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**Dueling Risk Assessments: Why the WTO  
and Codex Threaten U.S. Food Standards**

by

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DUELING RISK ASSESSMENTS:  
WHY THE WTO AND CODEX THREATEN  
U.S. FOOD STANDARDS

BY  
JOHN EWERS\*

*The explosion of international trade in recent years, while opening up new markets for United States exports, has also resulted in numerous challenges to domestic environmental laws. The next target of the international trade juggernaut could be the Food Quality Protection Act (FQPA). This Comment examines the potential effects of the World Trade Organization (WTO) Bovine Growth Hormone Decision and the WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) on United States food standards. The WTO has interpreted the SPS Agreement to require stringent, narrowly focused risk assessment analysis of potentially hazardous environmental agents. However, the FQPA uses a broad, sweeping, cumulative analysis of potentially hazardous environmental agents. The result of these different standards could lead to a conflict and a resulting shift in FQPA analysis to reflect the SPS Agreement's more narrowly focused risk assessment.*

I. INTRODUCTION

The onset of increased international trade during the 1980s and 1990s has resulted in numerous challenges to United States laws and regulations.<sup>1</sup> The next likely U.S. target of the international trade juggernaut could be the

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<sup>1</sup> See, e.g., World Trade Organization (WTO): United States—Import Prohibitions of Certain Shrimp and Shrimp Products, 38 I.L.M. 118 (Oct. 12, 1998) (ruling against the United States embargo of shrimp from nations that had not adopted comparable standards to safeguard endangered sea turtle species); WTO Appellate Body: Report of the Appellate Body in United States—Standards for Reformulated and Conventional Gasoline, 35 I.L.M. 603 (May 20, 1996) (ruling that provisions of the United States Clean Air Act relating to reformulated gasoline violated General Agreement on Trade and Tariffs (GATT) principles); GATT Dispute Settlement Panel Report, United States Restrictions on Imports of Tuna, 30 I.L.M. 1594 (Aug. 16, 1991) (ruling that a United States statute banning the importation of tuna caught in nets that also resulted in the killing of dolphins violated the GATT).

Food Quality Protection Act (FQPA).<sup>2</sup> The Bovine Growth Hormone (BGH) Decision,<sup>3</sup> a recent decision by the World Trade Organization (WTO)<sup>4</sup> concerning the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement),<sup>5</sup> threatens to trump U.S. food standards. This threat arises because the Environmental Protection Agency (EPA), the agency responsible for upholding the FQPA, makes risk assessment decisions that differ from those contemplated by the WTO's interpretation of risk assessment in the SPS Agreement.

The BGH Decision was the result of a refusal by the European Union (EU)<sup>6</sup> to import meat products treated with growth enhancing hormones.<sup>7</sup> Health risks associated with these hormones concerned the European Union and prompted the ban.<sup>8</sup> The United States challenged and defeated the European ban at a WTO dispute resolution panel hearing.<sup>9</sup> The European Union appealed the decision, but the appellate body affirmed the essence of the panel's ruling. The appellate body agreed with the panel that the European ban violated the SPS Agreement and requested that the European Union comply with the SPS Agreement.<sup>10</sup>

The SPS Agreement is an international trade compact that regulates laws or regulations that protect human or animal life from risks associated with food additives, toxins, or disease-causing organisms in food.<sup>11</sup> According to the appellate body, the European Union had violated the SPS

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<sup>2</sup> Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (amending the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y (1994 & Supp. IV 1998), and the Federal Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301-397 (1994 & Supp. IV 1998)).

<sup>3</sup> WTO Report of the Appellate Body, EC Measures Concerning Meat and Meat Products (Hormones), WTO Doc. WT/DS26/AB/R & WT/DS48/AB/R (Jan. 16, 1998) (reprinted at <<http://www.wto.org/wto/dispute/distab.htm>>) [hereinafter BGH Appellate Report].

<sup>4</sup> The World Trade Organization's operating provisions were established by the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 1 (1994), 33 I.L.M. 1125 [hereinafter Final Act]. The WTO replaced the General Agreement on Tariffs and Trade (GATT), an international organization created in 1947 to reduce trade barriers through multilateral negotiations. See General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 187 [hereinafter GATT].

<sup>5</sup> Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Final Act, pt. II, Annex IA (4) (reprinted at <<http://www.wto.org/wto/goods/spssagr.htm>>) [hereinafter SPS Agreement].

<sup>6</sup> The Maastricht Treaty turned the European Communities into the European Union. TREATY ON EUROPEAN UNION AND FINAL ACT, Feb. 7, 1992, 1992 O.J. (C 224) 1 (1992), 31 I.L.M. 247.

<sup>7</sup> WTO Report of the Panel, EC Measures Concerning Meat and Meat Products (Hormones), WTO Doc. WT/DS26/R/USA (Aug. 18, 1997) (reprinted at <<http://www.wto.org/wto/dispute/distab.htm>>) [hereinafter BGH Panel Report].

<sup>8</sup> Kristin Mueller, *Hormonal Imbalance: An Analysis of the Hormone Treated Beef Trade Dispute Between the United States and the European Union*, 1 DRAKE J. AGRIC. L. 97, 102 (1996).

<sup>9</sup> BGH Panel Report, *supra* note 7.

<sup>10</sup> BGH Appellate Report, *supra* note 3, at 98-100.

<sup>11</sup> SPS Agreement art. 5. SPS measures also protect animal or plant life from the spread of diseases or pests. *Id.* Annex A1.

Agreement because it had not based its ban on an appropriate risk assessment<sup>12</sup> of the hormones.<sup>13</sup> The SPS Agreement requires all member nations to base their sanitary and phytosanitary (SPS) measures on international standards or, if their SPS measures are more stringent than international standards, offer a scientific justification for their measures backed by risk assessments based on international standards.<sup>14</sup> The European SPS measures were neither based on international standards nor supported by a sufficient risk assessment, and they were declared inconsistent with the SPS Agreement because they did not focus on the specific risk at issue in the litigation—the genotoxic potential of the residue of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes.<sup>15</sup> Hence, risk assessments must focus exclusively on the particular risk of a hazardous environmental agent when used in a specific manner.

The WTO affirmed its highly particularized approach to evaluating risk assessments and scientific evidence in the Japan Fruit (JF) Decision.<sup>16</sup> Concerned that an alien pest—the codling moth—might sneak through customs, Japan required testing of all varieties of the same type of fruit to ensure that codling moth larvae were dead.<sup>17</sup> The United States challenged and defeated the Japanese SPS measure in a subsequent WTO dispute resolution panel hearing.<sup>18</sup> The appellate body affirmed the panel's approach of requiring Japan to show that testing of all varieties of the same type of fruit was necessary.<sup>19</sup>

The FQPA regulates the potency and use of pesticides by establishing a single health-based standard determined by a cumulative and an aggregate exposure assessment for pesticides<sup>20</sup> and heightened protection for infants and children from risks associated with pesticides.<sup>21</sup> Although the JF Decision seems unlikely to affect the FQPA because scientific evidence demonstrates the need for the added pesticide measures,<sup>22</sup> the BGH

<sup>12</sup> Risk assessment is an evaluation of scientific information on an environmentally hazardous agent and the likelihood of human exposure to that agent. NATIONAL RESEARCH COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT 25 (1994).

<sup>13</sup> BGH Appellate Report, *supra* note 3, at 82.

<sup>14</sup> SPS Agreement arts. 3.1 & 5.1–5.8.

<sup>15</sup> BGH Appellate Report, *supra* note 3, at 78.

<sup>16</sup> See WTO Report of the Appellate Body, Japan—Measures Affecting Agricultural Products, WTO Doc. WT/DS76/AB/R (Feb. 22, 1999) (reprinted at <<http://www.wto.org/wto/dispute/distab.htm>>) [hereinafter JF Appellate Report].

<sup>17</sup> WTO Report of the Panel, Japan—Measures Affecting Agricultural Products, WTO Doc. WT/DS76/R (Oct. 27, 1998) (reprinted at <<http://www.wto.org/wto/dispute/distab.htm>>) [hereinafter JF Panel Report].

<sup>18</sup> *Id.* at 110.

<sup>19</sup> JF Appellate Report, *supra* note 16, at 30–31.

<sup>20</sup> 21 U.S.C. § 346a(b)(2)(D)(vi) (Supp. IV 1998).

<sup>21</sup> *Id.* § 346a(b)(2)(C)(i)(II).

<sup>22</sup> See generally NATIONAL RESEARCH COUNCIL, PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN (1993) (exploring whether regulatory approaches for controlling pesticide residues in foods adequately protect children); NATURAL RESOURCES DEFENSE COUNCIL, AFTER SILENT SPRING: THE UNSOLVED PROBLEMS OF PESTICIDE USE IN THE UNITED STATES (1993) (describing deficiencies in federal regulation of pesticides and recommending reforms in the nation's

Decision will have an adverse effect on implementation of the FQPA. While the BGH Decision required a particularized assessment of a hazardous agent used in a specific manner to satisfy the SPS Agreement, the FQPA evaluates pesticides through assessment of exposure from multiple sources to particularly susceptible individuals.<sup>23</sup> The types of information that will satisfy the SPS Agreement and the FQPA inquiry are different and therefore could create a controversy.

To throw a little more fuel on the fire, the Codex Alimentarius Commission (Codex), the international agency that sets international standards for food safety,<sup>24</sup> also has responsibility for setting procedures for risk assessments under the SPS Agreement.<sup>25</sup> The risk assessment procedures used by EPA to deduce the risk an environmentally hazardous agent presents to the public are different from those used by Codex. For example, whereas EPA approaches risk assessment through a consumer health-oriented analysis,<sup>26</sup> Codex approaches risk assessment with the potentially conflicting goals of protecting consumer health and promoting the global food trade.<sup>27</sup> Thus, Codex sets the procedural standard for risk assessments under the SPS Agreement, and the WTO sets the substantive standards for the type of information that may be considered in an SPS analysis.

