

COMMENTS

TITLE III OF THE BIOTERRORISM ACT: SACRIFICING U.S. TRADE RELATIONS IN THE NAME OF FOOD SECURITY

CLAIRE S. BOISEN*

TABLE OF CONTENTS

Introduction.....	668
I. The Elements of a Trade Dispute: Title III of the Bioterrorism Act and the Basic Obligations under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures.....	674
A. Title III: Protecting the Safety and Security of the U.S. Food Supply.....	675
B. The SPS Agreement: Reducing Barriers to the Free Trade of Food.....	681
II. Title III Violates U.S. Trade Obligations Under the SPS Agreement and Fails to Provide Adequate Protection Against the Threat of Bioterrorism.....	689
A. In an Effort to Protect Americans from Food Bioterrorism, Title III Inadvertently Restricts International Trade and, Therefore, is Subject to the SPS Agreement.....	690
B. Title III Violates U.S. Trade Obligations to the WTO.....	694

* Junior Staff Member, *American University Law Review*, Volume 56; J.D. Candidate, May 2008, *American University Washington College of Law*; M.A. Candidate, International Affairs, *American University*; B.A. Business-Finance, *North Carolina State University*. I would like to thank the staff and editors of the *American University Law Review* and Professor Nancy Modesitt for their helpful guidance throughout the writing process. In addition, I would like to express my heartfelt gratitude to my fiancé, family, and friends for their continual love and support.

1. Title III discriminates against foreign industry in violation of Articles 2.3 & 5.5 of the SPS Agreement.....	695
2. Title III is not based on a proper risk assessment under Article 5.1	702
a. General deficiencies of the FDA Risk Assessment.....	704
b. The FDA Risk Assessment fails to satisfy the procedural and substantive requirements of Article 5.1 and does not demonstrate reasonable support for Title III	706
c. Title III exempts a number of significant food sources and fails to achieve its stated level of bioterrorism protection	713
III. Looking to the Future: Implications of the WTO Violation and Recommendations for a Future Bioterrorism Plan that is both Effective and Internationally Sensitive.....	715

INTRODUCTION

Emmentaler Exports is a food facility located in Bern, Switzerland that processes and packages a variety of Swiss cheeses for export to the United States. Gourmet Gouda, a domestic food facility located in Peoria, Illinois, similarly produces gourmet cheeses for the U.S. market and competes head-to-head with Emmentaler Exports.¹ In 2002, however, Gourmet Gouda gained a considerable competitive advantage over its rival, Emmentaler Exports, when the United States passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (“Bioterrorism Act”).² Designed to prevent and

1. Emmentaler Exports and Gourmet Gouda are fictitious companies used to illustrate the adverse trade effect of the recent U.S. legislation that is the subject of this Comment.

2. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (codified as amended in scattered sections of 7 U.S.C.A., 18 U.S.C.A., 21 U.S.C.A., and 42 U.S.C.A. (West 2006)). The Act amends parts of three existing legislative protections: the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 (2000), the Public Health Services Act, 42 U.S.C. § 210 (2000), and the Antiterrorism and Effective Death Penalty Act Pub. L. No. 104-132, 110 Stat. 1214 (1996). Section 511 of the Antiterrorism and Effective Death Penalty Act makes the movement and sale of biological agents a criminal offense. 42 U.S.C. § 262 (2000). The Bioterrorism Act was passed largely in response to the 2001 anthrax attacks, where letters laced with anthrax sent to news media offices and Senators on Capitol Hill infected twenty-two people. See David P. Fidler, *Bioterrorism, Public Health, and International Law*, 3 CHI. J. INT’L L. 7, 7 (2002) (illustrating how the “full-blown nightmare” of the anthrax attacks made bioterrorism in the United States “a terrifying reality”); James G. Hodge, *Bioterrorism Law and Policy: Critical Choices in Public Health*, 30 J.L. MED. & ETHICS 254, 255 (2002) (describing how the anthrax attacks fueled fears of future bioterrorism attacks among both government officials and the public at large).

respond to the threat of bioterrorism,³ Title III of the Bioterrorism Act—Protecting Safety and Security of Food and Drug Supply⁴—requires Emmentaler Exports, along with all foreign food facilities, to designate a U.S. agent⁵ and to provide prior notice of every shipment imported into the United States,⁶ at an annual cost of \$425 million per facility.⁷ Meanwhile, Gourmet Gouda and other domestic food facilities continue to access the U.S. market at no additional expense.⁸ The example of these hypothetical companies demonstrates the burdensome impact this legislation has on foreign imports.

With measures to streamline and enhance federal response,⁹ tighten control over existing biological agents in the United States,¹⁰

3. See pmbll., 116 Stat. at 594 (stating that the purpose of the Bioterrorism Act is “[t]o improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies”). Bioterrorism is the use of biological, infectious agents to cause death or suffering in humans or other organisms, presumably for an ideological or political purpose. See Hodge, *supra* note 2, at 254 (defining bioterrorism as “the intentional use of an infectious agent . . . to cause death or disease in humans or other organisms in order to negatively influence the conduct of government or intimidate a population”); see also Lisa Lovett, *Food For Thought: Consistent Protocol Could Strengthen Food Supply Security Measures*, 10 TEX. WESLEYAN L. REV. 465, 475 (2004) (describing food bioterrorism as the act of “tampering with any link in the food supply chain to intentionally harm consumers for presumably political purposes”).

4. §§ 301-336, 116 Stat. at 662-81 (codified as amended at scattered sections of 21 U.S.C.A. (West 2006)). As the relevant trade agreement does not address pharmaceutical or drug regulation, this Comment focuses solely on the food provisions of Title III, found in Subtitle A. See also *infra* note 21 (limiting further this Comment’s focus to those portions of the trade agreement relating to sanitary (food) measures).

5. 21 U.S.C.A. § 350d (West 2006) (requiring domestic and foreign food facilities producing food for consumption in the United States to register with the Food and Drug Administration (“FDA”) and additionally requiring foreign food facilities to include in their registration the name of a designated U.S. agent to serve as a communications link in both routine and emergency situations between the facility and FDA).

6. § 21 U.S.C.A. §§ 331, 381 (West 2006) (compelling foreign food exporters seeking access to the U.S. market to further provide advance notice of all food shipments before their arrival at a U.S. port).

7. See Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 70 Fed. Reg. 57,505, 57,507 (Oct. 3, 2005) (to be codified at 21 C.F.R. pt. 1, 20) (estimating the total annual costs of hiring and retaining a U.S. agent at \$164,500,000); Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,974, 59,062, tbl.47 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1) (interim rule) (calculating the total annual cost to foreign facilities of providing prior notice to the United States at \$260,633,000). Thus, foreign facilities required to comply with the new provisions of Title III of the Bioterrorism Act will spend a total of \$425,163,000 annually to gain access to the U.S. market.

8. See *supra* notes 5-6 (describing how the requirements and associated costs of registration and prior notice apply only to *foreign* food facilities).

9. See 42 U.S.C.A. § 300hh-11 (West 2006) (creating a new Assistant Secretary for Public Health and Emergency Preparedness to act as central command).

and protect the nation's food, drug, and water supply,¹¹ the Bioterrorism Act is declared to be the "first line of defense against bioterrorism."¹² Despite a general recognition that greater bioterrorism protection is needed,¹³ members of the international trade community have raised concerns about the trade-restrictive

10. 42 U.S.C.A. § 300hh-11 (West 2003); § 201-31, 116 Stat. at 637-62 (codified as amended at scattered sections of 7 U.S.C.A., 18 U.S.C.A., and 42 U.S.C.A. (West 2006)).

11. See §§ 301-336, 116 Stat. at 662-81 (codified as amended at scattered sections of 21 U.S.C.A. (West 2006)); §§ 401-403, 116 Stat. at 682-87 (codified as amended at scattered sections of 42 U.S.C.A. (West 2006)); see also Cindy Skrzycki, *A Heaping Helping of Food Security*, WASH. POST, Apr. 1, 2003, at E01 (reporting on the FDA's intent for the Bioterrorism Act to enhance food security without unnecessarily burdening the food industry or the Agency, but describing the Act as so sweepingly broad that lobster catchers in Maine will probably have to register with the FDA).

12. Ryan R. Kemper, *Responding to Bioterrorism: An Analysis of Title I and II of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, 83 WASH. U. L.Q. 385, 403 (2005). Kemper assesses the historical problems of bioterrorism, the 2001 anthrax attacks, and future bioterrorist threats, examines the roles of the various federal agencies responsible for components of bioterrorism prevention or response, and then proceeds to analyze the recent bioterrorism legislation.

13. See, e.g., Yonah Alexander, *Terrorism in the Twenty-First Century: Threats and Responses*, 12 DEPAUL BUS. L.J. 59, 91 (2000) (identifying a need for greater tools, resources, and inter-agency cooperation to manage the consequences of bioterrorism); David Johnston, *Report Calls U.S. Agencies Understaffed for Bioterror*, N.Y. TIMES, July 6, 2003, § 1, at 9 (citing a new report that calls federal agencies underprepared for a bioterrorism attack and predicts agencies would likely be overwhelmed by an attack, particularly due to a lack of sufficient medical and scientific personnel in agency ranks); Research!America, 2001 Public Opinion Poll on Bioterrorism & Research, Nov. 6, 2001, <http://www.researchamerica.org/poll/data/2001/bioterrorism2001.pdf> (polling Americans directly after the anthrax attacks and reporting that fifty-five percent of Americans were concerned with the future threat of bioterrorism); Trust for America's Health, Poll on America's Top Health Concerns and Emergency Preparedness from Trust for America's Health, Feb. 2005, <http://healthyamericans.org/reports/budget05/PollingMemo.pdf> (confirming with recent poll data that Americans continue to believe the United States is unprepared for a terrorist attack on the food supply). Experts disagree over the probability of a bioterrorist occurrence. Compare Prior Notice of Imported Food Under the Public Health Security Act of 2002, 68 Fed. Reg. at 59,064 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1) (indicating that historical evidence suggests an "intentional strike on the food supply is a low-probability . . . event"), with John G. Bartlett, MD, *Update in Infectious Diseases*, 131 ANNALS OF INTERNAL MED. 273, 277-78 (Aug. 17, 1999), available at <http://www.annals.org/cgi/reprint/131/4/273.pdf> (estimating a real risk from bioterrorism, as at least ten and possibly as many as seventeen nations possess agents of biological warfare) and Center for Disease Control, Bioterrorism Overview, <http://www.bt.cdc.gov/bioterrorism/overview.asp> (last visited Nov. 6, 2006) (reporting that biological agents are an attractive option for terrorists). However, most experts do agree that a successful attack would be devastating to American life, health, and the economy. See RISK ASSESSMENT FOR FOOD TERRORISM AND OTHER FOOD SAFETY CONCERNS pt. II.B.2, ¶ 2 (2003) (hereinafter "FDA RISK ASSESSMENT"), <http://www.cfsan.fda.gov/~dms/rabtact.html> (identifying the consequences of a bioterror attack as illnesses and death, social and political implications, and economic effects, especially as "one out of every eight Americans is estimated to work in an occupation directly linked to food production"); Minnesota Dept. of Health, Bioterrorism: Questions and Answers (2001), <http://www.health.state.mn.us/bioterrorism/bioterqa.pdf> (cautioning that bioterrorism is a "high consequence risk").

portions of the Act,¹⁴ mainly Title III.¹⁵ Title III discriminates between domestic and foreign food manufacturers by imposing increased transaction costs and procedural burdens solely on foreign facilities.¹⁶ As a consequence, Title III constitutes a barrier to trade likely to drive foreign food manufacturers out of the U.S. market.¹⁷

14. The Bioterrorism Act in general has elicited concerns and criticism. *See, e.g.*, Kemper, *supra* note 12, at 413-15 (analyzing Titles I and II of the Act and concluding that, although the Act helped to strengthen bioterrorism response mechanisms, further improvement is needed to consolidate the actions of the numerous federal agencies and improve coordination); Lovett, *supra* note 3, at 476-87 (criticizing the food provisions of the Act, including Title II (governing the regulation of milk and dairy products subject to the jurisdiction of the U.S. Department of Agriculture) and Title III (governing general food products and imports regulation by FDA) as inefficient and likely unenforceable). *See generally* Lori L. Buchsbaum, *The U.S. Public Health Response to Bioterrorism: Need for a Stronger Legislative Approach*, 7 J. MED. & L. 1, 25-29 (2003) (reviewing major pieces of legislation that address public health emergencies and critiquing the Bioterrorism Act).

