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# Updating American Administrative Law: WTO, International Standards, Domestic Implementation and Public Participation

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

**DAVID LIVSHIZ**

*The World Trade Organization has encouraged harmonization of domestic regulatory standards and policy in order to promote further liberalization of international trade. This harmonization agenda has come under sharp attack from critics arguing that it will result in a regulatory race to the bottom while eroding the opportunity of ordinary stakeholders to participate in the regulatory process. Despite the speculation, little is known about the actual impact that harmonization activities have on domestic regulatory law and policy. This paper offers the first systematic analysis of the impact that harmonization activities have had on domestic US regulatory policy. Finding that international regulatory activities, in particular the domestic use of international standards and mutual recognition agreements have had an impact on US administrative law and policy, the paper analyzes whether the internationalization of regulatory policy has also adversely impacted the ability of public stakeholders to participate in the regulatory process. Concluding that the internationalization of regulation has undermined public participation in regulation and administration, and threatens to return the United States to the regulatory environment that existed prior to the Ralph Nader-led participatory revolution of the 1960s and 1970s, the paper concludes by offering a few potential solutions to the legitimacy crisis facing international regulation.*

## **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

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<sup>1</sup> General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194.

to Trade Agreement (TBT)<sup>2</sup> and the Sanitary and Phytosanitary Measures Agreement (SPS)<sup>3</sup> were designed to promote 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.

Despite the fact that the SPS and TBT agreements were negotiated and implemented at the same time,<sup>5</sup> most of the harmonization work and public attention — at least where the United States is concerned—has centered on the SPS agreement.<sup>6</sup> Until recently, the U.S. government remained largely on the sidelines of the global battle over regulatory standards covered by the TBT agreement. This passive attitude has undergone an evolution, however, as the Department

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<sup>2</sup> Agreement on Technical Barriers to Trade, April 15, 1994, Marrkaesh Agreement Establishing the World Trade Organization, Annex 1A, Legal Instruments—Results Uruguay Round, vol. 31 [hereinafter TBT Agreement].

<sup>3</sup> Agreement on the Application of Sanitary and Phytosanitary Measures, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, Legal Instruments—Results Uruguay Round, vol. 31 [hereinafter SPS Agreement].

<sup>4</sup> While the word harmonization sometimes has a specific and distinct meaning within the literature of global administrative law, in this paper it is merely used to signify the process of reducing the costs associated with divergent regulatory standards. In that vein, I refer to activities such as mutual recognition or 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> Approval and Entry into Force of Uruguay Round Agreements, 19 U.S.C. § 3511 (1994).

<sup>6</sup> This is particularly so when one considers those harmonizing activities that are carried out directly by the federal government. Other than a few discrete actions undertaken by the NIST and the National Highway Traffic and Safety Administration (NHTSA), *see, e.g.*, Request for Comments on CITELE Multilateral Negotiations Regarding a Mutual Recognition Agreement for Telecommunications Equipment, 64 Fed. Reg. 1853 (Jan. 12, 1999); Rulemaking Procedures, 63 Fed. Reg. 26508 (May 13, 1998) (stating and reaffirming the NHTSA's position on harmonization activities), the majority of harmonization activities in which the U.S. government has participated in directly have been under the SPS agreement. This phenomena becomes obvious as one flips through the Federal Register, where references to the SPS agreement outnumber those to the TBT agreement by a ratio of roughly 5 to 1. One reason for this phenomena might be that, in the United States, most top-down regulation occurs in the area of food, animal, and plant health; meaning that most regulations covered under the TBT agreement are left within the province of voluntary, consensus-based standards often negotiated by industry members themselves.

While the government has not been very active in undertaking harmonization activities under the TBT, business representatives have also not met with much success in this area. 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 National Foreign Trade Council Inc., (September 1, 2004).

of Commerce, prodded by industry concerns about the use of regulatory policy to erect trade barriers, established the “Standards Initiative.”<sup>7</sup> After soliciting comments from businesses on the use of standards as barriers to market entry<sup>8</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>9</sup> The report, which is designed to serve as the basis of DOC policy,<sup>10</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>11</sup>

Such an active harmonization 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. 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. Regardless of the goal of harmonization activity, however, policy makers are unlikely to be at a loss for a mechanism through which to implement such harmonization activity as such an active harmonization agenda may be accomplished through a variety of activities. Ranging from relatively formal and legally binding international standards to relatively informal regulatory equivalence determinations – the menu of policy choices for US regulators, it seems, is only limited by their imaginations. The most formal harmonization activity involves the development of international standards. These

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<sup>7</sup> Press Release, Department of Commerce, A Call to Action to Strengthen U.S. Competitiveness: Initiative to Enhance Commerce Department Standards Activities (Mar. 19, 2003) (introducing the standards initiative and outlining its goals in eight broad strokes), *available at* [http://www.commerce.gov/opa/press/2003\\_Releases/March/19\\_Standards.htm](http://www.commerce.gov/opa/press/2003_Releases/March/19_Standards.htm).

<sup>8</sup> Request for Technical Input on Standards Issues and Foreign Markets, 68 Fed. Reg. 55288 (Sep. 24, 2003).

<sup>9</sup> Press Release, Department of Commerce, Evans Releases Report on Reducing Standards-Related Barriers to U.S. Exports Through Enhanced Department of Commerce Standards Activities (May 18, 2004).

<sup>10</sup> DON EVANS, STANDARDS AND COMPETITIVENESS – COORDINATING FOR RESULTS: REMOVING STANDARDS-RELATED TRADE BARRIERS THROUGH EFFECTIVE COLLABORATION 1 (2004).

<sup>11</sup> *Id.* at 15-22.

standards are usually developed by international organizations, and are then adopted domestically by individual member states.<sup>12</sup> A second tool in the toolbox 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>13</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.

Alternatively, regulators can choose to harmonize through the use of equivalency determinations. Unlike international standards or mutual recognition agreements, equivalency determinations are especially informal as they do not require any formal agreement and can be implemented directly through executive action. 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 public policy protection that they offer.<sup>14</sup> Over time, such determinations may harden into more formal agreements, and ultimately into mutual recognition agreements.<sup>15</sup> In implementing its “active harmonization agenda” under the

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<sup>12</sup> Often the international organizations are made up of member states where delegates of the member states negotiate the applicable standards. Some international standard setting organizations, however, are private bodies, such as for example the International Standards Organization, where industry representatives come together to decide upon the applicable standards. Because the SPS agreement, which is the primary subject of this paper, delegates standard setting activities to three intergovernmental organizations the analysis of this paper will focus heavily on the work of state driven international standard setting organizations. The public participation problems discussed in this paper, however, are as applicable, if not more so, to private standard setting bodies. These problems, and possible solutions to them will be noted as appropriate, though additional research is required to fully understand the scope of the public participation problem in private standard setting organizations.

<sup>13</sup> Kalypso Nicolaidis, *Globalization with Human Faces: Managed Mutual Recognition and the Free Movement of Professionals*, in *THE PRINCIPLE OF MUTUAL RECOGNITION IN THE EUROPEAN INTEGRATION PROCESS* 4 (Fiorella Kostoris and Pado Schioppa, ed. 2004) [hereinafter Nicolaidis, Human Faces].

<sup>14</sup> Richard A. Merrill, *The Importance and Challenges of Mutual Recognition*, 29 SEATON HALL L. REV. 736, 753 (1998) (explaining equivalency as one country telling another: “while 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>15</sup> While this paragraph makes it seem that these mechanisms of harmonization are distinct and separate, “practice may often blur the distinction between the adoption of a common standard...by government regulators and mutual

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

Stakeholder attention to harmonization activities under the TBT agreement is likely to grow, as goods are increasingly traded duty-free and harmonization of standards becomes increasingly important.<sup>16</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. 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 further harmonization.<sup>17</sup> A recent DOC-issued report indicates that the U. S. government has come to realize the importance, and advantages, of global regulatory standards—even referring to them as “the international language of commerce”<sup>18</sup>—and has decided to actively engage in harmonization activities on a global level.<sup>19</sup>

To date the primary focus of US harmonization activities have centered on harmonization 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, are likely to emerge. This paper reviews harmonization activities undertaken pursuant to the SPS

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recognition arrangements and equivalence practices by such regulators.” Richard B. Stewart, forthcoming, *U.S. Administrative Law: A Model for Global Administrative Law?*, 68 J. L. & CONTEMP. PROBS. 63, 66 – 67 (2005).

<sup>16</sup> NAT’L FOREIGN TRADE COUNCIL, VISION 2004: FREE TRADE AND BEYOND: RECOMMENDATIONS FOR THE DOHA DEVELOPMENT AGENDA 7 (2002) (noting that proliferation of regional trade agreements has resulted in fifty-five percent of world trade being duty free by 2002, and that this figure is likely to grow as more regional trade agreements are negotiated), at <http://www.nftc.org>.

<sup>17</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 (2002). However, it is important to note, that domestic producers are not the only ones who may benefit from harmonization. Domestic consumers are likely to benefit from lower prices, as reduced regulatory compliance costs are likely to lead to lower consumer prices.

<sup>18</sup> EVANS, *supra* note 10, at pml.

<sup>19</sup> *Id.* at 20-21.

agreement, their impact on US regulatory policy, and analyzes one potential legitimacy problem that is likely to impact any future harmonization agenda—that of public participation.<sup>20</sup> Presently stakeholder participation rights are insufficient, both domestically and in the international arena.<sup>21</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. 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 70s.<sup>22</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>23</sup> Acting on their own initiative, US courts resolved the legitimacy crisis of the 1960s by requiring greater transparency and accountability from regulatory agencies.<sup>24</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

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<sup>20</sup> Here a caveat is in order. Legitimacy means different things at different times. This paper 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 agreements. However, domestic stakeholders 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. Shaffer, *supra* note 17, at 30-31. The SPS and TBT agreements make huge leaps in solving this accountability deficit through their disciplines of notice and comment, transparency requirements, and other procedural guarantees. Sabino Cassese, *Global Standards for National Administrative Procedure*, 68 L. & CONTEMP. PROBS. 111 (2005). This paper in no way means to undermine Professor Cassese's conclusions, rather it merely points out that these agreements created a different accountability problem by withholding meaningful participation rights from domestic stakeholders.

<sup>21</sup> See *infra* parts III.

<sup>22</sup> Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1667, 1683 (1975) [hereinafter, Stewart, *Reformation*]. See generally CASS R. SUNSTEIN, *AFTER THE RIGHTS REVOLUTION: RECONCEIVING THE REGULATORY STATE* (1990).

<sup>23</sup> For example Public Citizen, an organization founded by Ralph Nader, is in the forefront of the anti harmonization movement, and Nader himself has supported their work in this area. Ralph Nader, *Introduction to* LORI WALLACH & MICHELE SFORZA, *THE WTO: FIVE YEARS OF REASONS TO RESIST CORPORATE GLOBALIZATION* (1999).

<sup>24</sup> Stewart, *supra* note 22, at 1712.

many diverse and varying 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 paper concludes, participation must be made available both domestically and internationally in narrowly tailored ways appropriate to the harmonization activity in question.<sup>25</sup>

Part I of this paper presents a brief outline of the SPS agreement and the varying tools of harmonization presently being used by the US government. In particular, Part I focuses on the three tools frequently used by the United States to promote its harmonization agenda: international standard setting, mutual recognition agreements, and equivalency determination. Lastly, because the SPS agreement specifies which international organizations are responsible for devising international standards,<sup>26</sup> Part I offers a brief outline of how these differing institutions function. Part II analyzes the impact that harmonization activities have had on domestic regulation, with particular focus being placed on the use of international standards and mutual-recognition agreements. 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 in this manner and considers whether these actors can, in the alternative, influence the process at the international level. Part IV offers several suggestions that could be implemented by various branches of the

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<sup>25</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 as part of domestic law. To get a handle 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 the stakeholders of the harmonization enterprise. As such, my paper suffers from the same defects faced by any oral history projects – human memories are frail, and results can be skewed by the desires of the interviewee to push their own agenda. I have tried to take account of these challenges in my research, and have hopefully mitigated the problems associated with oral history projects as best I could.

