>29</sup> In particular, public interest stakeholders are often left out of the harmonization process. The resulting inability of public interest stakeholders to effectively participate in the new regulatory process has undermined the legitimacy of harmonization as many feel that the entire enterprise has become captured by industry and corporate interests.<sup>30</sup> The result is a legitimacy crisis similar to the one that afflicted American regulatory policy prior to the court-driven participatory revolution of the 1960s and 1970s.<sup>31</sup> In fact, it is the same individuals and organizations that led the attack against the American regulatory state in the 1960s that are leading the attack against harmonization today, often making the same arguments.<sup>32</sup> Acting on their own initiative, U.S. courts resolved the legitimacy crisis of the 1960s by requiring greater transparency and accountability from regulatory agencies.<sup>33</sup> Similar accountability and transparency guarantees are needed to resolve the current legitimacy deficit faced by the harmonization agenda. However, because harmonization activities can occur in many diverse environments, at both domestic and international levels, no single avenue for public participation is likely to achieve the requisite level of transparency and accountability. Rather, as this Article concludes, participation must be made available both domestically and internationally in narrowly tailored ways appropriate to the harmonization activity in question.<sup>34</sup>

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agreements. Domestic stakeholders, however, are not the only relevant actors. As Gregory Shaffer points out, domestic regulations have a direct impact on foreigners who are often shut out of the domestic regulatory process. *Id.* at 30-31. The SPS and TBT agreements make huge leaps to solving this accountability deficit through practices of notice and comment, transparency requirements, and other procedural guarantees. Sabino Cassese, *Global Standards for National Administrative Procedure*, LAW & CONTEMP. PROBS., Summer/Autumn 2005, at 109, 111. The intent of this Article is not to undermine Professor Cassese's conclusions, but rather to point out that these agreements created a different accountability problem by withholding meaningful participation rights from domestic stakeholders.

<sup>29</sup> See *infra* Part III.

<sup>30</sup> *Id.*

<sup>31</sup> See Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1667, 1683 (1975). See generally CASS R. SUNSTEIN, *AFTER THE RIGHTS REVOLUTION: RECONCEIVING THE REGULATORY STATE* (1990).

<sup>32</sup> For example, Public Citizen, an organization founded by Ralph Nader, is at the forefront of the anti-harmonization movement, and Nader himself has supported the organization's work in this area. See, e.g., Ralph Nader, *Introduction*, in *THE WTO: FIVE YEARS OF REASONS TO RESIST CORPORATE GLOBALIZATION* 6-7 (Lori Wallach & Michelle Sforza eds., 1999).

<sup>33</sup> See Stewart, *supra* note 31, at 1712.

<sup>34</sup> At this point, a brief note on my methodology is necessary. To date, relatively few studies have been done on the integration of global regulatory standards into domestic law. To gain

Part I of this Article presents a brief outline of the SPS agreement and the various tools of harmonization presently used by the U.S. government. In particular, Part I focuses on the three tools frequently used by the United States to promote its harmonization agenda: international standard setting, MRAs, and equivalency determinations. Because the SPS agreement specifies which international organizations are responsible for devising international standards,<sup>35</sup> Part I offers a brief outline of how these different institutions function. Part II analyzes the impact that harmonization activities have had on domestic regulation, with particular focus placed on the use of international standards and MRAs. Part II also examines the ability of stakeholders to influence the harmonization process within the arena of domestic administrative law. Part III explains why it is nearly impossible for some actors to influence the harmonization process domestically and considers whether these actors can, in the alternative, influence the process at the international level. Finally, Part IV offers several suggestions that could be implemented by the three branches of the U.S. government to rectify the current position of impotence in which many stakeholders currently find themselves.

## I. THE SPS AGREEMENT AND ASSOCIATED BODIES

The SPS agreement applies to all sanitary and phytosanitary measures<sup>36</sup> that affect international trade.<sup>37</sup> While reaffirming that each member can choose its own appropriate level of protection,<sup>38</sup> the agreement focuses on promoting harmonization and lowering the costs and trade barriers associated with regulatory compliance. To achieve

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perspective on the impact that international regulatory activities may have on the domestic regulatory system, I have relied on interviews with members of the U.S. government, as well as representatives of business and public interest organizations, who view themselves as stakeholders of the harmonization enterprise. Because of this, the Article suffers from similar problems faced by any oral history project—human memories are frail, and results can be skewed by the desires of the interviewees to push their own agendas. I have taken these challenges into account and I have mitigated the problems associated with oral history projects as best I could.

<sup>35</sup> SPS Agreement, *supra* note 3, Annex A ¶ 3.

<sup>36</sup> The agreement defines sanitary and phytosanitary as any measures applied to protect human, animal or plant life from the importation, in various ways, of pests, diseases, toxins, or contaminants. *Id.* Annex A ¶ 1.

<sup>37</sup> *Id.* art.1 ¶ 1.

<sup>38</sup> *Id.* pmb1.

these goals, the SPS agreement offers two modules: full harmonization of standards and the doctrine of equivalence.<sup>39</sup> Unlike the TBT agreement, the SPS agreement does not specifically address MRAs pertaining to conformity assessment or rent-seeking by firms.<sup>40</sup> However, regulators seeking to promote harmonization have found this module useful as well. Below is an overview of these modules, offering a brief description of the nuts and bolts of harmonization.<sup>41</sup>

#### A. HARMONIZING STANDARDS AND THE BODIES THAT MAKE “INTERNATIONAL STANDARDS”

Under the SPS agreement, harmonization involves the adjustment of sanitary and phytosanitary measures until they are the same around the world.<sup>42</sup> The SPS agreement allows member states to determine their own appropriate level of protection.<sup>43</sup> However, hoping to promote harmonization, it requires them to base their measures on existing international standards.<sup>44</sup> To encourage members to comply with paragraph 1 of Article 3 (hereinafter Article 3.1), the SPS agreement grants a presumption of legality to those standards deemed to be based on international standards.<sup>45</sup> Should members want to implement measures that result in a higher level of protection than that which is provided for by the international standard, they may do so—but they must justify their actions via a costly risk-assessment procedure.<sup>46</sup>

The SPS agreement does not define what an international standard is, although, unlike the TBT agreement, it does task the development of such standards to specific, identifiable bodies.<sup>47</sup> In

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<sup>39</sup> *Id.* arts 3, 4.

<sup>40</sup> Compare TBT Agreement, *supra* note 2, art. 6, ¶ 3 with SPS Agreement, *supra* note 3, arts. 3-5.

<sup>41</sup> See generally Terence P. Stewart & David S. Johanson, *The SPS Agreement of the World Trade Organization and International Organizations: The Roles of the Codex Alimentarius Commission, The International Plant Protection Convention, and the International Office of Epizootics*, 26 SYRACUSE J. INT'L L. & COM. 27 (1998) (describing the SPS Agreement and the controversy that it has produced).

<sup>42</sup> See generally Trans-Atlantic Consumer Dialogue, *TACD Briefing Paper on Mutual Recognition Agreements (MRA's)* [sic], Mar. 2001, available at [http://www.tacd.org/db\\_files/files/files-270-filetag.doc](http://www.tacd.org/db_files/files/files-270-filetag.doc) (last visited Feb. 25, 2007) [hereinafter *MRA Briefing*] (providing a concise definition of what harmonization entails and the possible problems with the approach).

<sup>43</sup> SPS Agreement, *supra* note 3, art. 2 ¶ 1.

<sup>44</sup> *Id.*

<sup>45</sup> *Id.* art. 3 ¶ 2.

<sup>46</sup> *Id.* art. 3 ¶ 3.

<sup>47</sup> *Id.* Annex A ¶ 3. In this respect, problems associated with the SPS Agreement differ substantially, and may be easier to address than those faced by the TBT agreement. Under the

particular, the Codex Alimentarius Commission is charged with developing sanitary and phytosanitary measures in the areas of “food additives, veterinary drug and pesticide residues, [and] contaminants” as well as the development of codes and guidelines for hygienic practices.<sup>48</sup> Similarly, the International Office of Epizootics is charged with developing measures for animal health while the International Plant Protection Convention is responsible for plant health.<sup>49</sup> Because the SPS agreement itself does not provide an opportunity for stakeholder input,<sup>50</sup> the ability of stakeholders to contribute to the development of harmonization standards is left in the hands of the international bodies that develop those standards.

### 1. THE CODEX ALIMENTARIUS COMMISSION

Created in 1963 by the Food and Agriculture Organization (FAO) of the United Nations and the World Health Organization (WHO), the Codex Alimentarius Commission (“Codex”) was designed to promote international standards relating to human health.<sup>51</sup> While representation is structured on a country basis, in 2005, 98 percent of the world’s population was represented in the Codex as membership swelled to 171 countries.<sup>52</sup>

The Codex works through a network of subsidiary committees.<sup>53</sup> Normally, a standard proposal is submitted by a national government to the Codex.<sup>54</sup> Upon a decision by the commission or the executive

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TBT Agreement, private international organizations composed of industry representatives can also develop international standards. See TBT Agreement, *supra* note 2, Annex 3 ¶ B. In this environment, the public participation problem is particularly aggravated, because even the modest public participation opportunities available in the inter-governmental organization context tend to disappear.

<sup>48</sup> SPS Agreement, *supra* note 3, Annex A ¶ 3(a).

<sup>49</sup> *Id.* Annex A ¶¶ 3(b)-(c).

<sup>50</sup> *Cf. id.* Annex B (providing transparency requirements that member states must observe when implementing SPS measures).

<sup>51</sup> Food and Agric. Org. of the U.N. [FAO] & World Health Org. [WHO], *Understanding the Codex Alimentarius* 13, FAO Doc. W9114/E (2005), available at <ftp://ftp.fao.org/docrep/fao/008/y7867e/y7867e00.pdf> [hereinafter *Understanding the Codex Alimentarius*].

<sup>52</sup> *Id.* at 14. For a concise but detailed description of the Codex structure, see Michael A. Livermore, *Authority and Legitimacy in Global Governance: Deliberation, Institutional Differentiation, and the Codex Alimentarius*, 81 N.Y.U. L. REV. 766 (2006).

<sup>53</sup> *Understanding the Codex Alimentarius*, *supra* note 51, at 16; Livermore, *supra* note 52, at 772-73.

<sup>54</sup> For a step-by-step description of the standard adoption process see Livermore, *supra* note 52, at 773 n.33; *Understanding the Codex Alimentarius*, *supra* note 51, at 15-16. See also Joint FAO/WHO Food Standards Programme, *Codex Alimentarius Commission: Procedural Manual*

committee that a standard is necessary, the secretariat drafts the proposed standard and circulates it to national governments, which submit comments on the draft.<sup>55</sup> The comments are then considered by a subsidiary body in charge of the standard.<sup>56</sup> The committee's recommendations are presented to the commission and, if accepted by the commission, sent to member governments.<sup>57</sup> Depending on the standard under consideration, this process may take a number of years.<sup>58</sup> The commission may also revise or consolidate standards following the same process.<sup>59</sup>

Unlike most other international standard-setting organizations, the Codex has taken care to provide opportunities for stakeholders to participate. It allows international non-governmental organizations (NGOs) to apply for observer status, and a number of NGOs have been granted this status and are thus able to participate throughout the process.<sup>60</sup> Additionally, national delegations have long included business representatives, and recently several countries have begun incorporating other stakeholders as well.<sup>61</sup> Despite these advances, however, overall stakeholder participation in the work of the Codex remains limited as stakeholder input into the decision-making process is limited and infrequent.<sup>62</sup>

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19-28 (15th ed. 2005), available at [ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual\\_15e.pdf](ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_15e.pdf) (chapter entitled "Procedures for the Elaboration of Codex Standards and Related Texts").

<sup>55</sup> *Understanding the Codex Alimentarius*, *supra* note 51, at 15.

<sup>56</sup> *Id.*

<sup>57</sup> *Id.* at 15-16.

<sup>58</sup> *Id.* at 16.

<sup>59</sup> *Id.* at 16-17.

<sup>60</sup> *Understanding the Codex Alimentarius*, *supra* note 51, at 15. See also *Codex Alimentarius Commission: Procedural Manual*, *supra* note 54, at 35-39 (detailing the procedure and requirements for international non-governmental organizations in obtaining observer status). The inclusion of NGO observers in the Codex, however, does not mean that the Codex is overly receptive to public interest organizations. To date, the overwhelming majority of NGOs that have received observer status are industry and professional organizations. Livermore, *supra* note 52, at 20 n.33.

<sup>61</sup> Telephone Interview with Daryl Macer, Codex Observer (June 16, 2004).

<sup>62</sup> For an extensive discussion of stakeholder participation in the work of the Codex Alimentarius and the many challenges faced by stakeholders, see *infra* notes 173-82 and accompanying text.

## 2. OFFICE OF INTERNATIONAL EPIZOOTICS (OIE)

Founded in 1924, “[t]he OIE is an intergovernmental organization (IGO) of 152 Member Countries,”<sup>63</sup> devoted to promoting animal health. Working through a network of regional and specialist commissions and dedicated working groups, as well as a central bureau to coordinate the various bodies, the OIE has taken the lead in informing governments regarding the occurrence of animal diseases, coordinating studies on animal health, and—most importantly for our purposes—promulgating international standards concerning animal-health issues.<sup>64</sup>

Concerned about its legitimacy, the OIE has made efforts to consult with various stakeholders.<sup>65</sup> However, such consultations have not been fully effective as few stakeholders have participated in them, and the consultations themselves have been general in nature rather than aimed at specific regulatory initiatives. This lack of stakeholder participation can partially be explained by the subject area of the OIE. Unlike the Codex, which deals with standards relating to human health, the OIE is concerned with standards devoted to animal health. As a result, fewer organizations may be interested in participating and, perhaps more importantly given the limited budgets on which many public interest NGOs operate, willing to spend money on standards devoted to animal health as opposed to human health. However, the subject matter is not the whole story as the expense of participating in international meetings is likely to price out the smaller NGOs that are interested in animal health.

## 3. INTERNATIONAL PLANT PROTECTION CONVENTION (IPPC)

Founded in 1952, the IPPC is dedicated to preventing the spread of plant parasites and promoting plant health in general.<sup>66</sup> The IPPC is a

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<sup>63</sup> V. Welte, *Introduction to the Office International des Epizooties (OIE)*, in FAO, *Multilateral Trade Negotiations on Agriculture: A Resource Manual III: SPS and TBT Agreements*, ¶ 6.1, FAO DOC. X7354/E (2000), available at <http://www.fao.org/docrep/003/x7354e/x7354e06.htm> (last visited Feb. 25, 2007).

<sup>64</sup> *Id.* ¶¶ 6.2, 6.5-6.9. For a detailed organizational chart, see OIE Structure, [http://www.oie.int/eng/OIE/organisation/en\\_organisation\\_fichiers/slide0003.htm](http://www.oie.int/eng/OIE/organisation/en_organisation_fichiers/slide0003.htm) (last visited Nov. 23, 2006).

<sup>65</sup> One example of these efforts is OIE’s attempt to obtain input on its animal welfare initiative from interested NGOs. Office International des Epizooties, *The OIE’s Initiatives in Animal Welfare*, [http://www.oie.int/eng/bien\\_etre/en\\_introduction.htm](http://www.oie.int/eng/bien_etre/en_introduction.htm) (last visited Nov. 23, 2006).

<sup>66</sup> For a brief history of the IPPC and its evolution since the creation of the WTO, see Stewart & Johanson, *supra* note 41, at 46-48.

relatively new player on the harmonization stage<sup>67</sup> and is presently only focused on the development of conceptual, not substantive, standards.<sup>68</sup> As such, the IPPC is primarily concerned with developing standards for conformity assessment procedures rather than substantive standards relating to plant health. Ideas for new standards can be submitted by national or regional organizations,<sup>69</sup> the IPPC Secretariat, or the WTO itself.<sup>70</sup> The proposed standards are then presented to individual member countries for review and comments, which are subsequently evaluated by the IPPC Committee.<sup>71</sup> If the standards committee of the IPPC recommends that the proposed standard be adopted, it becomes an international standard.<sup>72</sup>

Throughout this process, stakeholder participation is limited. While stakeholders are allowed to submit suggestions for standards to the IPPC secretariat, IPPC experts openly acknowledge that neither industry groups nor civil-society representatives have a lot of say in the IPPC process.<sup>73</sup> Moreover, unlike the Codex or the OIE, stakeholders are unable to attain observer status or otherwise directly participate in the development of standards; their participation is limited to the submission of suggestions to the IPPC for consideration.