15. *See, e.g.*, Gary G. Yerkey, *Protectionist Pressures in U.S. Forcing Bush to Ignore WTO Obligations, EC Says*, 21 INT'L TRADE REP. 19, 19 (2004) (discussing the contents of the annual European Commission report on U.S. tariff and non-tariff barriers and citing a "growing concern in Europe" that new U.S. measures to counter bioterrorism have "unnecessarily trade-distorting effects"); Preliminary Comments of the European Commission on the Bioterrorism Act, Aug. 30, 2002, http://ec.europa.eu/food/international/trade/us_bio_act_prel_com_en.pdf (voicing initial concerns of the Commission, the body which represents the European Union, that the Bioterrorism Act is a major administrative and economic burden that creates a serious barrier to trade in a memo to the FDA). Among additional comments on the new legislation received by the FDA from domestic and foreign trade representative groups, nearly thirty embassies submitted their concerns that Title III negatively impacts trade relations. *See* FDA Dockets Management, <http://www.fda.gov/ohrms/dockets/default.htm> (providing a searchable database of the comments received by the FDA, and filed and published by Dockets Management). Criticism of Title III's adverse trade effect is not limited merely to foreign entities. *See* Rossella Brevetti, *Association Representing Millers Warns FDA Bioterrorism Proposal Would Hurt Trade*, 20 INT'L TRADE REP. 666, 666-67 (2003) (reporting that the North American Millers Association ("NAMA"), which represents the milling industry on the entire North American continent, has published concerns that the FDA's proposed implementation of prior notice is executed "in the most restrictive and commerce-restricting manner possible"); Christopher S. Rugaber, *Food Importers to Seek Flexibility in Proposed FDA Prior Notice Regulation*, 20 INT'L TRADE REP. 254, 254 (2003) (mentioning concerns of the Grocery Manufacturers of America, a trade association, about the prior notice regulation); Benjamin Onyango & Calum G. Turvey, *Impact of the 2002 Bioterrorism Act on the New Jersey Food Industry* (Food Policy Inst., Rutgers Univ., Working Paper No. WP-0603-010, 2003), *available at* <http://www.foodpolicyinstitute.org/docs/bioterrorism/impactofbioterrorismactNJfoodindustry.pdf> (voicing domestic industry fears that, as a result of the Bioterrorism Act's general restrictions, fewer foreign imports are likely and domestic business will suffer).

16. *See* 21 U.S.C.A. §§ 331, 350d, 381 (West 2006) (imposing two new regulations only upon foreign entities, which discriminates against foreign food suppliers and favors the domestic food industry); *see also infra* notes 120-125 (describing the disparate costs imposed on foreign facilities as a result of Title III regulation).

17. Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,894, 58,897 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1, 20) (interim rule) (lodging the complaint that "the proposed regulation is burdensome, costly, discriminatory, and will have a negative impact on foreign trade").

This Comment takes up the cries of the international trade community, analyzing Title III under the World Trade Organization (“WTO”) ¹⁸ Agreement on Sanitary and Phytosanitary Measures (“SPS Agreement”). ¹⁹ The SPS Agreement recognizes the right of WTO member countries ²⁰ to enact measures to protect against food-borne risks, ²¹ such as biological contamination, but seeks to ensure that such measures do not unduly restrict trade. ²² Title III violates this trade agreement because it discriminates against foreign food suppliers, thus restricting international trade, and is maintained without support from a risk assessment, as is required. ²³

Part I examines in detail the two conflicting laws that are the basis of this Comment—Title III of the Bioterrorism Act and the SPS

18. The World Trade Organization (“WTO”) was formed in 1995 as the successor to the General Agreement on Tariffs and Trade and is an international organization that operates as a multilateral trading system for countries worldwide. The main goal of the WTO is to facilitate free trade on a global level, which it accomplishes, in part, by administering and negotiating trade agreements. *See generally* BHAGIRATH LAL DAS, AN INTRODUCTION TO THE WTO AGREEMENT (1998) (presenting additional information on the WTO and discussing the major WTO Agreements, basic trade rules, and various administrative components of the system).

19. Agreement on the Application of Sanitary and Phytosanitary Measures, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, Multilateral Agreement on Trade in Goods, 1867 U.N.T.S. 493 (1994) [hereinafter SPS Agreement], available at http://www.wto.org/english/docs_e/legal_e/15-sps.pdf.

20. *See* World Trade Organization, Understanding the WTO: The Organization (2005), http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (listing all 149 WTO members as of Dec. 2005). By its membership in the WTO, the United States has pledged to abide by all WTO trade agreements, including the SPS Agreement.

21. *See* SPS Agreement, *supra* note 19, art. 2.1 (declaring the right of members to take sanitary and phytosanitary measures necessary for the protection of human, animal, or plant life). Because Title III of the Bioterrorism Act does not regulate plant or animal life or associated imports, this Comment focuses on the aspects of the SPS Agreement governing measures intended to protect human life or health.

22. *See id.* art. 2.3 (admonishing that sanitary measures enacted by member countries shall not be applied as disguised restrictions on trade in the form of discrimination between domestic and foreign industry); *see also* Nick Covelli & Viktor Hohots, *The Health Regulation of Biotech Foods Under the WTO Agreements*, 6 J. INT’L ECON. L. 773, 777-78 (2003) (echoing that the Agreement’s purpose is to govern sanitary measures and to limit the possibility that such measures are used as an excuse to restrict trade). *See generally* Kevin C. Kennedy, *Resolving International Sanitary and Phytosanitary Disputes in the WTO: Lessons and Future Directions*, 55 FOOD & DRUG L.J. 81 (2000) (reviewing the major provisions of the SPS Agreement and three of the four cases disputed in the WTO system under the Agreement, and suggesting possible future reforms to clarify and expand the application of the SPS Agreement). The fourth case disputed under the SPS Agreement was decided after the previous article’s publication. *See generally* Appellate Body Report, *Japan—Measures Affecting the Importation of Apples*, WT/DS245/AB/R (Nov. 26, 2003) [hereinafter *Japan-Apples*].

23. SPS Agreement, *supra* note 19, art. 5.1 (requiring all members to produce or obtain supportive risk assessments upon which sanitary measures should be based); *see infra* Part II.B (concluding that Title III violates two key principles of the SPS Agreement—the prohibition on discrimination and the requirement that members obtain risk assessments in support of enacted sanitary measures).

Agreement—focusing on those portions of Title III that adversely impact international trade.²⁴ Part I also presents the WTO case *EC Measures Concerning Meat and Meat Products (Hormones)*,²⁵ the first food regulation case disputed in the WTO system for a violation of the SPS Agreement.²⁶ This case clarified the two major principles of the SPS Agreement that are explored in this Comment: the prohibition on discrimination and the obligation to support trade-restrictive measures with an analytical risk assessment.²⁷ As such, it will be used as a tool to explain these principles and illustrate how a WTO member could successfully dispute Title III's compliance with the SPS Agreement.

Part II of this Comment analyzes Title III's conformity with the SPS Agreement. This Part establishes that Title III is subject to the SPS Agreement because it is a sanitary measure designed to protect human life and health from the threat of deliberate food contamination. Part II then argues that, while motivated by the real threat of bioterrorism,²⁸ Title III nonetheless violates the non-discrimination principle of Article 2.3 of the SPS Agreement by discriminating against foreign imports. Part II also argues that Title

24. See *infra* Part I.A (describing in detail the requirements imposed by the registration and prior notice provisions of Title III on food facilities); see also Peter Menyasz, *Newfoundland Raises Trade Concerns About Proposed U.S. Bioterrorism Regulations*, 20 INT'L TRADE REP. 647, 647 (2003) (describing the Newfoundland government's efforts to appeal to the U.S. government about the new bioterrorism legislation, particularly the prior notice provisions and their resulting impact on Newfoundland's substantial seafood exports to the United States); Daniel Puzin, *U.S. Trading Partners Concerning with Rules for Food Registration Under Bioterrorism Act*, 20 INT'L TRADE REP. 1158, 1158 (2003) (expressing concerns from WTO members such as the European Union, China, and Mexico, among others, that the registration requirements are more trade-restrictive than necessary).

25. Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R (Jan. 16, 1998) [hereinafter *EC-Hormones*].

26. *Id.* ¶¶ 253-255 (setting out the findings and conclusions of the Appellate Body and concluding that Article 5.1 of the SPS Agreement was violated). See generally Dale E. McNiel, *The First Case Under the WTO's Sanitary and Phytosanitary Agreement: The European Union's Hormone Ban*, 39 VA. J. INT'L L. 89, 93 (1999) (conducting a thorough analysis of the initial dispute between the European Union and the United States under the SPS Agreement).

27. See *EC-Hormones*, *supra* note 25, ¶¶ 210-246 (assessing the argument that the European Community ("EC") violated Articles 5.5 and 2.3 of the SPS Agreement, which prohibit discrimination); *id.* ¶¶ 178-209 (addressing the claim that the EC also violated Article 5.1 by maintaining a sanitary measure without adequate support from a risk assessment).

28. See *Challenges Before Indian Food Exporters*, THE HINDU, Nov. 3, 2003, <http://www.hindu.com/biz/2003/11/03/stories/2003110300040200.htm> (opining, in an article of the online edition of India's national newspaper, that the Bioterrorism Act was "clearly intended to prevent the possibility of" a bioterror attack "using the food chain," and disputing the argument that the Bioterrorism Act was motivated by protectionist pressures).

III violates Article 5 of the SPS Agreement because it is a trade restrictive regulation that is not based on a supportive risk assessment. Finally, Part II asserts that, because Title III exempts a large number of direct-to-consumer food sources from its administration, its overall ability to provide bioterrorism protection is significantly diminished.²⁹ This presents the question: if Title III fails to achieve its stated purpose, can it ever comply with the risk assessment principle of the Agreement?

Part III concludes that Title III of the Bioterrorism Act violates two key provisions of the SPS Agreement. Because the Bioterrorism Act as written specifically requires the trade-restrictive measures in question, Title III should be rejected in its entirety to remain consistent with U.S. trade obligations under the WTO.³⁰ This Part then evaluates the implications of Title III's breach of the SPS Agreement. If the United States retains the measure, it risks an adverse decision from the dispute settlement system of the WTO.³¹ In closing, Part III recommends that the United States collaborate with international trading partners in the future to achieve a global bioterrorism solution that is sensitive to trade considerations.³²

I. THE ELEMENTS OF A TRADE DISPUTE: TITLE III OF THE BIOTERRORISM ACT AND THE BASIC OBLIGATIONS UNDER THE WTO AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES

The most basic principle of international trade is that goods and services from exporting countries should enjoy virtually free access

29. See *infra* Part II.B.2.c (highlighting that registration exempts both restaurants and retail establishments from its requirements and arguing that these exemptions create gaping holes in Title III's bioterrorism protection, through which bioterrorists can easily slip).