<sup>26</sup> SPS Agreement, *supra* note 3, annex A at 3.

U.S. government that would 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>27</sup> that affect international trade.<sup>28</sup> While reaffirming that each member can choose its own appropriate level of protection,<sup>29</sup> the agreement focuses on promoting harmonization and lowering the costs and trade barriers associated with complying with these regulations. To achieve these goals, the SPS agreement offers two modules: full harmonization of standards, and the doctrine of equivalence. Unlike the TBT agreement, the SPS agreement does not specifically address mutual-recognition agreements pertaining to conformity assessment or rent seeking by firms.<sup>30</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>31</sup>

#### A. *Harmonizing Standards and the Bodies That Make Standards “International”*

Under the SPS agreement, harmonization involves the adjustment of sanitary and phytosanitary measures until they are the same around the world.<sup>32</sup> The SPS agreement allows member states to determine their own appropriate level of protection. However, hoping to promote harmonization, it further requires them to base their measures on existing international

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<sup>27</sup> The agreement defines sanitary and phytosanitary measures as any measures that are applied to protect human, animal or plant life from the importation in various ways of, inter alia, pests, diseases, toxins, or contaminants. SPS Agreement, *supra* note 3, annex A at 1.

<sup>28</sup> *Id.* at art.1.1.

<sup>29</sup> *Id.* at pmb1.

<sup>30</sup> Compare TBT Agreement *supra* note 2, at art.6.3 with SPS Agreement, *supra* note 3, at Art 3 - 5.

<sup>31</sup> For an extended description of the SPS agreement, and the controversy that it has engendered, see 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 (Fall 1998).

<sup>32</sup> For a concise definition of what harmonization entails, and possible problems with the approach, see TRANS-ATL. CONSUMER DIALOGUE, TACD BRIEFING PAPER ON MUTUAL RECOGNITION AGREEMENTS (MRA’S) (2001), available at <http://www.tacd.org> [hereinafter MRA BRIEFING].

standards.<sup>33</sup> To encourage members to comply with Article 3.1, the SPS Agreement grants presumption of legality to those standards deemed to be based on international standards.<sup>34</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 can do so—but they must justify their actions via a costly risk-assessment procedure.<sup>35</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>36</sup> In 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>37</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>38</sup> Because the SPS Agreement itself does not provide an opportunity for stakeholder input,<sup>39</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*

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<sup>33</sup> SPS Agreement, *supra* note 3, at art.3.1

<sup>34</sup> *Id.* at art.3.2.

<sup>35</sup> *Id.* at art.3.3.

<sup>36</sup> 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 TBT agreement international standards may also be developed by private international organizations made up of industry representatives. In this environment the public participation problem is particularly aggravated as even the modest public participation opportunities available in the inter-governmental organization context may disappear.

<sup>37</sup> SPS Agreement, *supra* note 3, at annex A at art.3(a).

<sup>38</sup> *Id.* annex A at art.3(b)-(c).

<sup>39</sup> *C.f. id.* at art.7, annex B (providing transparency requirements which member states must observe when implementing SPS measures).

Created in 1963 by the Food and Agriculture Organization (FAO) of the United Nations and the World Health Organization (WHO), the Codex Alimentarius Commission was designed to promote international standards relating to human health.<sup>40</sup> While representation is on a country basis, by 1998 over ninety-seven percent of the world's population was represented in the Codex, as membership swelled to over 160 countries.<sup>41</sup>

The Codex works through a network of subsidiary committees. Normally, a standard proposal is submitted by a national government to the Commission. Upon a decision by the Commission or the Executive Committee that a standard is necessary, the secretariat drafts a proposed standard and circulates it to national governments, which submit comments on the draft. Comments are then considered by the subsidiary body in charge of the standard. The committee's recommendations are presented to the commission and, if accepted by the commission, sent to member governments. Depending on the standard under consideration, this process may be repeated anywhere from five to eight times.<sup>42</sup>

Unlike most other international standard-setting organizations, the Codex has taken care to provide opportunities for stakeholders to participate. The Codex allows international non-governmental organizations (NGOs) to apply for observer status, and a number of international non-governmental organizations (NGOs) have been granted observer status and are able to participate throughout the process.<sup>43</sup> Additionally, national delegations have long included

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<sup>40</sup> The Codex System: FAO, WHO and the Codex Alimentarius Commission, (1999), *available at* <http://www.fao.org/docrep/w91143/W0114e04htm> [hereinafter The Codex System].

<sup>41</sup> *Id.* For a concise but detailed description of the Codex structure see Michael Livermore, forthcoming, *Authority and Legitimacy in Global Governance: Deliberation, Institutional differentiation, and the Codex Alimentarius*, 81 N.Y.U. L. REV. \_\_\_, \_\_\_ (2006).

<sup>42</sup> *Id.*, see also Codex Alimentarius Commission, *Procedures for the Elaboration of Codex Standards and Related Texts*, PROCEDURAL MANUAL 19-28 (2002). For a step by step description of the standard adoption process see Livermore, *supra* note 41, at \_\_\_.

<sup>43</sup> The Codex System, *supra* note 40. To see the requirements for obtaining observer status, as well as the procedure for doing so, see Codex Alimentarius Commission, NGO Participation, *available at* [http://www.codexalimentarius.net/ngo\\_participation.stm](http://www.codexalimentarius.net/ngo_participation.stm) [hereinafter NGO Participation]. The inclusion of NGO

business representatives and, recently, several countries have begun incorporating other stakeholders as well.<sup>44</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>45</sup>

## 2. *Office of International Epizootics (OIE)*

Founded in 1924, “the OIE is an intergovernmental organization (IGO) of 152 Member countries,”<sup>46</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 on informing governments of the occurrence of animal diseases, coordinating studies on animal health, and—most importantly for our purposes—promulgating international standards concerning animal-health issues.<sup>47</sup> Concerned about its legitimacy, the OIE has made efforts to consult with various stakeholders.<sup>48</sup> However, such consultations have not been fully effective, as few stakeholders have participated and the consultations themselves have been general in nature, rather than aimed at specific regulatory initiatives. This lack of participation by stakeholders can partially be explained by the subject area of the OIE. Unlike the Codex which deals with standards relating to human health, the OIE deals with standards devoted to animal health. As a result fewer organizations may be interested

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observers in the Codex, however, does not mean that the Codex is overly receptive to public interest organizations as to date the overwhelming majority of NGOs that have received observer status are industry and professional organizations. Livermore, *supra* note 41, at \_\_\_\_n.93.

<sup>44</sup> Interview with Daryl Macer, Codex Observer, June 16, 2004.

<sup>45</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 – 182 and associated text.

<sup>46</sup> V. WELTE, INTRODUCTION TO THE OFFICE INTERNATIONAL DES EPIZOOTIES (OIE), *available at* <http://www.fao.org/docrep/003/x7354e/x7354e06.htm>.

<sup>47</sup> *Id.* For a detailed organizational chart of the OIE, see Org. Int’l Epizootics, STRUCTURE, *available at* <http://www.oie.int/eng/OIE/organization>.

<sup>48</sup> One example of such efforts is OIE’s attempt to obtain input from interested NGOs on its animal welfare initiative. Org. Int’l Epizzotics, *The OIE’s Initiatives in Animal Welfare* (2003) at [http://www.oie.int/eng/bien\\_etre/en\\_introduction.htm](http://www.oie.int/eng/bien_etre/en_introduction.htm).

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 participating.

### 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>49</sup> The IPPC is a relatively new player on the harmonization stage<sup>50</sup> and is presently only focused on the development of conceptual, not substantive, standards.<sup>51</sup> As such, the IPPC is primarily concerned with developing standards for testing and other conformity assessment procedures, not substantive standards relating to plant health. Ideas for new standards can be submitted by national or regional organizations,<sup>52</sup> the IPPC Secretariat, or the WTO itself.<sup>53</sup> The proposed standards are then submitted to individual member countries for review and comments, which are subsequently reviewed by the IPPC Committee. If the Standards Committee of the IPPC recommends that the proposed standard be adopted, it

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<sup>49</sup> For a brief history of the IPPC and its evolution since the creation of the WTO, see Stewart & Johanson, *supra* note 31, at 46-48.

<sup>50</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* INT'L PLANT PROT. CONVENTION, THE 1997 REVISION OF THE IPPC, (2004) at [www.ippc.int](http://www.ippc.int).

<sup>51</sup> Telephone interview with John Greifer, Director of Animal and Plant Health Inspection Service Trade Support Team (March 19, 2003).

<sup>52</sup> While the IPPC allows for individual member states to submit proposals, the increasing attention paid to, and resulting politicization of, the standard-setting process has made this almost impossible. Typically, individual member states try to work through regional organizations to adopt the standard, only then submitting it 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 often the best, and sometimes only, time to impact the development of a standard is at the very inception of that standard, stakeholders wishing to participate effectively must do so at the regional as well as the IPPC level. This is particularly true as to standards that are submitted by regional organizations. This adds additional costs that further stretch already-limited resources.

<sup>53</sup> IPPC: Standard Setting Process, (2004) at <http://www.ippc.int>.

becomes an international standard.<sup>54</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>55</sup> Moreover, unlike the Codex or the OIE, stakeholders are not able to attain observer status, or otherwise directly participate in the development of standard, their participation is limited to the submission of suggestions to the IPPC for consideration.

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 input from non-governmental sectors.

#### B. *Equivalence: When Different Things Are Same*

The second module provided by the SPS agreement to encourage harmonization is the doctrine of equivalence. 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>56</sup> In other words, a determination of equivalence involves a judgment that two standards are sufficiently similar as to achieve the appropriate level of protection.<sup>57</sup> Members are required to enter into equivalence-determination negotiations upon a request for such negotiations from another member.<sup>58</sup> Because equivalence determinations are conducted by the government of the member state, the ability of stakeholders

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<sup>54</sup> For a more thorough discussion of the IPPC standard-setting process see a chart provided by the IPPC. *Id.*

<sup>55</sup> Greifer, *supra* note 51.

<sup>56</sup> SPS Agreement, *supra* note 3, at art.4.1.

<sup>57</sup> MRA BRIEFING, *supra* note 32 at 4.

<sup>58</sup> SPS Agreement, *supra* note 3, at art.4.2.

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>59</sup> Depending on the structure of the agreement and the parties involved, MRAs can be “based on harmonization, equivalence or an external standard,”<sup>60</sup> and can address issues as wide ranging as substantive standards, product testing, or conformity assessments.<sup>61</sup> To date most MRAs have focused on the latter, though it is increasingly likely that future MRA negotiations will be aimed at developing substantive not procedural standards.<sup>62</sup> Since MRAs are contracts between two governments,<sup>63</sup> the ability of stakeholders to impact the agreement depends on the administrative law of the parties negotiating the MRA.<sup>64</sup>

To date, the United States has not signed any MRAs as part of the SPS agreement. This is likely to change in the future, however, as MRAs will likely “be at the heart of trade

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<sup>59</sup> MRA BRIEFING, *supra* note 32, at 5.

<sup>60</sup> MRA BRIEFING, *supra* note 32, at 5.