Understandably, the potential effect of this decision on U.S. laws and regulations is tremendous.<sup>28</sup> This Comment examines the potential collision between the WTO's interpretation of risk assessment and Codex's risk assessment procedures on one side, and EPA's risk assessment procedures and the type of evidence used under the FQPA to justify regulation of pesticides on the other. Part II describes the principles of risk assessment and why the risk assessments of two different groups or agencies might vary even though both groups used pure scientific analysis. Part III examines the SPS Agreement and Codex's methods for setting the procedural requirements in the SPS Agreement. Part IV explains why the EPA and Codex procedural approaches to risk assessment could vary. Part V briefly summarizes the BGH and JF Decisions and explains why the EPA and WTO substantive risk assessments of a pesticide could vary. Finally, Part VI offers suggestions to avoid these conflicts.

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pesticide and agricultural policies).

<sup>23</sup> See 21 U.S.C. § 346a(b)(2)(C)(i)(II), (D)(vi) (Supp. IV 1998).

<sup>24</sup> *Statutes of the Codex Alimentarius Commission* art. 1, in *FAO/WHO PROCEDURAL MANUAL OF THE CODEX ALIMENTARIUS COMMISSION* 4 (9th ed. 1995) [hereinafter *Codex Statutes*]. Food safety standards include the safety of food additives, chemical contaminants, pesticide residues, veterinary drug residues, and biological agents. FOOD AND AGRIC. ORG. & WORLD HEALTH ORG., REPORT OF THE JOINT FAO/WHO EXPERT CONSULTATION, APPLICATION OF RISK ANALYSIS TO FOOD STANDARDS ISSUES 7 (1995) [hereinafter *FAO/WHO CONSULTATION*].

<sup>25</sup> SPS Agreement Annex A4.

<sup>26</sup> See 21 U.S.C. § 346a(b)(2)(A) (Supp. IV 1998).

<sup>27</sup> SPS Agreement art.1.

<sup>28</sup> "Enormous Opportunity" for Trade Disputes Created by FQPA, *Industry Consultant Says*, 22 CHEM. REG. REP. (BNA) 1039, 1040 (Sept. 25, 1998).

## II. RISK ASSESSMENT AND RISK MANAGEMENT

## A. Risk Assessment

Risk assessment is an evaluation of the likelihood and severity of harm to the environment or human health from exposure to a hazardous agent.<sup>29</sup> Risk assessment is essentially a four-step process.<sup>30</sup> The four steps of a risk assessment are 1) hazard identification, 2) dose-response assessment, 3) exposure assessment, and 4) risk characterization.<sup>31</sup> Hazard identification classifies the suspected hazardous agent, its concentration in the environment, the nature of the agent's toxicity, and the ways humans could be exposed to the agent.<sup>32</sup> Dose-response assessment involves a comparison between human exposure to the agent and the severity of the harm caused by the agent.<sup>33</sup> Exposure assessment specifies the population that could be exposed to the agent and identifies the ways in which the population could become exposed.<sup>34</sup> Finally, risk characterization summarizes the results of the previous three steps and estimates the likelihood of the population's exposure to the hazardous agent.<sup>35</sup> Risk characterization also involves discussion of the uncertainties associated with the risk estimate.<sup>36</sup>

Virtually all risk assessments are plagued by scientific uncertainty.<sup>37</sup> Uncertainties about a suspected hazardous agent create both intellectual

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<sup>29</sup> NATIONAL RESEARCH COUNCIL, *supra* note 12, at 25–26; see also JOHN J. COHRSEN & VINCENT T. COVELLO, *RISK ANALYSIS: A GUIDE TO PRINCIPLES AND METHODS FOR ANALYZING HEALTH AND ENVIRONMENTAL RISK* 7 (1989) (focusing on methods for hazard identification and risk assessment).

<sup>30</sup> NATIONAL RESEARCH COUNCIL, *supra* note 12, at 27. However, not every step in the risk assessment analysis must be followed. *Id.* Risk assessments sometimes focus on only a hazard assessment to determine the hazardous agent's potential to cause adverse health effects. *Id.* On other occasions, scientists will add steps to the process by ranking hazardous agents. *Id.* For example, the BGH appellate body decision affirmed the panel's decision to use a two-step approach to determine if the European Union conducted a risk assessment of the hormones. BGH Panel Report, *supra* note 7, at 227. The panel requested the European Union to demonstrate hazards associated with the hormones when used as growth promoters and the potential for the hazards to have adverse health effects. *Id.*

<sup>31</sup> NATIONAL RESEARCH COUNCIL, *supra* note 12, at 27.

<sup>32</sup> FAO/WHO CONSULTATION, *supra* note 24, at 6.

<sup>33</sup> COHRSEN & COVELLO, *supra* note 29, at 7.

<sup>34</sup> NATIONAL RESEARCH COUNCIL, *supra* note 12, at 26.

<sup>35</sup> FAO/WHO CONSULTATION, *supra* note 24, at 6.

<sup>36</sup> *Id.* at 12.

<sup>37</sup> COHRSEN & COVELLO, *supra* note 29, at 90. Uncertainty is a lack of knowledge about a particular subject, and it hinders each step of the risk assessment process. NATIONAL RESEARCH COUNCIL, *supra* note 12, at 161. Uncertainty may affect hazard identification through agent misclassification, unreliability of screening methods for identifying hazardous agents, and extrapolation mistakes from data taken from various scientific disciplines. FAO/WHO CONSULTATION, *supra* note 24, at 27. Uncertainty may affect dose response through miscalculations in models used to compare human exposure to the severity of the harm caused by the agent. *Id.* Exposure assessment involves the identification of possibly numerous pathways through which hazardous agents can reach humans, leaving enormous room for miscalculation. Pesticides, for example, can change between measurements in the soil, plants, animals, and raw food and later measurements pertaining to human ingestion. *Id.* at 29. Finally, risk characterizations may be erroneous because of cumulative inaccuracies added upon one

problems, because the risk assessors will not know the "scientific truth," and practical problems, because the risk assessors will find it more difficult to determine the risks to the population.<sup>38</sup> In the face of uncertainties, agencies responsible for setting safety standards must make science policy choices.<sup>39</sup> Science policy choices—also called default options or inference guidelines—are standard agency guidelines for making a particular choice when confronted with several scientifically plausible approaches.<sup>40</sup> That is, default options serve as bridges over data gaps in the scientific evidence.<sup>41</sup> Since virtually all scientific data is incomplete or ambiguous in some fashion, "risk assessments must use general knowledge and policy guidance to bridge data gaps."<sup>42</sup> Hence, risk assessment is primarily the collection and evaluation of data from a multitude of scientific disciplines—epidemiology, toxicology, statistics, and pathology, just to name a few.<sup>43</sup> Afterwards, the agency responsible for the data collection and evaluation then applies science policy choices to data areas plagued by uncertainties.<sup>44</sup>

### B. Risk Management

Risk management uses the information gathered through risk assessment to create policies to deal with a hazardous environmental or health agent.<sup>45</sup> Whereas risk assessment is limited to scientific inquiries, risk management includes economic, social, and political values.<sup>46</sup> Risk assessors are responsible for determining the risks of hazardous agents through scientific analysis, but risk managers are responsible for considering the results of risk assessments and competing societal goals and values and creating strategies for dealing with the hazardous agents.<sup>47</sup>

### C. Interplay Between Risk Assessment and Risk Management

Though the two concepts are supposed to be distinct, inevitable interplay exists between risk assessment and risk management.<sup>48</sup> Risk assessment includes science as well as policy decisions.<sup>49</sup> For example, decision makers and risk managers choose what type of default options—

another through the previous three steps. *Id.*

<sup>38</sup> NATIONAL RESEARCH COUNCIL, *supra* note 12, at 161.

<sup>39</sup> *Id.* at 27.

<sup>40</sup> *Id.*

<sup>41</sup> See Proposed Guidelines for Carcinogen Risk Assessment, 61 Fed. Reg. 17,960, 17,964 (Apr. 23, 1996).

<sup>42</sup> *Id.*

<sup>43</sup> NATIONAL RESEARCH COUNCIL, *supra* note 12, at 27.

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

<sup>45</sup> COHRSEN & COVELLO, *supra* note 29, at 8.

<sup>46</sup> *Id.*

<sup>47</sup> Science Policy Council, U.S. Env'tl. Protection Agency, *Guidance for Risk Characterization* 3 (visited Feb. 11, 1999) <<http://www.epa.gov/ordntrnt/ORD/spc/rcguide.htm>>.

<sup>48</sup> NATIONAL RESEARCH COUNCIL, *supra* note 12, at 87.

<sup>49</sup> *Id.*

such as degree of conservatism and acceptability of risk—risk assessors should use when faced with equally plausible scenarios or data gaps.<sup>50</sup> Risk managers give risk assessors the lenses through which they are supposed to view scientific uncertainty. Therefore, the risk priorities created by risk managers shape the decisions made by risk assessors.<sup>51</sup> The final product of a risk assessment is not necessarily based completely on scientific analysis; rather, the final product is based on the risk priorities created by the risk managers in charge of dealing with the hazardous environmental or health agent.<sup>52</sup>

For example, in the face of uncertainty, an agency's choice of the degree of conservatism to apply could affect the outcome of the analysis of a hazardous environmental agent. One view, known as the "plausible conservatism" approach, advises that an agency should err on the side of caution until there is a consensus among experts that the conservative default option is implausible.<sup>53</sup> Another view, known as the "maximum use" approach, does not find expert consensus necessary and advocates departure from a conservative default option if risk assessors "find the alternate approach more plausible than the default."<sup>54</sup> Using this line of reasoning, it is not very difficult to imagine a situation where an uncertainty presents itself, the hazardous nature of an environmental agent is questionable, and two different-minded decision makers prescribe different courses of action.