30. See *infra* notes 244-245 (describing how the letter of the Bioterrorism Act imposes measures that act as barriers to trade and constrains the FDA's ability to lessen its trade-restrictive effects); see also Peter A. Quinter, *Scrap the Bioterrorism Act*, JOURNAL OF COMMERCE 44, Feb. 15, 2004, available at http://www.becker-poliakoff.com/attorneys/bios/quinter_p.html (click on "Scrap the Bioterrorism Act" hyperlink under "Articles") (highlighting numerous problems with the Bioterrorism Act, including the fact that over seventy-five percent of companies failed to register by the required deadline of December 12, 2003, and describing the Act as "an affront to foreign countries" that "will not significantly increase the security of the U.S. food supply").

31. See *infra* note 90 and accompanying text (describing the quasi-judicial dispute settlement mechanism employed by the WTO to resolve trade disputes between WTO members).

32. See *infra* notes 253-254 (suggesting ways in which the United States can join efforts to form international, cooperative bioterrorism prevention proposals already underway).

into an importing country.³³ Tariffs, however, are an age-old mechanism used to protect domestic production from foreign competition by taxing imported goods.³⁴ Non-tariff barriers also exist, which have the same effect of a tariff, but are not in the easily recognizable form of a tax.³⁵ Food regulation has become an increasingly visible issue in trade disputes, as health and safety rules often disguise an underlying intent to favor domestic industry.³⁶

Title III of the Bioterrorism Act acts as a non-tariff barrier and restricts food imports by imposing increased transaction costs and procedural burdens on foreign food exporters trading with the United States.³⁷ As such, it directly conflicts with the objective of the WTO Agreements, and the SPS Agreement in particular, to reduce tariffs and non-tariff regulatory actions that impede free trade.

A. *Title III: Protecting the Safety and Security of the U.S. Food Supply*

In an effort to protect the food supply and prepare the nation for the possibility of a bioterrorist attack, Title III regulations augment the Food and Drug Administration's ("FDA")³⁸ authority over food

33. LAL DAS, *supra* note 18, at 1.

34. *Id.* at 19-27 (classifying and defining various types of tariffs).

35. See TIM JOSLING ET AL., INSTITUTE FOR INTERNATIONAL ECONOMICS, FOOD REGULATION AND TRADE: TOWARD A SAFE AND OPEN GLOBAL SYSTEM 1, 16-21, tbl.2.1 (2004) (categorizing various types of food regulations that may act as non-tariff barriers to trade); see also David G. Victor, *The Sanitary and Phytosanitary Agreement of the World Trade Organization: An Assessment after Five Years*, 32 N.Y.U. J. INT'L L. & POL. 865, 865 (2000) (illustrating that, although one success of the WTO trading system has been a sharp reduction in tariffs, many "governments have kept protectionism in place by simply shifting from tariff to non-tariff measures" to offer domestic industry protection from foreign competition).

36. See generally JOSLING ET AL., *supra* note 35, at 16 (describing a number of different factors that contribute to the growing dispute over food regulation). Because both the observable risk of a given measure and availability of information about potential risks may differ among nations, the benefits of a given regulation may exceed its costs in one nation, but not another. See *id.* at 29 (displaying a graphical analysis of "regulatory underprotection and overprotection"). Also, the general provision of farm support and protection policies, especially in wealthier nations, infuses politics into the already complicated system of regulation and can discourage developing nations from trade on a larger scale. See *id.* at 3-7 (conveying the international impact from the recent "globalization of the food system").

37. See *infra* notes 117-124 and accompanying text (demonstrating the title's negative effect on foreign trade as a result of its restrictions on food imports); see also Sean D. Murphy, *Bioterrorism Act's Notice Requirements for Food Imports*, 98 AM. J. INT'L L. 837, 838 (2004) (calling the Bioterrorism Act's prior notice provision a non-tariff barrier to trade).

38. As the FDA is the federal agency in charge of the majority of food regulation in the United States, its leadership in this area was a natural choice. Meat and dairy products, regulated by the United States Department of Agriculture, are not included under the auspices of Title III, but are touched upon elsewhere. See Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 7 U.S.C.A. § 8401 (West 2006); see also FDA Registration of Food Facilities, 21 C.F.R. § 1.226(g)

imports and enforce specific conditions on food manufacturers.³⁹ The FDA is charged with implementing Title III and has proceeded to do so through its normal process of rulemaking.⁴⁰ Of Title III's various provisions, section 305, Registration of Food Facilities ("Registration"),⁴¹ and section 307, Prior Notice of Imported Foods ("Prior Notice"),⁴² are of great concern to the international trade community because they each impose burdens solely on foreign facilities.

(2006) (exempting facilities regulated by the Department of Agriculture from registration requirements).

39. See 21 U.S.C.A. §§ 331, 334, 381 (West 2006) (expanding the FDA's administrative authority over food imports to prevent the spread of contaminated food articles); 21 U.S.C.A. § 350c (West 2006) (requiring domestic food facilities to maintain records of sales transactions and providing the FDA with the authority to inspect such records as needed).

40. See FDA Bioterrorism Act Homepage, <http://www.fda.gov/oc/bioterrorism/bioact.html> (providing a link to all FDA actions on the Bioterrorism Act generally, Title III specifically, and a summary document titled "FDA Actions on Bioterrorism Legislation"). See generally KENNETH R. PIÑA & WAYNE L. PINES, FOOD AND DRUG LAW INSTITUTE, A PRACTICAL GUIDE TO FOOD AND DRUG LAW AND REGULATION (1998) (giving an overview of food and drug law and explaining the FDA regulatory process governing food and drug products). Under the authority provided in Title III, the FDA has issued both an interim rule and a final rule with respect to registration. See Registration of Food Facilities, 21 C.F.R. §§ 1.225-1.243 (codifying the FDA regulations); Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 70 Fed. Reg. 57,505 (Oct. 3, 2005) (to be codified at 21 C.F.R. pt. 1, 20) (announcing the affirmation of the interim rule [Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,894 (Oct. 10, 2003) (interim rule)] and noting that the final rule does not make any changes to those regulatory requirements established in the interim final rule). For prior notice, the FDA has issued only an interim final rule; however, given the lack of substantive change between the interim and final version of the registration regulation, this likely constitutes the FDA's final determination of how to implement the prior notice requirements. See Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,974 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1) (interim rule); see also Joint FDA-CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes, <http://www.cfsan.fda.gov/~pn/pnplan2.html> (specifying three ways in which the FDA and CBP are partnering on prior notice requirements, and announcing the FDA's intention to publish a final rule on prior notice by June 2005, which has not yet been realized). The majority of references herein will be to the interim rules, with the understanding that for prior notice the interim rule is, in fact, the binding regulation.

41. See 21 U.S.C.A. § 350d (West 2006) (amending Chapter IV of the Federal Food Drug & Cosmetic Act by adding a new section, section 415, to the end of the existing text); see also 21 C.F.R. §§ 1.225-1.243 (implementing section 305 of Title III).

42. See 21 U.S.C.A. §§ 331, 381 (West 2006) (amending section 801 of the Federal Food, Drug & Cosmetic Act by adding a new section, section 801(m)(1), at the end of the existing text); see also FDA Prior Notice of Imported Food, 21 C.F.R. §§ 1.276-1.282 (2006) (implementing section 307 of Title III).

Section 305, Registration, requires domestic and foreign facilities that supply food for consumption in the United States⁴³ to register the name and address of the facility, all applicable trade names under which the facility or parent company operates, and the general food category of the product with the FDA.⁴⁴ Registration is designed to deter bioterrorism by providing a disincentive against intentional contamination,⁴⁵ and to respond to potential threats by facilitating rapid agency response.⁴⁶ Accordingly, non-compliance with registration is a prohibited act and any imports from foreign facilities

43. See 21 U.S.C.A. § 350d(a)(1) (West 2006) (defining the types of facilities that must register under the Bioterrorism Act as any facility “engaged in manufacturing, processing, packing, or holding food for consumption in the United States”). *But see id.* § 350d(b)(1) (exempting farms, restaurants, other retail food establishments, nonprofit food establishments in which food is prepared for or served directly to the consumer, and fishing vessels from Title III requirements); *see also id.* § 350d(b)(3)(B) (providing that if a foreign facility exports to another facility for further processing or packaging, the former facility is not required to register, but the latter is unless the subsequent processing is of a de minimis nature, such as labeling); *id.* § 350d(b)(3)(A) (requiring storage facilities to register, but exempting companies that merely trans-ship food products through the United States, intended for a final destination outside U.S. borders).

44. See *id.* § 350d(a)(1) (listing the various registration requirements); *id.* § 350d(a)(2) (pronouncing that the general food category should be included in registration, if determined to be necessary by the FDA through guidance); *see also* Guidance for Industry on Necessity of the Use of Food Product Categories in Registration of Food Facilities, 68 Fed. Reg. 42,415 (July 17, 2003) (concluding that information about food product categories is necessary for an effective response to food-related emergencies). Other contact information is also required under the FDA rules implementing the registration section. See 21 C.F.R. § 1.232(a)-(b), (e) (codifying the FDA regulations that add to the Title III requirements); Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 5,378 (proposed Feb. 3, 2003) (to be codified at 21 C.F.R. pt. 1) (proposing to add to the Bioterrorism Act the requirement that registration contain: the name of the parent company that owns the facility, if applicable, the phone number of the facility, and an emergency contact); *cf.* Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,894, 58,922 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1, 20) (interim rule) (justifying, in the response to comment 116, the FDA requirements that exceed those imposed by the legislative act).

45. See Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. at 58,951-52 (summarizing the benefits of the new registration provision and explaining that the added capability to trace incidents of contamination may deter individuals from intentionally contaminating the food supply, for fear of subsequent discovery and apprehension).

46. See *id.* (announcing additionally that the increased traceability under registration will enable the FDA to quickly track the roots of any incident of contamination and proceed accordingly to contain any outbreak). The Agency further believes that maintaining emergency contact information for domestic and foreign facilities will permit more timely communication with the FDA to occur and, consequently, allow both the Agency and the facility to respond effectively to limit the effects of a possible contamination. See *also infra* note 50 and accompanying text (clarifying that the role of the U.S. agent, required for foreign facilities, is to serve as a communications link with the FDA in both emergency and routine situations).

that are not properly registered will be detained and barred entry into the United States.⁴⁷

Foreign facilities that import FDA-regulated food products are additionally required to designate a U.S. agent in their registration with the FDA.⁴⁸ The FDA has issued only two requirements with respect to the responsibility, liability, and overall role of the U.S. agent: the agent must reside or maintain a place of business within the United States and must be physically present in the United States.⁴⁹ The agent's sole responsibility is to act as a communications link between the FDA and the facility in order to convey information in both routine and emergency situations.⁵⁰

In addition to the registration requirements, foreign facilities exporting food products into the United States must comply with section 307, Prior Notice, and submit advance notice of all imports in

47. See 21 U.S.C.A. § 331(dd) (West 2006) (making the failure to register in accordance with Title III a prohibited act under the existing Federal Food Drug and Cosmetic Act); 21 U.S.C.A. § 381(c) (subjecting the food product of a foreign facility that fails to register to immediate detainment until proper registration is received by the FDA); see also 21 C.F.R. § 1.241(a) (explaining that, because failure to comply with registration is a prohibited act under 21 U.S.C. § 331, both civil and criminal penalties may apply); *id.* § 1.241(b) (providing that if a facility fails to update its registration—for example, to reflect a change in ownership—the FDA may consequently cancel the registration); *id.* § 1.241(c) (giving the FDA authority to seize and detain any food shipments from foreign food facilities that have not properly registered).