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<sup>67</sup> Of the three organizations tasked with the development of international standards, the IPPC is the least prepared. Recognizing the limitations of the IPPC, member states amended the IPPC convention with the aim of making it more capable of addressing standards-related issues. *See id.* at 47-48. *See also* International Plant Protection Convention, Apr. 3, 1952, 23 U.S.T. 2767, 1952 U.N.T.S. 68 (revised Nov. 1997), *available at* <http://www.ippc.int> (follow “IPPC” hyperlink; then follow “1997—International Plant Protection Convention (New Revised Text)” hyperlink) (last visited Feb. 25, 2007).

<sup>68</sup> Telephone Interview with John Greifer, Dir. of Animal and Plant Health Insp. Serv. Trade Support Team (Mar. 19, 2003).

<sup>69</sup> While the IPPC allows for individual member states to submit proposals, the increased focus and politicization of the standard-setting process has made it nearly impossible to do so. Typically, individual member states try to work through regional organizations to adopt the standard before submitting their proposals to the IPPC for consideration. *Id.* From the viewpoint of public participation, this adds another hurdle that stakeholders must overcome in order to participate in the standard setting process. Because the best, and sometimes only, time to impact the development of a standard is at its very inception, stakeholders seeking to participate effectively must do so at the regional and the IPPC level. This is particularly true regarding standards that are submitted by regional organizations. This adds additional costs that further stretch already limited resources.

<sup>70</sup> International Phytosanitary Portal, International Plant Protection Convention: Standard Setting Process, <http://www.ippc.int> (follow “Standard Setting” hyperlink; then follow “Expanded text” hyperlink) (last visited Nov. 23, 2006).

<sup>71</sup> *Id.* § 2.

<sup>72</sup> For a more thorough discussion of the IPPC standard setting process, *see id.* § 3.

<sup>73</sup> Telephone Interview with John Greifer, *supra* note 68.

Overall, standard-setting activities in international organizations specified by the SPS agreement are conducted largely by the organizations themselves, with input from member states and limited participation from non-governmental sectors.

### **B. EQUIVALENCE: WHEN DIFFERENT THINGS ARE THE SAME**

The second module provided by the SPS agreement to encourage harmonization is the doctrine of equivalence.<sup>74</sup> The SPS agreement states that “Members shall accept the sanitary or phytosanitary measures of other Members as equivalent even if these measures differ from their own . . . if the exporting Member objectively demonstrates . . . that its measures achieve the importing Member’s appropriate level of . . . protection.”<sup>75</sup> In other words, a determination of equivalence involves a judgment that two standards are sufficiently similar so as to achieve the appropriate level of protection.<sup>76</sup> Members are required to enter into equivalence-determination negotiations upon request from another member.<sup>77</sup> Because equivalence determinations are conducted by the government of a member state, the ability of stakeholders to participate in the process of determining equivalence is controlled by the administrative law of the individual country.

### **C. MUTUAL RECOGNITION AGREEMENTS: EQUIVALENCE PERSONIFIED**

A mutual recognition agreement (MRA) emerges through a process where two countries “agree to recognize some aspect of the other’s regulatory regime as being interchangeable with their own.”<sup>78</sup> Depending on the structure of the agreement and the parties involved, MRAs can be “based on harmonization, on equivalence, or satisfaction of external criteria,”<sup>79</sup> and can address issues as wide ranging as substantive standards, product testing, or conformity assessments.<sup>80</sup> To date, most MRAs have focused on the latter, though it is increasingly

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<sup>74</sup> SPS Agreement, *supra* note 3, art. 4.

<sup>75</sup> *Id.* art. 4 ¶ 1.

<sup>76</sup> *MRA Briefing*, *supra* note 42, at 4.

<sup>77</sup> SPS Agreement, *supra* note 3, art. 4 ¶ 2.

<sup>78</sup> *MRA Briefing*, *supra* note 42, at 5.

<sup>79</sup> *Id.*

<sup>80</sup> *Id.*

likely that future MRA negotiations will be aimed at developing substantive, not procedural, standards.<sup>81</sup> Since MRAs are contracts between two governments,<sup>82</sup> the ability of stakeholders to impact the agreement depends on the administrative law of the negotiating parties.<sup>83</sup>

To date, the United States has not signed any MRAs as part of the SPS agreement. This should change in the future, however, as MRAs will likely “be at the heart of trade diplomacy in the coming decade.”<sup>84</sup> Several factors may combine to promote MRAs as the harmonization tool of choice in the future. First, MRAs negotiated with American trading partners in other areas may work to remove some of the regulatory distrust currently held between American regulators and their foreign counterparts. As trust is imperative to successful MRAs<sup>85</sup> because it requires “domestic regulators to accept the competency of their foreign counterparts,”<sup>86</sup> the development of trust through ongoing regulatory cooperation is likely to encourage future MRAs.<sup>87</sup> Second, the difficulty of negotiating agreeable international standards may spur countries to negotiate such agreements bilaterally where transaction costs are fewer. This is more so as “each new mutual recognition agreement

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<sup>81</sup> See generally Kalypso Nicolaïdis & Rebecca Steffenson, *Managed Mutual Recognition in the Transatlantic Marketplace*, in THE FUTURE OF TRANSATLANTIC ECONOMIC RELATIONS: CONTINUITY AMID DISCORD 139 (David M. Andrews et al. eds., 2005).

<sup>82</sup> See, e.g., KALYPSO NICOLAÏDIS, MUTUAL RECOGNITION OF REGULATORY REGIMES: SOME LESSONS AND PROSPECTS ¶ 3 (Harvard Jean Monnet Working Paper No. 7/97, 1997), <http://www.jeanmonnetprogram.org/papers/97/97-07.html> (last visited Feb. 25, 2007).

<sup>83</sup> To date, governments have negotiated the vast majority of MRAs. However, given the federal nature of the United States, which prohibits the federal government from regulating certain local activities, future MRAs may be negotiated among private industry groups or between U.S. industry groups and other nation states. Nicolaïdis & Steffenson, *supra* note 81, at 145-47. As with private standard-setting organizations, the direct involvement of private industry organizations in the negotiation of mutual recognition is likely to exasperate the public participation problem. This is because industry groups are unlikely to allow public interest representatives to participate in the negotiations, and traditional avenues of notice and comment are likely to be foreclosed (unless the private industry standard is then adopted as part of state legislation).

<sup>84</sup> NICOLAÏDIS, *supra* note 82, ¶ 1. For a list of pluses and minuses of prospective MRAs, see *id.* ¶¶ 19-31. Moreover, neither consumer groups nor business groups have warmed up to the idea of regulation through MRA. See, e.g., *MRA Briefing*, *supra* note 42, at 14-16 (outlining the costs of MRA to consumers); NAT'L ELEC. MFRS. ASS'N, 2004 TRADE PRIORITIES FOR THE ADMINISTRATION AND CONGRESS 3 (2004), available at <http://www.nema.org/gov/trade/positions/upload/NEMATradePriorities04.pdf> (noting that MRAs should be used sparingly, for example, only in cases where products are already subject to top-down regulation).

<sup>85</sup> Nicolaïdis, *supra* note 17, at 139.

<sup>86</sup> Nicolaïdis & Steffenson, *supra* note 81, at 144-45.

<sup>87</sup> See Shaffer, *supra* note 26, at 69 (noting that through regulatory cooperation, regulators in both countries “become more educated about each other’s systems”).

places pressure on third countries to enter into negotiations so that their firms are not disadvantaged.”<sup>88</sup>

In addition to understanding the harmonization tools that the SPS agreement provides, it is important to consider to what extent these tools have been utilized by the United States and whether stakeholders have had any say in the process.

## **II. DOMESTIC U.S. REGULATION AND INTERNATIONAL AUTHORITY: NEVER THE TWAIN SHALL MEET?**

A decade after the creation of the WTO and the implementation of the SPS agreement and its harmonization disciplines, much remains unanswered. In particular, the impact that these harmonization disciplines have had on domestic regulatory policy remains unclear. This section seeks to begin to answer some of these questions. Initially, it considers the impact that the harmonization disciplines in the SPS agreement have had on U.S. regulatory policy, both in terms of the adoption by the United States of internationally developed regulatory standards as well as the use of less formal harmonization arrangements, such as MRAs and equivalence determinations. Concluding that the United States is actively engaged in the harmonization process, the section then considers the ability of public interest representatives to participate in this process.

### **A. HARMONIZATION: FACT OR FICTION?**

#### **1. DOMESTIC IMPLEMENTATION OF INTERNATIONAL STANDARDS: DO INTERNATIONAL STANDARDS MATTER?**

While it is not possible to determine the full impact that the SPS agreement has had on U.S. regulatory policy, it is safe to say that it has affected the way in which the United States regulates sanitary and phytosanitary measures. When President Clinton sent the legislation implementing the Uruguay Agreements to Congress, he declared that the new SPS requirement of basing domestic regulatory standards on

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<sup>88</sup> *Id.* at 53.

international standards did not impose any additional obligations on U.S. regulatory authorities.<sup>89</sup> Subsequent practice, however, has demonstrated that the SPS agreement has had significant impact on the way in which domestic agencies develop, select, and adopt regulatory standards.

The largest difference in U.S. regulatory policy, subsequent to the implementation of the SPS agreement, is the way in which U.S. regulatory agencies justify the standards that they would like to adopt. Before the SPS agreement, agencies justified standards based on domestic regulatory considerations and would mention international standard-setting bodies, if at all, by merely noting that the agency was aware of the Codex standard.<sup>90</sup> Since the implementation of the SPS agreement, justifications for the introduction of new standards increasingly prioritize the consistency of the domestic standard with the relevant international one.<sup>91</sup> In cases where U.S. agencies have decided to adopt a standard other than the applicable international standard, they have justified these deviations by referring to the requirements of the SPS agreement and other WTO agreements.<sup>92</sup>

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<sup>89</sup> See MESSAGE FROM THE PRESIDENT OF THE UNITED STATES TRANSMITTING THE URUGUAY ROUND TRADE AGREEMENTS, TEXTS OF AGREEMENTS IMPLEMENTING BILL, STATEMENT OF ADMINISTRATIVE ACTION AND REQUIRED SUPPORTING STATEMENTS, H.R. DOC. NO. 103-316, at 670 (1994), as reprinted in 1994 U.S.C.C.A.N. 3773, 3784.

<sup>90</sup> See, e.g., Nutrient Requirements for Infant Formulas, 50 Fed. Reg. 45,106, 45,106 (Oct. 30, 1985) (codified as 21 C.F.R. § 107) (noting, in passing, that domestic standards complied with the standard developed by the Codex Alimentarius Commission).

<sup>91</sup> The importance of the SPS obligation to base domestic regulation on international standards is clearly noticeable when one considers the frequency with which agencies refer to international standard-setting organizations in justifying proposed regulations. In the fifteen years before the implementation of the SPS agreement, U.S. agencies referred to the OIE only once; in the nine years since the SPS came into being, they have referred to the OIE ninety-seven times. During the same time periods, U.S. agencies referred to the IPPC three times before, and forty-two times after the adoption of the SPS, and the Codex 217 times before, and over 400 times after the adoption of the SPS Agreement. See, e.g., Bovine Spongiform Encephalopathy: Minimal-Risk Regions and Importation of Commodities, 70 Fed. Reg. 460, 505-06 (Jan. 4, 2005) (codified at 9 C.F.R. pts. 93-96) (justifying the risk assessment for the proposed regulation as complying with the requirements demanded by the Codex and OIE); Bromoxynil, Diclofop-methyl, Dicofol, Diquat, Etridiazole et al., Proposed Tolerance Actions, 69 Fed. Reg. 47,051, 47,063 (Aug. 4, 2004) (codified at 40 C.F.R. pt. 180) (justifying a change in regulations to make them compliant with standards developed by Codex); Importation of Solid Wood Packing Material, 68 Fed. Reg. 27,480, 27,480 (May 20, 2003) (codified at 7 C.F.R. pt. 319) (“We propose to adopt the IPPC Guidelines because they represent the current international standard . . .”); Bitertanol, Chlorpropham, Cloprop, Combustion Product Gas, Cyanazine et al., Proposed Tolerance Actions, 68 Fed. Reg. 68,806, 68,811 (proposed Dec. 10, 2003) (codified at 40 C.F.R. pt. 180) (“EPA is working to ensure that the U.S. tolerance reassessment program under FQPA does not disrupt international trade. EPA considers Codex Maximum Residue Limits (MRLs) in setting U.S. tolerances . . .”).

<sup>92</sup> Telephone Interview with F. Edward Scarbrough, U.S. Mgr., Codex Alimentarius (Apr. 12, 2004).

While it is clear that the SPS agreement has had a procedural impact on U.S. regulatory policy, it is not immediately obvious whether international standards have altered the substance of U.S. regulations. Public interest organizations dedicated to monitoring government regulatory policies claim that efforts at international harmonization of regulatory standards have forced government regulators to preference trade-related concerns over environmental and consumer protection, resulting in a global regulatory race to the bottom.<sup>93</sup> However, a deeper inquiry of U.S. regulatory policy since the implementation of the SPS agreement does not allow one to easily agree with these assertions.

Undoubtedly, the adoption of international standards may result in lowering regulatory protection in a few specific areas. However, the dangers that Lori Wallach, the director of Public Citizen's Global Trade Watch and a vocal harmonization critic, and her associates decry seem to be more theoretical than real: Wallach is not able to produce an example where a U.S. regulatory agency has actually lowered its regulatory standard in favor of an international one.<sup>94</sup> Furthermore, even these critics concede that, as of now, U.S. administrations have resisted lowering regulatory standards to international levels and, instead, have justified their regulations under other provisions of the SPS agreement.<sup>95</sup> Specifically, U.S. regulatory agencies have relied on scientific data and risk assessment to explain deviations from international standards.<sup>96</sup> Moreover, the United States is unlikely to alter its policy and begin

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<sup>93</sup> Telephone Interview with Runako Kumbula, Equal Justice Works Fellow, Pub. Citizen's Global Trade Watch (Apr. 13, 2004). See also Lori M. Wallach, *Accountable Governance in the Era of Globalization: The WTO, NAFTA, and International Harmonization of Standards*, 50 U. KAN. L. REV. 823, 831 (2002); LORI WALLACH & MICHELLE SFORZA, *WHOSE TRADE ORGANIZATION? CORPORATE GLOBALIZATION AND THE EROSION OF DEMOCRACY: AN ASSESSMENT OF THE WORLD TRADE ORGANIZATION* xi, 55, 72 (1999).

<sup>94</sup> To date, the closest thing that Wallach has found to demonstrate the slackening of U.S. regulatory protection due to harmonization is the Department of Agriculture's June 1999 decision granting equivalency accreditation to Australia's Meat Safety Enhancement Program despite its record of ineffectiveness. Wallach, *supra* note 93, at 841-42. Critics point out that this and similar decisions sacrifice consumer safety on the altar of free trade. It is important to note, however, that in granting Australia's Meat Safety Enhancement Program, the USDA did not adopt an Australian or an international standard. Rather, they retained the domestic standard previously implemented by the USDA, but found that Australia's program was sufficient to meet this standard and, therefore, that the Australian producers who participated in the program were eligible to export their product to the United States. Wallach, however, focuses on the potential dangers that a strictly enforced SPS agreement may create and stresses the impact of harmonization requirements on the domestic regulatory policies of other states. *Id.* at 843-45.

<sup>95</sup> Telephone Interview with Runako Kumbula, *supra* note 93.