Thus, the point at which science is limited by uncertainty about a particular subject matter in a risk assessment is the point at which science ends and policy choices begin. So long as uncertainty exists, risk assessments will not be based solely on science. The values and goals of the agency or group responsible for implementing the strategies to deal with a hazardous agent bear directly on the type of risk assessment performed to determine the potential threat of an agent. Hence, if the duty of an agency or group is to protect human health and the environment, then this duty is reflected in any risk assessment of a hazardous agent performed by that agency or group. On the other hand, if an agency or group's goal is to facilitate economic growth and commerce, then this goal is reflected in any risk assessment performed by that agency or group. In short, the risk assessment analysis of hazardous agents might not be different from group to group, but the results of the risk assessment will vary according to the group or agency's objectives.

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<sup>50</sup> Science Policy Council, *supra* note 47, at 3.

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

<sup>53</sup> Proposed Guidelines for Carcinogen Risk Assessment, 61 Fed. Reg. 17,960, 17,965 (Apr. 23, 1996).

<sup>54</sup> *Id.*



## III. THE SPS AGREEMENT AND CODEX

A. *The WTO and the SPS Agreement*

The WTO evolved from the General Agreement on Tariffs and Trade (GATT),<sup>56</sup> organized by U.S. and European leaders at the end of World War II.<sup>56</sup> The WTO subsumed the GATT to create a stronger, permanent trade institution.<sup>57</sup> The WTO's purpose is to supervise world trade and adjudicate trade disputes.<sup>58</sup> The WTO's power lies in the contracts and agreements signed by member nations, which form the basis for the legal rules governing international trade.<sup>59</sup> One of these international contracts is the SPS Agreement.

The goal of the SPS Agreement is to use science to distinguish between valid and invalid SPS measures.<sup>60</sup> Although members may set SPS measures to protect human, animal, and plant life or health, these measures cannot function as disguised barriers to international trade.<sup>61</sup> Members are encouraged to harmonize their SPS standards with international standards, guidelines, or recommendations.<sup>62</sup> SPS measures that conform to international standards are presumed to be consistent with the SPS Agreement.<sup>63</sup> The SPS Agreement permits members to institute SPS measures more stringent than international standards,<sup>64</sup> but these measures

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<sup>56</sup> See *supra* note 4.

<sup>56</sup> Jeffrey L. Dunoff, *Institutional Misfits: The GATT, the ICJ and Trade-Environment Dispute*, 15 MICH. INT'L L. 1043, 1047 (1994). Many U.S. and European policy makers believed that the trade wars of the 1920s and 1930s sparked the political friction of that era that inevitably led many countries down the road of war. *Id.* The GATT was one of many initiatives launched to evade future trade wars and their attending consequences. *Id.* The principle aim of the GATT was to increase economic well-being and international trade by reducing tariffs and other international economic barriers and by eliminating discriminatory treatment in international commerce. GATT art.1.

<sup>57</sup> World Trade Org., *What is the World Trade Organization?* (visited Feb. 10, 1999) <<http://www.wto.org/wto/about/facts1.htm>>.

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

<sup>59</sup> *Id.*

<sup>60</sup> SPS Agreement art. 5; see also Vern R. Walker, *Keeping the WTO from Becoming the "World Trans-Science Organization": Scientific Uncertainty, Science Policy, and Fact-Finding in the Growth Hormone Dispute*, 31 CORNELL INT'L L. J. 251, 253 (1998) (arguing that the central strategy of the SPS Agreement is to use science to distinguish between those sanitary measures consistent with the Agreement and those in violation of the Agreement). Countries pressed by international competition can erect import bans based on SPS measures to defend their domestic producers. World Trade Org., *Understanding the WTO Agreement on Sanitary and Phytosanitary (SPS) Measures* (visited Sept. 17, 1998) <<http://www.wto.org/wto/goods/spsund.htm>>. Trade barriers disguised as SPS measures serve as effective protectionist devices because SPS measures are inherently complex and technical. *Id.* According to a United States Department of Agriculture (USDA) study of technical barriers, over five billion dollars per year in U.S. food exports are blocked by bogus, unscientific SPS measures. Richard Lawrence, *US Finds Slow Progress in Persuading Partners to Reform Health/Protectionism Rules*, J. OF COM., Feb. 5, 1999, at 9A.

<sup>61</sup> SPS Agreement pmbl.

<sup>62</sup> *Id.*

<sup>63</sup> *Id.* art. 3.2.

<sup>64</sup> *Id.* art. 3.3.

must have a scientific justification,<sup>65</sup> and they must comply with all the provisions in Article 5 of the SPS Agreement, which sets the risk assessment guidelines.<sup>66</sup>

### B. SPS Agreement's Reliance on Codex

Codex sets international standards for food safety relating to food additives and pesticide residues for the SPS Agreement.<sup>67</sup> The United Nations established Codex in 1962 to protect consumer health, facilitate smooth trade in the exchange of food, and coordinate all international food standards.<sup>68</sup> Codex membership is open to all members of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) interested in international food standards.<sup>69</sup> Although interested parties who are not Codex members may attend Codex sessions to submit information and memorandums,<sup>70</sup> standards can only be set by a majority vote of the member countries.<sup>71</sup>

The passage of the SPS Agreement placed increased responsibility and status on Codex, because its standards are given presumptive acceptance by the SPS Agreement,<sup>72</sup> while more stringent standards must have a scientific justification<sup>73</sup> and base themselves on Codex risk assessment decisions.<sup>74</sup> The SPS Agreement's reliance on Codex's food safety standards and risk assessment procedures implicates those standards and procedures in virtually every SPS challenge concerning food safety. Thus, member nations must take into account Codex's food safety standards and risk assessment procedures whenever they enact SPS measures.

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<sup>65</sup> *Id.* The SPS Agreement declares that a scientific justification exists if, "on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection." *Id.* n.2.

<sup>66</sup> *Id.* art. 5.1-5.8.

<sup>67</sup> *Id.* Annex A3(a). Codex also sets the international standards for veterinary drugs, contaminants, methods of analysis and sampling, and codes and guidelines for hygienic practice. *Id.*

<sup>68</sup> *Codex Statutes, supra* note 24, art. 1. Codex also bears the burden of establishing minimum SPS standards for less developed countries. Lucinda Sikes, *FDA's Consideration of Codex Alimentarius Standards in Light of International Trade Agreements*, 53 *FOOD DRUG COSM. L.J.* 327, 327 (1998). However, the United States does not accept Codex health standards. 21 C.F.R. § 130.6 (1999).

<sup>69</sup> *Codex Statutes, supra* note 24, art. 2. Currently Codex membership stands at 162 national governments. Sikes, *supra* note 68, at 328.

<sup>70</sup> *Codex Statutes, supra* note 24, rule VII.

<sup>71</sup> *Id.* rule VI.

<sup>72</sup> SPS Agreement art. 3.2.

<sup>73</sup> *Id.* art. 3.3.

<sup>74</sup> *Id.* art. 5.1.

## IV. DIFFERENT PROCEDURAL APPROACHES TO RISK ASSESSMENT

## A. Food Quality Protection Act and EPA

The FQPA resolved inconsistencies and updated archaic portions of both the Federal Food, Drug, and Cosmetics Act (FFDCA)<sup>75</sup> and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).<sup>76</sup> The FQPA sets a single health-based standard for all pesticides,<sup>77</sup> provides heightened protection from pesticides for children and infants,<sup>78</sup> and measures pesticide exposure by cumulative and aggregate assessments.<sup>79</sup> Environmental laws are based on a variety of health standards. For example, the laws may be risk-based,<sup>80</sup> feasibility-based,<sup>81</sup> or based on a cost/benefit analysis.<sup>82</sup> However, when Congress passed the FQPA it did not embrace any of these standards. Rather, Congress elected to adopt a new standard: a reasonable certainty that the pesticide will cause no harm.<sup>83</sup> The House Report states that a reasonable certainty of no harm exists when "any increase in lifetime risk, based on quantitative risk assessment using conservative assumptions, will be no greater than 'negligible.'"<sup>84</sup> "Negligible" is defined in the House Report as a one-in-one-million lifetime risk.<sup>85</sup> Although the FQPA does not explicitly contain the one-in-one-million lifetime risk language, the House Report is clear that EPA shall not alter the standard unless it can present evidence to support the alteration.<sup>86</sup> The FQPA's base level of protection is

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<sup>75</sup> 21 U.S.C. §§ 301-397 (1994 & Supp. IV 1998). For example, one of the heralded highlights of the FQPA was the resolution of the Delaney Paradox. U.S. Evtl. Protection Agency, *Major Issues in the Food Quality Protection Act of 1996* (visited Jan. 3, 1999) <<http://www.epa.gov/opppsp1/fqpa/fqpa-iss.htm>>. The Delaney Clause in the FFDCA set a no residue standard for foods containing carcinogenic pesticides. 21 U.S.C. § 348(c)(3)(A) (1994), amended by 21 U.S.C. § 346a(b)(2)(D)(vi) (Supp. IV 1998). Although well intentioned, this policy had a negative effect in terms of food safety, because pesticides that posed a greater noncancer health risk were used over carcinogenic pesticides that had a negligible health risk. U.S. Evtl. Protection Agency, *supra*. By setting a single health-based standard for pesticides, the FQPA resolved the Delaney Paradox. *Id.*

<sup>76</sup> 7 U.S.C. §§ 136-136y (1994 & Supp. IV 1998).

<sup>77</sup> 21 U.S.C. § 346a(b)(2)(D)(vi) (Supp. IV 1998).

<sup>78</sup> *Id.* § 346a(b)(2)(C)(i)(II).

<sup>79</sup> *Id.* § 346a(b)(2)(D)(v).

<sup>80</sup> The Clean Air Act's "adequate margin of safety" for air pollutants is a risk-based standard-setting approach. See 42 U.S.C. § 7409(b)(1) (1994).