48. See 21 U.S.C.A. § 350d(a)(1)(B); 21 C.F.R. § 1.232(d) (calling for the name, address and phone number of the U.S. agent to be included in the registration of any foreign food facility).

49. See 21 C.F.R. § 1.227(b)(13) (defining a “U.S. agent” and reiterating the two, seemingly similar requirements, that the person designated as “agent” maintain a physical address within the United States and be physically present at that address within the United States); see also *id.* § 1.227(b)(13)(i)-(ii) (defining the communication role of the agent and explaining that the FDA will, for all intents and purposes, treat representations made by the agent as representations of the foreign facility); Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. at 58,915 (describing, in the response to comment 84, the duties of the U.S. agent and clarifying the limited liability protection afforded to agents unless the agent knowingly submits false information to the FDA or the foreign facility and the agent are essentially the same entity).

50. Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. at 58,915. (describing, in the response to comment 85, the agent's communications role and providing the opportunity for facilities to designate an alternative emergency contact). Before publishing its final rule on registration, the FDA allowed comment on just two issues—the cost to foreign facilities of hiring and retaining a U.S. agent and the effect on domestic business if some foreign facilities cease export due to the new agent requirement—illustrating the controversy surrounding this particular provision. See Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 70 Fed. Reg. 57,505, 57,506 (Oct. 3, 2005) (to be codified at 21 C.F.R. pt. 1, 20) (explaining that although the FDA received over 200 comments on the interim rule, it rejected those outside the set scope).

order to gain access to the U.S. market.⁵¹ Prior notice must be submitted electronically⁵² and must include, inter alia, a description of the food article, the identity of the manufacturer, shipper, and grower of the article, the country from which the article originates, and the anticipated port of entry.⁵³ Congress gave the FDA discretion to determine the length of time necessary to receive, review, and respond sufficiently to prior notification submissions.⁵⁴ Accordingly, the FDA established the following scheme for food articles: prior notice must be received a minimum of two hours before arriving by vehicle, four hours before arriving by train or air, and eight hours before arriving by sea vessel.⁵⁵

After prior notice has been received and accepted, the FDA will not allow modifications without restarting the clock.⁵⁶ This means that if, for example, a facility needs to update its prior notice submissions to reflect a change in the anticipated port of entry due to weather conditions, it must submit the modified prior notice anew, either two, four, or eight hours before arrival, depending on the mode of

51. See 21 U.S.C.A. § 381 (West 2006); FDA Prior Notice of Imported Food, 21 C.F.R. § 1.277(a) (2006) (applying the regulation to all food, for humans or animals, that is imported or offered for import, with the exception of those items exempted in subsection (b)).

52. Compare 21 C.F.R. § 1.231(a)-(c) (permitting electronic registration, registration by fax or mail, and CD-ROM submissions for multiple registrations), with 21 C.F.R. § 1.280 (requiring prior notice to be submitted electronically, in English, through either the U.S. Custom and Border Protection ("CBP") Automated Broker Interface ("ABI/ACS") or the newly created FDA PIN System Interface). Prior notice submissions are allowed by email or fax, but only if one or both electronic systems are temporarily malfunctioning. 21 C.F.R. § 1.280(c)-(d). Thus, some facilities will be forced to update their technological capabilities specifically to comply with prior notice.

53. See 21 C.F.R. § 1.281; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,974, 58,978 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1) (interim rule) (listing the information that must be included in a prior notice submission); see also *id.* at 58,980 (comparing, in Table 1A, the information that must be submitted as prior notice for each specific mode of transportation).

54. See 21 U.S.C.A. § 381 (West 2006) (capping the FDA's response time at five days, but otherwise affording the FDA great latitude).

55. See 21 C.F.R. § 1.279; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. at 59,044 (setting forth the required time frame for Prior Notice submissions under option six, which was selected from twelve options considered in the FDA interim final rule); see *id.* at 59,045-46 (displaying estimated costs for option six, in Tables 23-25, including loss in value resulting from prior notice that must be resubmitted; learning, coordination, and technology costs; and the cost of actual employee time to fill out and submit the prior notice information).

56. See 21 C.F.R. § 1.282(a)(2) (explaining the procedure for resubmissions of prior notice, which must be completed each time information changes after the FDA has confirmed receipt of prior notice, and reiterating the fact that resubmissions must be received under the same time frames as an original prior notice submission).

transportation. The FDA believes that the time frames adopted in the interim rule⁵⁷ reduce the need for amended submissions and that its strict stance on modifications is therefore warranted.⁵⁸ Still, some facilities will inevitably experience unexpected change mid-shipment and the FDA's modification policy may prevent these facilities from meeting originally scheduled arrival times or subsequent deadlines.

The purpose of prior notice is to provide more precise information about what food products are being imported into the United States and to enable the FDA to respond to specific bioterrorism threats and prevent the dissemination of contaminated foods.⁵⁹ As a result, any food offered for import without proper prior notice will be

57. The FDA initially proposed that notice be received by noon on the calendar day before the food product arrived for import but, after multiple adverse comments were received, the FDA settled on a shorter time frame (option six) in the interim rule. See Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 5,428, 5,429 (proposed Feb. 3, 2003) (to be codified at 21 C.F.R. pt. 1) (proposing the above-described rule); see also Prior Notice of Imported Food Under the Public Health Security Act of 2002, 68 Fed. Reg. at 59,025 (listing the twelve regulatory options considered by the FDA, assessing the costs associated with each option, and settling finally on option six). Many of the concerned comments dealt with trade between the United States and its neighbors. See, e.g., FASonline Summary, United States-Canada Consultative Committee on Agriculture (Nov. 19, 2004), <http://www.fas.usda.gov/itp/canada/CCA-11-19-04.asp> (noting Canadian concerns that the prior notice rule will result in prohibitive costs for businesses and suggesting an alternative model for goods shipped via truck); Grocery Manufacturers of America, Inc. ("GMA"), Comment on Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness Act of 2002; Notice of Proposed Rulemaking, Apr. 4, 2003, http://www.gma.com/publicpolicy/docs/comment_p.cfm?DocID=1109 (commenting on the problems with the FDA's proposed rule and providing a helpful illustration of how such a requirement would seriously impact business with Canada and Mexico). The GMA's comment questions the efficiency of the enforcement of prior notice and provides the example of a hypothetical Canadian facility, located one hour north of the U.S. border, required to delay shipment after loading a truck in order to provide the required advance notice (two hours) of the truck's specific contents post-loading. *Id.*

58. See Prior Notice of Imported Food Under the Public Health Security Act of 2002, 68 Fed. Reg. at 59,013 ("FDA has chosen timeframes that provide it with very little leeway in the time it has to 'receive, review and respond' to the prior notice submissions. Thus, we concluded that we could no longer permit changes to prior notice without restarting the clock.").

59. See *id.* at 59,064 (predicting that enhanced knowledge of what articles of food are being imported into the United States will help the FDA identify which imports require further inspection and which are safe for entry). The FDA illustrates, in the interim rule, the benefit added by prior notice's increased information by analogizing to its past experience with the potentially devastating consequences of unintentional food contamination. *Id.* at 59,064-65. For example, just one truckload of diseased cantaloupes represents roughly 1,652 servings of fruit. *Id.* at 59,064. If the FDA receives advance information about a similar truckload of intentionally contaminated melons, such as a report that an employee at a facility that ships melons from Mexico to the United States has ties to suspected terrorists, prior notice will permit the FDA to act with Customs and Border Protection ("CBP") to detain the appropriate imports and investigate further, thus preventing the infected cantaloupes from reaching unsuspecting American mouths. *Id.* at 59,065.

refused admission into the United States.⁶⁰ Additionally, if notice is deficient or inaccurate, the FDA may detain the food at port until notice is corrected to its satisfaction.⁶¹ Finally, because the FDA expects registration and prior notice to work together to provide greater protection of the domestic food supply,⁶² failure to register under section 305 is treated as a failure to provide adequate notice under section 307.⁶³

B. The SPS Agreement: Reducing Barriers to the Free Trade of Food

WTO member countries negotiated the SPS Agreement to reduce traditional food disputes, as well as regulations that more subtly inhibit trade,⁶⁴ and to harmonize food regulation and trade conditions using international standards.⁶⁵ As such, the Agreement applies broadly to any regulation that is a sanitary or phytosanitary⁶⁶ measure and has an adverse effect on international trade.⁶⁷ The SPS

60. See Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 21 U.S.C.A. § 381 (West 2006); 21 C.F.R. § 1.283(a)(1)(i) (stating that food imports that reach a U.S. port without a proper prior notice submission will be detained and subject to refusal of admission).

61. See 21 C.F.R. § 1.283(a)(1)(ii)-(iii) (specifying that imported shipments are also subject to refusal of admission when prior notice submissions are inaccurate or not received within the appropriate time frame); Prior Notice of Imported Food Under the Public Health Security Act of 2002, 68 Fed. Reg. at 59,016 (describing that, to the extent possible, exporters submitting prior notice will be notified if the FDA identifies in advance a problem with the submission and the exporters will be allowed to correct the deficiency). If the FDA identifies and provides notice of a problem, but that problem is not corrected, the food article will be subject to normal sanctions, including refusal. *Id.*

62. See Prior Notice of Imported Food Under the Public Health Security Act of 2002, 68 Fed. Reg. at 58,985 (declaring that “[r]egistration is designed to work in concert with prior notice”).

63. See 21 C.F.R. § 1.285 (describing the interrelation between the regulations in Subpart I, governing prior notice submissions, and Subpart H, regulating mandatory registration); see also Prior Notice of Imported Food Under the Public Health Security Act of 2002, 68 Fed. Reg. at 59,022 (emphasizing the importance of registration so that the “FDA knows who is responsible for the information in the prior notice and can communicate with them when necessary”).

64. See SPS Agreement, *supra* note 19, at pmb1. (announcing that WTO members have entered into the SPS Agreement desiring to improve the human health situation in all member countries and to establish a “multilateral framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade”); see also JOSLING ET AL., *supra* note 35, at 40 (asserting that the SPS Agreement was negotiated to reduce trade conflicts, lower transactions costs, and “make it more difficult for countries to shelter domestic industries” behind restrictive regulations).

65. See Victor, *supra* note 35, at 875 (stating that the SPS Agreement’s primary purpose is to promote trade by restricting the use of sanitary measures as trade barriers).

66. The SPS Agreement also applies to phytosanitary measures, which this Comment will not discuss. See *supra* note 21.

67. See SPS Agreement, *supra* note 19, art. 1.1 (affirming that the Agreement applies to all sanitary measures negatively affecting international trade, either

Agreement contains five basic principles⁶⁸ that countries must adhere to when enacting domestic sanitary measures: scientific justification,⁶⁹ non-discrimination,⁷⁰ equivalence,⁷¹ harmonization,⁷² and risk assessment.⁷³

One of the most basic obligations under the SPS Agreement is that members must ensure that all sanitary measures are applied only to the extent necessary⁷⁴ to protect human life and health⁷⁵ and are

directly or indirectly). The Agreement applies to all measures enacted after January 1, 1995 and those pre-existing measures that continue to be in force.