<sup>96</sup> Telephone Interview with F. Edward Scarbrough, *supra* note 92.

wholesale acceptance of international standards in the near future.<sup>97</sup> Given the stated intentions, as well as the actions, of U.S. regulatory agencies, it appears that the United States has interpreted Article 3.1 of the SPS agreement as a procedural obligation rather than a substantive requirement.<sup>98</sup>

Critics of harmonization will point out that even the “mere procedural” interpretation of the SPS might diminish the regulatory protection afforded to U.S. citizens.<sup>99</sup> According to this view, the fear of a potential WTO legal challenge will cause domestic agencies to shy away from adopting regulatory standards that are in excess of the international standard when they otherwise may have done so, absent strict harmonization requirements.<sup>100</sup> In its strongest form, this argument also alleges that, over time, civil servants working on developing standards would be so conditioned by the need to follow harmonization procedures that they would be subconsciously prejudiced against deviating from international standards, even in cases where doing so is justified.<sup>101</sup> For these critics, even the procedural version of the SPS agreement therefore poses a danger that regulatory flexibility, which was, until recently, widely enjoyed by WTO member states, will completely disappear.

Moreover, even seemingly permissive procedural requirements may ultimately restrict the substance of a regulation. In its *Report on the European Communities Measures Concerning Meat and Meat Products (EC-Beef)*, the WTO Appellate Body (AB) went out of its way to point out that, in order to fulfill the “based on” requirement of Article 3.1, a standard does not necessarily have to conform to the international standard.<sup>102</sup> In doing so, the AB implicitly endorsed the procedural

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<sup>97</sup> *Id.*

<sup>98</sup> Under the procedural interpretation of Article 3.1, the international standard may be ignored if the member state demonstrates that it considered the international standard and conducted a risk assessment, based on scientific evidence, demonstrating the need for a divergent standard. On the other hand, the substantive interpretation of Article 3.1 requires that the member state adopt the prevailing international standard as a basis for its domestic standard, even if a scientific risk assessment has been conducted. For a more elaborate explanation of the differences between the “procedural” and “substantive” interpretation of Article 3.1 of the SPS agreement *see infra* notes 82-88 and accompanying text.

<sup>99</sup> *See* Wallach, *supra* note 93, at 830-31.

<sup>100</sup> *See id.*

<sup>101</sup> *See id.* at 831.

<sup>102</sup> Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, ¶¶ 163-166, WT/DS26/AB/R, WT/DS48/AB/R (Jan. 16, 1998) [hereinafter *EC-Beef*].

interpretation of SPS Article 3.1.<sup>103</sup> Under this procedural interpretation, a member could adopt a stricter standard once it showed that it had considered but rejected the international standard based on a risk assessment.<sup>104</sup> Moreover, once the member state fulfills the procedural requirements, it is able to wholly ignore the international standard in favor of its own domestic one.<sup>105</sup>

However, even with this permissive interpretation, the AB has severely constrained the ability of states to choose their own level of sanitary and phytosanitary protection by refusing to accept the precautionary principle, except on a provisional basis, as a valid justification for adopting stricter national standards in areas where scientific data is not yet available.<sup>106</sup> As advocates like the group Public Citizen point out, not all regulations are made for scientific reasons,<sup>107</sup> many are adopted as a response to social or cultural norms. Similarly, popular attitudes often shape the content of a country's regulatory policy.<sup>108</sup> It is these attitudes that may explain the European Union's decision to maintain their regulatory policy on beef hormones<sup>109</sup> or their desire to see strict traceability and labeling requirements for products containing genetically modified organisms.<sup>110</sup> However, because the AB has limited the ability of states to adopt restrictive regulations in areas where scientific data is not yet available,<sup>111</sup> even the bare procedural

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<sup>103</sup> *See id.*

<sup>104</sup> *Id.* ¶ 172.

<sup>105</sup> *Id.* ¶ 173.

<sup>106</sup> *See EC-Beef*, *supra* note 102, ¶¶ 122-123, 45 n.92. *See also* Panel Report, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, ¶¶ 7.3065-3066, WT/DS291/R, WT/DS292/R, WT/DS293/R (Sept. 29, 2006).

<sup>107</sup> Public Citizen, *On the U.S. Delegation to the Codex Committee* (Mar. 26, 1999), [http://www.publiccitizen.org/print\\_article.cfm?ID=4291](http://www.publiccitizen.org/print_article.cfm?ID=4291).

<sup>108</sup> Leaders of the business community also acknowledge the existence of this phenomenon. For example, William Reinsch, president of the National Foreign Trade Council, Inc., points out that one reason why harmonization has been slow to develop is the tendency of regulators to regulate in response to domestic political and social pressures. These pressures are often driven by factors other than science, and it is common for regulators to act without first considering the importance of harmonization. Telephone Interview with William Reinsch, *supra* note 7.

<sup>109</sup> *US Impatient with EU Ban on GMOs, Beef Hormones*, PLANET ARK (Dec. 18, 2002), <http://www.planetark.org/dailynewsstory.cfm/newsid/19112/story.htm>.

<sup>110</sup> Council Regulation 1829/2003, *Genetically Modified Food and Feed*, 2003 O.J. (L 268) 1, 3 (EC); Council Regulation 1830/2003, *Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced From Genetically Modified Organisms*, 2001/18/EC, 2003 O.J. (L 268) 24, 24-26 (EC).

<sup>111</sup> *See EC-Beef*, *supra* note 102, ¶¶ 122-123, 45 n.92; *see also* Panel Report, *supra* note 106, ¶¶ 7.3065-3066.

interpretation of Article 3.1 represents a shackle on the government's ability to regulate.

Finally, it is not clear whether the U.S. reading of the SPS agreement as procedural in nature will be sustainable over time. It is possible that even the relatively more permissive interpretation of Article 3.1 adopted in the *EC-Beef* decision might not survive. A few years after *EC-Beef*, it appeared that the AB was backing away from a purely procedural interpretation in deciding that "based on" meant that the domestic regulation must use the international standard as "the principal constituent or fundamental principle" of the domestic standard.<sup>112</sup> This move away from a relatively procedural interpretation of Article 3.1 is likely to continue in the future. As time goes on and WTO member countries become more comfortable with the SPS agreement and its requirements, they are likely to attempt to manipulate its requirements in order to recapture some of their traditional regulatory autonomy and, in some instances, to undertake protectionist policies. Should this occur, it is possible that the AB will choose to adopt a stricter interpretation of Article 3.1. This would likely result in further ascendance of the influence of international standards and a corresponding decrease in the regulatory autonomy of the United States and other WTO member nations.

The requirement that domestic standards must be based on international ones is a formidable hurdle for states seeking to independently choose the level of protection that they offer their citizens. Indeed, to date, no state has successfully defended a case arising out of the SPS agreement. Realizing the constraints that the SPS agreement has placed on their regulatory policies, many states have opted to get actively involved in the international organizations responsible for drafting and adopting international standards. This involvement has resulted in an increased polarization of these bodies and a relatively quick death of the consensus nature by which such organizations have traditionally functioned. Recently, a series of standards have been adopted by razor-thin majorities; for example, a draft standard for natural mineral water was approved by a vote of thirty-three for and thirty-one against, with ten abstentions.<sup>113</sup> The increased importance of participating in and

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<sup>112</sup> Appellate Body Report, *European Communities—Trade Description of Sardines*, ¶ 243, WT/DS231/AB/R (Sep. 26, 2002).

<sup>113</sup> See, e.g., Joint FAO/WHO Food Standards Programme: Codex Alimentarius Comm'n, June 23-28, 1997, *Report of the Twenty-Second Session of the Codex Alimentarius Commission*, ¶¶ 85-90,

influencing international standard-setting organizations has been reflected in the articulation of priorities by various regulatory agencies.<sup>114</sup> Moreover, realizing the economic consequences that adopted international standards are likely to pose, the United States has attempted to take the lead in developing standards in particularly controversial areas, such as those dealing with biotechnology.<sup>115</sup> This strategy has also been pursued through the active participation of the United States in various scientific bodies that draft international standards.<sup>116</sup>

## 2. HARMONIZING FROM HOME: THE USE OF EQUIVALENCE AND MRAS BY THE UNITED STATES

In sharp contrast to its leadership and active participation in international standard-setting bodies, the United States has been less willing to use equivalence determinations and MRAs in its efforts to promote harmonization under the SPS agreement.<sup>117</sup> This reticence, however, may owe more to a lack of suitable partners than to any unwillingness on the part of the United States government. In particular, a philosophical difference in regulatory philosophies between the United States and the European Commission has made it very difficult to negotiate MRAs, particularly on issues of high political salience.<sup>118</sup> As pointed out by Kalypso Nicolaidis and Rebecca Steffenson, the EU regulatory philosophy is trade-friendly whereas the United States regulatory officials are less concerned with promoting trade than with promoting safety and public health.<sup>119</sup> These divergent goals may have

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FAO Doc. ALINORM 97/37 (Aug. 1997). For a more detailed analysis of the polarization of the Codex Alimentarius Commission, see Stewart & Johanson, *supra* note 41, at 43-45.

<sup>114</sup> See, e.g., U.S. Food & Drug Admin., Ctr. for Food Safety & Applied Nutrition, Affirmative Agenda For Int'l Activities (1999), <http://www.cfsan.fda.gov/~comm/intlact.html> (last visited Feb. 25, 2007).

<sup>115</sup> *Id.*

<sup>116</sup> *Id.*

<sup>117</sup> While the SPS agreement does not explicitly provide for mutual recognition agreements, it does provide for equivalence agreements, which, if successful, can become formalized as mutual recognition agreements. SPS Agreement, *supra* note 3, art. 4 ¶ 2. In any case, the story of the mutual recognition agreements negotiated by the United States under the TBT Agreement allows one to draw general lessons on potential problems to be faced by the United States in negotiating future MRAs, either under the TBT or SPS agreements.

<sup>118</sup> See generally NICOLAÏDIS, *supra* note 82, ¶¶ 1-2, 37, 44 (arguing that different regulatory philosophies are among the largest hurdles that harmonization has to overcome).

<sup>119</sup> Nicolaïdis & Steffenson, *supra* note 81, at 147. It is worth noting that while agreeing that philosophical differences are one of the major barriers to successful harmonization activities, some influential American observers see the difference in other ways. For example, William

hindered the ability of the United States and the European Union to implement some of the MRAs that the parties negotiated in the mid-1990s.<sup>120</sup> This difference is further exasperated by the European demand that any regulatory convergence be to the European system or not at all.<sup>121</sup>

Similar philosophical differences may be the reason why agreements with other developed states have been difficult to achieve.<sup>122</sup> The psychological barriers to changing existing regulatory practices have been difficult to overcome, particularly as each regulatory philosophy is the result of a country's internal compromise, achieved after years of domestic debate.<sup>123</sup> When these psychological barriers are further reinforced by economic interest certain to be harmed by harmonization, it is not surprising that developed countries have not been eager to sign MRAs.<sup>124</sup>

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Reinsch, president of the National Foreign Trade Council, Inc., an American export-promoting organization, argues that a major block to successful harmonization has been the philosophical difference between the European Community, which regulates based on the precautionary principle, and the United States, which adheres to a market-driven regulatory philosophy. Telephone Interview with William Reinsch, *supra* note 7.

<sup>120</sup> As part of the New Transatlantic Agenda signed in 1995, the European Union and the United States agreed to negotiate a series of mutual recognition agreements. Nicolaïdis & Steffenson, *supra* note 81, at 139. The two sides negotiated a framework agreement that provided for mutual recognition agreements to be negotiated in six discrete sectors. *Id.* The enthusiasm for MRAs as a harmonization strategy, however, faded quickly as three of the six sectors failed to reach operation status by the appropriate deadlines. *Id.* According to Nicolaïdis and Steffenson, the diverging regulatory philosophies of EU and American regulators (in particular, views held by the FDA and OSHA) were a major reason that three of the sectors failed to become operational. *Id.* at 145.

<sup>121</sup> See Shaffer, *supra* note 26, at 73 (pointing out that in cases where regulatory adaptation has been required in order to negotiate a transatlantic MRA, the United States has been forced to make the majority of the changes); NICOLAÏDIS, *supra* note 82, ¶¶ 45-46 (arguing that the EU's demand for convergence to the EU system is one of three major barriers preventing MRA negotiations between the United States and the EU).

<sup>122</sup> John Meaker, manager of international trade for one of the largest industry groups, points out that a major barrier to harmonization is the global difference in regulatory philosophies. Telephone Interview with John Meaker, Mgr., Int'l Trade for the Nat'l Elec. Mfr. Assoc. (Sept. 1, 2004). According to Meaker, the main barrier to harmonization is the reliance many developed countries have on top-down regulation, an approach that is largely rejected by the United States. *Id.*

<sup>123</sup> *Id.* (arguing that harmonization is more likely when the product is new and a regulatory order can be created from scratch, as opposed to changing existing practice). It is also important to note that similar psychological barriers and transaction costs exist in the United States and this may explain the refusal of the United States to adopt alternative regulatory philosophies. *Id.*

<sup>124</sup> See generally NICOLAÏDIS, *supra* note 82 (noting that the only successful use of MRAs has been within the EU—where regulatory systems differed less, and were encouraged by exogenous motivations).

Unable to negotiate MRAs with other developed countries, the United States has likewise been unsuccessful in negotiating such agreements with developing countries. The reluctance of the United States to enter into MRAs with developing countries may be explained by their differences in technological know-how. Regulatory measures impacted by the SPS Agreement are typically very technical, and developing countries are unlikely to be able to offer the same level of protection as required in the United States or a comparably developed country.<sup>125</sup>

Moreover, the European attitude may also have made negotiations with developing countries difficult. One of the side effects of mandated harmonization has been increased regulatory competition between the United States and Europe.<sup>126</sup> As part of this competition, the European Commission has, on several occasions, withdrawn trade concessions from countries disobeying European regulations.<sup>127</sup> As Professor Gregory Shaffer points out, the growing size of the European market, which is already larger than that of the United States, provides the European Union with substantial leverage as “firms that desire access to the large EC market can pressure their national officials to adapt their national system” to European standards.<sup>128</sup> Under such pressure many countries have accepted, sometimes reluctantly, European regulatory preferences, thereby making MRAs with the United States difficult and unlikely.<sup>129</sup> Europe’s refusal to compromise over regulatory philosophy

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<sup>125</sup> WTO member states recognized this problem, which is why the agreement specifically calls for developed countries to help developing countries obtain the capability to offer effective regulation. SPS Agreement, *supra* note 3, art. 9.

<sup>126</sup> Telephone Interview with William Reinsch, *supra* note 7. See also Stewart & Johanson, *supra* note 41, at 41-46 (offering examples of regulatory competition).

<sup>127</sup> An example of this behavior can be seen in the current genetically modified organism (GMO) dispute, where the European Union has threatened countries importing genetically modified food from the U.S. with trade sanctions. Justin Gillis, *Debate Grows Over Biotech Food: Efforts to Ease Famine in Africa Hurt by U.S., European Dispute*, WASH. POST, Nov. 30, 2003, at A1 (noting that some developing countries “have resisted biotech crops for fear adopting them would hurt their ability to sell exports to Europe”); Harvey E. Lapan & GianCarlo Moschini, *Innovation and Trade with Endogenous Market Failure: The Case of Genetically Modified Products*, 86 AM. J. AGRIC. ECON. 634 (2004) (providing an overview of the GMO dispute). For an extensive analysis of the impact of the U.S.-EU GMO dispute on developing countries, see Michelle K. McDonald, *International Trade Law and U.S.-EU GMO Debate: Can Africa Weather This Storm?*, 32 GA. J. INT’L & COMP. L. 501, 528-38 (2004).

<sup>128</sup> Shaffer, *supra* note 26, at 73-74.

<sup>129</sup> *Id.*

combined with its economic influence has made some developing countries unwilling to challenge the European regulatory system.<sup>130</sup>

Similarly, the United States has been unwilling or unable to take full advantage of the equivalence provisions in the SPS agreement. While acknowledging that the SPS agreement does not insist on equivalence determinations, the Food and Drug Administration has indicated that they are required to consult with interested members with that goal in mind.<sup>131</sup> Despite the obligation to negotiate and the fact that several countries have requested such negotiations,<sup>132</sup> few agreements have been reached. Moreover, those few that have been negotiated have largely focused on recognizing the equivalence of the exporter's conformity assessment procedures, not their substantive regulatory standards.