<sup>61</sup> *Id.*

<sup>62</sup> Kalypso Nicolaidis and Rebecca Steffenson, *Managed Mutual Recognition in the Transatlantic Marketplace*, in TRANSATLANTIC ECONOMIC RELATIONS 4 (Pollack and Shaffer, eds. 2005) [hereinafter, Nicolaidis and Steffenson, *Managed Mutual Recognition*].

<sup>63</sup> Nicolaidis, *infra* note 65, at [www.jeanmonnetporogram.org/papers/97/97-07.html](http://www.jeanmonnetporogram.org/papers/97/97-07.html).

<sup>64</sup> To date the vast majority of MRAs have been negotiated by governments. However, given the federal nature of the United States which excludes the federal government from regulating certain local activities, future MRAs may be negotiated among private industry groups or between a US industry groups and other nation states. Nicolaidis and Steffenson, *Managed Mutual Recognition*, *supra* note 59, at 13. 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 as 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).

diplomacy in the coming decade.”<sup>65</sup> Several factors may combine to promote MRAs as the harmonization tool of choice in the future. First, it is likely that MRAs negotiated with American trading partners in other area may work to remove some of the regulatory distrust currently existing between American regulators and their foreign counterparts. As trust is imperative to successful MRAs<sup>66</sup> because it requires “domestic regulators to accept the competency of their foreign counterparts,<sup>67</sup> the development of trust through ongoing regulatory cooperation is likely to encourage future MRA.<sup>68</sup> Second, the difficulty of negotiating agreeable international standards may spur countries to negotiate such agreements bilaterally where transactions costs are fewer. This is more so as “each new mutual recognition agreement places pressure on third countries to enter into negotiations so that their firms are not disadvantaged.”<sup>69</sup>

In addition to an understanding of the harmonization tools that the SPS agreement provides, it is important to consider to what extent these tools have been applied by the United States, and whether or not 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

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<sup>65</sup> Kalypso Nicolaidis, *Mutual Recognition of Regulatory Regimes: Some Lessons and Prospects*, JEAN MONNET WORKING PAPER SERIES 97-107, available at <http://www.jeanmonnetprogram.org/papers/97/97-07.html>. One possible reason for the lack of MRAs could be their controversial nature. For a list of pluses and minuses of prospective MRAs, see *id.* Moreover, neither consumer groups nor business groups have warmed up to the idea of regulation through MRA. See, e.g. MRA BRIEFING, *supra* note 32, at 14-17 (outlining costs of MRA to consumers); NAT’L ELEC. MFR.S ASS’N, 2004 TRADE PRIORITIES FOR THE ADMINISTRATION AND CONGRESS, (2004), at <http://www.nema.org> (noting that MRAs should be used sparingly, i.e., only in cases of products already subject to top-down regulation).

<sup>66</sup> Nicolaidis, *Human Faces*, *supra* note 13, at 9.

<sup>67</sup> Nicolaidis and Steffenson, *Managed Mutual Recognition*, *supra* note 62, at 5.

<sup>68</sup> Shaffer, *supra* note 17, at 69 (noting that through regulatory cooperation, regulators in both countries “become more educated about each other’s systems”).

<sup>69</sup> *Id.* at 53.

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 US regulatory policy; both in terms of the adoption by the United States of international developed regulatory standards, as well as through the use of less formal harmonization arrangements such as mutual recognition agreements and equivalence determination. Concluding that the US is actively engaged in the harmonization process, it then considers the ability of public interests 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 had a non-insignificant effect on 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, basing domestic regulatory standards on international standards, did not add any additional obligations to those with which agencies had to comply prior to the completion of the Uruguay agreements.<sup>70</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 demonstrated by the way in which U.S. regulatory agencies justify the

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<sup>70</sup> See *Agreement on the Application of Sanitary and Phytosanitary Measures*, 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, 1994 U.S. Code Cong. and Adm. News 3773 (Sept. 1994).

standards that they would like to adopt. Before the SPS agreement, agencies would justify 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>71</sup> Since the implementation of the SPS agreement, justifications offered by domestic agencies for the introduction of new standards increasingly prioritize the consistency of the domestic standard with the relevant international one.<sup>72</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 reference to the requirements of the SPS agreement and other WTO agreements.<sup>73</sup>

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. regulatory policies. Public-interest organizations dedicated to monitoring government regulatory policies claim that efforts at international harmonization of regulatory standards have forced government regulators to preference the value of trade over that of environmental and

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<sup>71</sup> See e.g. Nutrient Requirements for Infant Formulas, 21 C.F.R. § 107 (1985) (noting in passing that domestic standard complied with standard developed by Codex Alimentarius).

<sup>72</sup> See e.g. Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities, 70 Fed. Reg. 460, 505-06 (Jan. 5, 2005) (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 Tolernace Actions, 69 Fed. Reg. 47, 051, 47,055 (Aug. 4, 2004) (to be codified as 40 C.F.R. pt. 180) (justifying a change in regulation 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) (to be codified at 7 C.F.R. pt. 319) (“We propose to adopt the IPPC Guidelines because they represent the current international standard . . .”), see also Bitertanol, Chlopropham, Cropop, Combustion Product Gas, Cyanzine et al., 68 Fed. Reg. 68, 806, 68, 811 (proposed Dec. 10, 2003) (to be 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 . . .”). 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 after, the adoption of the SPS, and the Codex 217 times before, and over 400 times after the adoption of the SPS Agreement.

<sup>73</sup> Telephone interview with F. Edward Scarbrough, United States Manager for Codex Alimentarius (April 12, 2004).

consumer protection, resulting in a global regulatory race to the bottom.<sup>74</sup> A deeper inquiry of U.S. regulatory policy since the implementation of the SPS agreement does not allow one to easily agree with these public-interest organizations. Undoubtedly, the adoption of international standards may result in the lowering of 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>75</sup> Rather, Wallach focuses on the potential dangers that a strictly enforced SPS agreement may create. To this effect, Wallach stresses the impact of harmonization requirements on the domestic regulatory policies of other states.<sup>76</sup>

Furthermore, even these critics concede that, as of now, U.S. administrations have resisted lowering regulatory standards to international levels, and have instead thought to justify them under other provisions of the SPS agreement.<sup>77</sup> Specifically, U.S. regulatory agencies have justified their deviation from international standards by relying on scientific data and the performance of the pertinent risk assessment.<sup>78</sup> Moreover, the United States is unlikely to alter

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<sup>74</sup> Telephone interview with Runako Kumbula, Equal Justice Works Fellow at Public Citizen's Global Trade Watch (April 13, 2004), *see also* Lori M. Wallach, *Accountable Governance in the Era of Globalization: The WTO, NAFTA, and International Harmonization of Standards*, 50 KAN. L. REV. 823, 831 (2002) [hereinafter *Accountable Governance*]; LORI WALLACH & PATRICK WOODALL, *WHOSE TRADE ORGANIZATION? CORPORATE GLOBALIZATION AND THE EROSION OF DEMOCRACY: AN ASSESSMENT OF THE WORLD TRADE ORGANIZATION* (1999).

<sup>75</sup> To date, the closest thing that Wallach has found to demonstrate the slackening of US regulatory protection because of harmonization is the June 1999 decision of the Department of Agriculture to grant equivalency accreditation to Australia's Meat Safety Enhancement Program despite a record of its ineffectiveness. Wallach, *Accountable Governance*, *supra* note 74, at 841 – 42. Critics point out that this and similar decisions sacrifice consumer safety on the altar of free trade. However, it is important to note 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 those Australian producers who participated in the program were eligible to export their product to the United States.

<sup>76</sup> *Id.* at 838, 843-45.

<sup>77</sup> Kumbula, *supra* note 74.

<sup>78</sup> Scarbrough, *supra* note 73.

its policy and begin wholesale acceptance of international standards in the near future.<sup>79</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>80</sup>

Critics of harmonization will point out that even the “mere procedural” interpretation of the SPS might have the effect of diminishing the regulatory protection afforded to U.S. citizens. 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>81</sup> In its strongest form, this argument also alleges that, over time, civil servants working on the development of standards would be so conditioned by the need to follow harmonization procedures, that they would be subconsciously prejudiced against deviation from international standards, even in cases where this may be called for. For these critics, even the procedural version of the SPS agreement therefore poses the danger that the regulatory flexibility which was, until recently, widely enjoyed by member states will completely disappear.

Moreover, it is not clear whether the U.S. reading of the SPS agreement as procedural in nature will be sustainable over time. The WTO Appellate Body (AB) has previously gone out of its way to point out that, in order to fulfill the “based on” requirement of Article 3.1, a standard

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

<sup>80</sup> Under the procedural interpretation of Article 3.1 the international standard can be wholly ignored upon the demonstration that the member state had considered the international standard and has conducted a risk assessment based on scientific evidence which demonstrates the need for a divergent standard. On the other hand, a substantive interoperation would require the domestic standard to use the prevailing international standard as a basis of its domestic standard, even if a scientific risk assessment had 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>81</sup> Wallach, *Accountable Governance*, *supra* note 74, at 830.

does not necessarily have to conform to the international standard.<sup>82</sup> In doing so, the AB implicitly endorsed the procedural interpretation of SPS Article 3.1. 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. 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. Even with this permissive interoperation, however, the AB has severely constrained the ability of states to choose their own level of sanitary and phytosanitary protection. As advocates like Public Citizen point out, not all regulations are made for scientific reasons.<sup>83</sup> Often, regulations are passed as a response to social or cultural norms prevalent in a society. Similarly, popular attitudes often shape the content of a country's regulatory policy.<sup>84</sup> It is these attitudes that may explain the decision of the European Union to maintain their regulatory policy in regard to beef hormones<sup>85</sup> or their desire to see strict traceability and labeling requirements for products containing genetically modified organisms.<sup>86</sup> However, by refusing to accept the precautionary principle, except on a provisional basis, as a valid justification for adopting national standards that are more restrictive than their international counterparts, the AB has limited the ability of states to adopt restrictive regulations in areas

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<sup>82</sup> WTO Appellate Body Report on the European Communities Measures Concerning Meat and Meat Products, WT/DS26/AB/R (Jan. 16, 1998) at 174-77 [hereinafter *EC-Beef*].

<sup>83</sup> Public Citizen, Comment on The U.S. Delegation to the Codex Committee, March 26, 1999, [http://www.publiccitizen.org/print\\_article.cfm?ID=4291](http://www.publiccitizen.org/print_article.cfm?ID=4291).

<sup>84</sup> This phenomena is equally accepted by business leaders. For example, William Reinsch, the president of the National Foreign Trade Council, points out that one of the main reasons that harmonization has been slow to come is the propensity of regulators to regulate in response to domestic political and social pressures which are often driven by factors other than science. When acting in response to such pressures regulators often act without considering the importance of harmonization. Reinsch, *supra* note 6.

<sup>85</sup> *US Impatient with EU Ban on GMOs, Beef Hormones*, Reuters, Dec. 18, 2002.

<sup>86</sup> Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, 2003 O.J. 268; Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, 2003 O.J. 268.

where scientific data is not yet available.<sup>87</sup> In this way, even the bare procedural interpretation of Article 3.1 represents a shackle on the government's ability to regulate.

Moreover, 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 "a principal constituent or fundamental principle" of the domestic standard.<sup>88</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 game its requirements in order to recapture some of their traditional regulatory autonomy and, in some instances, in order 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 a further ascendancy of the influence of international standards and a corresponding decrease in the regulatory autonomy of the United States and other member states of the WTO.

The requirement that domestic standards must be based on international ones is a formidable hurdle to the ability of states to independently choose the level of protection that they offer to 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 the increasing polarization of these bodies, and the relatively quick death of the consensus nature

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<sup>87</sup> *EC-Beef*, *supra* note 82, at 123.