68. See Lisa K. Seilheimer, Note, *The SPS Agreement Applied: The WTO Hormone Beef Case*, 4 ENVTL. L. 537, 548 (1998) (alternatively depicting three broad categories of the Agreement: "Article 2 denotes the basic rights and obligations of Members under the Agreement. Article 3 deals with the goal of establishing consistency of sanitary measures Article 5 imposes the obligation of risk assessment and discusses how Members should determine and apply appropriate sanitary measures").

69. See SPS Agreement, *supra* note 19, art. 2.2 (stating that sanitary measures must be based on scientific principles).

70. See *id.* art. 2.3; see also *id.* art. 5.5 (reflecting Article 2.3 non-discrimination principles by instructing members to avoid arbitrary or unjustifiable distinctions in the levels of protection deemed appropriate in different situations).

71. See *id.* art. 4 (asserting that member countries must accept the sanitary measures of other members as equivalent).

72. See *id.* art. 3; see also *id.* Annex A.2 (defining harmonization as "the establishment, recognition and application of common sanitary and phytosanitary measures by different Members").

73. See *id.* art. 5 (explaining the various risk assessment requirements and emphasizing the need for members to ensure that sanitary measures take into account relevant health risks). It is important to note the somewhat overlapping application of these SPS Agreement principles. For example, the scientific evidence that is required as a basis for measures under Article 2.2 can be used to support a deviation from harmonization with an international standard under the procedure outlined in Article 3.3, and must be taken into account in the assessment of risks under Article 5.2. See *EC-Hormones*, *supra* note 25, ¶ 187 (enumerating the factors to be considered in a risk assessment and focusing on both the consideration of scientific evidence in the form of controlled experiments and the real world risk to human societies); see also *infra* note 85 (discussing the interplay between the risk assessment Articles 5.1 and 5.5, and the non-discrimination Articles 2.2 and 2.3 respectively). Additionally, while discrimination is prohibited explicitly in Article 2.3, it is also incorporated in one of the specific risk assessment principles: Article 5.5. See *supra* note 70 (noting also the relationship between the two non-discrimination articles); *infra* note 228 (describing how there is an additional connection between Article 5.1 and the harmonization principle of Article 3.3, so that a violation of Article 5.1 can trigger, in and of itself, a violation of Article 3.3).

74. A Dispute Panel under the GATT, the international trade agreement that was the precursor to the WTO Agreement, provides some basis for interpreting this term. See Covelli & Hohots, *supra* note 22, at 778 (citing Report of the Panel, *Thailand—Restrictions on Importation of and Internal Taxes on Cigarettes*, Nov. 7, 1990, GATT B.I.S.D. (37 Supp.) (1990)). Covelli & Hohots note that under this Panel's decision a sanitary measure that is not the least trade-restrictive measure available to protect human health will likely violate trade law.

75. See SPS Agreement, *supra* note 19, arts. 2.3, 5.6 (admonishing members to ensure that measures enacted are not more trade restrictive than necessary to achieve the desired level of protection and urging members to avoid applying measures in a manner that would constitute a disguised barrier to trade).

based on scientific principles and evidence.⁷⁶ Members pledge also not to discriminate arbitrarily or unjustifiably where similar conditions prevail; in other words, members cannot impose different conditions on different countries or set different conditions between domestic and foreign industry.⁷⁷ Equivalence provides another opportunity to reduce discrimination between nations.⁷⁸ If an exporting member objectively demonstrates that its own domestic measure provides an equivalent level of sanitary protection to that deemed appropriate by the importing member, the importing member must recognize and accept the equivalent measure.⁷⁹

76. See *id.* arts. 2.1, 2.2 (acknowledging that members have the right to enact appropriate sanitary measures in Article 2.1, but nonetheless requiring, under Article 2.2, that members support those measures with scientific evidence); see also Kennedy, *supra* note 22, at 84 (explaining that members are free to set their own levels of protection, including a “zero risk” level, so long as the level of protection is defensible with scientific justification and Article 5 risk assessment); cf. Victor, *supra* note 35, at 872 (arguing that the scientific justification and risk assessment principles are the two most critical elements of the SPS Agreement). But see SPS Agreement, *supra* note 19, art. 5.7 (permitting members to provisionally adopt sanitary measures on the basis of pertinent available information, as an exception to the scientific justification rule, when relevant scientific evidence is insufficient). This principle, the so-called “precautionary principle,” has been the subject of considerable debate in the international community among academics, legal practitioners, and judges alike. See *EC-Hormones*, *supra* note 25, ¶ 123 & n.92 (discussing the principle, in the context of the EC’s argument that the principle should apply to its ban on hormones, and providing a sample of the differing views on the principle’s application as a rule of international law). Significantly, for the purposes of this Comment, the Appellate Body found that, while the precautionary principle is specifically written into Article 5.7 of the SPS Agreement, an adjudicating body must apply normal principles of interpretation to examine the SPS Agreement as a whole. *Id.* ¶ 124. Therefore, the precautionary principle does not, by itself, override the remaining provisions of the Agreement that are otherwise inconsistent with the principle, such as Article 5, which requires members to complete a risk assessment with relevant scientific evidence. *Id.* Thus, the United States cannot validly assert the precautionary principle in support of Title III or use it to rebut the argument that the title violates Article 5.

77. See SPS Agreement, *supra* note 19, art. 2.3 (compelling members to ensure that the application of sanitary measures is not applied in such a manner as to constitute a disguised restriction on trade); see also *id.* art. 5.5 (requiring, under the risk assessment principles, that different levels of protection be supported by a risk assessment, and that there be no arbitrary distinctions); Victor, *supra* note 35, at 882 (noting the “curious tension” between the non-discrimination articles and the rest of the Agreement, which repeatedly underscores member countries’ ability to set their own levels of appropriate protection).

78. See SPS Agreement, *supra* note 19, art. 4.

79. See *id.* art. 4.1 (directing members to accept exporting countries’ measures when they are shown to provide an equivalent level of protection as the importing countries’ measures); *id.* art. 4.2 (expecting members to consult and negotiate among themselves an equivalent procedure or measure); see also Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems, CAC/GL 34-1999, available at http://www.codexalimentarius.net/web/standard_list.do (listing all available Codex guidelines); Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems, CAC/GL 53-2003, available at http://www.codexalimentarius.net/download/standards/10047/CXG_053e.pdf (outlining

To harmonize conditions between member countries and achieve international consensus with respect to food standards, members are required to base⁸⁰ newly-enacted sanitary measures on existing international standards.⁸¹ For food regulation, the SPS Agreement endorses the guidelines promulgated by the Codex Alimentarius Commission.⁸² However, members may enact more stringent sanitary measures than the relevant international standard⁸³ if the higher level of protection is justified by scientific evidence or based on a risk analysis.⁸⁴ Independent from this requirement, all sanitary measures must be based on a risk assessment.⁸⁵ The risk assessment must

the process to develop and achieve equivalence agreements for inspection and certification systems, to provide guidance to WTO members).

80. See SPS Agreement, *supra* note 19, art. 3.2 (asserting that a sanitary measure that conforms to international standards is permissible per se); see also Kennedy, *supra* note 22, at 85 (noting that the SPS Agreement, in Article 3.2, has built in an incentive that encourages members to comply with relevant international standards by establishing a “rebuttable presumption” that a measure conforming to an international standard is valid).

81. See SPS Agreement, *supra* note 19, art. 3.1 (recognizing that although in some areas of food regulation no international standards exist (an unresolved loophole in the application of the trade agreement) members must, nonetheless, look to international standards for guidance whenever possible).

82. See *id.* Annex A3 (reiterating that the Codex Alimentarius Commission’s standards apply to issues of food safety); see also Codex Alimentarius Commission Website, http://www.codexalimentarius.net/web/index_en.jsp (last visited Nov. 11, 2006) (providing Codex standards in a searchable database and in list form).

83. See SPS Agreement, *supra* note 19, art. 3.3. Paradoxically, the SPS Agreement permits member countries to enact sanitary measures that provide lower levels of protection than the relevant international standards. See Bruce A. Silverglade, *The WTO Agreement on Sanitary and Phytosanitary Measures: Weakening Food Safety Regulations to Facilitate Trade?*, 55 FOOD & DRUG L.J. 517, 520-22 (2000) (arguing that the SPS Agreement, as a trade instrument, fails to provide safe and sanitary foods because of its focus on minimizing trade effects). Silverglade asserts that because nothing in the Agreement allows a member country to challenge another member’s food safety standards as too low, downward harmonization of global food safety standards is inherently built into the trade agreement. Silverglade thus advocates for “an international food safety agreement, not just an international trade agreement on food safety” to upwardly harmonize global food conditions. *Id.* at 517. But see Kennedy, *supra* note 22, at 86 (asserting that the SPS Agreement does not require “downward harmonization” through the adoption of less stringent measures).

84. See SPS Agreement, *supra* note 19, art. 3.3 (stating that members may introduce higher levels of sanitary protection if there is scientific justification, or if the member determines under Article 5 Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection that the higher level is justified); see also Victor, *supra* note 35, at 876 (perceiving that there are two alternatives with respect to international standards: implement the standard, or deviate from it with adequate support).

85. See SPS Agreement, *supra* note 19, arts. 5.1-5.5 (directing members to consider international risk assessment guidelines, available scientific evidence, relevant economic factors, the objective of minimizing negative trade effects, and the principle of non-discrimination in the assessment of risks). Note that the purpose of the risk assessment differs depending on whether the measure in question is intended to protect human or animal life or health, or plant life or health. See *id.* Annex A.4 (stating that a risk assessment to protect human or animal life and health must establish that there is a risk arising from the presence of additives, toxins, or

demonstrate that the measure is necessary to achieve the level of sanitary protection that the WTO member has deemed appropriate.⁸⁶ Furthermore, other WTO members may request justification for deviations from an international standard.⁸⁷

Because all members pledge to abide by the SPS Agreement's restrictive provisions, members have the right to take action against other countries whose sanitary measures are not in compliance.⁸⁸

disease-causing organisms, while alternatively depicting that a risk assessment to protect plant life and health must show the likelihood of entry, establishment, or spread of a pest or disease and the associated biological and economic consequences). Two Article 5 provisions are influenced by other principles of the SPS Agreement. First, Article 2.2 (scientific justification) informs Article 5.1, which contains the basic requirement that members base measures on risk assessments; Article 5.1 can thus be viewed as a "specific application" of the scientific obligations contained in Article 2.2. *EC-Hormones*, *supra* note 25, ¶ 180. The Appellate Body emphasized in *EC-Hormones* that "Articles 2.2 and 5.1 should constantly be read together." *Id.* Second, a violation of Article 5.5 necessarily implicates a violation of Article 2.3 (non-discrimination), because Article 5.5 embodies the non-discrimination principle with respect to the risk assessment requirements. Appellate Body Report, *Australia—Measures Affecting Importation of Salmon*, ¶¶ 243-255, WT/DS18/AB/R (Oct. 20, 1998) [hereinafter *Australia-Salmon*]. In *Australia-Salmon*, the Appellate Body explored the connection between these two non-discrimination provisions of the SPS Agreement and concluded that a violation of Article 2.3 can be established by "following the complex and indirect route worked out and elaborated by Article 5.5." *Id.* ¶ 252. The Appellate Body bolstered this conclusion with reference to its earlier discussion in the *EC-Hormones* case, where it held that Article 5.5 marks out "a particular route leading to the same destination set out in Article 2.3" but stressed that Article 5.5 is not the only route leading to a violation of the first sentence of Article 2.3. *Id.* ¶ 252 n.195 (citing *EC-Hormones*, *supra* note 25, ¶ 212).