A possible reason for the lack of equivalence determinations is their prohibitive political cost. The purely unilateral and largely import-specific nature of these determinations makes them particularly vulnerable to special interest critique. Domestically, the primary benefactors of equivalence agreements are ordinary consumers, a group that is too diffuse to mobilize and demand equivalency determinations. On the other hand, domestic industries hurt by imports and civil society organizations, many of which oppose harmonization on principle,<sup>133</sup> are likely to agitate against them.<sup>134</sup> While the relatively low visibility of equivalence determinations, especially when compared to other methods of harmonization, may serve to mute criticism from civil society organizations, the general criticism of the harmonization project may have cautioned the U.S. government against an aggressive use of equivalence determinations.

Despite these obstacles, the United States has remained open to the idea of equivalence. Since publishing its *Draft Guidance on Equivalence Criteria for Food*,<sup>135</sup> where the process of attaining equivalence decision was first articulated, the USDA and FDA (regulatory agencies responsible for the implementation of the SPS

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<sup>130</sup> *Id.*

<sup>131</sup> Draft Guidance on Equivalence Criteria for Food, 62 Fed. Reg. 30,593, 30,593 (June 4, 1997). See also SPS Agreement, *supra* note 3, art. 4 ¶ 1.

<sup>132</sup> Draft Guidance on Equivalence Criteria for Food, 62 Fed. Reg. 30,593, 30,593 (June 4, 1997).

<sup>133</sup> Telephone Interview with Runako Kumbula, *supra* note 93.

<sup>134</sup> This may be further magnified by the reluctance of U.S. trade partners to grant reciprocal equivalence determinations. Lacking hope of securing better market access elsewhere, U.S. exporters are unlikely to pressure the government to grant equivalence determinations.

<sup>135</sup> Draft Guidance on Equivalence Criteria for Food, 62 Fed. Reg. at 30,593.

agreement) have indicated on a half-dozen occasions their willingness to consider requests for equivalence decisions.<sup>136</sup> Notwithstanding this willingness to enter into consultations about equivalence, there have been few findings of equivalence noticed in the federal register.<sup>137</sup>

This phenomena, however, is likely to change in the near future. As the federal government itself notes, the equivalence doctrine has only recently found use in international trade law despite the fact that it was part of the original SPS agreement in 1995.<sup>138</sup> The proximity of its relevance, combined with the lengthy process required for an equivalence decision,<sup>139</sup> may explain why few actual equivalence decisions have been rendered. As countries get used to the idea of

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<sup>136</sup> See, e.g., Federal Measures to Mitigate BSE Risks: Consideration for Further Action, 69 Fed. Reg. 42,288, 42,299-300 (July 14, 2004) (codified at 21 C.F.R. pt. 589) (requesting comments about making equivalence determinations for countries free of Mad Cow disease); Irradiation Phytosanitary Treatment of Imported Fruits & Vegetables, 67 Fed. Reg. 65,016, 65,016 (Oct. 23, 2002) (codified at 7 C.F.R. pts. 305 & 319) (indicating a willingness to grant equivalence status to several alternative methods of protecting against fruit flies); Mandatory Inspection of Ratites and Squabs, 67 Fed. Reg. 13,253, 13,253 (Mar. 22, 2002) (codified at 9 C.F.R. pts. 362 & 381) (extending the period during which countries can request equivalence decisions and noting that the equivalence process may take years to complete); Australia's Meat Safety Enhancement Program [MSEP], 64 Fed. Reg. 30,299, 30,299 (June 7, 1999) (finding Australia's system of meat inspection equivalent).

<sup>137</sup> See, e.g., Australia's Meat Safety Enhancement Program, 64 Fed. Reg. at 30,299. It must be noted, however, that looking at the federal register may not produce an accurate account of every equivalence decision rendered to date. The FDA has made clear that it does not intend to note "each equivalence determination that is completed." Letter from Joseph C. Famulare, FDA Joint Sectoral Comm. Rep., to Mary Bottari, Dir., Pub. Citizen's Global Trade Watch (Sept. 22, 2000), available at <http://www.citizen.org/trade/harmonization/MRA/articles.cfm?ID=4303> [hereinafter Famulare Letter]. In particular, where the equivalency determination is made as part of a larger framework agreement, U.S. regulators may choose not to publish a separate notice and comment for each individual equivalency determination. *Id.* Moreover, U.S. law currently only requires notice and comment when an equivalence determination is granted to an SPS measure of a trading partner. See 19 U.S.C. § 2578(a) (2000). Therefore, when equivalence determinations are made as part of the TBT Agreement, notice and comment may not be required unless the administering agency decides to formalize the determination of a regulation or other measure that is legally binding on that administrative agency. See Stewart, *supra* note 22, at 69 (providing an example of a situation where notice and comment are not likely to be used).

<sup>138</sup> Final Guidance: Importation of Pasteurized Milk Ordinance [PMO] Defined Dairy Products (M-I-00-4), 65 Fed. Reg. 39,912, 39,913 (June 28, 2000).

<sup>139</sup> See, e.g., Mandatory Inspection of Ratites and Squabs, 67 Fed. Reg. at 13,253 (noting that the eighteen-month time period originally granted for equivalence determinations was not sufficient to allow the equivalence process to run completely). The current process of equivalence determination requires the regulatory officials of the state seeking equivalence to demonstrate the sufficiency of its procedures to provide for the level of public safety demanded by U.S. regulations. This process requires both "a paper review, [and] an on-site verification review" and often a notice and comment. Draft Guidance on Equivalence Criteria for Food, 62 Fed. Reg. at 30,595. All together, the process of attaining an equivalency determination may well take longer than a year to complete.

equivalence determination, and as the time required for the process shrinks, the number of equivalence findings is likely to increase.

The impact that equivalence decisions may have on domestic regulatory policy should not be presumptively overstated. Most areas where equivalence has been provided have been aimed at conformity assessment and methods used to achieve protection rather than the substance of the standards themselves.<sup>140</sup> This type of procedural harmonization is designed to maintain the same level of protection that existed before the equivalence decision while reducing the costs imposed by redundant testing.<sup>141</sup>

Those who oppose harmonization generally criticize equivalence decisions on two grounds. First, they argue that pushing conformity assessments to other countries may lower the level of protection because other countries are not likely to be as vigilant in their review as U.S. authorities. Second, they argue that because the ability of U.S. regulatory authorities to monitor foreign bodies is likely to become strained by fatigue and budget shortfalls, enforcement will suffer.<sup>142</sup>

Neither argument is terribly persuasive. Foreign regulatory bodies are unlikely to be lax in their enforcement because of the high political and economic costs if evidence of enforcement defects were discovered, particularly as sanitary and phytosanitary measures tend to have large political footprints. Meanwhile, to the extent that resources are available, the same political footprint is likely to encourage domestic regulatory authorities to monitor and review foreign bodies deemed equivalent.<sup>143</sup> Because regulatory failure in such highly visible areas is unlikely, equivalence decisions aimed at verifying the conformity of goods with regulatory standards should have little impact on domestic levels of protection.

Additionally, equivalence decisions may merely be more formal codifications of previously negotiated memoranda of understanding

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<sup>140</sup> See, e.g., Irradiation Phytosanitary Treatment of Imported Fruits and Vegetables, 67 Fed. Reg. at 65,016; Australia's Meat Safety Enhancement Program, 64 Fed. Reg. at 30,299; Equivalence Evaluation Process for Foreign Meat and Poultry Food Regulatory Systems; Response to Comments, 64 Fed. Reg. 70,690 (Dec. 17, 1999).

<sup>141</sup> One commentator has described such agreements as "labor saving rather than law changing," alluding to the reduction in labor costs likely to prevent the elimination of redundant and unnecessary testing. Merrill, *supra* note 18, at 754.

<sup>142</sup> See Equivalence Evaluation Process for Foreign Meat and Poultry Food Regulation Systems, 64 Fed. Reg. at 70,691-92 (providing examples of the critiques and the government's answers to them).

<sup>143</sup> As they have already promised to do on other occasions. See, e.g., *id.* at 70,691.

(MOU). Prior to the inception of the SPS agreement, the United States negotiated several such MOUs with trading partners in an effort to streamline regulatory approval of particular products.<sup>144</sup> Typically, such agreements would stipulate that the U.S. trade partner agreed to implement particular safety measures in exchange for easier access to the U.S. market.<sup>145</sup> Traditionally, however, these MOUs tended to focus on specific problems between the United States and its trading partner, not on recognizing “foreign food control systems as providing the same level of protection as those in the United States.”<sup>146</sup> Recently, various countries benefiting from MOUs have expressed interest in converting them into full-scale equivalence agreements that would be larger in scope than the existing MOUs and would focus on recognizing the equivalence of their regulatory systems in providing the same level of protection as in the United States. Such equivalence agreements, if successfully negotiated, are likely to entrench existing regulatory policy rather than create new policy.

There are, however, valid reasons to be concerned about the potential impact of equivalence decisions on U.S. regulatory policy. Specifically, while U.S. regulators are unlikely to overlook regulatory lapses abroad, excessive focus on the benefits of equivalence may result in the refusal of American regulators to elevate appropriate protection levels or demand newer technology when it would either nullify an existing equivalence agreement or make additional ones difficult to achieve.<sup>147</sup> A second danger is that while presently equivalence determinations are focused on procedural matters, increased familiarity with this harmonization tool might encourage regulators to use equivalence determinations to alter substantive standards as well—which could potentially result in a lower level of protection.

Unlike equivalence determinations, which, while slow to start, have become an important mechanism for harmonization, MRAs have been unable to breach the wall of differences separating U.S. regulators

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<sup>144</sup> For several examples of such MOUs, *see* Draft Guidance on Equivalence Criteria for Food, 62 Fed. Reg. at 30,594.

<sup>145</sup> *See id.*

<sup>146</sup> *Id.*

<sup>147</sup> This is because the political costs of failing to implement a new regulation are likely to be less when a standard addressing an inherently uncertain topic is not adopted, as compared to a situation in which already existing laws and regulations are not enforced. Furthermore, failing to enforce a law is more likely to be subjected to a legal challenge from domestic consumer groups than would occur in a case of inherently discretionary regulatory judgment. *See Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 839-40 (1984).

and their colleagues in other countries. However, some brief observations from the MRAs negotiated under the TBT agreement may help paint a picture of what MRAs in the SPS area are likely to look like. To date, the half dozen or so MRAs negotiated by the United States have been with major trading partners and focused on issues of conformity assessment procedures.<sup>148</sup> Because MRAs can generally be viewed as bilateral and reciprocal equivalence determinations, much of the above analysis about the potential impact of equivalence decisions on U.S. regulatory policy applies to MRAs as well.

Overall, it is fair to say that as a result of the SPS agreement, the U.S. regulatory system has been impacted by international standard-setting much more than by individual equivalence decisions and MRAs. Moreover, the United States has taken a proactive approach in promoting harmonization in international standard-setting organizations and attempting to use equivalence decisions and MRAs. As the following section explains, this pro-harmonization posture has been accompanied by a decrease in the opportunities for stakeholders to shape the process in the domestic arena.

### **B. STAKEHOLDER PARTICIPATION: DECREASING OPPORTUNITIES, DECREASING INFLUENCE**

One of the explicit goals underlying the SPS agreement was the desire to eliminate arbitrary and discriminatory regulatory standards. In

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<sup>148</sup> See, e.g., Comm. on Technical Barriers to Trade, *Agreement Reached by a Member with Another Country or Countries on Issues Related to Technical Regulations, Standards or Conformity Assessment Procedures*, G/TBT/10.7/N/46 (July 21, 2004) (notifying an agreement between U.S. and the European Community on conformity assessment procedures); Comm. on Technical Barriers to Trade, *Agreement Reached by a Member with Another Country or Countries on Issues Related to Technical Regulations, Standards or Conformity Assessment Procedures*, G/TBT/10.7/N/42 (Jan. 8, 2003) (notifying an agreement between Brazil, Canada and the U.S. on conformity assessment); Comm. on Technical Barriers to Trade, *Agreement Reached by a Member with Another Country or Countries on Issues Related to Technical Regulations, Standards or Conformity Assessment Procedures*, G/TBT/10.7/N/41 (Dec. 12, 2002) (notifying an agreement between Brazil and various developed countries, including the U.S.); Comm. on Technical Barriers to Trade, *Agreement Reached by a Member with Another Country or Countries on Issues Related to Technical Regulations, Standards or Conformity Assessment Procedures*, G/TBT/10.7/N/20 (Mar. 1, 1999) (notifying a conformity assessment agreement between the U.S. and the European Community). *But see* Comm. on Technical Barriers to Trade, *Agreement Reached by a Member with Another Country or Countries on Issues Related to Technical Regulations, Standards or Conformity Assessment Procedures*, G/TBT/10.7/N/36 (Apr. 18, 2002) (notifying an agreement between the U.S. and Japan where Japan agreed to grant equivalence to U.S. technical regulations, standards and conformity assessment procedures related to the U.S. National Organic Program).

order to accomplish this goal, the drafters of the SPS agreement hoped to insulate the standard-drafting process from domestic special interests. Given this history, it is not surprising that the displacement of standard-setting activities into international organizations has reduced both the opportunities for stakeholder participation and the influence of public interest groups in cases where participation is possible. In the United States, where stakeholders have traditionally found a welcoming seat at the table of regulatory policy, particularly after the reforms of the 1960s, the marginalization of opportunities for public participation has been especially obvious.

While legislation that would incorporate the Uruguay Agreements<sup>149</sup> as part of U.S. domestic law was being drafted, concerns emerged regarding the impact that the increasing importance of international standard-setting activities would have on U.S. stakeholders.<sup>150</sup> Congress was particularly concerned about two potential developments. The first was the secretive nature of international standard-setting organizations. Congress was worried that, with the displacement of standard-setting activities from domestic agencies to international organizations, regulatory standards might be negotiated in the dead of night, without U.S. stakeholders having an opportunity to participate.<sup>151</sup> Second, Congress was concerned that the harmonization of regulatory standards would result in the adoption of standards that were harmful to U.S. interests.<sup>152</sup>

In an effort to alleviate these concerns, Congress inserted several provisions into the Uruguay Round Agreements Act.<sup>153</sup> These provided

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<sup>149</sup> Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, 33 I.L.M. 1 (1994).

<sup>150</sup> See, e.g., 140 CONG. REC. S15,077, S15,087 (daily ed. Nov. 30, 1994) (statement of Sen. Metzenbaum); 140 CONG. REC. S15,077, S15,112 (daily ed. Nov. 30, 1994) (statement of Sen. Hatch); 140 CONG. REC. S15,271, S15,311 (daily ed. Dec. 1, 1994) (statement of Sen. Thurmond); 140 CONG. REC. H11,493, H11,507 (daily ed. Nov. 29, 1994) (statement of Rep. Vento). See also James Risen, *New Trade Body's Power Called Overrated*, L.A. TIMES, Dec. 2, 1994, at A18; Ralph Nader, *Reject this Flawed Treaty*, USA TODAY, Nov. 22, 1994 at 10A; Claude Barfield, *Will the New World Trade Organization Work?; Sure it Will—If We Resist Protectionist Pressures*, WASH. POST, June 26, 1994, at C3.

<sup>151</sup> Telephone Interview with Runako Kumbula, *supra* note 93.

<sup>152</sup> See, e.g., 140 CONG. REC. S15,271, S15,359 (daily ed. Dec. 1, 1994) (statement of Sen. Kerry). In particular, it is worthwhile noting that Congress was not only concerned with the economic impact that harmonized standards might have, but also with the impact that such standards might have on environmental and consumer protection statutes. See, e.g., 140 CONG. REC. S15,077, S15,124-25 (daily ed. Nov. 30, 1994) (statement of Sen. Heflin).