<sup>88</sup> WTO Appellate Body Report on European Communities-Trade Description of Sardines, WT/DS231/AB/R (Sep. 26, 2002) at 243 [hereinafter *EC-Sardines*].

by which such organization 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 33 for, 31 against with ten abstentions.<sup>89</sup> This increased importance of participation in, and influencing of, international standard-setting organizations has been reflected in the articulation of priorities by various regulatory agencies.<sup>90</sup> Moreover, realizing the economic consequences that international standards, once adopted, are likely to pose, the United States has attempted to take the lead in the development of standards in particularly controversial areas, such as those dealing with biotechnology.<sup>91</sup> This strategy has further been supported by the active participation of the United States in various scientific bodies in which work standards are developed and adopted.<sup>92</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 the tools of equivalence and mutual recognition agreements in its efforts to promote harmonization under the SPS agreement.<sup>93</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

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<sup>89</sup> CODEX ALIMENTARIUS COMMISSION, REPORT OF THE 22<sup>ND</sup> SESSION, at 20, ALINORM 97/37 (Aug. 1997). For a more detailed analysis of the polarization of the Codex Alimentarius Commission see, Stewart & Johanson, *supra* note 31, at 29, 42-45.

<sup>90</sup> See e.g., Ctr. for Food Safety and Applied Nutrition, U.S. Food and Drug Admin., Affirmative Agenda for International Activities, (1999), at <http://www.cfsan.fda.gov/~comm/intlact.html>.

<sup>91</sup> *Id.*

<sup>92</sup> *Id.*

<sup>93</sup> While the SPS agreement does not explicitly provide for mutual recognition agreements as such, it does provide for equivalence agreements, which if successful can become formalized as mutual recognition agreements. In any case, the story of the mutual recognition agreements negotiated by the United States under the TBT agreement allows us to draw general lessons on potential problems likely to be faced by the United States in negotiating future MRAs either under the TBT or SPS agreement.

to negotiate mutual recognition agreements, particularly on issues of high political salience.<sup>94</sup> As pointed out by Nicolaidis and 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>95</sup> These divergent goals may have hindered the ability of the United States and the European Union to implement some of the mutual recognition agreements that the parties negotiated in the mid-1990s.<sup>96</sup> This difference is further exasperated by the European demand that any convergence be to the European system, or not at all.<sup>97</sup>

Similar philosophical difficulties may be the reason why agreements with other developed states have been difficult to achieve.<sup>98</sup> The psychological barriers to changing already existing regulatory practices have been difficult to overcome, particularly so as each regulatory philosophy is a result of an internal compromise achieved by each country after years of internal

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<sup>94</sup> See Nicolaidis, *supra* note 65 (arguing that different regulatory philosophies are among the highest hurdles that harmonization has to overcome).

<sup>95</sup> Nicolaidis and Steffenson, *Managed Mutual Recognition*, *supra* note 62, at 7. 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 differently. For example, William Reich, president of the National Foreign Trade Council – an American export promoting organization, argues that a major bloc to successful harmonization has been the philosophical difference between the EC which regulates based on the precautionary principle and the United States which adheres to a market driven regulatory philosophy. Reich, *supra* note 6.

<sup>96</sup> As part of the New Transatlantic Agenda signed in 1995 by the European Union and the United States agreed to negotiate a series of mutual recognition agreements. The two sides negotiated a framework agreement that provided for mutual recognition agreements to be negotiated in six discrete sectors. The enthusiasm for MRAs as a harmonization strategy quickly faded however, as three of the six sectors failed to reach operation status by the appropriate deadlines. Nicolaidis and Steffenson, *Managed Mutual Recognition*, *supra* note 62, at 1. According to Nicolaidis and Steffenson, it was the divergent regulatory philosophies of EU and American regulators (in particular views held by the FDA and OSHA) that were a big reason for the failure of the three sectors to become operational. *Id.* at 7n.9.

<sup>97</sup> Schaffer, *supra* 17, at 73 (pointing out that in cases where regulatory adaptation has needed to happen to negotiate a transatlantic MRA, the United States has been forced to make the majority of the changes). See also Nicolaidis, *supra* note 65, at [www.jeanmonnetprogram.org/papers/97/97-07.html](http://www.jeanmonnetprogram.org/papers/97/97-07.html) (arguing that the EU demand of convergence to the EU system is one of the three major barriers preventing the negotiations of MRAs between the United States and the EU).

<sup>98</sup> John Meaker, the manager of international trade for one of the largest industry groups, points out that the a major barrier to harmonization is the global difference in regulatory philosophies. According to Meaker the main barrier to harmonization is the reliance by many developed countries on top down regulation, an approach largely rejected by the United States. Telephone interview with John Meaker, Manger of International Trade for the National Electric Manufacturers Association (Sep. 1, 2004).

debate.<sup>99</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>100</sup>

Unable to negotiate MRAs with other developed countries the US has likewise been unable to negotiate such agreements with developing countries. The reluctance of the United States to enter into mutual recognition negotiations with developing countries is explained by the difference in technological know how between the US and the developing countries. 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 can be offered by the United States, or a comparable developed country.<sup>101</sup>

Moreover, the European attitude may also have made negotiations with developing countries difficult. One of the side effects of mandated harmonization has been increasing regulatory competition between the United States and Europe.<sup>102</sup> As part of this competition the European Commission has, on several occasions, withdrawn trade concessions from countries not obeying European regulations.<sup>103</sup> As Professor Shaffer points out, the growing size of the

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<sup>99</sup> *Id.* (arguing that harmonization is much 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 key to note that the same psychological barriers and transaction costs exist in the United States, which may explain the refusal of the United States to adopt alternative regulatory philosophies.

<sup>100</sup> See Nicolaidis, *supra* note 65, at [www.jeanmonnetprogram.org/papers/97/97-07.html](http://www.jeanmonnetprogram.org/papers/97/97-07.html) (pointing out that the only successful use of MRAs has been within the EU – where regulatory systems differed less, and were encouraged by exogenous motivations).

<sup>101</sup> WTO Member States realized 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, at art. 9.

<sup>102</sup> Reinsch, *supra* note 6. See also Stewart and Johanson, *supra* note 31, at 41-52 (offering examples of such regulatory competition).

<sup>103</sup> One example of such behavior can be drawn from the current GMO dispute where the European Union threatened countries importing US genetically modified food with trade sanctions. Justin Gills, *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 third world countries have “have resisted biotech crops for fear adopting them would hurt their ability to sell exports to Europe.”). For an extensive overview of the GMO dispute see Harvey E. Lapan and Gian Carlo Moschini, *Innovation and Trade with Endogenous Market Failure: The Case of Genetically Modified Products*, 86 AM. J. OF AGRIC. ECON. 634 (Aug. 1, 2004). For a more colloquial discussion of the dispute see

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>104</sup> Under such pressure many countries have accepted, sometimes reluctantly, European regulatory preferences thereby making MRAs with the United States difficult and unlikely. The European refusal to compromise over regulatory philosophy combined with its economic influence has made some developing countries unwilling to challenge the European regulatory system.

Similarly, the United States has been unwilling or unable to take full advantage of the equivalence provisions of 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 potential goal in mind.<sup>105</sup> Despite acknowledging the obligation to negotiate and that several countries have requested such negotiations<sup>106</sup> for now, few such agreements have been negotiated. 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 standard.

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 and unlikely to mobilize and demand equivalency determinations. On the other hand, domestic industry likely

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Wikipedia, *Trade War Over Genetically Modified Food* (2004) at [http://www.fact-index.com/t/trade\\_war\\_over\\_genetically\\_modified\\_food.html](http://www.fact-index.com/t/trade_war_over_genetically_modified_food.html). For an extensive analysis of the impact of the U.S.-EU GMO dispute on third world countries see, Michelle K. McDonald, Note, *International Trade Law and U.S.-EU GMO Debate: Can Africa Weather This Storm?*, 32 GA. J. INT’L & COMP. L. 501 (2004).

<sup>104</sup> Shaffer, *supra* note 17, at 73-74.

<sup>105</sup> Draft Guidance on Equivalence Criteria for Food, 62 Fed. Reg. 30593, 30593 (June 4, 1997) [hereinafter Equivalence Guidance]. See also SPS Agreement, *supra* note 3, at art. 3.1.

<sup>106</sup> *Id.*

to be hurt by imports and civil society organizations, many of which oppose harmonization on principle<sup>107</sup> are likely to agitate against such equivalence determinations.<sup>108</sup> While the relative low visibility of equivalence determinations, especially when compared to traditional methods of harmonization may serve to mute criticism from civil society organizations, the large scale criticism of the harmonization project may have cautioned the US government against an aggressive use of equivalence determinations.

Despite these obstacles the US has remained open to the idea of equivalence. Since publishing its *Draft Guidance on Equivalence Criteria for Food*<sup>109</sup> where the process of attaining equivalence decision was first articulated, the USDA and FDA (regulatory agencies responsible for the implementation of the SPS agreement) have indicated on a half-dozen occasions their willingness to consider requests for equivalence decisions.<sup>110</sup> Despite this willingness to enter into consultations about equivalence, there have been few actual findings of equivalence noticed in the federal register.<sup>111</sup>

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<sup>107</sup> Kulumba, *supra* note 74.

<sup>108</sup> This may further be magnified by the reluctance of US trade partner to grant reciprocal equivalence determinations. Lacking any hope of securing better market access elsewhere, US exporters are unlikely to pressure the government to grant equivalence determinations.

<sup>109</sup> 62 Fed. Reg. 30593 (June 4, 1997).

<sup>110</sup> See e.g. Federal Measures to mitigate BSE Risk: Consideration for Further Action, 69 Fed. Reg. 42,288 (Jul. 14, 2004) (requesting comments about making equivalence determination for countries free of Mad Cow disease) [hereinafter Mad Cow]; Irradiation Phytosanitary Treatment of Imported Fruits & Vegetables, 67 Fed. Reg. 65,016 (Oct. 23, 2002) (to be codified at 7 C.F.R. pt. 305 and 319) (indicating a willingness to grant equivalence status to several alternative methods of protecting against fruit flies pending further negotiations) [hereinafter Fruit Flies]; Mandatory Inspection of Rutites and Squabs, 67 Fed. Reg. 13253 (Mar. 22, 2002) (to be codified at 9 C.F.R. Pts. 362 and 381) (extending a period during which countries could request equivalence decisions, and noting that the equivalence process may take years to complete) [hereinafter Squabs]; Australia's meat Safety Enhancement Program (MSEP), 64 Fed. Reg. 30299 (June 7, 1999) (finding Australia's system of meat inspection equivalent) [hereinafter Australia's Meat].

<sup>111</sup> Australia's Meat, *supra* note 110. It must be noted however, that looking at the federal register may not produce an accurate account of all equivalence decisions that have been rendered to date as the FDA has made clear it does not intend to notice "each equivalence determination that is completed." Letter from Joseph C. Famulare, FDA Joint Sectoral Committee Representative to Mary Bottari, Director, Public Citizen's Global Trade Watch (Sept. 22, 2000) available at [www.publiccitizen.org/print/article.cfm?ID=4303](http://www.publiccitizen.org/print/article.cfm?ID=4303) [hereinafter Famulare Letter]. In particular, where the equivalency determination is made as part of a larger framework agreement US regulators may choose not to publish a separate notice and comment for each individual equivalency determination. *Id.* Moreover, at present US law only requires notice and comment when an equivalence determination is granted to an SPS measure of a trading partner,

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>112</sup> This combined with the lengthy process required for an equivalence decision<sup>113</sup> may explain why to date few actual equivalence decision have been rendered. As countries get used to the idea of equivalence determination, and as the time required for the equivalence process passes the number of equivalence findings is likely to increase.