86. See SPS Agreement, *supra* note 19, art. 5; *EC-Hormones*, *supra* note 25, ¶ 193 (stating that Article 5, when properly read in conjunction with Article 2.2 (scientific principle), requires that the results of the risk assessment must warrant, or reasonably support, the sanitary measure in question and the corresponding level of protection imposed by that measure).

87. See SPS Agreement, *supra* note 19, art. 5.8 (permitting a member to request justification in the form of a risk assessment for a measure if the member believes the measure constrains, or has the potential to constrain, its exports); see also *supra* note 84 and accompanying text (detailing the procedure to impose a higher level of protection when measures depart from international standards).

88. See SPS Agreement, *supra* note 19, art. 11 (describing the right to consultation and dispute settlement under the Agreement). To date, there have been four cases fully disputed in the WTO for violations of the SPS Agreement. In each, the WTO member was found to have violated the Agreement. See *Japan—Apples*, *supra* note 22, ¶¶ 243-244 (finding that Japan's phytosanitary measure to restrict the import of apples contaminated with *Erwinia Amylovora*, or fire blight, violated Articles 2.2 and 5.1 of the SPS Agreement); Appellate Body Report, *Japan—Measures Affecting Agricultural Products*, ¶¶ 143-144, WT/DS76/AB/R (Feb. 22, 1999) [hereinafter *Japan-Testing*] (holding that Japan's prohibition on the import of eight agricultural products, on the basis that these foods may be a host for codling moth, is a phytosanitary measure that violates Articles 2.2 and 5.1, and also Article 7 of the Agreement (requiring members to notify other WTO members of any changes in their sanitary or phytosanitary measures in an effort to promote transparency between nations)); *Australia—Salmon*, *supra* note 85, ¶¶ 279-280 (concluding that Australia's import ban on fresh, chilled, or frozen salmon caught in the Pacific Ocean is a sanitary measure violating Articles 2.2, 2.3, 5.1, and 5.5 of the SPS Agreement); *EC-Hormones*, *supra* note 25, ¶ 253 (determining that the European

The WTO Dispute Settlement Understanding (“DSU”)⁸⁹ provides a quasi-judicial forum where members may bring disputes and resolve claims of non-compliance with any of the WTO Agreements.⁹⁰ A WTO member can, therefore, bring a dispute against the United States alleging that Title III of the Bioterrorism Act violates U.S. obligations under the SPS Agreement.⁹¹

The case of *EC Measures Concerning Meat and Meat Products (Hormones)* (“*EC-Hormones*”) is relevant to the present issue because it considered, and resolved under the dispute settlement system, allegations that the European Community (“EC”)⁹² had violated the SPS Agreement by discriminating against foreign imports and maintaining a sanitary measure without support from a risk

Community violated Articles 3.3 and 5.1 of the SPS Agreement); *see also* Kennedy, *supra* note 22, at 91-100 (providing an overview of both the Panel and Appellate Body decisions in the cases of *Australia-Salmon*, *EC-Hormones*, and *Japan-Testing*).

89. *See* Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1125 (1994) [hereinafter DSU].

90. *See* William J. Davey, *Has the WTO Dispute Settlement System Exceeded its Authority? A Consideration of Deference Shown by the System to Member Government Decisions and its Use of Issue-Avoidance Techniques*, 4 J. INT’L ECON. L. 79, 79 (2001) (asserting that the DSU is the hallmark of the WTO system and is used extensively by WTO members to resolve trade disputes with other members). *See generally* Kim Van der Borgh, *The Review of the WTO Understanding on Dispute Settlement: Some Reflections on the Current Debate*, 14 AM. U. INT’L L. REV. 1223 (1999) (describing the development of the dispute settlement mechanism as a fundamental change from the former GATT to the current WTO system and reporting that, generally, WTO members who have employed the dispute settlement system to resolve trade disputes are satisfied with its operation); WTO Webpage, Understanding the WTO: Settling Disputes, http://www.wto.org/english/thewto_e/whatis_e/tif_e/displ_e.htm (last visited Nov. 11, 2006) (describing the dispute settlement process as the “central pillar of the [WTO] multilateral trading system” and further defining a dispute as “when one country adopts a trade policy measure or takes some action that one or more fellow-WTO members considers to be breaking the WTO agreements, or to be a failure to live up to obligations”). There are two levels of review in the dispute settlement system. Initially, there is a trial-like review by a Panel, which issues a report with its findings. A WTO member can then appeal a decision of the Panel to the Appellate Body, the highest level of review in the dispute settlement system, which will issue a final determination. WTO Webpage, *supra*.

91. *Cf.* Panel Report, *EC Measures Concerning Meat and Meat Products (Hormones), Complaint by the United States*, ¶ 8.51, WT/DS26/R/USA (Aug. 18, 1997) [hereinafter *EC-Hormones, Complaint by the United States*] (declaring that the complaining WTO member in any dispute under the DSU bears the initial burden of making a prima facie case of non-compliance with the Agreement).

92. The European Community (“EC”) is the predecessor to what is now commonly known as the European Union. *See* RANDY CHARLES EPPING, *A BEGINNER’S GUIDE TO THE WORLD ECONOMY* 111-14 (Vintage Books 3d ed. 2001) (1992) (describing the birth of the European Union). Epping traces the history of European economic unification from the original European Coal and Steel Community, formed in 1957 as a common market for steel and coal among six Western European nations, to the current free-trade “megazone” that is the European Union. *Id.*

assessment.⁹³ Concerned about possible health dangers, the EC imposed an import ban on all meat products from animals injected with growth hormones.⁹⁴ After both the United States and Canada challenged the measure, the Appellate Body in *EC-Hormones* considered principally whether the EC had violated the SPS Agreement's principles of harmonization, discrimination, and risk assessment.⁹⁵

In the context of this Comment, the Appellate Body's construction and interpretation of the obligations under Article 2.3 and 5.5 (non-discrimination) and Article 5.1 (risk assessment) are particularly important. The case outlined a three-part test to determine whether a measure unjustifiably discriminates against other members in

93. See *EC-Hormones*, *supra* note 25, ¶¶ 1-8 (introducing the issues on appeal to the Appellate Body). The Appellate Body consolidated two Panel Reports, resolving complaints lodged against the EC by the United States and Canada respectively, into one case at the appellate level because both Panels consisted of the same three Panel members and considered the identical issue: that of the legitimacy of the import ban on hormone-treated meat products. See *id.* ¶ 1; see also Panel Report, *EC Measures Concerning Meat and Meat Products (Hormones), Complaint by Canada*, WT/DS48/R/CAN (Aug. 18, 1997) [hereinafter *EC-Hormones, Complaint by Canada*]; *EC-Hormones, Complaint by the United States*, *supra* note 91. See generally Victor, *supra* note 35, at 898-904 (outlining the specific findings of both of the Panels and the Appellate Body with respect to the EC import ban on meat products).

94. See *EC-Hormones*, *supra* note 25, ¶¶ 1-5 (laying out the facts on appeal); *EC-Hormones, Complaint by the United States*, *supra* note 91, ¶¶ II.26-33 (describing the events that prompted the EC ban, beginning with the growing, illegal use of diethylstilboestrol (DES) in veal production operations in France, and corresponding European concerns about the health-related risks that might stem from the use of such hormones).

95. See *EC-Hormones*, *supra* note 25, ¶¶ 157-177 (examining the Panels' findings that the EC ban was a more stringent measure than the relevant international standard and, thus, violated the harmonization principles in Articles 3.1 and 3.3 of the SPS Agreement); *id.* ¶¶ 178-209 (discussing the SPS Agreement's requirement that measures be based on a risk assessment under Article 5 of the Agreement); *id.* ¶¶ 210-246, (reviewing the Panels' determinations that the EC ban violated the SPS Agreement by discriminating against foreign industry). The Appellate Body's discussion of the non-discrimination and risk assessment principles is pertinent to this Comment. However, its examination of the principle of harmonization, and explicit reversal of the Panels' holdings on this point, is "perhaps its single most important ruling on SPS-related issues." Victor, *supra* note 35, at 900. Victor explains that the Appellate Body overturned the Panels' interpretations, which would have required sanitary measures to conform to international standards, in favor of a "more common-sense definition . . . [that] a measure can be based on international standards without conforming" to them, thus allowing member countries significantly more flexibility to implement domestic measures. *Id.* (emphasis added). While the Appellate Body reversed a finding of an Article 3.3 violation on this basis, it ultimately concluded that the EC measure was, in fact, inconsistent with Article 3.3 of the Agreement because of the interrelation between the harmonization and risk assessment principles and because of its conclusion that Article 5.1 was violated. See *EC-Hormones*, *supra* note 25, ¶ 209; see also *infra* note 228 (explaining the interactions between Article 3 harmonization and Article 5 risk assessment).

violation of Articles 2.3 and 5.5.⁹⁶ *EC-Hormones* also set forth a framework to analyze a member's obligation to justify sanitary measures with a supportive risk assessment under Article 5.1.⁹⁷ The Appellate Body ultimately determined that the EC import ban did not discriminate against foreign industry,⁹⁸ yet it concluded that the measure violated the SPS Agreement because it was not supported by a proper risk assessment.⁹⁹ This Comment proceeds to analyze Title III under the SPS Agreement using *EC-Hormones* as a guide through the WTO dispute settlement process. Analysis of the Title and analogy to *EC-Hormones* will demonstrate how Title III violates Articles 2.3 and 5.5 of the SPS Agreement by discriminating against foreign

96. See *EC-Hormones*, *supra* note 25, ¶¶ 210-215 (deriving the following three-part test from the text of the SPS Agreement, which determines that Article 5.5 has been violated if: (1) the member failed to require comparable levels of protection in comparable situations; (2) the application of varied levels of protection in comparable situations resulted in arbitrary or unjustifiable differences; and (3) the arbitrary or unjustifiable differences resulted in discrimination or a disguised restriction on trade). Under this holding, all three elements of the test must be satisfied to sustain a violation of Article 5.5. *Id.* ¶ 215; *but cf.* WTO Website, Dispute Settlement System Training Module Chapter 7, Legal Effect of Panel and Appellate Body Reports, http://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c7s2p1_e.htm (explaining that, there is no rule of stare decisis (binding precedent) in WTO proceedings and that the Appellate Body is not required maintain the same legal interpretations it has advanced in the past). However, if the past interpretation is persuasive and its reasoning sound, it is likely a panel or the Appellate Body will subsequently follow it. *Id.*; see, e.g., *Australia-Salmon*, *supra* note 85, ¶ 252 n.195 (discussing and retaining the interpretation of *EC-Hormones* with respect to the interplay between the non-discrimination and risk assessment Articles of the Agreement).

97. See *EC-Hormones*, *supra* note 25, ¶¶ 178-209 (reviewing the Panels' statutory constructions with respect to Article 5, conducting its own examination of the Article, and interpreting Article 5.1 to contain a two-part test that sanitary measures be both procedurally and substantively "based on" a risk assessment conforming to the additional requirements of Articles 5.2-5.6); see also *infra* Part II.B.2.b (outlining the two-part test of Article 5.1).

98. See *EC-Hormones*, *supra* note 25, ¶ 246 (reversing the Panels' conclusions that the European Community acted inconsistently with Article 5.5 or violated the SPS Agreement under that principle); see also Victor, *supra* note 35, at 903 (opining that the Appellate Body deemed the third prong of the discrimination test, whether the differences in levels of protection harmed trade, to be the most important in finding that Article 5.5 was not violated); *infra* Part II.B.1 (comparing the discrimination inherent in Title III regulations to the finding of the Appellate Body in the *EC-Hormones* case).