<sup>153</sup> See, e.g., 140 CONG. REC. H11,493, H11,524 (daily ed. Nov. 29, 1994) (statement of Rep. Dingell) (noting that Congress specifically inserted notice and comment procedures to be used in cases of international standard setting to ensure stakeholders' ability to participate in the

for notice and comment when the United States engaged in international standard-setting or in making equivalency determinations.<sup>154</sup> These provisions, developed with the interest representation model of administrative law in mind, were designed to ensure that the harmonization process would occur under the light of public scrutiny. In particular, Congress authorized the president to designate specific agencies to monitor the standard-setting activities of the relevant international organizations and to annually notify the public about these activities.<sup>155</sup> Furthermore, Congress required the administration to solicit and consider public input regarding potential negotiating positions being taken by U.S. representatives at the various meetings of these standard-setting organizations.<sup>156</sup>

Unfortunately, the congressional expectation that these obligations, when added to the usual requirement of notice and comment rulemaking under U.S. law,<sup>157</sup> would ensure adequate space for public participation and influence in the negotiating process remains unfulfilled. Increasingly, public participation, both in the development of U.S. negotiation positions and in the substance of standards, appears to have been relegated to a purely ceremonial role, resulting in the alienation of the public from the international harmonization process. The result is a regulatory environment oddly reminiscent of the pre-1960s regulatory world: regulators listen to those they are supposed to govern but not to those who stand to benefit from regulatory protection.<sup>158</sup>

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process); 140 CONG. REC. H11,493, H11,531 (daily ed. Nov. 29, 1994) (statement of Rep. Collins). The result of these efforts is evident. See 19 U.S.C. § 2578 (2000).

<sup>154</sup> While MRAs are not explicitly mentioned in 19 U.S.C. § 2578 (2000), it is likely that Congress intended the notice and comment procedures to apply to MRAs, as well as to equivalency determinations, because MRAs in effect operate as formalized equivalency determinations.

<sup>155</sup> 19 U.S.C. §§ 2578(a)-(c). Using the power granted to him under § 2578(a), the president designated the Department of Agriculture's Codex Office with the responsibility of monitoring and informing stakeholders of all activities pertaining to the work of the Codex Alimentarius Commission. Proclamation No. 6780, 60 Fed. Reg. 15,845, 15,846 (Mar. 23, 1995). Similarly, the Department of Agriculture's Animal, Plant and Inspection Service was placed in charge of monitoring the standard-setting activities undertaken by the International Plant Protection Convention and the Office of International Epizootics. *Id.*

<sup>156</sup> 19 U.S.C. § 2578(d).

<sup>157</sup> 5 U.S.C. §§ 553(b)-(c) (2000).

<sup>158</sup> See SUNSTEIN, *supra* note 31, at 211 (noting that the shift to the interest representation model was caused by the feeling of inequity in a process where the subject of the regulation had more protection than the beneficiaries).

1. NEGOTIATING THE NEGOTIATION: PUBLIC PARTICIPATION  
IN THE FORMULATION OF U.S. NEGOTIATING PRIORITIES  
IN MULTILATERAL NEGOTIATIONS.

By law, agencies involved in international standard-setting activities in accordance with the SPS agreement must provide an opportunity for interested stakeholders to comment on the subject of impending negotiations.<sup>159</sup> In practice, this means that, prior to the meeting of a standard-setting IGO (or a subcommittee for a particular standard of the IGO) the agency will conduct a notice and comment, and at times a public meeting, in an effort to solicit public input.<sup>160</sup> Typically, stakeholders interested in the outcome of the negotiations will be informed of the proposed U.S. negotiating position and asked to comment on it.<sup>161</sup> After receiving comments (either in written form or orally at the meeting), the U.S. delegate may choose to incorporate the views expressed in these comments and modify the proposed negotiating position, though he or she is under no obligation to do so.<sup>162</sup>

This broad discretion towards agency action is somewhat analogous to the deference that was shown to domestic rulemaking agencies prior to the development of the interest-based model of administrative law and the articulation of hard-look review in the late 1960s.<sup>163</sup> Just as, prior to the adoption of “searching judicial inquiry,” agencies did not have to justify their decisions in rulemaking procedures, the present-day delegate does not have to justify why a particular negotiating position was adopted. Since delegates do not have to respond to comments and judicial review is not available,<sup>164</sup> there is no

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<sup>159</sup> Telephone Interview with F. Edward Scarbrough, *supra* note 92.

<sup>160</sup> *Id.* See also International Standards under the International Plant Protection Convention, 66 Fed. Reg. 53,978 (Oct. 25, 2001); International Sanitary and Phytosanitary Standard-Setting Activities, 67 Fed. Reg. 54,615 (Aug. 23, 2002).

<sup>161</sup> International Sanitary and Phytosanitary Standard-Setting Activities, 67 Fed. Reg. at 54,615.

<sup>162</sup> Telephone Interview with F. Edward Scarbrough, *supra* note 92.

<sup>163</sup> See *Scenic Hudson Pres. Conference v. Fed. Power Comm'n*, 354 F.2d 608, 620 (2d Cir. 1965). See also Stewart, *supra* note 31, at 1675-76 (arguing that in the traditional regulatory model, judicial review was only available for issues which Congress had given direct guidance, with the agency receiving discretion on all other issues); STEPHEN G. BREYER ET AL., *ADMINISTRATIVE LAW AND REGULATORY POLICY: PROBLEMS, TEXT, AND CASES* 215-17 (5th ed. 2002) (explaining the development of searching review by courts in agency actions as a response to the large amounts of discretion granted to agencies and the resulting charges of administrative capture).

<sup>164</sup> For a detailed explanation of why procedural review is unavailable for executive negotiating decisions, see Stewart, *supra* note 22, at 79-81.

way to verify that public concerns have been addressed in the formation of the negotiating position.<sup>165</sup>

A second way in which representatives of the public interest may influence the negotiation of international standards is by being a part of an official delegation to the meetings and committees of the IGOs. This too, however, is not entirely effective in bringing the opinions of the public into the negotiations. Under the current process, each delegate is tasked with forming his or her delegation, which will attend the meetings where the development and adoption of international standards are considered.<sup>166</sup> The delegate has broad discretion in selecting members of the negotiating team and has no obligation to accept representatives of the public interest as members of the delegation.<sup>167</sup> Nonetheless, several public interest organizations have been members of such delegations.<sup>168</sup>

While the ability to be a member of the negotiating team looks like everything that a stakeholder could want, in reality, it is no guarantee that the opinions of that organization will in any way affect the negotiating position of the United States. First, regulatory agencies typically impose a limit on the number of public representatives they are willing to accept as members of the negotiating team.<sup>169</sup> While this limitation is probably necessary to ensure the cohesion and effectiveness of the negotiating team, it may have the unfortunate effect of excluding many representatives of the public interest from participating.<sup>170</sup> The

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<sup>165</sup> Dr. Scarbrough argues that such verification is available through the informal network of individuals who are working on these issues. According to Scarbrough, this verification takes the form of informal communications between the delegate and interested parties, and decisions to modify the negotiating position are clearly visible to those who are following the process. Telephone Interview with F. Edward Scarbrough, *supra* note 92. While there may be good reasons not to make the final negotiating position of the United States public, the informal process described by Dr. Scarbrough is probably insufficient to address stakeholder concerns. Not only does it fail to insure that the concerns of public interest organizations are adequately addressed, but it leaves the agency subject to accusation of capture by special interest groups. *See, e.g.,* Wallach, *supra* note 93, at 836-38.

<sup>166</sup> International Standard-Setting Activities, Codex Alimentarius Commission; Duties of United States Delegates and Delegation Members Including Non-Government Members, 63 Fed. Reg. 7,118, 7,119 (Feb. 12, 1998); Telephone Interview with F. Edward Scarbrough, *supra* note 92.

<sup>167</sup> International Standard-Setting Activities, Codex Alimentarius Commission; Duties of United States Delegates and Delegation Members Including Non-Government Members, 63 Fed. Reg. at 7,118-19.

<sup>168</sup> Telephone Interview with F. Edward Scarbrough, *supra* note 92.

<sup>169</sup> International Standard-Setting Activities, Codex Alimentarius Commission; Duties of United States Delegates and Delegation Members Including Non-Government Members, 63 Fed. Reg. at 7,119.

<sup>170</sup> It is clear that organizations representing similar interests are likely to cooperate in an attempt to ensure that all the pertinent viewpoints are represented. While this is likely to be an effective solution, it should be recognized that it is at best a poor man's substitute for actual participation.

exclusion problem is further complicated by the fact that the delegate has complete, unassailable discretion in selecting the members of the delegation.<sup>171</sup> As decisions regarding the makeup of the delegation are likely to be reflected in the opinions that a delegate receives, this process for selecting non-governmental members of delegations creates a potential for agency capture.

A second problem is the cost that this method of participation entails. Under present regulations, non-governmental members of the U.S. delegation must pay their own way.<sup>172</sup> Not only are negotiations often held in hard-to-reach places,<sup>173</sup> thereby driving up the costs of participation, but the lengthiness of the standard-setting process further increases these costs. The expense of participation in standard-setting activities makes it impossible for many public interest organizations to participate. Corporate interests, however, not having similar budgetary constraints, are able to, and often do, take full advantage of their ability to participate.<sup>174</sup> The result is an environment where only one side of the debate is represented, and many of the stakeholders are left without a say in the process.<sup>175</sup>

The problem of stakeholder participation is further exacerbated by the fact that, even in the rare circumstance when a public interest organization is chosen as a member of a U.S. delegation, it is not

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In such cases, interests of organization X may well be represented by a member of organization Y at the IGO meeting. Representatives of organization Y, while being in agreement with organization X, and therefore be willing to represent it at a particular international meeting, may not have the same level of expertise with issues important to organization X, and therefore may not be the most effective advocate of the constituency of organization Y.

<sup>171</sup> International Standard-Setting Activities, Codex Alimentarius Commission; Duties of United States Delegates and Delegation Members Including Non-Government Members, 63 Fed. Reg. at 7,118-19; Telephone Interview with F. Edward Scarbrough, *supra* note 92 (explaining that decisions of delegates are not challengeable in court and are, therefore, final).

<sup>172</sup> International Standard-Setting Activities, Codex Alimentarius Commission; Duties of United States Delegates and Delegation Members Including Non-Government Members, 63 Fed. Reg. at 7,118.

<sup>173</sup> Telephone Interview with Runako Kumbula, *supra* note 93.

<sup>174</sup> In the TBT context, this is further exasperated by the multitude of standard-setting bodies. Stakeholders, in both business and civil society, complain that the large number of standard-setting bodies make it too expensive to track all of the relevant activities. The result is less stakeholder participation in the process because stakeholders are often altogether unaware of the standard-setting activities or find out about the activities at a point where an effective, informed delegation (or delegate) cannot attend the meeting. Telephone Interview with William Reinsch, *supra* note 7 (noting that business interests are unable to keep up with all the standard-setting activities undertaken by multiple bodies); Telephone Interview with Runako Kumbula, *supra* note 93 (noting that civil society organizations can't keep track of the work undertaken by the numerous standard-setting organizations).

<sup>175</sup> Wallach, *supra* note 93, at 836.

provided with an opportunity to constructively shape the substance of the negotiations.<sup>176</sup> While members of the delegation can travel to IGO meetings, they do not have the ability to actively participate during the negotiations; to date, U.S. policy has been that only the official delegate can speak on behalf of the United States.<sup>177</sup> This means that the public interest representative's ability to inform the standard-setting body of the concerns held by the organization's constituency is entirely dependent on the official delegate's desire to bring these issues to the table during negotiations. Even if a public interest representative should convince the delegate to do so, he or she will not necessarily be an expert in the relevant area and may not be able to effectively advocate for that position.<sup>178</sup> Moreover, the need to articulate the views of multiple constituents in a very limited time period necessarily forces some issues from the agenda.<sup>179</sup>

Ultimately, because public interest representatives have no way to effectively present their viewpoints in the course of IGO negotiations, many find that being part of the U.S. delegation is not worthwhile given the huge cost involved.<sup>180</sup> As public interest representatives have little, if any, opportunity to shape the negotiating position adopted by the United

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<sup>176</sup> Telephone Interview with Runako Kumbula, *supra* note 93; Telephone Interview with F. Edward Scarbrough, *supra* note 92.

<sup>177</sup> Telephone Interview with F. Edward Scarbrough, *supra* note 92.

<sup>178</sup> The Codex and other IGOs have procedures that allow a delegate to defer speaking time to a different member of the delegation. In practice, however, the United States has never allowed a member of the negotiating team who was not an employee of the U.S. government to speak at one of these meetings. Telephone Interview with F. Edward Scarbrough, *supra* note 92. Some commentators argue that the public has already had an opportunity to express its feelings in the domestic forum, therefore giving the organization an opportunity to address the IGO represents a second bite of the apple. See, e.g., Philip M. Nichols, *Extension of Standing in World Trade Organization Disputes to Nongovernmental Parties*, 17 U. PA. J. INT'L ECON. L. 295, 310-12 (1996). This logic, while intuitive, is inappropriate in a regulatory setting. In the context of domestic regulations, it was long ago concluded that an agency might not be the most effective advocate of the public interest and, therefore, individual stakeholders are now allowed to have a seat at the table. See *Century Communications Corp. et al. v. F.C.C.*, 835 F.2d 292 (D.C. Cir. 1987). Moreover, the arguments that a stakeholder presents at a domestic meeting and the arguments a stakeholder raises in the international context are likely to be different. Similarly, the goals of an NGO are likely to differ in these two venues. It would, therefore, be more accurate to categorize the action of an NGO as having one bite from two different apples, rather than two bites from the same apple. Steve Charnovitz, *Opening the WTO to Nongovernmental Interests*, 24 FORDHAM INT'L L. J. 173, 207 (2000).

<sup>179</sup> Telephone Interview with Darryl Macer, *supra* note 61. Darryl Macer, a civil society organization representative to the Codex, points out that one of the difficulties with the current arrangement is that NGO representatives can't speak because of time limitations. At the same time, most official delegates are also unable to make all of their points with sufficient clarity and articulation in the short time period provided. *Id.*

<sup>180</sup> Telephone Interview with Runako Kumbula, *supra* note 93.

States, it is fair to say that the ability of stakeholders to have a say in the standard-setting process, in the manner that Congress envisioned, has not come to pass.

## 2. PUBLIC INFLUENCE OVER THE DOMESTIC ADOPTION OF INTERNATIONAL STANDARDS

This unfortunate phenomenon is further complicated by the fact that these regulatory standards, once agreed upon by international organizations, are unlikely to be altered in the domestic forum. The domestic implementation of regulatory standards is a final action and is therefore covered by the Administrative Procedure Act (APA).<sup>181</sup> As such, the regulating agency is obliged to follow the notice and comment procedure.<sup>182</sup> As part of the judicially imposed scrutiny, regulatory agencies must take comments from interested parties into account and justify their decision to impose a standard deviating from the comment.<sup>183</sup> While these procedural checks seldom result in major deviations from the standards initially proposed by the agencies, they do provide stakeholders with adequate assurances that their views have been considered.

When an agency adopts a standard previously negotiated in an international forum, these procedural protections are substantially reduced. Government officials insist that an international standard is not immune to alteration during the notice and comment procedures.<sup>184</sup> However, public interest representatives point out that once a standard is successfully negotiated in an international setting, it is unlikely that the United States would be willing to consider divergent standards.<sup>185</sup> Furthermore, because “officials participating in the adoption of a global regulatory norm will most likely be strongly committed to its

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<sup>181</sup> 5 U.S.C. § 704 (2000). *See also* *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 882 (1990).

<sup>182</sup> 5 U.S.C. § 553(b).

<sup>183</sup> 5 U.S.C. § 553(c).

<sup>184</sup> Telephone Interview with F. Edward Scarbrough, *supra* note 92.