However, the impact that such equivalence decisions may have on domestic regulatory policy should not be presumptively overstated. In the first place, to date, most areas where equivalence guidance has been provided have been aimed at conformity assessment and methods used to achieve protection rather than the substance of the standards themselves.<sup>114</sup> This type of procedural harmonization is designed to result in the same level of protection as existed before the equivalence decision while reducing cost imposed by redundant testing.<sup>115</sup>

Those who oppose harmonization generally criticize such equivalence decisions on two grounds. First they argue that pushing conformity assessment to other countries may result in

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19 U.S.C. § 2578 (a), therefore when equivalence determinations are made as part of the TBT agreement notice and comment may not be required unless the administrating agency decides to formalize the determination an regulation or other measure that is legally binding on the administrative agency. For example of a situation where a notice and comment are unlikely to be used see Stewart, *U.S. Administrative Law*, *supra* note 15, at 69.

<sup>112</sup> Final Guidance: Importation of Pasteurized Milk Ordinance (PMO) Defined Dairy Products (M-I-00-4), 65 Fed. Reg. 39912, 39912 (June 28, 2000)

<sup>113</sup> See Squabs, *supra* note 110, at 13,253 (noting that the 13 month 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 US regulations. This process requires both “a paper review, [and] an on-cite verification review” and often a notice and comment. Equivalence Guidelines, *supra* note 105, at 30595. All together, the process of attaining equivalency determinations may well take longer then a year to complete.

<sup>114</sup> See *e.g.* Fruit Flies, *supra* note 110; Australian Meat, *supra* note 110, Equivalence Evaluation Process for Foreign Meat and Poultry Food Regulatory System, Response to Comments, 64 Fed. Reg. 70690 (Dec. 17, 1999) [hereinafter Meat Response].

<sup>115</sup> One commentator has described such agreements as “labor saving, rather than law changing” alluding to the reduction in labor costs likely to ensure from the elimination of redundant and unnecessary testing. Merrill, *supra* note 14, at 754.

lower level of protection because other countries are not likely to be as vigilant in their review as domestic US authorities. Second, they argue that because the ability of US regulatory authorities to monitor foreign regulatory bodies is likely to become strained as regulatory fatigue and budget shortfalls occur causing enforcement to suffer.<sup>116</sup> Neither argument is terribly persuasive however. Foreign regulatory bodies are unlikely to be lax in their enforcement as the costs, both political and economic, of discovery are likely to be high, particularly as sanitary and phytosanitary measures tend to have large political footprints. Meanwhile, the same political footprint is likely to encourage domestic regulatory authorities to monitor and review bodies that have deemed equivalent, to the extent that resources are available.<sup>117</sup> Because regulatory failure in such highly visible areas is relatively unlikely, and equivalence decisions aim at the procedure of verifying that a good has met a certain level of protection, equivalence decisions of these types are unlikely to have a large impact on domestic levels of protection.

A second reason that equivalence decisions are not likely to substantially alter US regulatory policy is that they may well be a more formal codification of previously negotiated memoranda of understanding (MOU) between the US and various countries. Prior to the inception of the SPS agreement the US negotiated several such MOUs with trading partners in an effort to streamline regulatory approval of particular products.<sup>118</sup> Typically, such agreements would stipulate that the US trade partner would agree to implement particular safety measures in exchange of easier access to the US market.<sup>119</sup> Traditionally, however, these MOUs, tended to focus on specific problems that arose 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

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<sup>116</sup> For examples of these critiques see Meat Response, *supra* note 114 at 70691-92 (providing both an example of the critiques and the governments answers to them).

<sup>117</sup> As they have already promised to do on other occasions. *Id.* at 70691.

<sup>118</sup> For several examples of such MOUs see, Equivalence Guidelines, *supra* note 105 at 30,594.

<sup>119</sup> *Id.*

the United States.”<sup>120</sup> Recently, various countries benefiting from such MOUs have expressed interest in converting the MOUs into full scale equivalence agreements that would be larger in scope than the existing MOUs and would be focused on recognizing the equivalence of their regulatory system as providing the same level of protection as is provided in the United States. Such equivalence agreements, if they are negotiated, are likely to more firmly entrench already existing regulatory policy, than create a new one.

There is however valid reasons to be concerned about the potential impact of the use of equivalence decisions or mutual recognition agreements on US regulatory policy. In particular, while the concerns articulated by anti-harmonization groups about the lack of regulatory vigor by foreign regulators is not persuasive, a slightly different concern merits mention. In particular, while US regulators are unlikely to overlook regulatory lapses abroad, excessive focus on the benefits of equivalence may result in US regulators refusing 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>121</sup> A second danger is that while present equivalence determinations are focused on procedural matters, an increase level of comfort by regulators employing this harmonization tool might 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 entered the toolbox of SPS regulators, MRAs have been unable to breach the wall of differences separating US regulators and their colleagues in other countries. However, some brief observations from the

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<sup>120</sup> *Id.*

<sup>121</sup> This is particularly so as the political costs of failing to implement a new regulation are likely to be less in a case of not adopting a standard addressing an inherently uncertain topic than failing to enforce already existing laws and regulations. Moreover, failing to enforce a law is more likely to be subject to a legal challenge from domestic consumer groups, than would be likely in a case of inherently discretionary regulatory judgment. *Chevron, Inc. v. Natural Res. Def. Council*, 467 U.S. 837 (1984).

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 US have been focused on issues of conformity assessment procedures and have been negotiated with major trading partners.<sup>122</sup> Because, MRAs, can generally be viewed as bilateral and reciprocal equivalence determinations much of the analysis above about the potential impact of equivalence decisions on US regulatory policy applies to MRAs as well.

Overall, it is fair to say that as a result of the SPS agreement the US regulatory system has been impacted by international standard setting much more than by individual equivalence decision and MRAs. Moreover, the US has taken an active and proactive posture in promoting harmonization in international standard setting organizations and through the attempted use of equivalence decisions and MRAs. This pro-harmonization posture has been accompanied by a decrease in the opportunities that stakeholders have had 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 order to accomplish this goal, the drafters

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<sup>122</sup> Committee 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 (Jul. 21, 2004) (notifying an agreement between US and the European Commission on conformity assessment procedures); Committee 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 US on conformity assessment); Committee 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 United States); Committee 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*, T/TBT/10.7/N/20 (Mar. 1, 1999) (notifying a conformity assessment agreement between the US and the EC) *But see* Committee 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 US and Japan where Japan agreed to grant equivalence to US technical regulations, standards and conformity assessment procedures related to the US National Organic Program)

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.

When legislation that would incorporate the Uruguay Agreements<sup>123</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>124</sup> Congress was particularly concerned about two potential developments. The first was the secretive nature of international standard-setting organizations. Congress was concerned 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>125</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>126</sup>

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<sup>123</sup> Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994; *Legal Instruments—Results of the Uruguay Round*, 33 I.L.M. 81, (1994).

<sup>124</sup> See, e.g., 140 Cong. Rec. S15077, S15087 (1994) (Statement of Sen. Metzenbaum); 140 Cong. Rec. S15077, S15112 (1994) (Statement of Sen. Hatch); 140 Cong. Rec. S15271-03, S15312 (1994) (Statement of Sen. Thurmond) [hereinafter Thurmond Statement]; 140 Cong. Rec. H11493, H11507 (1994) (Statement of Rep. Vento); see also James Risen, *New Trade Body's Power Called Overrated; Pact: Foes Say the WTO Will Erode U.S. Sovereignty. But Proponents Say Fears of Global Government Are Unfounded and Cite Agency's American Origins*, L.A. TIMES, Dec. 2, 1994, at 18A; 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>125</sup> Kumbula, *supra* note 74.

<sup>126</sup> 140 Cong. Rec. S15271, S15359 (1994) (Statement of Sen. Kerry). In particular, it is worthwhile to note that Congress was not only concerned with the economic impact that harmonized standards might have, but also with the

In an effort to alleviate these concerns, Congress inserted several provisions into the Uruguay Round Agreements Act.<sup>127</sup> These procedures provided for notice and comment when the United States was engaged in international standard setting or was in the process of making an equivalency determination.<sup>128</sup> These provisions, developed with the interest representation model of administrative law in mind, were designed to insure 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>129</sup> Furthermore, Congress required that the administration 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>130</sup> Unfortunately, the Congressional expectation that these requirements, when added to the usual requirement of notice and comment rulemaking under U.S. law,<sup>131</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

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impact that such standards might have on environmental and consumer protection statutes. *See, e.g.* 140 Cong. Rec. S 15077, S15124-25 (1994) (Statement of Sen. Heflin).

<sup>127</sup> 140 Cong. Rec. H11493, 11517 (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 process); 140 Cong. Rec. H11493, H11531 (1994) (Statement of Rep. Johnson). The result of these efforts is evident. 119 U.S.C. § 2578.

<sup>128</sup> While MRAs are not explicitly mentioned, because they in effect operate as formalized equivalency determination it is likely that Congress intended the notice and comment procedures to apply to MRAs, as well as to equivalency determinations.

<sup>129</sup> 19 U.S.C. § 2578(a)-(c). Using the power granted to him under section a, the President designated the U.S. Codex Office in the Department of Agriculture as the department having the responsibility of monitoring and informing the stakeholders of all activities pertaining to the work of the Codex Alimentarius Commission. Similarly, the Animal, Plant and Inspection Service in the USDA was placed in charged of monitoring the standard-setting activities undertaken by the International Plant Protection Convention and the Office of International Epizootics. Proclamation No. 6780, 60 Fed. Reg. 15845 (Mar. 23, 1995).

<sup>130</sup> 19 U.S.C. § 2578(d).

<sup>131</sup> Administrative Procedure Act, 5 U.S.C. § 553(b)-(c).

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 those who stand to benefit from regulatory protection.<sup>132</sup>

1. Negotiating the Negotiation: Public Participation in the Formulation of US 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>133</sup> In practice, this means that, prior to the meeting of the standard-setting IGO (or the subcommittee for a particular standard of the IGO), the agency will conduct a notice and comment, and at times conduct a public meeting, in an effort to solicit public input.<sup>134</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. 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 U.S. negotiating position, though he or she is under no obligation to do so.<sup>135</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 development of hard-look review in the late 1960s.<sup>136</sup> Just as, prior to

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<sup>132</sup> Sunstein, *supra* note 22, at 211 (noting that the shift to the interest representation model was caused from the feeling of inequity in a process where the subject of the regulation had more protection than the beneficiaries).

<sup>133</sup> Scarbrough, *supra* note 73.

<sup>134</sup> *Id.*; see also, e.g., 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>135</sup> Scarbrough, *supra* note 73.

<sup>136</sup> See *Scenic Hudson Preservation Conference v. PFC (I)*, 354 F.2d 608 (2<sup>nd</sup> Cir. 1965); see also Stewart, *supra* note 22, at 1675-76 (arguing that in the traditional regulatory model judicial review was only available on issues on 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 (5<sup>th</sup> ed. 2002) (explaining evolution of searching review by courts of agency action as response to great amount of discretion granted to agencies, and resulting charges of administrative capture).

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, there is no way in which to verify that public concerns have been addressed in the formation of the negotiating position<sup>137</sup> because there is no procedural review available.<sup>138</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 will be considered.<sup>139</sup> The delegate has broad discretion as to who is selected to make up the negotiating team, and has the authority to accept or reject representatives of the public interest as members of the delegation. In the past, several public interest organizations have been members of such delegations.<sup>140</sup>

While the ability to be a member of the negotiating team looks like everything that a stakeholder could want, in reality, the ability to be a part of the negotiating team is in no way a guarantee that the opinions of that organization will in any way affect the negotiating position of

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<sup>137</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 the decisions to modify the negotiating position are clearly visible to those who are following the negotiations. Scarbrough, *supra* note 73. 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 not 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, *Accountable Governance*, *supra* note 74, at 836-38.