<sup>81</sup> The Clean Water Act's standards for water toxins are based on technological feasibility. See 33 U.S.C. § 1311(b)(2)(A) (1994) (requiring the "application of the best available technology economically achievable").

<sup>82</sup> The FIFRA standard for application of pesticides to substances that cause "unreasonable adverse effects" is based on a cost/benefit analysis. See 7 U.S.C. § 136(bb) (1994 & Supp. IV 1998) (defining unreasonable adverse effects as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide").

<sup>83</sup> 21 U.S.C. § 346a(b)(2)(A) (Supp. IV 1998).

<sup>84</sup> H.R. REP. NO. 104-669(II), at 41 (1996), reprinted in 1996 U.S.C.C.A.N. 1268, 1280.

<sup>85</sup> *Id.* The one-in-one-million lifetime risk is based on EPA's standard definition of "negligible." *Id.*

<sup>86</sup> *Id.* The House Report provides that "the new interpretation should be adopted by regulation and should be at least equally protective of public health. . . . [Furthermore, EPA

further enhanced by provisions that measure pesticide exposure by its cumulative and aggregate effects<sup>87</sup> and by whether children are placed at a greater risk of harm.<sup>88</sup>

Pesticides under the FQPA are assessed by an evaluation of the cumulative and aggregate exposure to pesticides.<sup>89</sup> That is, EPA must consider all avenues of pesticide exposure when determining a standard—*e.g.*, drinking water and residential exposure—not just the pesticides encountered on foods.<sup>90</sup> Residential exposure includes exposure to pesticides in and around the home, as well as parks, schools, and daycare centers.<sup>91</sup> Congress undoubtedly adopted a cumulative and aggregate exposure assessment, out of concern that the previous EPA risk assessments had underestimated the risks associated with pesticides.<sup>92</sup> For example, in the past, EPA measured pesticide exposure individually, even though the average consumer encountered numerous pesticides from a multitude of sources.<sup>93</sup>

Although the aggregate exposure assessment is a bold endeavor, the heightened protection given children and infants is the FQPA's most prominent feature.<sup>94</sup> Evidence that children and infants are at a greater risk of exposure to pesticides prompted policy makers to give them special protection in the FQPA.<sup>95</sup> The FQPA directs EPA to use an additional tenfold safety factor when assessing a child's dietary risk to pesticides.<sup>96</sup> Safety factors are used to determine the threshold level at which exposure to a hazardous agent has an adverse effect on human health.<sup>97</sup> Hence, the new regulations that control pesticides must take into account not only

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must] bear the burden to demonstrate that the revised interpretation is equally protective of the public." *Id.*

<sup>87</sup> See 21 U.S.C. § 346a(b)(2)(D)(v) (Supp. IV 1998).

<sup>88</sup> See *id.* § 346a(b)(2)(C)(i)(II).

<sup>89</sup> See *id.* § 346a(b)(2)(D)(vi).

<sup>90</sup> See *id.*

<sup>91</sup> Pesticides; Science Policy Issues Related to the Food Quality Protection Act, 64 Fed. Reg. 162,165 (Jan. 4, 1999).

<sup>92</sup> See NATURAL RESOURCES DEFENSE COUNCIL, *supra* note 22, at 22 (discussing EPA's previous underestimation of pesticide risks).

<sup>93</sup> *Id.*

<sup>94</sup> At least one analyst has commented that the child safety provision is the "core" of the FQPA. Lynn R. Goldman, Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances, U.S. Env'tl. Protection Agency, *Food Quality Protection Act of 1996: New Directions in Public Health Protection* (visited Jan. 7, 1999) <<http://www.epa.gov/oppfead/l/fqpa/sphgold1.htm>>.

<sup>95</sup> NATIONAL RESEARCH COUNCIL, *supra* note 22, at 3. The typical infant's behavior—crawling on the floor and putting things in its mouth—places it at a greater risk of exposure to pesticides. Goldman, *supra* note 94. A child's diet also exposes it to pesticides more frequently than adults because children eat proportionally more fruits and vegetables and drink proportionally more water. *Id.*

<sup>96</sup> Framework for Addressing Key Science Issues Presented by the Food Quality Protection Act (FQPA) as Developed Through the Tolerance Reassessment Advisory Committee (TRAC), 63 Fed. Reg. 58,038, 58,039 (Oct. 29, 1998).

<sup>97</sup> NATIONAL RESEARCH COUNCIL, *supra* note 12, at 30.

cumulative and aggregate exposure, but infant and child susceptibility, as well.

### B. Conflict with Codex

The SPS Agreement requires all SPS measures more stringent than those set by Codex to have a scientific justification and to satisfy all other provisions of the SPS Agreement.<sup>98</sup> This includes Article 5 of the SPS Agreement, which requires members to "ensure that their sanitary or phytosanitary measures are based on an assessment . . . of the risks . . . taking into account risk assessment techniques developed by . . . international organizations."<sup>99</sup>

Codex sets international food safety standards and assists in the international trade of food products.<sup>100</sup> It supports the international food trade by attempting to coordinate food standards among different governmental organizations and "ensuring fair practices in the food trade."<sup>101</sup> Thus, Codex advances two potentially conflicting goals: promotion of food safety and promotion of international trade. EPA's paramount goal, on the other hand, is to protect public health and the environment by implementing protective statutes.<sup>102</sup> Unlike Codex, EPA does not bear the responsibility of promoting trade or economic growth, and consequently, it is not burdened by two potentially conflicting goals.

#### 1. Codex Procedure for Setting Pesticide Standards

Codex's infrastructure is designed in such a way as to disfavor safety standards and encourage international trade.<sup>103</sup> Codex sets pesticide standards through an eight-step process.<sup>104</sup> First, Codex must decide to promulgate a new standard and assign the task to the proper subsidiary body.<sup>105</sup> The Codex Committee on Pesticide Residues (CCPR) is the subsidiary body to which food safety issues relating to pesticide residues are referred.<sup>106</sup> Scientific input is also provided by the Joint FAO/WHO Meeting

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<sup>98</sup> SPS Agreement art. 3.3.

<sup>99</sup> *Id.* art. 5.1.

<sup>100</sup> *Codex Statutes*, *supra* note 24, art. 1.

<sup>101</sup> *Id.* art. 1.

<sup>102</sup> *See, e.g.*, Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), 42 U.S.C. §§ 9601-9675 (1994 & Supp. III 1997); Solid Waste Disposal Act, 42 U.S.C. §§ 6901-6992k (1994 & Supp. III 1997); Endangered Species Act of 1973, 16 U.S.C. §§ 1531-1544 (1994).

<sup>103</sup> Sikes, *supra* note 68, at 328.

<sup>104</sup> *Procedures for the Elaboration of Codex Standards and Related Texts*, pt. 1, in FAO/WHO PROCEDURAL MANUAL OF THE CODEX ALIMENTARIUS COMMISSION, *supra* note 24 [hereinafter *Codex Procedures*].

<sup>105</sup> *Id.*

<sup>106</sup> FAO/WHO CONSULTATION, *supra* note 24, at 7. The Codex Committee on Food Additives and Contaminants sets standards for food additives and chemical contaminants. *Id.* The Codex Committee on Residues of Veterinary Drugs in Foods sets standards for veterinary drug

on Pesticide Residues (JMPR).<sup>107</sup> Decisions to even *consider* an adoption of a new pesticide standard must satisfy a gauntlet of criteria before referral to CCPR.<sup>108</sup> Although one of the criteria is consumer protection, the majority of the factors pertain to economic and international trade impacts and practicality concerns.<sup>109</sup> For example, the Commission must consider “the volume of production and consumption in individual countries and volume and pattern of trade between countries,” possible impediments to international trade, and “international or regional market potential.”<sup>110</sup>

Second, the Secretariat of Codex prepares a proposed draft standard that includes, if available, scientific input from JMPR.<sup>111</sup> Codex also receives input from the Joint FAO/WHO Expert Consultations.<sup>112</sup> For example, the Joint FAO/WHO report concerning risk management advocated that “human health should be the overriding determinant in risk management decisions.”<sup>113</sup> Although Codex noted the conclusions and recommendations of the report concerning risk management, it only “requested the relevant Codex Committees to consider the recommendations and to propose action as necessary.”<sup>114</sup> CCPR generally supported the Joint FAO/WHO recommendations and conclusions, but it elected to wait until the Codex Committee on General Principles (CCGP) established risk management principles.<sup>115</sup> However, CCGP has yet to define Codex’s general principles for risk management.<sup>116</sup>

Third, Codex members receive the proposed draft standard and an evaluation of the proposed standard’s economic impact.<sup>117</sup> Fourth, the Secretariat receives comments on the proposed draft and forwards the comments to CCPR, which has the power to amend the proposed standard.<sup>118</sup> Fifth, CCPR enters any changes to be made to the proposed draft standard—changing it into the official draft standard—and resubmits the standard to the Secretariat who in turn resubmits the draft standard to

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residues. *Id.* at 10. Two Codex subsidiary bodies, the Codex Committee on Food Hygiene and the Codex Committee on Meat Hygiene, set the safety standards for biological agents. *Id.* at 11.

<sup>107</sup> *Id.* at 7.

<sup>108</sup> *Criteria for the Establishment of Work Priorities and the Establishment of Subsidiary Bodies of the Codex Alimentarius Commission*, in FAO/WHO PROCEDURAL MANUAL OF THE CODEX ALIMENTARIUS COMMISSION 1 (10th ed. 1997).

<sup>109</sup> *See id.*

<sup>110</sup> *Id.*

<sup>111</sup> *Codex Procedures*, *supra* note 104, pt. 1.

<sup>112</sup> *See* FAO/WHO CONSULTATION, *supra* note 24, at 1; FOOD AND AGRIC. ORG. & WORLD HEALTH ORG., REPORT OF THE JOINT FAO/WHO EXPERT CONSULTATION: RISK MANAGEMENT AND FOOD SAFETY (1997) [hereinafter FAO/WHO MANAGEMENT CONSULTATION].