<sup>185</sup> Telephone Interview with Runako Kumbula, *supra* note 93. The chances of U.S. regulators deviating from international standards are so small that one commentator described the domestic rulemaking process following an international agreement as being akin to a “train that follows an engine.” David Zaring, *Best Practices*, 81 N.Y.U. L. REV. 294, 305 (2006). The commentator argued that “[a]lthough it may look like any other form of administrative action, its outcome is *preordained* by what has already happened abroad.” *Id.* (emphasis added).

implementation . . . the justifications given by an agency for its domestic decision may be a rationalization of a *fait accompli*.”<sup>186</sup>

Moreover, in contrast to domestic regulation, which can be challenged in U.S. courts, international standards developed by IGOs are unlikely to be struck down by the courts.<sup>187</sup> While U.S. courts are unlikely to invalidate a negotiated standard out of deference to the executive branch’s authority to enter into an international agreement, they are also unlikely to act while the standard is still in negotiation. In *Public Citizen v. USTR*, public interest organizations sued to compel the U.S. trade representative to carry out an environmental impact statement for NAFTA while it was still being negotiated.<sup>188</sup> Arguing that an agreement still in negotiation is not a final action within the meaning of the APA, and reasoning that such an agreement might be significantly altered, making intervention prior to the conclusion of the agreement unnecessary, the D.C. Circuit Court refused to order the impact statement.<sup>189</sup>

A similar phenomenon is evident in the context of negotiated equivalence determinations and MRAs. Because the nature of such agreements is inherently technical and because they are negotiated by a network of professional regulators, stakeholders are not typically able to take part in the negotiations.<sup>190</sup> This is particularly so in the case of equivalence decisions, which are not publicly announced until after a positive determination has been rendered, if they are announced at all.<sup>191</sup> As a result, often the only time stakeholders have a chance to provide

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<sup>186</sup> Stewart, *supra* note 22, at 78-79.

<sup>187</sup> Meinhard Hilf, *The Role of National Courts in International Trade Relations*, 18 MICH. J. INT’L L. 321, 324 (1997) (arguing that domestic courts defer to international institutions). Even if U.S. courts were willing to invalidate decisions reached by international organizations, they would be unlikely to do so in cases of negotiated regulation. Rather, they would be more likely to consider the internationally negotiated standard as a product of executive action and would show discretion to the executive’s authority to negotiate international agreements. See *Dames & Moore v. Regan*, 453 U.S. 654 (1981) (upholding presidential authority to negotiate agreements without requiring congressional consent in areas of traditional presidential powers).

<sup>188</sup> *Pub. Citizen v. Office of U.S. Trade Representatives*, 970 F.2d 916 (D.C. Cir. 1992).

<sup>189</sup> *Id.* at 919-20.

<sup>190</sup> Famulare Letter, *supra* note 137 (explaining that the presence of non-governmental officials during negotiations would diminish the ability of regulators to be effective).

<sup>191</sup> See Letter from Mary Bottari, Dir., Harmonization Project, Pub. Citizen’s Global Trade Watch, to Charles Gaylord, Office of Int’l and Constituent Relations, Food and Drug Admin. (Sept. 22, 2000), available at <http://www.citizen.org/trade/harmonization/MRA/articles.cfm?ID=4302> [hereinafter Bottari Letter]; Famulare Letter, *supra* note 137 (stating that the Food and Drug Administration has no intention of undertaking a notice and comment procedure each time there an equivalence determination is made).

input on these matters is in the guise of a notice and comment after a determination has been made or an agreement negotiated.

While this posture promotes efficiency in negotiations, it has created a situation where stakeholders, at best, register discontent rather than actively participate in the regulatory process.<sup>192</sup> This is particularly so because despite the fact that the FDA's equivalence guidelines call for a full round of notice and comment procedures,<sup>193</sup> to date, comments submitted by stakeholders have not been successful at convincing the government to alter its decisions.<sup>194</sup> The inability of stakeholders to use notice and comment procedures to change regulatory policies aimed at harmonizing regulatory activities and regulations is a likely result of the same two-level game that has precluded stakeholders from influencing the determination of international standards once they have been negotiated internationally.<sup>195</sup> The cost of renegeing on a promise given to a negotiating partner will usually be high enough to discourage an agency from altering an equivalence decision or attempting to alter an MRA.

Because agencies are unlikely to modify a negotiated international standard prior to its domestic adoption and because the courts are unlikely to interfere, the procedural protection of the APA begins to look more like a cosmetic than an actual opportunity for meaningful input by affected stakeholders.

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<sup>192</sup> It must be noted, however, that the ability to register discontent is not altogether useless because it allows for the development of a record that can be used in future litigation.

<sup>193</sup> Draft Guidance on Equivalence Criteria for Food, 62 Fed. Reg. at 30,595-96.

<sup>194</sup> See, e.g., Equivalence Evaluation Process for Foreign Meat and Poultry Food Regulatory Systems, 64 Fed. Reg. at 70,692. It is notable that in at least one recent case the U.S. government initiated a notice and comment before starting negotiations on harmonization activities. Federal Measures to Mitigate BSE Risks, 69 Fed. Reg. at 42,288. See, e.g., Equivalence Evaluation Process for Foreign Meat and Poultry Food Regulatory Systems, 64 Fed. Reg. at 70,692. It is notable that in at least one recent case the U.S. government initiated a notice and comment before starting negotiations on harmonization activities. Federal Measures to Mitigate BSE Risks, 69 Fed. Reg. at 42,288.

<sup>195</sup> See generally Robert D. Putnam, *Diplomacy and Domestic Politics: The Logic of Two-Level Games*, 42 INT'L ORG. 427 (1988).

### III. JUMPING THE HURDLE: EVOLUTION OF PUBLIC PARTICIPATION IN INTERNATIONAL STANDARD SETTING

Frustrated by the inadequacy of opportunities for participation in the domestic arena of the international standard-setting process, several public interest NGOs have attempted to find methods of participation in the international arena while continuing to apply political pressure on regulatory agencies at home.<sup>196</sup>

Domestically, several NGOs initiated a public-relations campaign against harmonization efforts as part of the implementation of the SPS agreement. For some organizations, the transition from lobbying against the ratification of the Uruguay Agreements to protesting the various harmonization initiatives was quite seamless. While some NGOs opposed harmonization as a matter of principle,<sup>197</sup> for the majority, the criticism was a result of being unable to find a seat at the negotiating table.<sup>198</sup> To this effect, many public interest organizations campaigned for, and participated in, meetings designed to provide input into the positions taken by the United States in negotiations within international organizations, such as Codex, OIE, and IPPC. However, over time, NGO participation in such meetings, in either written or oral form, has declined. Today, a meeting dedicated to the development of international regulatory standards may draw as few as two participants, with only those meetings devoted to the most controversial subjects drawing substantial attendees.<sup>199</sup>

There are competing explanations for this phenomenon. Government regulators believe that a primary reason for sparse attendance is the highly technical nature of the standard-setting process,

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<sup>196</sup> Telephone Interview with F. Edward Scarbrough, *supra* note 92.

<sup>197</sup> Telephone Interview with Runako Kumbula, *supra* note 93. These organizations argue that the development of regulatory standards inherently implicates the cultural and social norms of a country. Because of this, each country should develop regulatory standards domestically and individually. These organizations oppose harmonization as a matter of principle, not because it fails to provide for adequate public participation.

<sup>198</sup> Telephone Interview with Darryl Macer, *supra* note 61 (noting that while some NGOs eschew participation on principle, most are more concerned with the ability to influence regulatory policy and participate when they can). *See also* Telephone Interview with William Reinsch, *supra* note 7 (indicating surprise that some NGOs oppose harmonization on principle, and describing the debate as being one over the proper place for public participation, not over whether harmonization should occur).

<sup>199</sup> Telephone Interview with F. Edward Scarbrough, *supra* note 92.

which places it largely below the radar of most NGOs.<sup>200</sup> Others explain the lack of attendance as a response by public interest representatives to the real, or perceived, cosmetic nature of meetings conducted by agencies.<sup>201</sup> When one considers the amount of attention, and the intensity of the critique, that harmonization activities receive from stakeholder organizations,<sup>202</sup> lack of interest seems an unlikely reason for the decreasing attendance at agency meetings.

Finding it effectively impossible to contribute to the standard-setting process at home and recognizing that domestic legal process does not extend to the international arena where real decisions are being made, many NGOs have taken their fight directly to the international forums in charge of standard-setting activities.<sup>203</sup> Initially, public interest representatives found these forums inhospitable to their participation.<sup>204</sup> Over time, however, the IGOs have relaxed their resistance to NGO participation and, in the case of the Codex Alimentarius Commission, have gone so far as to grant some NGOs observer status.<sup>205</sup> An organization qualifying for observer status gains the ability to participate and contribute at meetings of the commission and particular committees, although the ability to cast a vote is still reserved exclusively to member states.<sup>206</sup> Despite their inability to vote, NGOs have met at least some success in their advisory capacity in the Codex. In particular, NGOs have been successful in proposing topics, such as nutrition labeling, for

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<sup>200</sup> *Id.*

<sup>201</sup> Telephone Interview with Runako Kumbula, *supra* note 93; Telephone Interview with Edmund Mierzwinski, Consumer Advocate, Nat'l Ass'n of State Pub. Interest Research Groups [U.S. PIRG] (June 28, 2004). A recent incident shows the sense of frustration felt by stakeholder organizations representing public interests. At the 2004 U.S.-EU Summit, the Trans-Atlantic Consumer Dialogue [TACD] (an umbrella organization representing consumer protection, environmental, and other public interest NGOs) boycotted a meeting with senior officials to protest the favored treatment given to the Trans-Atlantic Business Dialogue [TABD] by government officials. Press Release, Trans-Atlantic Consumer Dialogue, U.S.-EU Summit Puts Business CEOs Ahead of Consumer Groups (June 23, 2004), <http://www.tacd.org/cgi-bin/db.cgi?page=view&config=admin/press.cfg&id=39>.

<sup>202</sup> *See, e.g.*, Pub. Citizen, Harmonization, <http://www.citizen.org/trade/harmonization> (last visited Nov. 23, 2006); Ctr. for Int'l Env't Law, Trade and Sustainable Development, <http://www.ciel.org/Tae/programtae.html> (last visited Nov. 23, 2006). In addition to the information on its website, Public Citizen administers a full-scale harmonization project dedicated to tracking developments related to the harmonization of regulatory standards. Pub. Citizen, Harmonization Alert, <http://www.citizen.org/trade/harmonization/alerts> (last visited Nov. 23, 2006).

<sup>203</sup> Telephone Interview with F. Edward Scarbrough, *supra* note 92.

<sup>204</sup> Wallach, *supra* note 93, at 837.

<sup>205</sup> *Codex Alimentarius Commission: Procedural Manual*, *supra* note 54, at 35-39.

<sup>206</sup> *Id.*

international standard-setting negotiations.<sup>207</sup> Moreover, recently several member states have begun including representatives of various stakeholders, including public interest groups, in their delegations and entrusting these representatives with substantial responsibility.<sup>208</sup> This has allowed some stakeholder representatives to gain a foothold in the Codex process.

Success in other areas, such as agenda-setting, has been limited, causing some stakeholders to get frustrated.<sup>209</sup> This is particularly true in the Codex, where many NGOs have found that participation does not ensure their input in the decision-making process. For example, decisions between U.S. and European delegates are frequently made over lunch or dinner, where stakeholders cannot participate.<sup>210</sup> The informality of decision-making, combined with the frequency of meetings and NGOs' inability to properly organize for effective participation,<sup>211</sup> have prompted some NGOs to eschew participation as a waste of time and money.<sup>212</sup>

The OIE, the organization to which the SPS agreement delegated authority to develop international standards in the area of animal health, has also developed new ways in which to receive input from NGOs. As part of its initiative to draft international regulatory standards on animal welfare, covering such topics as the quality and quantity of living environments for animals, standards for caretaker behavior, and the quality of food and water given to animals, the OIE organized a conference with the purpose of explaining its regulatory activities to

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<sup>207</sup> Telephone Interview with F. Edward Scarbrough, *supra* note 92.

<sup>208</sup> Telephone Interview with Darryl Macer, *supra* note 61 (pointing out that, in recent years, the governments of Sweden and Japan have delegated more and more responsibility to public interest representatives). Professor Macer sees this trend continuing and that, over time, smaller countries might allow public interest representatives to take the lead and act in an official capacity at various Codex meetings. *Id.* This is more likely to be true for smaller countries with limited budgets, particularly when the meeting involves a subcommittee dealing with a certain standard, rather than the Codex body as a whole. *Id.* According to Professor Macer, this may benefit developing countries because NGOs with their specific agenda may be in a better position to represent the interests of a country than its official diplomats, who are not likely to be informed about the technical nature of the negotiations due to lack of funding. *Id.*

<sup>209</sup> Telephone Interview with Runako Kumbula, *supra* note 93; Telephone Interview with Darryl Macer, *supra* note 61.

<sup>210</sup> Telephone Interview with Darryl Macer, *supra* note 61 (noting that these informal sessions often result in a final text that delegates then bring to the official body and which is usually adopted). For additional analysis of why attaining observer status does not, by itself, equalize the participatory field, see Livermore, *supra* note 52, at 784-85.

<sup>211</sup> See Livermore, *supra* note 52, at 784-85.

<sup>212</sup> Telephone Interview with Runako Kumbula, *supra* note 93.

NGOs as well as soliciting their input.<sup>213</sup> Similarly, the IPPC provides an opportunity for stakeholders to submit proposals for standard-setting activities.<sup>214</sup> However, in both cases, once standards are drafted, the public has minimal ability to modify the drafted standards directly and must do so predominantly by lobbying member states.

Despite the increased opportunities available for public participation in the IGO standard-drafting process, the ability for public involvement is still largely limited. The ability to participate is not open to all NGOs, but only to those that are international in their work.<sup>215</sup> This limits participation to the few large and well-organized NGOs that have global reach. Despite the fact that standard-setting activities often involve regional and local concerns, smaller local NGOs are unable to participate in relevant standard-setting activity. While smaller NGOs may be able to jump this hurdle by networking with other small NGOs from around the globe, this added level of difficulty likely prevents many of them from participating in the work of standard-setting organizations.<sup>216</sup>

The conditions imposed on NGOs before they may attain observer status are also problematic because they create accountability issues. An NGO must apply to the Codex Commission to attain observer status.<sup>217</sup> This means that an NGO potentially may be denied this status. The inability to appeal to a higher body means that there is no check on the judgments of the commission. While government officials insist that any such denial would be premised on objective factors, NGOs may have a different viewpoint,<sup>218</sup> and many remain distrustful of the commission or see the ability to participate in the work of the Codex as a measure

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<sup>213</sup> Office International des Epizooties, *supra* note 65. See also Office International des Epizooties, Applying Science to Animal Welfare, [http://www.oie.int/eng/Welfare\\_2004/context%20paper.htm](http://www.oie.int/eng/Welfare_2004/context%20paper.htm) (last visited Nov. 23, 2006).

<sup>214</sup> International Phytosanitary Portal, *supra* note 70.

<sup>215</sup> For example, the Codex considers an NGO eligible for observer status if it has an official relationship with one of the two parent organizations, the FAO or the WHO, or if it is "international in structure and scope of activity." *Codex Alimentarius Commission: Procedural Manual*, *supra* note 54, at 35-39. In practice, this means that an NGO must do work in three different countries and in at least two regions of the world in order to receive observer status in the Codex. Telephone Interview with F. Edward Scarbrough, *supra* note 92. The OIE has similar requirements for NGOs wishing to participate.

<sup>216</sup> Telephone Interview with Runako Kumbula, *supra* note 93. *But cf.* Telephone Interview with Darryl Macer, *supra* note 61 (arguing that the requirement that only international organizations can be observers is necessary given the unique space, time, and resource constraints of the Codex, and that the requirement does not usually present an obstacle).

<sup>217</sup> Telephone Interview with F. Edward Scarbrough, *supra* note 92.

<sup>218</sup> *Id.*

designed to quiet their objections rather than as a meaningful opportunity to participate.<sup>219</sup>

Stakeholders have encountered similar limited success in obtaining a voice in harmonization initiatives undertaken by individual countries. One example is the Trans-Atlantic Consumer Dialogue (TACD), which was set up in concert with the Trans-Atlantic Business Dialogue (TABD) to promote the development of free trade between the United States and the European Union.<sup>220</sup> Together the TACD and the TABD serve as an umbrella organization tasked with bringing the concerns of their constituencies to the attention of regulators trying to negotiate harmonization initiatives.