99. See *EC-Hormones*, *supra* note 25, ¶¶ 198-200, 208 (agreeing with the Panels that the scientific evidence presented by the EC, purportedly to support the hormone ban, merely represented general studies that failed to address the particular risk at issue and, as such, the EC failed to advance "relevant documentation" to support its import prohibition); see also *infra* note 213 and accompanying text (describing the *EC-Hormones* holding with respect to risk assessment and comparing that holding to the assessment of Title III's compliance with the SPS Agreement).

food exporters and further violates the risk assessment requirement of Article 5.1.¹⁰⁰

II. TITLE III VIOLATES U.S. TRADE OBLIGATIONS UNDER THE SPS AGREEMENT AND FAILS TO PROVIDE ADEQUATE PROTECTION AGAINST THE THREAT OF BIOTERRORISM

Title III is subject to the SPS Agreement because it is a sanitary measure and it adversely affects international trade by imposing high costs on foreign exporters seeking access to the U.S. market.¹⁰¹ Despite the FDA's assertions to the contrary,¹⁰² Title III violates U.S. trade obligations under the SPS Agreement. First, Title III discriminates against foreign exporters in violation of Articles 2.3 and

100. This comparison is also appropriate because the import ban at issue in *EC-Hormones* is analogous to Title III's regulation of food imports. First, although Title III is largely a responsive, and therefore innovative, measure to be regulated under the SPS Agreement, it is comparable to the EC ban because both are designed to minimize harmful additives in the food supply and to restrict trade as a result. See Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, pmbl., 116 Stat. 594, 594 (expressing that the Act's purpose is to prevent, prepare for, and respond to bioterrorism); *id.* §§ 301-336, 116 Stat. at 662-81 (codified as amended at scattered sections of 21 U.S.C.A. (West 2006)) (acting with the goal to protect the safety and security of the food supply specifically, under the auspices of the Act's general goal of bioterrorism prevention and response); *EC-Hormones, Complaint by the United States*, *supra* note 91, ¶¶ 2.2-2.10 (describing the EC Directives and banning three naturally occurring and three artificially-produced hormones from being administered to farm animals). Second, highly publicized health incidents instigated both measures. Compare *id.* ¶ 2.26 (explaining that the EC ban responded to reports in the 1970s and 1980s of developmental problems in children, suspected to be caused by hormone-injected meat, and that, as a result of a subsequent consumer boycott of veal and other meat products that severely affected the European market, one goal of the hormone ban was to restore confidence in the market), with Hodge, *supra* note 2, at 254 (detailing how in the United States, the 2001 anthrax attacks ignited widespread concern about the threat of bioterrorism, particularly because the letters were mailed to government and media members in three states and the District of Columbia), and Fidler, *supra* note 2, at 10 (noting the public coverage of the anthrax incidents and that the "nation watched" as the situation unfolded and the government scrambled to respond). See also Research!America, *supra* note 13 (reporting that, shortly after the attacks and before passage of the Bioterrorism Act, nearly ninety percent of Americans doubted the government's ability to prevent or respond to future biological attacks).

101. See *infra* Part II.A (analyzing Title III under the requirements of the SPS Agreement and concluding that the measure is subject to the Agreement's jurisdiction).

102. See Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,894, 58,897 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1, 20) (interim rule); Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,974, 58,981 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1) (interim rule) (questioning Title III's compliance with international trade obligations, under comments to registration and prior notice respectively, with each comment eliciting the same generic FDA response: "FDA is aware of the international trade obligations . . . [and believes these regulations are] consistent with these international obligations").

5.5 because it causes foreign industries to incur significantly increased transaction costs in order to trade with the United States and imposes procedural conditions on foreign facilities alone.¹⁰³ Second, because no risk assessment supports Title III, it further violates Article 5.1 of the Agreement.¹⁰⁴

*A. In an Effort to Protect Americans from Food Bioterrorism, Title III
Inadvertently Restricts International Trade and, Therefore, is Subject to the
SPS Agreement*

The SPS Agreement applies only to those sanitary measures that, directly or indirectly, restrict international trade.¹⁰⁵ Therefore, one must establish primarily that the protectionary measure in question, in this case Title III, is a sanitary measure as defined in the Agreement¹⁰⁶ and then further demonstrate that the sanitary measure negatively impacts trade.¹⁰⁷ Title III is subject to the SPS Agreement because it satisfies the SPS Agreement's broad definition of a sanitary measure and restricts free trade by imposing increased costs exclusively on foreign food exporters.

Title III meets the definition of a sanitary measure as described in the SPS Agreement because it aims to "protect human . . . life or health . . . from risks arising from additives, *contaminants*, *toxins* or disease-causing organisms in foods, beverages or feedstuffs."¹⁰⁸ Title III imposes dual levels of protection against bioterrorism: to prevent an attack using biological agents from being realized, using information provided in prior notice submissions¹⁰⁹ and to respond

103. See *infra* Part II.B.1 (contending that Title III violates the three-part non-discrimination test set forth in *EC-Hormones*).

104. See *infra* Part II.B.2 (analyzing Title III under the two-part framework also announced in *EC-Hormones* and maintaining that the measure fails to satisfy Article 5.1 of the SPS Agreement).

105. SPS Agreement, *supra* note 19, art. 1.1.

106. See *id.* Annex A.1 (providing four alternative definitions, each of which qualify as a sanitary or phytosanitary measure).

107. See Kennedy, *supra* note 22, at 83 (elaborating that the SPS Agreement applies only to measures with direct or indirect effects on trade). Notice that benign measures that ensure sanitary protection but do not harm international trade are not subject to the SPS Agreement. SPS Agreement, *supra* note 19, art. 1.1.

108. SPS Agreement, *supra* note 19, Annex A.1(b) (emphasis added); see Aaron A. Ostrovsky, Note, *The New Codex Alimentarius Commission Standards for Food Created with Modern Biotechnology: Implications for the EC GMO Framework's Compliance with the SPS Agreement*, 25 MICH. J. INT'L L. 813, 823 (2004) (performing a similar analogy to define the "Deliberate Release Directive," a European Community regulation pertaining to the production and movement of genetically modified foods within the European Union, as an SPS measure subject to the SPS Agreement). Ostrovsky explains that the EC ban on hormones qualifies as a sanitary measure under the definition contained in Annex A, subparagraph (a). *Id.*

109. See *supra* note 59 and accompanying text (predicting that prior notice will aid both prevention and response to bioterrorism activities by providing the Agency with

effectively to limit the spread of diseased or infected food products, using registration information and other administrative authority.¹¹⁰

Although the SPS Agreement has traditionally been applied to import bans on specific food products,¹¹¹ nothing in the language, context, or interpretation of the Agreement bars its application to import controls affecting food products generally.¹¹² So long as Title III's protective controls are intended to protect Americans and the American food supply from the danger of deliberate contamination and the use of biological toxins in food, it is immaterial how that level of protection is achieved for the purpose of defining the title as a sanitary measure.¹¹³ The overall purpose of the Bioterrorism Act—to prevent, prepare for, and respond to bioterrorism¹¹⁴—and the specific mandate of Title III—to protect against the purposeful use of biological contamination in the food supply¹¹⁵—demonstrates that Title III can be defined as a sanitary measure to protect human life and health from the dangers of food bioterrorism.¹¹⁶

increased information about food shipments imported into the United States, thus allowing the Agency to preemptively respond to threats and prevent potential contamination from entering the United States, or from being disseminated throughout the United States).

110. See *supra* notes 45 & 46 and accompanying text (listing among the benefits of registration that the provision will help the FDA deter and respond to bioterrorism, thus protecting the American public from bioterrorist activities).

111. See, e.g., *Australia-Salmon*, *supra* note 85 (challenging Australia's import ban on Pacific salmon); *EC-Hormones*, *supra* note 25 (contesting the EC ban on growth hormones in meat products).

112. See SPS Agreement, *supra* note 19, art. 1.1 (describing the broad subjects to which the Agreement applies).

113. See *id.* Annex A.1 (defining sanitary measures broadly, without mention of specific or traditional types of food regulation, such as import bans).

114. *Supra* note 3 and accompanying text.

115. See Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, §§ 301-336, 116 Stat. 594, 662-81 (codified as amended at scattered sections of 21 U.S.C.A. (West 2006)) (clarifying its purpose in the title: "Protecting Safety and Security of Food and Drug Supply").

116. Title III alternatively qualifies as a sanitary measure under the SPS Agreement, which includes approval procedures in the definition of sanitary measures. See SPS Agreement, *supra* note 19, Annex A.2; see also *id.* Annex C.1 (defining approval procedures expansively as procedures to check or ensure the fulfillment of a sanitary measure). Only full compliance with Title III will make a food product eligible for entry into the United States; thus, Title III is an approval procedure under the Agreement. Consequently, Title III is a sanitary measure under either the definition in Annex A.1(b) or under the approval procedure of Annex C. Because the provisions applicable to approval procedures mirror those in the broader Agreement, it is unnecessary to distinguish between the two definitions. Compare *id.* Annex C.1(a) ("Members shall ensure . . . that: (a) such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products."), with *id.* art. 2.3 ("Members shall ensure that their sanitary . . . measures do not arbitrarily or unjustifiably discriminate between Members . . . including between their own territory and that of other Members."). Hence, both the general Agreement and Annex C embrace the

In addition to meeting the criteria of a sanitary measure, Title III's detrimental effect on international trade ultimately subjects it to the Agreement's jurisdiction. Title III is burdensome and costly for foreign food facilities.¹¹⁷ Registration and prior notice provisions discriminate against foreign facilities, both by the letter of the regulation and by the disparate costs imposed. Efficient businesses operate in markets only where it is profitable to do so.¹¹⁸ Rather than incur increased costs and administrative burdens for the privilege to compete in the U.S. market, some foreign manufacturers may simply cease exporting to the United States.¹¹⁹

The FDA has acknowledged the disparate cost to foreign food exporters imposed by registration and prior notice. Of the nearly \$330 million in projected first year registration costs,¹²⁰ the FDA estimates over ninety-three percent will be borne by foreign facilities.¹²¹ This discrepancy only increases in subsequent years.¹²²

notion that a member should not favor its domestic industry over foreign trading industries.

117. *Compare* Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,894, 58,949, tbl.12 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1, 20) (interim rule) (summarizing the total annual cost to foreign food facilities to comply with registration at \$228,800,000), *and* Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,974, 59,046, tbl.25 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1) (interim rule) (computing total annual prior notice costs to foreign food facilities at \$260,633,000), *with* Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. at 58,948, tbl.11 (estimating domestic expenses as a result of registration at only \$6,900,000). Note that there is no corresponding expense to domestic food facilities as a result of section 307 prior notice because this provision is applicable to foreign industry only.

118. *See* EPPING, *supra* note 92, at 9 (providing a basic snapshot of how international trade operates and stressing that trade is a mechanism for wealth, as "[n]o country would sell something abroad unless it could make a profit").

119. *See* Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. at 58,943 (predicting that sixteen percent of food facilities will cease export to the United States rather than comply with Title III provisions); *cf.* Daniel Pruzin, *WTO Review Urges U.S. to Head Off Protectionism; China Criticizes Port Reaction*, 23 INT'L TRADE REP. 437, 437-38 (2006) (citing WTO's past praises of the United States for its role as a "key engine of global growth" in providing the world's largest market for foreign exporters, but current calls for the United States to reduce recent protectionist regulation, including the Bioterrorism Act).