<sup>113</sup> FAO/WHO MANAGEMENT CONSULTATION, *supra* note 112, at 15.

<sup>114</sup> *Report of the Twenty-Second Session of the Codex Alimentarius Commission*, Codex Doc. ALINORM 97/37, at 163 (June 23–28, 1997) [hereinafter 22d Codex Session].

<sup>115</sup> *Report of the Thirtieth Session of the Codex Committee on Pesticide Residues*, Codex Doc. ALINORM 99/24, at 12 (Apr. 20–25, 1998) [hereinafter 30th CCPR Session].

<sup>116</sup> *Report of the Thirteenth Session of the Codex Committee on General Principles*, Codex Doc. ALINORM 99/33, at 23 (Sept. 7–11, 1998) [hereinafter 13th CCGP Session].

<sup>117</sup> *Codex Procedures*, *supra* note 104, pt. 1.

<sup>118</sup> *Id.*

the Codex members.<sup>119</sup> The draft standard also includes an evaluation of the economic impacts of the food safety standard.<sup>120</sup> During steps six and seven, the draft standard is submitted to interested international organizations for their comments, and once again, for an evaluation of the economic impacts of the standard.<sup>121</sup> Finally, after all members and international organizations submit their comments, the Secretariat presents the draft standard to Codex members for a vote on whether to adopt the standards.<sup>122</sup>

Economic and international trade concerns influence the pesticide standard-setting process from start to finish. Of the eight required steps, economic interests are allowed to influence four of them.<sup>123</sup> Furthermore, Codex does not have a codified standard that determines whether consumer health is being adequately protected.<sup>124</sup> As a result, its standards reflect the scientific values and opinions offered by interested observers or made by the standard drafters and member nations.<sup>125</sup> The FQPA, on the other hand, directs EPA to establish pesticide standards that reduce the risk of harm posed by pesticide exposure to one in one million.<sup>126</sup> Unlike Codex standards, the FQPA's "reasonable certainty that no harm will result" pesticide standard<sup>127</sup> leaves little question that it is first and foremost a health-based statute and that it eschews economic considerations.

## 2. *Codex Adoption of Pesticide Standards*

Once a pesticide standard has been set, Codex members vote whether to adopt the standard.<sup>128</sup> Economic concerns also influence the adoption of food safety standards.<sup>129</sup> Food safety standards are set by a majority vote of Codex members.<sup>130</sup> All Codex members are entitled to vote and comment on food safety standards, regardless of whether those members have a self-interest in a lower standard.<sup>131</sup> Industrial representation of economic and trade priorities at Codex meetings has always dominated the Codex setting.<sup>132</sup> For example, industrial titans such as Coca-Cola, Pepsi-Cola, Monsanto, and Pfizer and trade groups such as the International Dairy Federation, the International Council of Grocery Manufactures Associations,

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

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

<sup>121</sup> *Id.*

<sup>122</sup> *Id.*

<sup>123</sup> *Id.*

<sup>124</sup> PUBLIC CITIZEN & ENVTL WORKING GROUP, TRADING AWAY U.S. FOOD POLICY 52 (1994).

<sup>125</sup> *Id.*

<sup>126</sup> H.R. REP. NO. 104-669, pt. 2, at 41 (1996), reprinted in 1996 U.S.C.C.A.N. 1268, 1280.

<sup>127</sup> *Id.* at 40, reprinted in 1996 U.S.C.C.A.N. at 1279.

<sup>128</sup> *Codex Procedures*, supra note 104, at 4.

<sup>129</sup> PUBLIC CITIZEN & ENVTL WORKING GROUP, supra note 124, at 53.

<sup>130</sup> See *Codex Statutes*, supra note 24, rule VI.

<sup>131</sup> For example, European countries that sell nonpasteurized cheese object to Codex standards that require pasteurization, and Portugal and Spain object to stringent lead standards for the sake of their pottery industry. Sikes, supra note 68, at 328.

<sup>132</sup> PUBLIC CITIZEN & ENVTL WORKING GROUP, supra note 124, at 52.

the International Organization of the Flavour Industry, the International Soft Drink Council, and the International Glutamate Technical Committee attended the Twenty-Second Session of the Codex Alimentarius Commission.<sup>133</sup> Codex has even gone so far as to praise industry by noting that “[industry groups] can and [do] make valuable contributions in terms of scientific and economic information. . . . [T]hey bring a great wealth of information and advice to Codex discussions.”<sup>134</sup>

However, consumer and health interest groups have not received the same appreciation. The lack of public interest participation also underscores Codex's commitment to furthering international trade concerns over safety concerns.<sup>135</sup> Although Codex theoretically allows for nonmember participation,<sup>136</sup> the manner in which Codex sets and adopts standards hampers the public interest.<sup>137</sup> For example, documents necessary to form opinions as to the food safety standards are distributed without enough time for public comment, and full disclosure of consumer perspectives is often precluded by the Secretariat.<sup>138</sup> Hence, although Codex claims to serve dual functions—protecting consumers and enhancing trade—it is inherently geared more toward enhancing trade than promoting food safety.

### 3. *Codex and EPA Risk Assessments*

Unlike EPA, Codex conducts risk assessments of pesticide exposure without taking into account exposure from multiple sources or exposure to susceptible individuals—such as infants and children.<sup>139</sup> The FQPA requires EPA to set pesticide standards that take into account cumulative and aggregate exposure and infant and child susceptibility.<sup>140</sup> The FQPA sets a stringent standard for pesticides based on a consumer safety mentality by

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<sup>133</sup> Sikes, *supra* note 68, at 330.

<sup>134</sup> PUBLIC CITIZEN & ENVTL. WORKING GROUP, *supra* note 124, at 52–53 (citing FOOD STANDARDS PROGRAMME, FOOD AND AGRIC. ORG. & WORLD HEALTH ORG., INTRODUCING THE CODEX ALIMENTARIUS (1990)).

<sup>135</sup> Patti Goldman, *The Democratization of the Development of United States Trade Policy*, 27 CORNELL INT'L L.J. 631, 631 (1994).

<sup>136</sup> *Codex Statutes*, *supra* note 24, rule VII.

<sup>137</sup> Sikes, *supra* note 68, at 329. Codex precluded consumer advocates from participating in Codex Sessions prior to 1991. Goldman, *supra* note 135, at 679. Consumer advocate uproar in the United States concerning the lack of public interest input in the Codex standard-setting process compelled EPA, the Food and Drug Administration (FDA), and the USDA to provide guidance to environmental and consumer groups interested in participating in the Codex standard-setting process. *Id.* However, the complexity of the Codex standard-setting process, the head start of industrial interests, and the limited resources with which consumer groups operate has discouraged public interest participation. *Id.* For example, public interest groups represented only 3 out of the 37 nongovernmental interest groups at the 22d Codex Alimentarius Commission Session. Sikes, *supra* note 68, at 329.

<sup>138</sup> Sikes, *supra* note 68, at 329. Coincidentally, the decision to adopt maximum residue limits for growth-promoting hormones was conducted by secret ballot in a private session closed off from public participation. *Id.*

<sup>139</sup> See 30th CCPR Session, *supra* note 115, at 33.

<sup>140</sup> 21 U.S.C. § 346a(b)(2)(C)(i)(II), (D)(vi) (Supp. IV 1998).



directing EPA to use conservative assumptions when setting pesticide exposure standards.<sup>141</sup> JMPR has considered the issue of interaction and aggregate exposure, but it determined that the analysis was too difficult at the international level and should be conducted on a national level.<sup>142</sup> JMPR's position appears to absolve pesticide standards set by child, aggregate, and cumulative exposure assessments from scrutiny; however, the SPS Agreement, regardless of JMPR's assertion, could still trump the aggregate, cumulative, and child provisions.

The SPS Agreement requires all SPS measures more stringent than those set by Codex to have a scientific justification and to satisfy all other provisions of the SPS Agreement.<sup>143</sup> Importantly, members must "ensure that their sanitary or phytosanitary measures are based on an assessment . . . of the risks . . . taking into account risk assessment techniques developed by . . . international organizations."<sup>144</sup> Although the cumulative and child exposure assessments may have an adequate scientific justification,<sup>145</sup> EPA and Codex's risk assessment techniques could differ.

In situations where science is unable to produce all the answers concerning the risk of a hazardous agent, Codex would apply its default options to bridge the data gaps.<sup>146</sup> Since Codex risk managers and decision makers craft default options, the risk assessments of hazardous environmental agents conducted by Codex could reflect its bias toward promoting the international food trade. Risk assessments performed by EPA under the FQPA, on the other hand, are motivated by food safety concerns. The goals advanced by EPA and Codex are inherently different and could create risk assessments that conflict at the point where science ends and policy choices—default options—begin.

Codex's risk assessments have undoubtedly led to weaker safety standards than those found in the United States. For instance, a United States General Accounting Office comparison of United States and Codex standards in 1991 found that a majority of the standards were not comparable because the standards were defined differently.<sup>147</sup> However, in over half of the standards that were comparable, the United States had more stringent pesticide standards.<sup>148</sup> Moreover, the United States has banned 1539 of the 3285 pesticide/crop combinations for which Codex has standards.<sup>149</sup> The United States has also banned 40 of the 569 pesticides for which Codex has standards.<sup>150</sup> Hence, Codex's risk assessments, which

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<sup>141</sup> H.R. REP. NO. 104-669, pt. 2, at 41 (1996), reprinted in 1996 U.S.C.C.A.N. 1268, 1279.

<sup>142</sup> PUBLIC CITIZEN & ENVTL. WORKING GROUP, *supra* note 124, at 49.

<sup>143</sup> SPS Agreement art. 3.3.

<sup>144</sup> *Id.* art. 5.1 (emphasis added).