<sup>138</sup> For a detailed explanation of why procedural review of executive negotiating decisions is unavailable see Stewart, *US Administrative Law*, *supra* note 15 at 79 – 81.

<sup>139</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) [hereinafter Delegates] See also Scarbrough, *supra* note 73.

<sup>140</sup> Scarbrough, *supra* note 73.

the United States. Initially, regulatory agencies typically impose a limit on the number of public representatives they are willing to accept as members of the negotiating team.<sup>141</sup> While this limiting 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>142</sup> The exclusion problem is further complicated by the fact that the delegate has complete, unassailable discretion over the content of the delegation.<sup>143</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 the potential for agency capture.

A further problem is the cost that this method of participating entails. Under present regulations, non-governmental members of the U.S. delegation must pay their own way.<sup>144</sup> Not only are negotiations often held in hard-to-reach places,<sup>145</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 budget constraints, are able to, and often do, take full advantage of their ability to participate.<sup>146</sup> The

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<sup>141</sup> Delegates, *supra* note 139 at 7, 119.

<sup>142</sup> It is clear that organizations representing similar interests are likely to cooperate in an attempt to insure 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. 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>143</sup> Delegates, *supra* note 139, at 7, 118. Scarbrough, *supra* note 73 (explaining that decisions of delegates are not challengeable in court and are therefore final).

<sup>144</sup> Delegates, *supra* note 139, at 7, 118.

<sup>145</sup> Kumbula, *supra* note 74.

<sup>146</sup> In the TBT context this is exasperated even further by the multitude of standard setting bodies. Stakeholders, both business and civil society, complain that the large number of standard setting bodies makes it prohibitively expensive to track all of the standard setting activities. This then results in less stakeholder participation in the process as stakeholders are often either not aware of the standard setting activities all together, or find out at a point

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>147</sup>

The problem of stakeholder participation is further exacerbated by the fact that, even in the rare circumstances when a public-interest organization becomes a member of a U.S. delegation, they are not provided with an opportunity to constructively shape the substance of the negotiations.<sup>148</sup> While members of the delegation can travel to IGO meetings, they do not have the ability to actively participate during the negotiations as does the official delegate, as to date US policy has been that only the official delegate can speak on behalf of the United States.<sup>149</sup> This means that the public-interest representative's ability to inform the standard-setting body of the concerns held by its constituency is entirely dependent on the official delegate's desire to bring these issue to the table during negotiations. Even should a public-interest representative 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>150</sup> Moreover, the need to articulate the views of multiple constituents in a very limited time period necessarily forces some issues of the

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where an effective, informed delegation (or delegate) can not attend the meeting. Reinsch, *supra* note 6 (noting that business interest are unable to keep up with all the standard setting activities undertaken by multiple bodies); Kumbula, *supra* note 74 (noting that civil society organizations can't keep track of the word undertaken by the numerous standard setting organizations).

<sup>147</sup> Wallach, *Accountable Governance*, *supra* note 74 at 836.

<sup>148</sup> Kumbula, *supra* note 74; Scarbrough, *supra* note 73.

<sup>149</sup> Scarbrough, *supra* note 73.

<sup>150</sup> The Codex and other IGOs have procedures where a delegate can 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. Scarborough, *supra* note 73. Some have argued that the public has had an opportunity to express its feelings in the domestic forum and, therefore, giving the organization an opportunity to address the IGO would represent a second bite of the apple. Phillip 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, we have long ago concluded that an agency might not be the most effective advocate of the public interest and, therefore, have opted to allow the individual stakeholders themselves to have a seat at the table. See *United Church of Christ v. FCC*, 486 U.S. 1032 (1988). Moreover, the arguments that a stakeholder will present at a domestic meeting and the arguments that it will raise in an international context are likely to be different, as the goals of the NGO are likely to be different 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).

agenda.<sup>151</sup> Ultimately, because public-interest representatives have no way in which to effectively present their viewpoint in the course of the IGO negotiations, many find that being part of the U.S. delegation is not worthwhile, given the huge cost involved.<sup>152</sup> As representatives of the public interests have little, if any, opportunity to shape the negotiating position adopted by the United 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 Adopting of International Standards

This unfortunate phenomenon is further complicated by the fact that these regulatory standards, once agreed to 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>153</sup> As such, the regulating agency is obliged to follow the notice and comment procedure, as laid out in the APA.<sup>154</sup> As part of the judicially imposed scrutiny, regulatory agencies must take comments of interested parties into account and justify their decision to impose a standard deviating from the comment. While these procedural checks seldom result in major deviations from the standards initially proposed by 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

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<sup>151</sup> Macer, *supra* note 44. Daryl Macer, a representative of a civil society organization 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, on the other hand most official delegates are unable to make all the points with sufficient clarity and articulation in such a short period of time. *Id.*

<sup>152</sup> Kumbula, *supra* note 74.

<sup>153</sup> Administrative Procedure Act, 5 U.S.C. §704; *see also* Lujan v. National Wildlife Federation, 497 U.S. 871 (1990).

<sup>154</sup> § 553(b).

international standard is not immune from alteration during the notice and comment procedures as part of domestic implementation of international standards.<sup>155</sup> However, public-interest representatives point out that once a standard is successfully negotiated in an international setting, the commitment effect makes it unlikely that the United States will be willing to consider divergent standards.<sup>156</sup> Furthermore, because “officials participating in the adoption of a global regulatory norm will most likely be strongly committed to its implementation...the justifications given by an agency for its domestic decision may be a rationalization of a *fait accompli*.”<sup>157</sup>

Moreover, unlike a domestic regulation, which can be challenged in domestic courts, international standards developed by IGOs are unlikely to be struck down by the courts.<sup>158</sup> While judicial review will likely be unavailable once a standard is internationally agreed upon because US courts are unlikely to invalidate the decision of the executive branch to enter into an international agreement, U.S. courts are also unlikely to act while the standard is still being negotiated. 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 the NAFTA was still being negotiated.<sup>159</sup> Arguing that an agreement still being negotiated is not a final action within the meaning of the APA, and reasoning that such an agreement might be

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<sup>155</sup> Scarbrough, *supra* note 73.

<sup>156</sup> Kumbula, *supra* note 74.

<sup>157</sup> Stewart, *US Administrative Law*, *supra* note 15, at 79.

<sup>158</sup> Meinhard Hilf, *The Role of National Courts in International Trade Relations*, 18 MICH. J. INT'L L. 321, 324 (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 the case 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 authority of the executive 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>159</sup> 970 F.2d 916.

significantly altered, making intervention prior to the conclusion of the agreement unnecessary, the D.C. Circuit Court refused to order the impact statement.<sup>160</sup>

A similar phenomenon is evident in the context of negotiated equivalence determinations or 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 be a part of the negotiations.<sup>161</sup> This is particularly so in the case of equivalence decisions which are not publicly announced until after a positive determination has been rendered, and even then not always.<sup>162</sup> As a result, often the only time stakeholders have a chance to provide 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 likely promotes efficiency in negotiations, it has resulted in a situation where stakeholders can at best register discontent rather than be an active player in the regulatory process.<sup>163</sup> This is particularly so because despite the fact that the FDA's equivalence guidelines calls for a full round of notice and comment procedures,<sup>164</sup> to date comments submitted by stakeholders has not been successful at convincing the government to alter their decisions.<sup>165</sup> This inability of stakeholders to use notice and comment procedures to change regulatory policies aimed at harmonization of regulatory activities and regulations is a likely result of the

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<sup>160</sup> *Id.* at 919-20.

<sup>161</sup> Famulate Letter, *supra* note 111 (explaining that the presence of non-governmental officials during negotiations would diminish the ability of regulators to be effective).

<sup>162</sup> Letter from Mary Bottari, Director, Harmonization Project, Public Citizen's Global Trade Watch to Charles Gaylord, Office of International and Constituent Relations, Food and Drug Administration (Apr. 28, 2000) available at [www.publiccitizen.org/print\\_article.cfm?ID-4303](http://www.publiccitizen.org/print_article.cfm?ID-4303) [hereinafter Bottari Letter]; Famulare Letter, *supra* note 108 (stating that the Food and Drug Administration has not intention of undertaking a notice and comment procedure each time there is an equivalence determination made).

<sup>163</sup> It must be noted however, that this ability to register discontent is not wholly useless as it allows for a development of a record to be used in future litigation.

<sup>164</sup> Equivalence Guidance, *supra* note 102, at 30595-96.

<sup>165</sup> *See e.g.* Meat Response, *supra* note 114, at 70,692. Thought it is notable that at least in one recent case, the US government initiated a notice and comment before starting negotiations on harmonization activities. Mad Cow, *supra* note 107. Whether this action represents a broader shift in US regulatory philosophy or merely an attempt to avoid a political confrontation on a particularly sensitive issue is not yet clear.

same two level game that has precluded stakeholders from influencing the determination of international standards once they have been negotiated internationally.<sup>166</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 the MRA.

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

### 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 domestic agencies at home.<sup>167</sup>

Domestically, several NGOs initiated a public-relations campaign against harmonization efforts under way 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>168</sup> for the majority, the criticism was a result of being unable to find a

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<sup>166</sup> Robert D. Putnam, *Diplomacy and Domestic Politics: The Logic of Two-Level Games*, 42 INT'L ORG. 427 (1988).

<sup>167</sup> Scarbrough, *supra* note 73.

<sup>168</sup> Kumbula, *supra* note 74. These organizations argue that the development of regulatory standards inherently implicates the cultural and social norms of a country and, as such, it should be done domestically and individually by each country. These organizations oppose harmonization as a matter of principle, not because it fails to provide for adequate public participation.

seat at the negotiating table.<sup>169</sup> To this effect, many public-interest organizations campaigned for, and participated in, meetings designed to provide input into the negotiating positions taken by the United States in negotiations occurring with international organizations such as the 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 of subjects drawing substantial attendance.<sup>170</sup> There are competing explanations of this phenomenon. On the one hand, those in government believe that a primary reason for sparse attendance is the highly technical nature of the standard-setting process, which places the process largely below the radar of most NGOs.<sup>171</sup> On the other hand, the lack of attendance can also be explained as a response by public-interest representatives to the real, or perceived, cosmetic nature of meetings conducted by agencies.<sup>172</sup> When one considers the amount of attention that harmonization activities receive from stakeholder organizations,<sup>173</sup> a lack of interest seems an unlikely reason for the decreasing attendance at agency meetings.

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<sup>169</sup> Macer, *supra* note 44 (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* Reinsch, *supra* note 6 (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>170</sup> Scarbrough, *supra* note 73.

<sup>171</sup> *Id.*

<sup>172</sup> Kumbula, *supra* note 74. Telephone interview with Edward Mierzwinsky, Public Interest Research Group (June 28, 2004). A recent incident indicates the sense of frustration felt by stakeholder organizations representing public interests. At a recent US/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 unequal treatment with which government officials treated the TACD vis a vis the Trans Atlantic Business Dialogue (TABD). Press Release, Trans Atlantic Consumer Dialogue, U.S. – EU Summit Puts Business CEOs Ahead of Consumer Groups (June 23, 2004).

<sup>173</sup> *See e.g.*, Public Citizen, Harmonization, at <http://www.publiccitizen.org/trade/harmonization/>; Ctr. for Int'l Envtl. Law, Trade and Sustainable Development, at <http://www.ciel.org/Tae/programtae.html>. In addition to this site, Public Citizen administers a full-scale harmonization project dedicated to tracking developments related to the harmonization of regulatory standards.