While the creation of TACD-like institutions has created a chance for public interest organizations to have a say in the regulatory process, it has not fully resolved the concerns expressed by stakeholders. In particular, public interest representatives point out that even when they are given a chance to participate, they are treated as second-class citizens. As Edmund Mierzwinsky, a member of the TACD executive board, points out, business groups are granted more access because every industry gets a representative, whereas public interest organizations get only one representative.<sup>221</sup> This results in a situation where not all views are represented adequately, and some views not at all. Furthermore, Mierzwinsky points out that business interests are often given higher levels of access, thereby creating an uneven environment where some stakeholders are treated better than others.<sup>222</sup>

Public participation in international harmonization bodies (whether multilateral, regional or bilateral) is further inhibited by a lack of resources. In order to participate effectively in harmonization initiatives, public interest representatives have to commit to traveling to every meeting. The frequency of these meetings, as well as their remote locations, makes participation unaffordable for many interested

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<sup>219</sup> Telephone Interview with Runako Kumbula, *supra* note 93.

<sup>220</sup> Trans-Atlantic Consumer Dialogue, About TACD, <http://www.tacd.org/about/about.htm> (last visited Nov. 23, 2006); Trans-Atlantic Business Dialogue, About the TABD, <http://www.tabd.com/about> (last visited Nov. 23, 2006); Telephone Interview with Jeff Werner, Executive Dir., U.S. Trans-Atlantic Bus. Dialogue (June 28, 2004) (noting that the TABD is one of several groups used by businesses to present their views to governments); Telephone Interview with Edmund Mierzwinski, *supra* note 200 (explaining that the TACD was designed to ensure that regulators would have access to different views).

<sup>221</sup> Telephone Interview with Edmund Mierzwinski, *supra* note 200.

<sup>222</sup> *Id.*

organizations.<sup>223</sup> Moreover, as harmonization activities proliferate, both in the multilateral as well as in regional and bilateral contexts, the number of institutions undertaking harmonization tasks is likely to grow. This, in turn, will pose additional challenges to stakeholders wishing to participate in the process. Additional bodies, organizations, and undertakings require resources simply to be aware of pending harmonization initiatives. In fact, even business interests with substantial resources have indicated concern about the difficulty of keeping up with and being ready to participate in the various harmonization activities.<sup>224</sup> This is particularly relevant for those stakeholders who attempt to represent broad cross-sections of society, as they cannot focus their attention on the work of only one or two institutions.<sup>225</sup>

Overall, while opportunities for public participation in the standard-setting work of the IGOs have been far from perfect, the increased representation of public interest organizations has lessened the amount of criticism levied at these international groups. However, this newfound external legitimacy<sup>226</sup> has come with a cost. As standard-setting IGOs became more visible, organizations, which traditionally worked by consensus, became polarized by internal division; standards were adopted by razor-thin majorities, and coherence and effectiveness suffered.<sup>227</sup> Responding to this challenge, several IGOs have reshaped their internal procedures, adopting qualified, as opposed to simple, majority-voting schemes.<sup>228</sup>

This metamorphosis, however, is likely to further elevate the problem of public participation. The increased number of votes needed to pass a standard is likely to lower the standards adopted by

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<sup>223</sup> Telephone Interview with Runako Kumbula, *supra* note 93.

<sup>224</sup> Telephone Interview with William Reinsch, *supra* note 7 (describing the concerns espoused by business interest groups about the expense associated with participating in harmonization activities, particularly the effort required to monitor the numerous harmonization initiatives).

<sup>225</sup> Telephone Interview with Darryl Macer, *supra* note 61 (pointing out that the groups that are able to participate successfully in institutions, such as the Codex, tend to be those who have a narrow agenda and are able to allocate their resources effectively).

<sup>226</sup> See generally J.H.H. WEILER, THE RULE OF LAWYERS AND THE ETHOS OF DIPLOMATS: REFLECTIONS ON THE INTERNAL AND EXTERNAL LEGITIMACY OF WTO DISPUTE SETTLEMENT (Harvard Jean Monnet Working Paper No. 9/00, 2000), available at <http://www.jeanmonnetprogram.org/papers/00/000901.html> (last visited Feb. 25, 2007) (explaining the internal and external legitimacy divide).

<sup>227</sup> See Stewart & Johanson, *supra* note 41, at 48, 52.

<sup>228</sup> See International Plant Protection Convention, *supra* note 67. See also Stewart & Johanson, *supra* note 41, at 47-48; Revision of the International Plant Protection Convention, 62 Fed. Reg. 8,210, 8,211 (Feb. 24, 1997).

international organizations, a practice of which harmonization is frequently accused.<sup>229</sup> The evolution that standard-setting organizations are undergoing serves as an invitation to reexamine the proper way to ensure that representatives of the public interest are able to participate in this critical work.

#### IV. PUBLIC PARTICIPATION VERSUS ACCOUNTABILITY: DRAWING THE BALANCE

For more than a decade, public interest groups have been fighting for a say in the development of international regulatory procedures, whether they are developed through international standard-setting, MRAs, or domestic equivalency determinations. Having failed to obtain meaningful access in the domestic arena, NGOs moved their battle to the international sector. Here, representatives of public interests have met with marginally more success. Yet, many public interest representatives have remained unsatisfied with the status quo, claiming that their participation is limited to raising issues, which may be ignored with impunity by the IGO, and that as a result, the international regulatory process is tilted toward corporate interests.<sup>230</sup> Similarly, business interests have expressed dissatisfaction with the process as it is often difficult for them to keep track of, and thus effectively participate in, various initiatives.<sup>231</sup> As international regulatory activities continue to increase in importance, these criticisms are unlikely to go away. Absent an amicable resolution, they may become a cancer eating away at the legitimacy of international regulatory initiatives.

In considering how best to provide for public participation in the international regulatory process, it is also important to consider the other side of the coin. The key to the success of international regulatory processes, and in particular of the standard-setting organizations, is the ability to effectively develop international standards and to draw a balance between promoting free trade and upholding the safety that regulatory standards are designed to provide. In light of this, when considering the proper level of stakeholder involvement, it is important to strike a balance that promotes accountability and participation but

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<sup>229</sup> Wallach, *supra* note 93, at 836-38.

<sup>230</sup> Telephone Interview with Runako Kumbula, *supra* note 93.

<sup>231</sup> Telephone Interview with William Reinsch, *supra* note 7.

does not “compromise the ability of international regimes to successfully carry out their primary functions.”<sup>232</sup>

In deciding how to best provide for public participation, two questions must be answered. First, at what level—domestic or international or both—should this participation take place? Second, what reforms must be instituted domestically to provide for effective participation? As the processes of setting international standards, negotiating MRAs, and making equivalency determinations differ in their impact on domestic regulations and the ability of stakeholders to participate, the answers to these questions may vary depending on the activity in question. Therefore, in order to best outline the different solutions that are available, this section will look at each of the activities separately—analyzing where public participation should occur and how it can be achieved.

Before we consider these three methods of international regulation, however, it is worthwhile to pause on one action that could promote transparency for all three methods of international regulatory development. Specifically, U.S. regulatory agencies must do a better job of informing the public about the various harmonization activities that are currently underway. One of the main criticisms levied against harmonization activities has been their secretive nature.<sup>233</sup> In particular, *both* business and public interest representatives have expressed frustration with their inability to find out about these initiatives in a timely fashion. While various agencies sometimes publish *Federal Register* notices about major initiatives,<sup>234</sup> this is presently done on a case by case or, at best, on an IGO by IGO basis, rather than by presenting a comprehensive overview of various initiatives. This makes it difficult for stakeholders to get an accurate picture of the scope of the

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<sup>232</sup> Richard B. Stewart, *Administrative Law in the Twenty-first Century*, 78 N.Y.U. L. REV. 437, 460 (2003). For an example of how excessive access by civil society may be disruptive, see Bronwen Morgan, *Local Participation and Global Rule-making: The Case of Transnational Water Regulation* (also titled *Emerging Global Water Welfarism: Access to Water, Transnational Regulation and Unruly Consumers*) 38, available at <http://www.law.nyu.edu/kingsburyb/spring04/globalization/BronwenMorgan.pdf> (discussing how great influence given to civil society in South Africa did not lead to effective regulatory policy, but instead produced a “schizophrenic policy environment of contradictory signals”).

<sup>233</sup> Wallach, *supra* note 93, at 833. See also Bottari Letter, *supra* note 191 (critiquing the closed nature of joint commission meetings during which equivalence determination agenda is set); Telephone Interview with Runako Kumbula, *supra* note 93.

<sup>234</sup> See, e.g., International Sanitary and Phytosanitary Standard-Setting Activities, 69 Fed. Reg. 51,443 (Aug. 19, 2004) (publishing a notification of various standard-setting activities being undertaken in the Codex, IPPC and OIE).

international regulatory activity under way and to prioritize the activities that they find important over those that may not concern them. This defect could easily be ratified through the creative use of government websites. For example, a single, comprehensive website posting scheduled meetings and topics of international and domestic regulatory activities in a timely fashion could go a long way towards relieving this frustration.

However, while this would help inform stakeholders of the initiatives that are currently underway, it would not resolve the issue of stakeholder participation—which may well lie at the heart of the debate surrounding transnational regulatory activities. To better understand this debate we now consider the three main types of these activities individually.

#### **A. INTERNATIONAL STANDARD-SETTING THROUGH INTERNATIONAL ORGANIZATIONS**

When transnational regulations are developed as part of international standard-setting activity, it appears that if the ability of stakeholders to participate is limited to one arena (be it domestic or international), it is unlikely to provide the appropriate solution to the current problem. The current trend has been to push for stakeholder participation in the international arena. This development is possibly a result of the difficulties inherent in giving stakeholders a voice in the negotiating process domestically. The high stakes that standard-setting activities often implicate make it unwise for a country to be locked down in a negotiating position. At the same time, giving non-governmental delegates a greater role in the formation of international negotiating positions is also unwise, since these actors are inherently acting in the interest of their pet cause and not necessarily in the interests of the United States as a whole.<sup>235</sup> These and other questions of stakeholder accountability may well be some of the reasons why stakeholders have found a warmer reception in the international arena where these risks are inherently minimized.

Despite the dangers that increased participation of stakeholders in international standard-setting activities poses, allowing for public participation *only* at the international level is likely to draw criticism.

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<sup>235</sup> Nichols, *supra* note 177, at 317-18.

The cost of participating in standard-setting activities in the international arena will price out smaller NGOs who are not wealthy or large enough to have an international reach. Moreover, absent an accountability check on the work of the standard-setting IGOs,<sup>236</sup> a seat at the negotiation table is unlikely to resolve concerns about the legitimacy of the harmonization process. Given long-standing perceptions that harmonization is a corporate-driven phenomenon that seeks to preference the value of trade over that of environmental and consumer protection, a seat at the table will not satiate the demands of civil society, especially if they perceive the table to be tilted against them.<sup>237</sup>

Opening the doors of standard-setting IGOs to NGO participation is crucial to legitimating the harmonization process—both by removing the perception of secrecy and by allowing NGOs to assist in the work that these organizations seek to accomplish. Unlike

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<sup>236</sup> Organizations involved in the setting of international regulatory standards are inherently unaccountable. Putting aside democratic accountability, it may be worthwhile to consider whether standard-setting organizations are accountable in other ways. Ruth Grant and Robert Keohane have outlined seven potential sources of accountability. Ruth W. Grant & Robert O. Keohane, *Accountability and Abuses of Power in World Politics*, 99 AM. POL. SCI. REV. 29, 35-37 (2005). Interestingly, standard-setting organizations are unlikely to be controlled through any of these factors. The lack of a veto system, or ability of any one state to dominate the standard-setting procedures, means that a hierarchical system of accountability would not be effective. At the same time, these organizations are unlikely to be held accountable via a supervisory method, as they lack the necessary institutional features. As funding is provided by various other IGOs, a fiscal system of accountability would be equally unhelpful. A lack of profit motive means that a market-driven system is ineffective. The final two methods of accountability suggested by Grant and Keohane do offer a potential theory of accountability for standard-setting IGOs, although rather an unlikely one. *Id.* In the first case, accountability may be provided by peer institutions. Alternatively, accountability may be provided by public reputation. Unfortunately, as one considers these methods more closely, it becomes clear that neither is appropriate in the present context. On the one hand, peer accountability works through *ex ante* judgments about the accuracy of a group's decisions. However, as standard-setting is an exercise in subjective judgment, based on inherently uncertain science, often looking far into the future to predict risks, it is unlikely that a mistaken standard, or even several mistaken standards, would damage the status of the organization sufficiently so as to constrain its actions. For the same reasons, a decline in the esteem that the organization enjoys in the public perception is also unlikely to be effective. Moreover, the incredibly esoteric nature of the work conducted by these organizations ensures that few in the public at large will be aware of the existence of the organization, let alone its track record in setting standards. Similarly, membership accountability is also unlikely to work in this context as the economic consequences of non-participation are severe enough that it is unlikely that any member would unilaterally withdraw from the system. In fact, because the standard-setting bodies are blessed by the WTO, a country would be unlikely to withdraw from the organizations unless they were willing to withdraw from the WTO.

Returning briefly to the idea of democratic accountability, it becomes clear that it, too, is not well tailored to promote the accountability of standard-setting IGOs. As the work is highly esoteric, as mentioned above, it is unlikely to be an issue of sufficient public salience to alter the behavior of the executive.

<sup>237</sup> Telephone Interview with Runako Kumbula, *supra* note 93.

environments where questions under negotiation are value judgments,<sup>238</sup> standard-setting activities require a great deal of scientific expertise and particularized knowledge. In these situations, the ability of a broad array of stakeholders to inform the standard-setting body directly should make the work of these organizations more effective.<sup>239</sup> While the same information can be provided to a delegate from the stakeholder's state, there is no guarantee that the delegate will have the requisite scientific knowledge to articulate the wide range of technical data as effectively as the stakeholders could do if they presented the arguments themselves.<sup>240</sup>

In this highly technical environment, the optimal solution seems to provide for avenues of participation at both the domestic and international levels. On the international level, this means that the United States should actively push for international standard-setting bodies to be open to participation by public interest organizations, although these organizations need not necessarily have voting privileges.<sup>241</sup> This strategy could further be supported through judicial intervention. U.S. courts can refuse to allow the implementation of standards developed by international bodies insulated from public participation. This bottom-up approach, aimed at promoting procedural

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<sup>238</sup> See generally James Salzman, *Decentralized Administrative Law in the Organization for Economic Cooperation and Development*, LAW & CONTEMP. PROBS., Summer/Autumn 2005, at 189, 206-11 (discussing export credit agencies and the role of domestic administrative procedures in ensuring civil society participation).

<sup>239</sup> See *id.* at 200-205 (discussing Mutual Acceptance of Data program).

<sup>240</sup> Telephone Interview with F. Edward Scarbrough, *supra* note 92 (noting that U.S. delegates are often professional bureaucrats). This is especially true if delegates are likely to engage in open debate within the standard-setting body. The experience of the stakeholder representative with the particular data and arguments in question will likely make that person better equipped to debate the finer points of the argument.

<sup>241</sup> In promoting transparency in international standard-setting organizations, the United States can play a role similar to that which it has played in pushing for the admission of amicus briefs in the WTO and in disputes brought under regional trade agreements. See generally Chris Tollefson, *Games Without Frontiers: Investor Claims and Citizen Submissions Under the NAFTA Regime*, 27 YALE J. INT'L L. 141 (2002). In the case of regional trade agreements, for example, the United States has been successful in getting countries to accept amicus briefs as a necessary part of the dispute settlement procedures provided for by these agreements. Similarly, the vocal support of the United States in the WTO may have contributed to a decision of the appellate body that dispute settlement panels have authority to accept such submissions, and did play a role in convincing the dispute settlement body not to explicitly overturn the appellate body's decision. As in the case of amicus briefs, the United States is used to offering stakeholders an input in its domestic regulatory process, and it may be able to use this experience to encourage other nations to allow for it as well.

fairness, might motivate the standard-setting IGOs to allow stakeholders access to the relevant negotiations.<sup>242</sup>

In the domestic arena, the question of the appropriate level of stakeholder participation is complicated by the need to provide ample room for the executive branch to conduct negotiations. There are good reasons not to allow private stakeholders too much influence in the development of U.S. negotiation positions: U.S. negotiators have to juggle multiple agendas whereas stakeholders are often interested in their own particular issues. Allowing stakeholders too much access may hurt the flexibility that the executive needs in order to conduct effective negotiations.