<sup>145</sup> See NATIONAL RESEARCH COUNCIL, *supra* note 22, at 23-47 (exploring the special characteristics of children that make them especially susceptible to pesticide exposure).

<sup>146</sup> See *supra* Part ILC.

<sup>147</sup> U.S. GEN. ACCOUNTING OFFICE, INTERNATIONAL FOOD SAFETY: COMPARISON OF U.S. AND CODEX PESTICIDE STANDARDS 22 (1991).

<sup>148</sup> *Id.* at 4.

<sup>149</sup> PUBLIC CITIZEN & ENVTL. WORKING GROUP, *supra* note 124, at 65.

<sup>150</sup> *Id.* The World Health Organization listed eight of those banned pesticides as highly

reflect its economic and trade promotion goals, invariably lead to weaker standards than those found in the United States.

## V. THE WTO'S INTERPRETATION OF RISK ASSESSMENT

### A. *The Bovine Growth Hormone and Japan Fruit Decisions*

#### 1. *The Bovine Growth Hormone Decision*

The United States and the European Union waged an expensive trade war during the late 1980s and early 1990s over the European Union's refusal to import meat products treated with hormones.<sup>151</sup> Health risks associated with the banned hormones<sup>152</sup> prompted EU policy makers to ban the sale and import of meat products treated with growth-enhancing hormones.<sup>153</sup> The EU BGH measures set a zero-residue standard for the hormones in meat and meat products, which the European Union claimed was necessary to protect human health.<sup>154</sup> Hence, meat products with a detectable quantity of hormones were banned from European markets.<sup>155</sup> The creation of the SPS Agreement, however, provided the United States with the perfect vehicle to challenge the European measures.<sup>156</sup>

The United States subsequently filed a complaint with the WTO and contended that the European measures had violated Article 5.1 of the SPS

hazardous, yet Codex has 116 food tolerances for those pesticide residues. *Id.* at 66.

<sup>151</sup> The United States exported millions of dollars worth of beef and veal to Europe annually in the years preceding the ban. First Submission of the United States, WTO Dispute Settlement Panel, European Communities—Measures Concerning Meat and Meat Products, 1996 WL 807619, at \*1 (Aug. 28, 1996) [hereinafter U.S. Submission]. However, upon implementation of the ban, U.S. exports dropped to nearly zero. *Id.* The U.S. cattle industry estimated that it lost nearly \$250 million annually as a result of the ban. Lisa K. Seilheimer, Note, *The SPS Agreement Applied: The WTO Hormone Beef Case*, 4 ENVTL. LAW. 537, 543 (1998). The United States responded to the ban by placing 100% ad valorem duties on selected imported European products. *Id.*

<sup>152</sup> The banned hormones were both natural -oestradiol-17, progesterone, and testosterone- and synthetic -trenbolone acetate, melengestrol acetate, and zeranol. BGH Appellate Report, *supra* note 3, at 2. Animals treated with the banned hormones grow 8 to 25% faster, require less food, and weigh up to 20% more than animals without the hormone treatment. Seilheimer, *supra* note 151, at 542. Currently, 90% of U.S. cattle are treated with hormones, although at the time of the European ban, 70% of U.S. cattle were treated. *Id.* at 543.

<sup>153</sup> Mueller, *supra* note 8, at 102. European consumers doubted the credibility of studies that demonstrated the safety of meat products treated with hormones and questioned whether industry had manipulated the studies. *Id.* Rumors about Italian infants who had physical characteristics of the opposite sex caused by consumption of baby food treated with hormones fueled consumer fears. *Id.*

<sup>154</sup> First Written Submission of the European Community to the Panel on European Community, WTO Dispute Settlement Panel, Measures Concerning Meat and Meat Products (Hormones), 1996 WL 807621, at \*52 (Sept. 20, 1996) [hereinafter EC Submission].

<sup>155</sup> See U.S. Submission, *supra* note 151, at \*1.

<sup>156</sup> From the U.S. perspective, if the European measures were disguised trade barriers designed to protect European meat producers, the SPS Agreement was the best way to expose the measures as international trade barriers, because the SPS Agreement was intended for just this purpose. See World Trade Org., *supra* note 57.

Agreement, which sets the risk assessment requirements, because the European Union had never performed risk assessments on the hormones.<sup>157</sup> Conversely, the European Union defended their measures and argued that they were in compliance with the SPS Agreement.<sup>158</sup> The European Union argued that its risk assessments of the hormones were based on studies that showed the carcinogenic potential of the hormones and that a good deal of uncertainty still existed concerning the safety of hormonal residue in meat products.<sup>159</sup> The European Union also presented studies that concluded the hormones were safe, but questioned the assumptions on which the studies were based.<sup>160</sup> The EU noted that the assumptions on which the studies were based were still uncertain and that more research was needed.<sup>161</sup>

The panel ruled that the European ban conflicted with Article 5.1 of the SPS Agreement.<sup>162</sup> The panel held that in order to satisfy Article 5.1, the European Union must justify its measures by identifying the hazards associated with the hormones when used as growth promoters and determine the possibility<sup>163</sup> of the hazards causing adverse health effects in humans.<sup>164</sup> The European Union appealed the decision to the appellate body; however, the appellate body affirmed the panel's substantive finding that the European Union had not engaged in a proper risk assessment of the hormones.<sup>165</sup>

The appellate body reasoned that the bulk of the evidence showed that the hormones were safe, even though the assumptions on which those studies stood were questionable.<sup>166</sup> The appellate body also affirmed the panel's decision to disregard scientific evidence that the hormones posed a general carcinogenic risk because the evidence did not pertain to the particular risk at issue in the litigation: "the carcinogenic or genotoxic potential of the residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes."<sup>167</sup> Under the appellate body's interpretation of risk assessment, member nations must produce evidence to demonstrate that the hazardous nature of a particular environmental agent, when used in a certain way and

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<sup>157</sup> U.S. Submission, *supra* note 151, at \*17.

<sup>158</sup> The European Union contended that the different levels of protection offered by the two parties pertaining to the hormones represented their different views on consumer protection. EC Submission, *supra* note 154, at \*31. The European Union claimed that it valued consumer protection over the United States preference for accommodating farming and pharmaceutical interests. Mueller, *supra* note 8, at 108.

<sup>159</sup> EC Submission, *supra* note 154, at \*18-20.

<sup>160</sup> *Id.* at \*20.

<sup>161</sup> *Id.*

<sup>162</sup> BGH Panel Report, *supra* note 7, at 227.

<sup>163</sup> The panel originally used the term "probability," which the appellate body rejected in favor of "possibility." BGH Appellate Report, *supra* note 3, at 70-71. The appellate body was concerned that "probability" would be misconstrued as allowing only a quantitative analysis of the risk. *Id.*

<sup>164</sup> BGH Panel Report, *supra* note 7, at 214.

<sup>165</sup> BGH Appellate Report, *supra* note 3, at 99.

<sup>166</sup> *Id.* at 76.

<sup>167</sup> *Id.* at 78.

encountered in a specific manner, justifies the creation of SPS measures. Thus, the appellate body's interpretation of risk assessment is highly particularized and focuses analysis in a specific manner.

## 2. *The Japan Fruit Decision*

Japan prohibits the importation of certain types of plants into the country.<sup>168</sup> During June of 1950, Japan designated eight products from the United States as prohibited because the plants serve as potential hosts for an alien pest called the coddling moth.<sup>169</sup> In 1978 Japan lifted the import ban for certain varieties of fruit.<sup>170</sup> Although Japan lifted the ban, it required testing of all varieties of the same type of fruit to ensure that the coddling moth larvae were dead.<sup>171</sup>

The United States used the SPS Agreement to challenge Japan's varietal testing requirements and argued that if it had proven that all coddling moth larvae were killed in one variety of fruit, then the same procedure could be used for all varieties of the same type of fruit.<sup>172</sup> Japan countered with studies that indicated the lethal dose for the coddling moths differed among the various varieties of the same type of fruit.<sup>173</sup> They also presented evidence that the CxT values—the “relationship between the fumigant gas concentration in the fumigation chamber and the time-period of fumigation”—differed among the numerous varieties.<sup>174</sup> Japan contended that “differences in CxT values between varieties could be an indicator of differences in the efficacy of fumigation treatment.”<sup>175</sup>

The panel concluded that Japan had maintained its varietal testing requirement without sufficient scientific evidence, because Japan had not proven an actual causal link between the differences in the test results and the presence of varietal differences.<sup>176</sup> Although Japan had presented evidence that the test results varied, it had not presented evidence that the

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<sup>168</sup> JF Panel Report, *supra* note 17, at 98. These prohibited products were apples, apricots, cherries, plums, pears, quinces, peaches, and walnuts. *Id.*

<sup>169</sup> *Id.*

<sup>170</sup> *Id.* The impetus for the fruit-testing dispute originated when Washington apple growers “sought to sell in volume to Japanese markets.” Tim Shorrock, *U.S. to Investigate Japanese Barriers to Fruit Imports; Tokyo's Testing Rules Are an Issue for the WTO*, J. OF COM., Oct. 17, 1997, at A9. However, once U.S. apple growers entered the Japanese markets they “encountered resistance from Japanese bureaucrats concerned that U.S. produce would bring in pests and diseases unknown to Japan.” *Id.* Despite the stringent testing requirements, in 1995 U.S. fruit growers supplied 29.6% of Japan's food imports. *Id.* Japan is also the largest market for U.S. farm exports; it consumes \$417 million worth of fruit—nearly one-fifth of U.S. fruit exports. *Japanese Fruit Tests Unfair, Panel Rules*, HOUSTON CHRONICLE, Feb. 23, 1999, Business Section, at 5.

<sup>171</sup> JF Panel Report, *supra* note 17, at 98.

<sup>172</sup> *Id.* at 102.

<sup>173</sup> *Id.* at 103–04.