Finding it effectively impossible to contribute to the standard-setting process domestically, and recognizing that domestic legal process do not extend to the international arena where real decisions are being made, many NGOs took their fight directly to the international forums in charge of standard-setting activities.<sup>174</sup> Initially, public-interest representatives found these forums inhospitable to their participation.<sup>175</sup> Over time, however, the IGOs have relaxed their resistance to NGO participation and, in the case of the Codex Alimentarius commission, have gone as far as to give some NGOs observer status.<sup>176</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>177</sup> Despite their inability to vote, NGOs have met with 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 which international standards should be negotiated.<sup>178</sup> Moreover, recently several member states have begun including representatives of various stakeholders, including public interest representatives, in their delegations, and entrusting these representatives with substantial responsibility.<sup>179</sup> This has allowed some stakeholder representatives to gain an effective foothold into the Codex process.

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<sup>174</sup> Scarbrough, *supra* note 73.

<sup>175</sup> Wallach, *Accountable Governance*, *supra* note 74, at 837.

<sup>176</sup> Codex Alimentarius, Principles Concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission, at [http://www.codexalimentarius.net/ngo\\_participation.stm](http://www.codexalimentarius.net/ngo_participation.stm).

<sup>177</sup> *Id.*

<sup>178</sup> Scarbrough, *supra* note 73.

<sup>179</sup> Macer, *supra* note 44 (pointing out that in recent years the governments of Sweden and Japan have begun delegating more and more responsibility to public interest representatives). Professor Macer sees this trend continuing, with a possible conclusion that over time smaller countries might allow public interest representatives to take the lead and act in an official capacity at various Codex meetings. This may be particularly likely in cases of smaller countries with limited budgets and particularly when the meeting in question is one of a subcommittee dealing with a particular standard, not the Codex body as a whole. According to Professor Macer, this may benefit developing countries because NGOs with their specific agenda may very well be in a better position to represent the interests of a country than official diplomats who are not likely to be informed about the technical nature of the negotiations due to lack of funding. *Id.*

Success in other areas, such as agenda setting has been limited causing some stakeholders to get frustrated<sup>180</sup> This is particularly true as many NGOs have found that participation in the Codex did not insure input in the decisions making process, as decisions are frequently made over lunch or dinner among US and European delegates, a situation where stakeholders can't participate.<sup>181</sup> This combined with the frequent meetings, and NGOs inability to properly organize for effective participation<sup>182</sup> has prompted some NGOs to eschew participation as a waste of time and money.<sup>183</sup>

The OIE, which the SPS agreement delegated with 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 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 their regulatory activities to NGOs as well as soliciting their input.<sup>184</sup> Similarly, the IPPC provides an opportunity for stakeholders to submit proposal for standard-setting activities.<sup>185</sup> However, in both cases, once standards are drafted, the public has minimal abilities to modify the drafted standards directly, and must do so predominantly by lobbying member states.

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<sup>180</sup> Kumbula, *supra* note 74. Macer, *supra* note 44.

<sup>181</sup> Macer, *supra* note 44 (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 41, at \_\_\_\_.

<sup>182</sup> *Id.*

<sup>183</sup> Kumbula, *supra* note 74.

<sup>184</sup> Org. Int'l Epizootics, The OIE's initiatives in Animal Welfare, at [http://www.oie.int/eng/bein\\_etre/en\\_introduction.htm](http://www.oie.int/eng/bein_etre/en_introduction.htm) (last visited Apr. 16, 2004); *see also* Org. Int'l Epizootics, Applying Science to Animal Welfare, at [http://www.oie.int/eng/Welfare\\_2004/context%20paper.htm](http://www.oie.int/eng/Welfare_2004/context%20paper.htm) (last visited Apr. 16, 2004).

<sup>185</sup> Int'l Plant Prot. Convention, IPPC: Standard Setting Process, at <http://www.ippc.int> (last visited Apr. 16, 2004).

Despite the increased opportunities available for public participation in the IGO standard-drafting process, the ability for public involvement is still largely limited and constrained. Initially, the ability to participate is not open to all NGOs, but only to those that are international in their work.<sup>186</sup> This has the impact of limiting 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, a smaller, local NGO is thus unable to participate in the 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 small NGOs from participating in the work of standard-setting organizations.<sup>187</sup>

The conditions imposed on NGOs before they become able to attain observer status are also problematic because they create accountability issues. An NGO must apply to the Codex Commission to attain observer status.<sup>188</sup> This means that an NGO potentially may be denied observer status. The inability of 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>189</sup> and many remain distrustful of the Commission or see the ability to participate in the work of the Codex as a measure designed to quiet their objections, rather than a meaningful opportunity to participate.<sup>190</sup>

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<sup>186</sup> For example, the Codex considers an NGO eligible for observer status if it has official relation with one of the two parent organizations, the FAO or the WHO, or if it is “international in structure and scope of activity.” NGO Participation, *supra* note 43. In practice, this means that, in order to receive observer status in the Codex, an NGO must do work in three different countries, in at least two regions of the world. Scarborough, *supra* note 73. The OIE has similar requirements for NGOs wishing to participate.

<sup>187</sup> Kumbula, *supra* note 74. *But c.f.* Macer, *supra* note 44 (arguing that the requirement that observers be international organizations is required given the unique space/time/resource constraints of the Codex, and that the requirement is not a major obstacle under normal circumstances).

<sup>188</sup> Scarborough, *supra* note 73.

<sup>189</sup> *Id.*

<sup>190</sup> Kumbula, *supra* note 74.

Similarly, stakeholders have attempted, and have at least partially succeeded in getting 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>191</sup> Together the TACD and the TABD serve as umbrella organizations tasked with bringing the concerns of their constituencies to the attention of regulators trying to negotiate harmonization initiatives.

While the creation of the 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 Edward 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>192</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>193</sup>

Public participation in international harmonization bodies (whether they be multilateral or regional or bilateral) is further inhibited by a lack of resources. Initially, in order to effectively participate in harmonization initiatives, public-interest representatives have to commit to

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<sup>191</sup> Trans Atl. Consumer Dialogue, ABOUT TACD at <http://www.tacd.org/about/about.htm>; Trans. Atl. Bus. Dialogue, ABOUT THE TABD at <http://www.tabd.com/about>. See also telephone interview with Jeff Werner, Executive Director of the U.S. Office of the Trans Atlantic Business Dialogue (June 28, 2004) (noting that TABD is one of several groups used by business interest to present their views to governments); Mierzwinsky, *supra* note 167 (explaining that the TACD was designed to ensure that regulators would have access to different views).

<sup>192</sup> Mierzwinsky, *supra* note 172.

<sup>193</sup> *Id.*

traveling to every meeting. The frequency of these meetings, as well as their remote locations, makes participation unaffordable for many interested organizations.<sup>194</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 their substantial resources have indicated concern about the difficulty of keeping up with, and being ready to participate in the various harmonization activities.<sup>195</sup> This is particularly relevant for those stakeholders who attempt to represent broad cross sections of society, as they can't focus their attention on the work of only one or two institutions.<sup>196</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 in their work has led to a lessening of the amount of criticism levied at these organizations. However, this new-found external legitimacy<sup>197</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

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<sup>194</sup> Kumbula, *supra* note 74.

<sup>195</sup> Reinsch, *supra* note 6 (describing concerns espoused by business interest about the expense associated with participating in harmonization activities, particularly the effort required to monitor the numerous harmonization initiatives).

<sup>196</sup> Macer, *supra* note 44 (pointing out that groups that are able to participate effectively in institutions such as the Codex tend to be those that have a narrow agenda are able to focus their resources effectively).

<sup>197</sup> The internal versus external legitimacy divide is best explained in J.H.H. Weiler, *The Rule of Lawyers and the Ethos of Diplomats: Reflections on the Internal and External Legitimacy of WTO Dispute Settlement* 12 (Harvard Jean Monnet Working Paper 9/00, 2000), at <http://www.jeanmonnetprogram.org/papers/00/0090.html>

effectiveness suffered.<sup>198</sup> Responding to this challenge, several IGOs have reshaped their internal procedures, adopting qualified, as opposed to simple, majority voting schemes.<sup>199</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 result in a further lowering of standards adopted by international organizations, a practice that harmonization is frequently accused of.<sup>200</sup> The evolution that standard-setting organizations are undergoing serves as an invitation to reexamine the proper way to insure that representatives of the public interest are able to participate in this critical work.

#### IV

##### **PUBLIC PARTICIPATION VERSUS ACCOUNTABILITY: DRAWING THE BALANCE**

For almost 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, mutual recognition agreements, or domestic equivalency determinations. Having failed to obtain meaningful access in the domestic arena, NGOs moved their battle to the international one. Here representatives of public interests 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 tasked with the work of developing international standards, and that, as a result, the international regulatory process is tilted toward corporate interests.<sup>201</sup> Similarly, business interests have expressed dissatisfaction with process as it often makes it difficult to keep

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<sup>198</sup> See Stewart & Johanson, *supra* note 31, at 52.

<sup>199</sup> See Int'l Plant Prot. Convention, THE 1997 REVISION OF THE IPPC (2004) at [www.ippc.int](http://www.ippc.int). See also Stewart & Johanson, *supra* note 31, at 47-48; Revision of the International Plant Protection Convention, 62 Fed. Reg. 8, 210 (Feb. 24, 1997).

<sup>200</sup> Wallach, *Accountable Governance*, *supra* note 74, at 836-38.

<sup>201</sup> Kumbula, *supra* note 74.

track of, and effectively participate in, various initiatives.<sup>202</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 process, 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 does not “compromise the ability of international regimes to successfully carry out their primary functions.”<sup>203</sup>

In deciding how to best provide for public participation two questions must be answered. First, at what level – domestic or international or mix – should this participation take place? A second question is what reforms must be instituted domestically to provide for effective participation? As the process of setting international standards, negotiating mutual recognition agreements, or making equivalency determinations differ in the impact they have on domestic regulations and in the ability of stakeholder to participate the answers to these questions may vary depending on the activity in question. Therefore, in order to best outline the different

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<sup>202</sup> Reintsch, *supra* note 6.

<sup>203</sup> Richard Stewart, *Administrative Law in the 21<sup>st</sup> Century*, 78 N.Y.U. L. REV. 437, 460 (2003). For an example of how excessive access by civil society may be disruptive, see Brownen Morgan, *Local Participation and Global Rule-Making: The Case of Transnational Water Regulation* (forthcoming) (discussing how great influence given to civil society in South Africa did not lead to effective regulatory policy, but instead produced “schizophrenic policy environment of contradictory signals”) (on file with author).

solutions that are available this section will analyze 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, US regulatory agencies must do a better job of informing the public about various harmonization activities underway. One of the main criticisms levied against harmonization activities has been the secretive nature of such activities.<sup>204</sup> In particular, both business and public interest representatives have expressed frustration about their inability to find out about these initiatives in a timely fashion. While various agencies sometimes publish *Federal Register* notices about major initiatives,<sup>205</sup> this is presently done on a case by case, or at best on an IGO by IGO basis, rather than presenting a comprehensive overview of various initiatives. This makes it difficult for stakeholders to get an accurate picture of the scope of the international regulatory activity under way, and to prioritize those activities that they find important over those that they may not be concerned about. This defect could easily be ratified through a creative use of government websites. For example, a single central website posting the scheduled meetings and topics of international and domestic regulatory activities in a timely fashion could go a long way towards relieving this frustration. While this would help by informing the stakeholders of the initiatives 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.