However, it may be possible to provide for meaningful public participation without constraining executive leeway in negotiations by utilizing traditional stakeholder participation devices, such as notice and comment. For example, regulatory agencies engaged in international negotiations could publish draft standards before negotiations commence and request public comments. The agency could be required to briefly respond to these comments in a way that would not prejudice the nation's negotiating position and yet would demonstrate that the agency has considered the views of the public. In effect, such a requirement would mean that the domestic rulemaking process would be initiated at the same time as the international rulemaking process. This dynamic would allow the public to have a say in the substantive makeup of the standard before it is locked in place on the international level.

Other possible ways by which to promote increased public participation in the development of global regulatory norms include appointing a high level official to act as a liaison with public interest and business organizations, or pursuing other policies that aim to demonstrate that the internationalization of standard-setting has not made the viewpoints of stakeholders irrelevant.

One brief caveat is in order at this point. The above procedures, particularly the use of an invigorated notice and comment procedure or the appointment of a high level liaison, presuppose a government role in the development of the standard. These options may be unavailable in cases where the standard is negotiated by private standard-setting organizations. However, when dealing with private standard-setting bodies, stakeholder representation could be assured through other

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<sup>242</sup> For a description of the bottom-up approach to developing global administrative law, *see* Stewart, *supra* note 22, at 76–88.

measures. Recently, private enterprises engaged in global regulatory activity have requested greater governmental involvement in the development of international standards.<sup>243</sup> One possibility is to condition governmental support for such activities on the opening up of private international institutions to public interest stakeholders. Alternatively, the government could condition its support on the inclusion of public interest stakeholders in the U.S. delegation to the meetings of the private standard-setting bodies. Even less odious may be a requirement that U.S. industries engaged in private standard-setting take actions to inform stakeholders about the issues being discussed and thereby provide an opportunity for stakeholder input. None of these measures are likely to be fully successful, particularly given the level of distrust that industry representatives sometimes have for public interest stakeholders;<sup>244</sup> they may, however, be the first of many steps that ultimately result in better stakeholder participation in the work of private standard-setting organizations.

The initiative of promoting meaningful public participation in international standard-setting could come from the executive, legislative, or judicial branch. The inherent strengths and weaknesses of these respective branches pose unique benefits and costs to their leadership over such a controversial topic. The political nature of the executive and legislative branches, as well as their frequent participation in transnational regulatory activities, make these branches perhaps the best candidates to initiate such reforms.

The executive branch is possibly the best equipped to deal with the issues of stakeholder participation. To begin with, the Constitution entrusts the executive with the exclusive power to negotiate agreements and conduct foreign policy on behalf of the United States.<sup>245</sup> Therefore, the executive has a great deal of discretion in how it conducts negotiations and could take measures to include stakeholders in the decision-making process. Moreover, regardless of what action it took—be it implementing an invigorated notice and comment procedure, appointing a public official to act as a liaison with stakeholders, or

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<sup>243</sup> DEP'T OF COMMERCE, *supra* note 12, at 1.

<sup>244</sup> Telephone Interview with Jeff Werner, *supra* note 220.

<sup>245</sup> *United States v. Curtiss-Wright Exp. Corp.*, 299 U.S. 304, 319-21 (1936); U.S. CONST. art. II, § 2, cl. 2. *See also* Phillip R. Trimble, *The President's Foreign Affairs Power*, in *FOREIGN AFFAIRS AND THE U.S. CONSTITUTION* 39, 41-45 (Louis Henkin et al., eds. 1990) (noting that, in the Budget Act of 1921, Congress delegated to the president plenary authority over foreign commerce).

something else—by leading the initiative, the executive branch would be able to ensure that its needs and concerns in the realm of negotiating such standards were taken into account.

At the same time, action by the executive branch to increase stakeholder participation is not without its problems. In particular, the reality that administrations change every four to eight years may result in an environment where advances gained by public interest representatives in one administration may be eroded in the next.<sup>246</sup> This concern, however, can be addressed through the action of the legislative branch. Agreements establishing organizations that participate in the development of international standard-setting directly implicate international commerce, an area of traditional congressional regulation.<sup>247</sup> As such, any agreement establishing such an organization to which the United States is a party will need congressional approval.<sup>248</sup> Congress can use its oversight ability through either ex-ante (fast track) or ex-post (implementing legislation) measures. In either case, however, Congress could require the executive to provide adequate opportunities for stakeholder participation. Moreover, Congress could simply refuse to approve an agreement absent a promise from the executive to provide for adequate stakeholder input.

Alternatively, Congress could pass a general statute that would provide procedural safeguards for stakeholders in international regulatory activities. The statute could possibly be modeled on the APA.<sup>249</sup> In creating an International Administrative Procedure Act (IAPA), Congress could provide for adequate stakeholder participation through an appropriate combination of notice and comment procedures, public notice requirements when negotiations are ongoing, and provisions guaranteeing judicial review. This general statute should also account for the reality that regulatory activities in the international arena

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<sup>246</sup> One example of an analogous situation can be seen in the change-over from the Clinton to Bush administrations. Frustrated by President Clinton's habit of implementing policy changes through agency action, the Bush administration promised to undo many of Clinton's regulatory initiatives. For a discussion of President Clinton's habit of governing through agency action, see Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2281-2319 (2001). For a discussion of efforts on the part of the Bush administration to overturn Clinton's regulatory legacy, see Felicity Barringer, *Bush's Record: New Priorities in Environment*, N.Y. TIMES, Sept. 14, 2004, at A1.

<sup>247</sup> U.S. CONST. art. I, § 8, cl. 3.

<sup>248</sup> *United States v. Guy W. Capps, Inc.* 204 F.2d 655, 658 (4th Cir. 1953) (holding that in the area of commercial affairs the executive cannot avoid complying with a regulation prescribed by Congress in concluding a sole executive agreement).

<sup>249</sup> 5 U.S.C. §§ 551-559 (2006).

may also implicate important U.S. security or foreign policy interests. Therefore, it would be appropriate to provide exceptions from the obligations of the IAPA when issues of national security or foreign policy interest are at stake.<sup>250</sup>

One major downside to congressional action is that the requirements may raise constitutional questions. Previous congressional attempts to provide for adequate stakeholder participation drew complaints from the executive branch regarding the constitutionality of such arrangements. In particular, the executive branch objected when Congress attempted to insert mandatory notice and comment provisions in the implementation legislation for the Stockholm Convention on Persistent Organic Pollutants.<sup>251</sup> The convention bans several types of organic pollutants and establishes an international process for adding other chemicals to the treaty.<sup>252</sup> In drafting implementing legislation, Congress included mandatory notice and comment procedures to provide stakeholders with an opportunity to weigh in during future discussions. These provisions drew criticism as the executive branch felt that by requiring notice and comment Congress was encroaching on executive powers.<sup>253</sup> The executive's objections were largely based on the opinion of the Supreme Court in *United States v. Curtiss-Wright Export Corporation* where the Court declared that "the president alone has the power to speak or listen as a representative of the nation . . . he alone negotiates."<sup>254</sup>

Potential constitutional issues concerning congressional regulation of international regulatory activity are largely beyond the scope of this Article and require further research. However, a few brief thoughts may act as an initial starting point in this debate. There are several arguments against finding congressional regulation of international regulatory activity, through procedural safeguards, unconstitutional. First, Congress has traditionally used its oversight power to require substantive as well as procedural protections when

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<sup>250</sup> In drafting these exceptions guidance can be gleaned from the APA which provides for exceptions from the notice and comment requirements in cases involving military and foreign affairs functions. 5 U.S.C. § 553(a)(1) (2006).

<sup>251</sup> Stockholm Convention on Persistent Organic Pollutants, May 22, 2001, 40 I.L.M. 532, available at [www.pops.int/documents/convtext/convtext.en.pdf](http://www.pops.int/documents/convtext/convtext.en.pdf).

<sup>252</sup> *Id.*

<sup>253</sup> Letter from William Moschella, Ass't Att'y Gen., to Sen. Tom Harkin (Mar. 25, 2004) (on file with author).

<sup>254</sup> 299 U.S. 304, 319 (1936).

authorizing the executive to commence economic negotiations.<sup>255</sup> Second, Congress may argue that the authority of executive agencies (the EPA and the USDA, for example) to negotiate international regulatory agreement derives from acts of Congress. As such, Congress can limit its delegation so as to require sufficient stakeholder participation. Lastly, *Curtiss-Wright's* pronouncements on the president's exclusive power to negotiate do not address issues of notice and comment. Requiring such consultations, while speaking to the process by which executive actions should be taken, would not significantly erode the executive's broader monopoly on negotiating the substance of international agreements. These arguments, however, are neither exhaustive nor without counter-arguments, and a definitive answer to the question of congressional ability to restrict executive power in the realm of international regulatory law will have to await further research.

If neither of the political branches acts, the judiciary may be able to provide for adequate stakeholder influence, much as it did in the 1960s when it reacted to a popular perception that political means were unavailable to protect the interests of broad public interests.<sup>256</sup> Such an approach would, however, demand a reconsideration of the court's decision in *Public Citizen v. USTR*. In this case, the court determined that mere negotiations do not constitute a final rule within the meaning of the APA.<sup>257</sup> The court reasoned that since negotiations are not always completed and differing policy priorities often emerge during negotiation, it would be a drain on resources to treat each draft of an international agreement as a final rule.<sup>258</sup> The unique nature of standard-setting organizations is that once negotiations on a standard have begun, they are likely to be completed. In addition, substantial changes are not likely to be made between drafts. In such an environment, it would be prudent, not wasteful, to force the agency to consider public comments while negotiations are still in progress. This is doubly so in the case of international standards as they are not subject to the same checks as normal trade treaties, such as the requirement of senatorial consent.

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<sup>255</sup> For a recent example, see Bipartisan Trade Promotion Authority Act (BTPAA) of 2002, 19 U.S.C. §§ 3801-3813 (2002). For a discussion of Congressional oversight over the executive ability to negotiate treaties, see Joel R. Paul, *The Geopolitical Constitution: Executive Expediency and Executive Agreements*, 86 CAL. L. REV. 671 (1998) (tracing the rise and fall of Congressional control over the executive's ability to negotiate agreements).

<sup>256</sup> Richard B. Stewart, *The Global Regulatory Challenge to U.S. Administrative Law*, 37 N.Y.U. J. INT'L L. & POL. 695, 698 (2005).

<sup>257</sup> *Pub. Citizen v. U.S. Trade Representatives*, 970 F.2d 916, 919 & n.3 (D.C. Cir. 1992).

<sup>258</sup> *See id.* at 920.

Therefore, to accommodate the unique nature of international harmonization activities, courts may become willing to consider the mere act of being engaged in international harmonization negotiations as a final act within the meaning of the APA, thereby requiring increased transparency and accountability from the executive branch.

In sum, when dealing with standard-setting activities undertaken by international organizations, stakeholders should be given ample opportunity to participate both in the domestic and international fora. Moreover, these reforms can be implemented by any of the three branches of the United States government. These arrangements, however, may not be appropriate when more transnational approaches to international regulatory law are considered.

## **B. MUTUAL RECOGNITION AGREEMENTS**

Unlike international standard-setting activities, which often take place in organized international fora, mutual recognition agreements are negotiated directly by the governments of individual states. As such, it may be less appropriate, and quite difficult, to provide for increased stakeholder participation at the international level. Allowing stakeholders to sit directly at negotiations may undermine the efficiency of these negotiations. In addition, some countries, particularly those unaccustomed to stakeholder participation, may refuse MRAs if non-governmental organizations are given a formal seat at the negotiations.<sup>259</sup> For these reasons it may be best to provide for stakeholder participation at the domestic level when the regulatory activity in question is the negotiation of an MRA.

The highly technical, and rather informal, nature of MRAs also poses challenges as to how stakeholder participation can best be guaranteed. The problem of stakeholder participation in regard to MRAs can largely be ameliorated by providing for robust notice and comment procedures before negotiations begin (or between successive rounds of negotiations). This would allow for adequate stakeholder input without unduly burdening U.S. negotiators. Even if the government were

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<sup>259</sup> This may prove to be particularly true in cases of negotiations with poorer countries, which, due to a lack of NGOs, are not able to rely on stakeholders to participate in negotiations, and consequentially are worried that allowing stakeholders into negotiations would further exacerbate challenges that they may have to overcome. While this is also true in the case of international organizations, such as the Codex, this problem is particularly aggravated in the bilateral context as opportunities for collective action which exist in the multilateral context disappear.

required to respond to stakeholder comments, this would, at worst, hinder its flexibility in terms of its opening position—with the government retaining the flexibility to adjust this position throughout the course of the negotiations.

Because MRAs are often negotiated directly by the regulatory agencies involved in their implementation,<sup>260</sup> the executive branch is perhaps the best positioned to implement these reforms. As negotiations, procedures, and styles are likely to differ from agency to agency, it is the agencies themselves that are best positioned to provide for adequate stakeholder participation. Moreover, because MRAs often deal with issues such as conformity assessment procedures and other matters of pure executive discretion, Congress may find it difficult to regulate such judgments, particularly as agencies move away from structured international agreements and towards more informal negotiations and consultations.<sup>261</sup> This informal nature may also make judicial review difficult, though not impossible, as courts concerned with stakeholder participation in international regulatory activities may find ways to provide for stakeholder participation through aggressive implementation of the APA and its notice and comment procedures. In short, executive action is likely to be the most efficient way of providing for stakeholder input into the negotiation of MRAs.

### C. EQUIVALENCY DETERMINATIONS

As equivalency determinations are largely unilateral decisions of U.S. regulatory authorities, the only forum in which stakeholders could participate is the domestic one. Adequate participation could be assured via the notice and comment procedures discussed above. In particular, a commitment by the executive to undergo notice and comment, not only upon a finding of equivalence, but also when countries request the United States to make an equivalency determination and a final decision is reached (be it positive or negative), would assure stakeholders of a say in the process. Moreover, because stakeholders may not possess access to relevant information about the state requesting the equivalency determination, such information should be made available so that stakeholders are able to participate effectively. Because some states may

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<sup>260</sup> Nicolaïdis & Steffenson, *supra* note 81, at 6-12.

<sup>261</sup> ANNE MARIE SLAUGHTER, *NEW WORLD ORDER* (2005) (discussing the development of informal regulatory networks).

object to the public release of such information, a careful balance may have to be designed so that it both provides for adequate transparency and discourages countries from requesting equivalency determinations.

Once again, the difficult policy choices implicit in the structuring of public participation in the realm of equivalency determinations suggest that initiatives providing for stakeholder participation should be carried out by the executive branch. However, congressional action is also possible as Congress could require regulatory agencies to follow particular procedural safeguards while making an equivalency determination. Because the act of determining equivalency does not involve negotiations with foreign countries, congressional authority in the area of equivalency determinations may be at its strongest. Likewise, courts could refuse to recognize equivalency determinations when made absent public participation. In the end, however, executive action may well offer the simplest way of providing for adequate stakeholder participation.

### **CONCLUSION**

The efficacy of the SPS and TBT agreements is likely to depend on the ability of the global community to negotiate international regulatory standards. To do so while maintaining public support and legitimacy, the process must allow for meaningful participation by stakeholder representatives. This effectively requires a multilevel strategy. At the international level, the United States should promote the ability of stakeholders to participate in the process by encouraging international standard-setting organizations to open themselves up to stakeholder participation. Concurrently, the United States should promote participation domestically by subjecting draft standards to the type of notice and comment procedures typically reserved for domestic regulatory standard-setting. While any of the three constitutional branches of government can influence stakeholder participation in international regulatory activities, efforts to promote such participation should be aimed at the executive branch, which is best positioned, both institutionally and in terms of constitutional pedigree, to promote such reforms.