<sup>174</sup> *Id.*

<sup>175</sup> *Id.*

<sup>176</sup> *Id.* at 108.

results had been a product of varietal differences.<sup>177</sup> The panel noted that the different test results could have been caused by leakage in the fumigation tank, fruit load, or experimental error.<sup>178</sup> Japan appealed the decision, but the appellate body upheld the panel's conclusion that the Japanese measures had been maintained without sufficient scientific evidence for the same reasons enumerated by the panel.<sup>179</sup>

## B. Implications for the FQPA and EPA

### 1. Sufficient Scientific Evidence

It is unlikely that the JF Decision will have an adverse impact on the FQPA. The FQPA's aggregate, cumulative, and child pesticide exposure provisions are backed by scientific evidence that documents their need.<sup>180</sup> For example, the additional safety factor to protect children from pesticide exposure has been documented by the National Research Council.<sup>181</sup> Based on its JF decision, the WTO would ask that EPA demonstrate the necessity of an additional safety factor for children if an FQPA standard is challenged based on sufficient scientific evidence grounds. However, EPA could point to studies demonstrating that children are at a greater risk because they encounter pesticides more frequently than adults and in a proportionately greater amount.<sup>182</sup> Scientific evidence also demonstrates the need for considering aggregate and cumulative exposure when contemplating pesticide standards.<sup>183</sup>

### 2. Narrow Interpretation of Risk Assessment

In the BGH decision, despite the fact that the European Union presented evidence of the carcinogenic potential of the hormones, the appellate body upheld the panel's narrow, highly specific interpretation of risk assessment.<sup>184</sup> The appellate body upheld the panel's requirement that the European Union present evidence that the hormones were hazardous

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

<sup>178</sup> *Id.*

<sup>179</sup> JF Appellate Report, *supra* note 16, at 8. The impact of the appellate body's ruling has yet to be determined; however, some industry groups suggest that the change "could allow U.S. apple growers to carve out a \$100 million slice of Japan's \$1.6 billion [fruit] industry." Mark Magnier, *WTO Tells Japan It Must Open Its Markets to Foreign Apples*, L.A. TIMES, Oct. 30, 1998, at C1. California and West Coast fruit farmers could expect to receive \$100 million in increased revenues from the newly opened markets. *Id.*

<sup>180</sup> See generally NATIONAL RESEARCH COUNCIL, *supra* note 22 (discussing this scientific evidence).

<sup>181</sup> *Id.* at 7 (arguing that expected total exposure to pesticide residues should reflect the unique characteristics of the diets of infants and should factor in nondietary sources of pesticides).

<sup>182</sup> See *id.* at 314-15.

<sup>183</sup> NATURAL RESOURCES DEFENSE COUNCIL, *supra* note 22, at 22-23.

<sup>184</sup> BGH Appellate Report, *supra* note 3, at 75-82.

when used for growth promotion purposes.<sup>185</sup> It reasoned that the general studies, "submitted by the [European Union] . . . do indeed show the existence of a general risk of cancer; but they do not focus on and do not address the particular kind of risk here at stake—the carcinogenic or genotoxic potential of the residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes."<sup>186</sup> Thus, the appellate body found that because the bulk of the European evidence indicated only the general danger presented by the hormones and not the danger of the hormones when used as growth promoters, the European Union had not done a risk assessment of the hormones.<sup>187</sup> The appellate body's interpretation of risk assessment under Article 5 of the SPS Agreement presents a possible conflict with the FQPA's requirement that pesticides be measured by cumulative and aggregate exposure.

The appellate body's interpretation of risk assessments seems to require that countries not only identify the dangers of a hazardous agent, but also pinpoint the dangers of a hazardous agent when used in a certain way. Thus, in the case of pesticides, the appellate body would demand that the risk assessments of a single, particular pesticide identify the hazard of exposure to the pesticide when encountered in a certain, particular way. However, pesticides regulated under the FQPA are measured by their cumulative and aggregate exposure.<sup>188</sup> EPA measures pesticide exposure not by a single exposure to a single pesticide from a single source, but rather, by exposure to a *combination* of pesticides with a common mechanism of toxicity from a *multitude* of sources.<sup>189</sup> For example, under the appellate body's narrow interpretation of risk assessment, it will demand that countries measure only Pesticide A when Pesticide A is encountered on a particular piece of fruit. EPA's approach to measuring Pesticide A, on the other hand, will consider not only Pesticide A but the cumulative effects of Pesticide A and Pesticides B and C. EPA's approach under the FQPA will also measure pesticides encountered through not only fruit, but in drinking water and residential exposure as well. Thus, the two approaches to risk assessment will conflict, because the appellate body has adopted a narrow, highly specific risk assessment, while EPA measures pesticides by a broad, sweeping risk assessment of exposure from multiple sources.

### 3. *Maximum Use Versus Plausible Conservatism*

Although the appellate body recognized the importance of minority, divergent opinions, it indicated that the evidence weighed so strongly

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<sup>185</sup> *Id.* at 78.

<sup>186</sup> *Id.* at 81–82.

<sup>187</sup> *Id.*

<sup>188</sup> 21 U.S.C. § 346a(b)(2)(D)(vi) (Supp. IV 1998).

<sup>189</sup> See Framework for Addressing Key Science Issues Presented by the Food Quality Protection Act (FQPA) as Developed Through the Tolerance Reassessment Advisory Committee (TRAC), 63 Fed. Reg. 58,038, 58,041–43 (Oct. 29, 1998).

against the European Union ban that the panel was justified in finding that the evidence did not reasonably support the ban.<sup>190</sup> The appellate body remarked that “[a]ll of the scientific studies outlined above came to the conclusion that the use of the hormones at issue for growth promotion purposes is safe.”<sup>191</sup> The appellate body seemingly ignored the European Union’s concern that the studies showing that the hormones were safe were based on unproven and questionable assumptions.<sup>192</sup>

The appellate body appears to have taken a maximum use of scientific information approach to risk assessment. The maximum use approach advocates that it is not necessary for experts to reach a consensus that the default option has been rendered implausible; rather, “it should be sufficient that risk assessors find the alternate approach more plausible than the default.”<sup>193</sup> European risk assessors were faced with a scientific uncertainty, in that there was no scientific consensus on the safety of the hormones, because the studies finding that the hormones were safe were based on questionable assumptions.<sup>194</sup> Rather than follow the majority opinion concerning the safety of the hormones, the European Union elected to err on the side of caution and followed the dissenting point of view. However, the appellate body ruled that the European decision to follow the dissenting opinion was inconsistent with the SPS Agreement, because the majority opinion was more plausible than the dissenting opinion.<sup>195</sup>

However, EPA does not endorse the maximum use approach to risk assessment. Although EPA recognizes the maximum use approach, it generally follows the plausible conservative approach.<sup>196</sup> Plausible conservatism advocates adherence to default options unless there is a consensus among experts that the default option is not plausible.<sup>197</sup> Although EPA does not endorse either approach, plausible conservatism seems to be EPA’s predominant approach. EPA generally uses conservative health-based risk assessment techniques.<sup>198</sup> That is, when EPA risk assessors are faced with a scientific uncertainty, the default options applied by EPA overestimate the risk posed by an environmentally hazardous agent.<sup>199</sup> For example, the proposed guidelines for carcinogen risk assessment are self-admittedly conservative with regard to public health.<sup>200</sup> The guidelines for neurotoxicity risk assessment are also based on a plausible conservative

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<sup>190</sup> BGH Appellate Report, *supra* note 3, at 75–77.

<sup>191</sup> *Id.* at 76–77.

<sup>192</sup> *See id.*

<sup>193</sup> Proposed Guidelines for Carcinogen Risk Assessment, 61 Fed. Reg. 17,960, 17,965 (Apr. 23, 1996).

<sup>194</sup> U.S. Submission, *supra* note 151, at \*16–18.

<sup>195</sup> BGH Appellate Report, *supra* note 3, at 77.

<sup>196</sup> 61 Fed. Reg. at 17,965.

<sup>197</sup> NATIONAL RESEARCH COUNCIL, *supra* note 12, at 601.

<sup>198</sup> *Id.* at 7.

<sup>199</sup> *Id.*

<sup>200</sup> 61 Fed. Reg. at 17,964.

approach to risk assessment.<sup>201</sup> Thus, EPA risk assessments of hazardous agents generally err on the side of caution for the benefit of public safety.

Because EPA bases the majority of its risk assessments concerning hazardous agents on plausible conservatism, its approach to risk assessment likely differs from that of the appellate body. Many of the pesticides that EPA regulates under the FQPA have carcinogenic side effects or are neurotoxins.<sup>202</sup> A plausible conservative approach is the basis for the risk assessments regarding neurotoxins.<sup>203</sup> Although the proposed guidelines for risk assessments concerning carcinogens does not adopt either a maximum use or a plausible conservative approach, it is conceivable that some of the risk assessments will follow a plausible conservative approach.<sup>204</sup> Thus, EPA is likely to follow the plausible conservative approach in its regulation of pesticides under the FQPA. This is likely to violate the SPS Agreement, because the FQPA standards do not embrace the maximum use approach.

## VI. SUGGESTIONS TO AVOID CONFLICT

### A. Codex

As noted previously, the Joint FAO/WHO Expert Consultation on risk management proposed that Codex should use "adverse effects on human health [as its] overriding determinant in risk management decisions."<sup>205</sup> Codex took note of the Joint FAO/WHO recommendations and referred the adoption of the recommendations to the various Codex Committees.<sup>206</sup> Many of the Codex Committees, including the Codex Committee on Pesticide Residues (CCPR), are waiting for the Codex Committee on General Principles (CCGP) to elaborate on the Joint FAO/WHO recommendations.<sup>207</sup> CCGP produced a number of opinions as to what constituted a proper definition of risk management and working principles for risk analysis.<sup>208</sup>

The delegations agreed that protection of human health was the first priority of risk assessment.<sup>209</sup> CCGP needs to adopt human health as the first

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<sup>201</sup> Guidelines for Neurotoxicity Risk Assessment, 63 Fed. Reg. 26,926, 26,929 (May 14, 1998).