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<sup>204</sup> Wallach, *supra* note 74, at 833; *see also* Bottari Letter, *supra* note 162 (critiquing the closed nature of joint commission meetings during which equivalence determination agenda is set); Kumbula, *supra* note 74.

<sup>205</sup> *See e.g.* International Sanitary and Phytosanitary Standard-Setting Activities, 69 Fed. Reg. 51443 (Aug. 19, 2004) (publishing a notification of various standard setting activities being undertaken in the Codex, IPPC and OIE).

### *A. International Standard Setting through International Organizations*

When transnational regulations are developed as part of international standard setting activity it appears that the ability of stakeholders to participate, if limited to one arena (be it domestic or international), 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 into a negotiating position. At the same time, giving non-governmental delegates a greater role in the formulation of international negotiating positions is 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>206</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. The cost of participating in standard-setting activities in the international arena is likely to price smaller NGOs who are not wealthy or large enough to have an international reach out of the process entirely. Moreover, absent an accountability check on the work of the standard-setting IGOs,<sup>207</sup> a seat at the table in the negotiations is unlikely to resolve concerns

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<sup>206</sup> Nichols, *supra* note 150, at 317-18.

<sup>207</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 outline seven potential sources of accountability in their paper, *Accountability and Abuses of Power in World Politics* 99 AM. POL. SCI. REV. 29 (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

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>208</sup>

At the same time, 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 environments where questions under negotiations are value judgments,<sup>209</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 is likely to make the work of these organizations more effective.<sup>210</sup> While the same information can be provided to the delegate of the stakeholder's state, there is no guarantee that delegate will

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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. 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 the actions of the organization. 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, as the standard setting bodies are blessed by the WTO, a country would be unlikely to withdraw from these 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 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>208</sup> Kumbula, *supra* note 74.

<sup>209</sup> See James Salzman, *Decentralized Administrative Law in the Organization for Economic Cooperation and Development*. 68 L. & CONTEMP. PROBS. 191 (2005) (discussing Export Credit Agencies and role of domestic administrative procedures in insuring civil-society participation).

<sup>210</sup> *Id.* (discussing Mutual Acceptance of Data program).

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>211</sup>

In this highly technical environment, the optimal solution seems to provide for avenues of participation in 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>212</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 fairness, might motivate the standard-setting IGOs to allow stakeholders access to the relevant negotiations.<sup>213</sup>

In the domestic arena the question of 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 stakeholder to have too much influence in the development of U.S. negotiation positions: US negotiators have to juggle multiple agendas whereas stakeholders are often interested in their own particular issues.

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<sup>211</sup> Scarbrough, *supra* note 73 (noting that US 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 him better equipped to debate the finer points of the argument.

<sup>212</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 disputes brought under regional trade agreements. 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 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 bodies decision. Like the situation 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.

<sup>213</sup> For a description of the bottom-up approach to developing global administrative law, see Richard Stewart, *U.S. Administrative Law*, *supra* note 15, at 76 – 88.

Allowing stakeholders too much access then 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 in other ways. In particular, traditional stakeholder participation devices, such as notice and comment, can be used in such a way as to provide for ample stakeholder participation without destroying the flexibility that US negotiators may need in negotiations. For example, regulatory agencies engaged in international negotiations could publish drafts 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 U.S. negotiation 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 rule making process. Such a 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 in which to promote increased public participation in the development of global regulatory norms is the appointment of a high level official to act as a liaison with public interest and business organizations, or through other policies that aim to demonstrate that the internationalization of international standard setting has not made the viewpoints of the 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 presupposes 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 measures. Recently, private enterprises engaged in global regulatory

activity have requested greater government involvement in the development of international standards.<sup>214</sup> One possibility is to condition such governmental support for such activities on the opening up of the private international institution to public interest stakeholders. Alternatively, the government could condition its support on the fact that public interest stakeholders be included in the US delegation to the meetings of the private standard setting bodies. Even less odorous may be a requirement that US industries engaged in private standard setting take actions to inform the stakeholders about 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 interests stakeholders,<sup>215</sup> they may however, be the first of many steps that ultimately results 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 strength and weaknesses of these respective branches pose unique benefits and costs to their taking 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 makes these branches perhaps the best candidates to initiate such reforms.

The executive branch is perhaps 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,<sup>216</sup> and to conduct foreign policy on behalf of the United States.<sup>217</sup>

Therefore, the executive has a lot of discretion in how it conducts negotiations, and could take

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<sup>214</sup> Evans, *supra* note 10, at 1.

<sup>215</sup> Werner, *supra* note 186.

<sup>216</sup> US CONST. art. II, §2, cl. 2.

<sup>217</sup> *United States v. Curtis-Wright Export Corp.*, 299 U.S. 304, 319-21 (1936). *See also* LOUIS HENKIN, FOREIGN AFFAIRS AND THE CONSTITUTION, 41-45 (1996).

measures to include stakeholders in its decision-making process. Moreover, regardless of what action the executive branch took, whether implementing an invigorated notice and comment procedure or by appointing a public official to act as a liaison with stakeholders, or something else, by acting 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 at least every eight years may result in an environment where advances gained by public interest representatives in one administration may be eroded in the next.<sup>218</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>219</sup> As such any agreement establishing such an organization, and to which the United States is a party will need Congressional approval.<sup>220</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.

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<sup>218</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 (2001). For a discussion of efforts on the part of the Bush administration to overturn Clinton's regulatory legacy see Felicity Barringer, *Bush Record: New Priorities in Environment*, N.Y. TIMES at A1 (Sept. 14, 2004).

<sup>219</sup> U.S. CONST. Art. I, § 8, cl. 2.

<sup>220</sup> *United States v. Guy W. Capps, Inc.* 204 F. 2d 655 (4<sup>th</sup> Cir. 1953) (holding that in the area of commercial affairs the executive can not conclude a sole executive agreement because he needs Congressional approval).

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 Administrative Procedure Act which provides this protection for regulatory activities undertaken in the United States.<sup>221</sup> In creating such an International Administrative Procedure Act (IAPA) Congress could provide for adequate stakeholder participation through an appropriate combination of notice and comment procedures, requirement of public notices when negotiations are ongoing, and provisions guaranteeing judicial review. However, such a general statute should also account for the reality that regulatory activities in the international arena may also implicate important security and foreign policy of the United States. Therefore, it would be appropriate to provide exceptions from the obligations of the IAPA when issues of national security or great foreign policy interest are at stake.<sup>222</sup>

One major downside to Congressional action to provide for stakeholder participation is that any such requirement 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 (POPs).<sup>223</sup> The convention bans several organic pollutants and establishes an international process for adding other chemicals to the treaty.<sup>224</sup> In drafting implementing legislation, Congress provided for a mandatory notice and comment procedures to provide stakeholders with

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<sup>221</sup> 19 U.S.C. § 551 et. seq.

<sup>222</sup> In drafting these exceptions guidance can be gleaned from the APA which provides for exceptions from the notice and comment requirements in cases of national security and foreign policy concern. 19 U.S.C. § 553(a)(1).

<sup>223</sup> Stockholm Convention on Persistent Organic Pollutants, May 22, 2001, 40 I.L.M. 532.

<sup>224</sup> CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW, THE STOCKHOLM CONVENTION ON PERSISTENT ORGANIC POLLUTANTS (2004) at [http://www.ciel.org/POPs/pops\\_stockholm.html](http://www.ciel.org/POPs/pops_stockholm.html).

an opportunity to weight 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>225</sup> The executive's objections were largely based on the opinion of the Supreme Court in *United States v. Curtiss-Wright Export Corporation*,<sup>226</sup> 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>227</sup>

Potential constitutional issues that Congressional regulation of international regulatory activity are largely beyond the scope of this paper, and require further research. However, a few brief thoughts may act as an initial starting point in this debate. Initially, it is unlikely that Congressional attempts to provide for procedural safeguards on the activity of the executive in international regulatory fora would be found unconstitutional. Congress has traditionally used its oversight power to require substantive, as well as procedural protections when authorizing the executive to commence economic negotiations.<sup>228</sup> Moreover, Congress may also be able to justify its action by arguing that the authority of executive agencies (such as 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

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<sup>225</sup> Letter from William Moschella, Assistant Attorney General to Senator Tom Harkin (Mar. 25, 2004) (on file with author).

<sup>226</sup> 299 U.S. 304 (1936).

<sup>227</sup> *Id.* at 319.

<sup>228</sup> For a recent example see, *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 CALIF. L. REV. 671 (1998) (tracing the rise and fall of Congressional control over executive's ability to negotiate agreements).

agreements. These arguments, however, are neither exhaustive nor without counter arguments and a definitive answer to the question of Congressional ability to restrict executives power in the realm of international regulatory law will have to await further research.

If neither of the political branches acts, however, 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>229</sup> Such an approach would, however, demand a reconsideration of the court's decision in *Public Citizen*. In this case, the court determined that mere negotiations do not constitute a final rule within the meaning of the APA.<sup>230</sup> The court reasoned that, since negotiations are not always completed and since differing policy priorities often emerge during negotiation, it would be a drain of resources to treat each draft of an international agreement as a final rule.<sup>231</sup> The unique nature of standard-setting organizations is that, once negotiations on a standard are 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. Therefore, to accommodate this 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 of the executive branch.

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<sup>229</sup> Richard B. Stewart, forthcoming, *The Global Regulatory Challenge to U.S. Administrative Law*, \_\_ N.Y.U. J. INT'L L. & POL. \_\_, \_\_ (2005) (on file with author).

<sup>230</sup> *Public Citizen v. USTR*, 970 F.2d 916, 919.

<sup>231</sup> *Id.* at 920.

In sum, when dealing with standard setting activities being undertaken by international organization stakeholders should be given ample opportunity to participate both in the domestic and international fora. Moreover, these reforms could be implemented by any of the three branches of governments. These, arrangement 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 the individual states. As such, it may be less appropriate, and quite difficult, to provide for increased stakeholder participation on the international level. Allowing stakeholders to sit directly at negotiations may undermine the efficiency of these negotiations. Moreover, some countries, particularly those unused to stakeholder participation, may refuse MRAs if non governmental organizations are given a formal seat at the negotiations.<sup>232</sup> For these reasons it may be best to provide for stakeholder participation at the domestic level when the regulatory activity in question is a negotiation of a mutual recognition agreement.

The highly technical, and rather informal, nature of mutual recognition agreements also poses challenges as to how stakeholder participation can best be guaranteed. The problem of stakeholder participation in regards to mutual recognition agreements could largely be ameliorated by providing for a robust notice and comment procedures before negotiations begin (or between successive rounds of negotiations). This would allow for adequate stakeholder input, without unduly burdening US negotiators. Even if the government was required to

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<sup>232</sup> This may prove to be particularly true in cases of negotiations with poorer countries, who because of their 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 exasperate 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.

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>233</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 agency 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 towards more informal negotiations and consultations.<sup>234</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 mutual recognition agreements.

### *C. Equivalency Determinations*

As equivalency determinations are largely unilateral decisions of US regulatory authorities, the only forum in which stakeholders could participate is the domestic one. Adequate participation could be assured via 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

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<sup>233</sup> Nicolaidis and Steffenson, *supra* note 59, at 6-12.

<sup>234</sup> ANNE MARIE SLAUGHTER, *NEW WORLD ORDER* (2005) (discussing the development of informal regulatory networks).

determination, and when 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 equivalency determination, such information should be made available so that stakeholders are able to participate effectively. Because some states may 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 yet does discourage 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 initiative of providing for stakeholder participation should be carried out by the executive branch. However, Congressional action is also possible as Congress could require regulatory agency to undergo particular procedural safeguards while in the process of 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, the 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. To do so effectively requires a multilevel strategy. On the one hand, 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.