<sup>202</sup> See NATURAL RESOURCE DEFENSE COUNCIL, *supra* note 22, at 8–17 (detailing the risks of cancer and neurotoxicity as a result of exposure to pesticides).

<sup>203</sup> 63 Fed. Reg. at 26,929.

<sup>204</sup> See 61 Fed. Reg. at 17,964.

<sup>205</sup> FAO/WHO MANAGEMENT CONSULTATION, *supra* note 112, at 15.

<sup>206</sup> 22d Codex Session, *supra* note 114, at 163.

<sup>207</sup> 30th CCPR Session, *supra* note 115, at 12.

<sup>208</sup> 13th CCGP Session, *supra* note 116, at 18–23.

<sup>209</sup> *Id.* Several delegations also requested that the precautionary principle be included in the working principles for risk analysis. *Id.* The precautionary principle reduces the likelihood of environmental harm by instituting a policy that anticipates environmental harm before the threshold of risk is reached. Gregory D. Fullem, Comment, *The Precautionary Principle: Environmental Protection in the Face of Scientific Uncertainty*, 31 WILLAMETTE L. REV. 495, 497–98 (1996). The appellate body declined to incorporate the precautionary principle into the SPS Agreement. BGH Appellate Report, *supra* note 3, at 98. However, if Codex were to expressly include the precautionary principle in its working principles of risk analysis, the appellate body would be obliged to follow the precautionary principle, because the SPS



priority of a risk management scheme. Since risk management and risk assessment are interwoven by the choice as to which default option to use when presented with a scientific uncertainty, the adoption of a human health priority will help alleviate the potential conflict between EPA and Codex risk assessments. Some delegations requested that CCGP consider consumers at a high risk of exposure to hazardous agents.<sup>210</sup> This suggestion would appear to take into account the FQPA's additional safeguard for children.<sup>211</sup> The Thirteenth Session of CCGP did not produce a consensus as to what constitutes the proper definition of risk management or working principles for risk analysis and "return[ed] the Proposed Draft Principles to Step 2 for re-drafting by the Secretariat."<sup>212</sup> Further consideration of these suggestions is on the agenda for the Fourteenth CCGP Session.<sup>213</sup> If the suggestions pass through CCGP, the Twenty-Third Codex Alimentarius Commission Session will consider them.<sup>214</sup> Thus, there still exists a chance that Codex will adopt a "food safety first" approach to replace its current "international food trade first" approach.

### B. *The Appellate Body*

Although the goal of the SPS Agreement is the slow, eventual harmonization of national and international standards, the SPS Agreement still recognizes a nation's right to enact SPS measures to protect its citizens from hazardous agents.<sup>215</sup> Article 3.3 of the SPS Agreement recognizes a member's right to maintain SPS standards that result in a higher level of protection than international standards require if there is a scientific justification or "as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the

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Agreement requires adherence to Codex's standards, guidelines, and recommendations. SPS Agreement Annex A-3. EPA uses the precautionary principle in various statutes, and it is fairly well entrenched in the U.S. administrative structure. Fullem, *supra*, at 509. Although the precautionary principle cuts off risk assessments before they can start, incorporation of the precautionary principle would also help reconcile EPA and Codex standards, because the precautionary principle is part of EPA's approach to analyzing hazardous agents. See, e.g., 42 U.S.C. § 7409 (1994) (Clean Air Act ambient air quality standards that reflect a precautionary approach); 33 U.S.C. § 1311(a) (1994) (Clean Water Act "no discharge" provision that arguably represents a precautionary approach to water pollution).

<sup>210</sup> 13th CCGP Session, *supra* note 116, at 21.

<sup>211</sup> See 21 U.S.C. 346a(b)(2)(C)(i)(II) (Supp. IV 1998).

<sup>212</sup> 13th CCGP Session, *supra* note 116, at 21.

<sup>213</sup> *Provisional Agenda of the Fourteenth Session of the Codex Committee on General Principles*, Codex Doc. CL 1998/33-GP, CX/GP 99/3, CX/GP 99/4, CX/GP5 99/5 (Apr. 19–23, 1999).

<sup>214</sup> *Provisional Agenda of the Twenty-Third Session of the Codex Alimentarius Commission*, Codex Doc. ALINORM 99/9 (June 28–July 3, 1999).

<sup>215</sup> See BGH Appellate Report, *supra* note 3, at 64 (noting that "[i]t is clear to us that harmonization of SPS measures of Members on the basis of international standards is projected in the Agreement, as a goal, yet to be realized in the future."); see also SPS Agreement pmbl. (listing the further use of harmonized sanitary and phytosanitary measures between members as a goal).

relevant provisions of paragraph 1 through 8 of Article 5.<sup>216</sup> Among other requirements, Article 5 orders members to base their SPS measures on an assessment of the risks.<sup>217</sup> Article 3.3 is an explicit recognition of a member's right to maintain SPS measures that the *member determines* to be necessary to protect its citizens. Thus, so long as a member bases its SPS measure on an assessment of the risk that a hazardous agent presents, the member's SPS measure should withstand an SPS challenge.<sup>218</sup>

The appellate body reasoned that the divergent opinion used by the European Union to justify its SPS measure was outweighed by the majority of the evidence, which indicated that the hormones were safe when used as growth promoters.<sup>219</sup> In other words, the available scientific evidence was more plausible than applying a default option. By taking this line of reasoning, the appellate body violated the SPS Agreement because it applied its own default option in place of the European Union's default option. The SPS Agreement guarantees its members the right to maintain standards more stringent than international standards if they are based on an assessment of risk.<sup>220</sup> Hence, the appellate body should let the members of the SPS Agreement decide what type of default option they wish to apply.

The appellate body's narrow interpretation of risk assessment compounds the problem. By adopting such a narrow interpretation, the appellate body was able, in one fell swoop, to disregard the majority of the scientific evidence indicating that the hormones were hazardous.<sup>221</sup> The appellate body reasoned that the evidence did not address the specific issue in the case—the toxicity of the hormones when used as growth promoters.<sup>222</sup> The appellate body even upheld the panel's decision to disregard the European evidence concerning the synthetic hormone melengestrol acetate (MGA).<sup>223</sup> Although neither the European Union nor the United States presented studies concerning MGA, the European Union argued that MGA closely mimics the natural hormone progesterone.<sup>224</sup> Because MGA and progesterone act similarly, the European Union argued that the studies concerning progesterone were relevant to MGA.<sup>225</sup> The Panel disagreed, despite the fact that there was no international standard concerning MGA, and held that the studies on progesterone were not relevant to MGA.<sup>226</sup>

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<sup>216</sup> SPS Agreement art. 3.3 (emphasis added).

<sup>217</sup> *Id.* art. 5.1.

<sup>218</sup> However, as argued above, Codex's risk assessment techniques are influenced by its institutional goal of promoting the food trade. See *supra* Part IV.B.3. Hence, Codex's risk assessments and standards are more likely to be conducive to international commerce than to protecting the food supply. If Codex adopts a "food safety first" approach to risk management, Codex's priorities are likely to shift. Thus, Codex's risk assessments and standards will begin to more closely resemble those of nations with prominent public health concerns.

<sup>219</sup> BGH Appellate Report, *supra* note 3, at 77.

<sup>220</sup> SPS Agreement art. 3.3.

<sup>221</sup> See BGH Appellate Report, *supra* note 3, at 78.

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

<sup>223</sup> *Id.*

<sup>224</sup> *Id.*

<sup>225</sup> *Id.*

<sup>226</sup> *Id.*

The appellate body's narrow interpretation of risk assessment is not only unreasonable, but is unsupported by the SPS Agreement as well. The appellate body's interpretation of risk assessment suggest that every nation's SPS measures are inconsistent with the SPS Agreement until a specifically focused study justifies the measure.<sup>227</sup> This interpretation of risk assessment casts a shadow over premarket approval programs that bar the import of a product until the product manufacturer produces studies to show its safety.<sup>228</sup> However, these programs are still risk-based in that they are supposed to identify broad categories of risk.<sup>229</sup> Article 5.1 of the SPS Agreement requires that members base their SPS measures on an assessment of the risks to human, animal, and plant life.<sup>230</sup> Article 5.1 does not require specificity; it only requires SPS measures to be based on an assessment of the risks.<sup>231</sup> Hence, the appellate body read the specificity requirement into the SPS Agreement. The appellate body must recognize a nation's sovereign right to implement its own default options when confronted with uncertainty regarding a suspected hazardous agent. Thus, the appellate body should reconsider its definition of what constitutes an appropriate assessment of risk and allow nations to use their own default options in the face of scientific uncertainty.

#### VII. CONCLUSION

The FQPA faces a very real threat from the WTO's interpretation of risk assessment and reliance on Codex as an international standard creator. Because the FQPA sets pesticide standards according to conservative health-based default options, these standards are likely to differ from those of Codex, because Codex promotes the international food trade over food safety. To help resolve the potential conflict between its risk assessments and those conducted by EPA, Codex must adopt human health as its first priority in its risk management decisions.

The appellate body's interpretation of risk assessment and its decision to apply a maximum use approach to risk assessment threatens the FQPA's standards as well. EPA is more likely to follow a plausible conservative approach to risk assessment, which is likely to conflict with the appellate body's maximum use approach. Finally, the FQPA's cumulative, aggregate, and child exposure assessments do not conform to the appellate body's narrow interpretation of risk assessment. The appellate body must reconsider its decision by loosening its constricted interpretation of risk assessment.

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<sup>227</sup> Walker, *supra* note 60, at 300.

<sup>228</sup> *Id.*

<sup>229</sup> *Id.*

<sup>230</sup> SPS Agreement art. 5.1.

<sup>231</sup> Walker, *supra* note 60, at 300.