120. Note that this figure is much higher than the amount referenced *supra* in note 7 with respect to registration costs. This is because the amount in note 7 reflects only the cost of the U.S. agent requirement of the registration provision, while the above stated amount accounts for all costs associated with registration compliance, including the U.S. agent costs, as well as expenses for the collection and submission of registration information, periodic updates, and incidental costs of non-compliance. Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. at 58,949, tbl.12.

121. *See id.* at 58,950, tbl.13 (condensing into table form a summary of the predicted costs of registration to all affected food producers in the four years after

The FDA also estimates that first year costs of prior notice, applicable only to foreign industry, will top \$360 million and it projects an annual cost of \$260 million thereafter.¹²³ Therefore, in the first year of implementation, foreign food exporters seeking access to the U.S. market will be forced to pay almost \$670 million¹²⁴ just to comply with Title III registration and prior notice.¹²⁵

While the FDA has modified some of its regulations in an effort to reduce the costs of Title III compliance,¹²⁶ these changes fail to fully

the implementation date). The total foreign share of first-year registration costs is roughly \$306 million. *Id.*

122. *See id.* (forecasting that the foreign share of registration costs will increase to ninety-seven percent for each year predicted after the first year of implementation).

123. *See* Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. at 59,046, tbl.25 (summarizing the estimated costs of prior notice for the first year, and annual costs thereafter).

124. *See supra* notes 121 and 123 and accompanying text (calculating the first-year costs of \$306 million for registration and \$360 million for prior notice, totaling \$666 million for first year Title III costs); Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 70 Fed. Reg. 57,505, 57,507 (Oct. 3, 2005) (to be codified at 21 C.F.R. pt. 1, 20) (finding that the expense of hiring and maintaining a U.S. agent in order to comply with registration will likely remain consistent at \$165 million). Therefore, although the costs of Title III compliance will drop after the first year, foreign facilities will still incur expenses of approximately \$425 million each year thereafter, which domestic facilities will not incur. *See supra* text accompanying note 123 (providing the prior notice figure, which, when added with the above amount of compliance with the U.S. agent requirement, yields the approximate total yearly expenses of registration and prior notice compliance).

125. This financial burden will disproportionately affect small business foreign exporters who have fewer financial resources and ship lower quantities of imports into the United States. As these businesses generally have tight monetary constraints, many are likely to cease export to the U.S. rather than suffer the increased costs. *See* Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. at 58,943 (estimating that of the sixteen percent of firms predicted to cease export to the United States, most facilities that will be affected are small businesses that annually export relatively few items to the United States). In turn, the absence of these exporters from the U.S. trade market will adversely affect domestic small business importers who will be forced to find alternative sources of goods. *See* White House Fact Sheet: Opening New Markets for America's Small Businesses (Mar. 24, 2004), <http://www.whitehouse.gov/news/releases/2004/03/20040324-7.html> (stating that ninety-seven percent of all U.S. exporters are small to medium-sized businesses that likely rely on small business foreign counterparts). *See generally* Onyango & Turvey, *supra* note 15 (reporting that small businesses within the United States fear the domestic economic repercussions of the Bioterrorism Act if some foreign firms are forced out of business).

126. *See, e.g.*, Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. at 58,898 (noting changes in registration regulations with regard to the definition of "food" and "farm" and other general clarifications that will benefit all facilities required to register but do nothing to alleviate the particular cost to foreign facilities of hiring and retaining a U.S. agent); Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. at 58,981 (documenting that the FDA considered its action to reduce the timeframe for

address foreign trade concerns. Foreign facilities are still responsible for the costs of hiring a U.S. agent and submitting prior notice while domestic facilities freely move shipments inside the United States without financial burden.¹²⁷ Consequently, WTO members, whose cries have fallen on deaf FDA ears, can claim that Title III, as a sanitary measure that adversely affects international trade, violates the SPS Agreement.

B. Title III Violates U.S. Trade Obligations to the WTO

Title III violates Articles 2.3 and 5.5 of the SPS Agreement by arbitrarily discriminating against the foreign food industry.¹²⁸ Because the measure is not supported by a risk assessment, Title III also violates Article 5.1 of the Agreement.¹²⁹ Furthermore, plausible arguments¹³⁰ can be made, but which are not the subject of this Comment, that Title III also disregards the remaining major principles under the Agreement of scientific justification,¹³¹ equivalence,¹³² and harmonization.¹³³

submission of prior notice as one of the changes made to minimize the impact of the requirement.

127. See *supra* note 117 (contrasting the financial burden on foreign facilities with the relative financial freedom of domestic industry).

128. See *infra* Part II.B.1.

129. See *infra* Part II.B.2.

130. These arguments are valid, but speculative. For example, with respect to harmonization, the WTO could find that the Bioterrorism Act's deviations from existing standards do not impose higher, but instead comparable, levels of protection. Member's must base measures on international standards and guidelines, but are only required to justify *higher* levels of sanitary protection under Article 3.3. SPS Agreement, *supra* note 19, art. 3.3.

131. The FDA analogized to scientific evidence gathered from past incidents of accidental contamination to express the risk of bioterrorism. See, e.g., Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. at 58,953, tbl.15 (using data from previous accidental food outbreaks, including incidents caused by imported foods, to show the possible costs and risks of a bioterrorist strike against the food supply). However, Title III's measures cannot be justified under Article 2.2 without scientific data signifying the threat and effect of *intentional* contamination. This failure to support Title III with scientific data pertaining specifically to deliberate contamination arguably violates Article 2.1. See *infra* note 217 (highlighting the difference between intentional and accidental food contamination).

132. The FDA has indicated unequivocally that it will not allow any comparable communications link, such as a foreign embassy or designated agent living abroad, to fulfill the U.S. agent requirement. See, e.g., Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. at 58,915 (requesting that the FDA allow the agent for foreign facilities to be located outside the United States, to which the FDA responded that the requirement that the agent be physically present in the United States is "consistent with the plain language of the Bioterrorism Act" and is further consistent with FDA's regulation of other imported products, such as drugs and medical devices). The Agency has also affirmed that any imported food must submit prior notice to gain entry to the U.S. market. See Prior Notice of Imported Food Under the Public

1. *Title III discriminates against foreign industry in violation of Articles 2.3 & 5.5 of the SPS Agreement*

Title III violates Articles 2.3 and 5.5 because it arbitrarily imposes unequal levels of sanitary protection in comparable situations and acts to restrict foreign trade and discriminate against foreign industry. Articles 2.3 and 5.5 work in tandem to prohibit WTO members from maintaining unjustifiably different levels of protection in comparable situations.¹³⁴ These two provisions of the Agreement embody the broader goal of achieving consistency in the application of sanitary measures on a global scale.¹³⁵ Under the three part test

Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,974, 59,016 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1) (interim rule) (rejecting a comment that a waiver should be adopted for imports that are deemed safe but have completed only partial prior notice and stating that such a waiver would be “antithetical” to the goal of prior notice and insisting that admission will be refused to any product with incomplete prior notice). Therefore, any exporting country’s domestic measure that achieves the same level of sanitary protection against bioterrorism through means other than the use of a U.S. agent and prior notice will likely be rejected by the FDA. This implicit prohibition on the use of any equivalent measure designed to prevent and respond to bioterrorism by WTO members directly contradicts the equivalence principle contained in Article 4.2. SPS Agreement, *supra* note 19, art. 4.2.

133. Critics could make an additional argument that Title III imposes a higher level of sanitary protection than the two relevant Codex Alimentarius Commission standards and, thus, is not fully harmonized with international standards. Title III imposes a higher level of protection than the standard for the exchange of information in emergency situations by requiring foreign facilities to designate an agent specifically for the purpose of emergency communication. *See* Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations, Codex Alimentarius Commission Guideline, CAC/GL 19-1995, revised in 2004, available at http://www.codexalimentarius.net/download/standards/36/CXG_019_2004e.pdf (emphasizing that the “global nature of food trade requires that [emergency] communication occur between nations at the appropriate governmental level”) (emphasis added). Title III also adds another level of protection to the international standard for routine food rejections by refusing the importation of pure, uncontaminated foods merely for a lack of technical reporting under registration or prior notice. *See* Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food, Codex Alimentarius Commission Guideline, CAC/GL 25-1997, available at http://www.codexalimentarius.net/download/standards/353/CXG_025e.pdf (noting that the primary reason for imported food rejections is usually food impurities in content or packaging). Accordingly, it is possible that Title III violates, outright, Article 3.3. *See also infra* note 228 (concluding that Title III violates Article 5.1 of the Agreement and discussing the interrelation between this finding and the harmonization principle established in Article 3.3).

134. *See EC-Hormones, supra* note 25, at ¶ 212 (reading Article 5.5 in context with Article 2.3 and finding they elaborate the same objectives); *see also supra* note 85 (explaining the interrelation between Article 2.3 and 5.5 in greater detail).

135. *See EC-Hormones, supra* note 25, ¶ 213 (emphasizing that the objective of Article 5.5 is to achieve “consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection”). The Appellate Body stressed that the goal set is not “absolute or perfect consistency,” but that over time consistency will develop with the continued administration of the SPS Agreement and enforcement against arbitrary or unjustifiable inconsistencies. *Id.*

enunciated in *EC-Hormones*, a member has violated Article 5.5, and by association Article 2.3, if: (1) the member applies different levels of protection in comparable situations; (2) the application of the different levels of protection is arbitrary or unjustifiable; and (3) either discrimination or a disguised restriction on trade results.¹³⁶ A dispute for discrimination under the SPS Agreement will consider each of these three elements.¹³⁷

Title III's registration and prior notice requirements impose disproportionate levels of protection on foreign and domestic food producers. To examine and compare these levels of protection, there are two relevant inquiries: the level of basic protection against contaminated foods under prior notice and the level of responsive protection via increased communication under registration.

Title III imposes different levels of preventative protection between imported and domestic food products. Prior notice is required for foreign imports to prevent contaminated foods from entering the U.S. market.¹³⁸ However, no equivalent reporting procedure is required of domestic facilities before their food products move within the United States.¹³⁹ This artificial distinction appears to rest on the assumption that imported products are more likely to be used as a vehicle for bioterrorism, an assumption that the FDA does not fully justify or support.¹⁴⁰

Domestic facilities are required to establish and maintain certain records under section 306 of the Bioterrorism Act—Maintenance and Inspection of Records for Foods (“Records Maintenance”)¹⁴¹—but

136. *See id.* ¶ 214 (elaborating the three-part test stemming from Article 5.5). In other cases, the Appellate Body has considered factors in addition to this basic three-part test. *See Davey, supra* note 90, at 91 (imparting two additional factors considered in *Australia-Salmon*: “the change in the conclusion between the draft risk assessment and final risk assessment; and the absence of measures controlling internal fish movements within Australia”).

137. *See EC-Hormones, supra* note 25, ¶ 215 (describing the three-part test as cumulative and, as a result, emphasizing that each condition must be fulfilled in order to sustain a violation of Article 5.5); *see also supra* note 96 (explaining that, while prior decisions are not binding in the WTO system, they are given deference if persuasive and well-reasoned).

138. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 21 U.S.C.A. §§ 331, 381 (West 2006).

139. *See id.* (limiting its provisions to “the case of an article of food that is being imported or offered for import into the United States”).

140. *See infra* notes 218-219 and accompanying text (concluding, under the analysis of the risk assessment principle, that Title III maintains an artificial foreign/domestic distinction that is neither explicitly supported by either FDA or Congress, nor is implicitly supported by data of past incidents of intentional food contamination in the United States, which all suggest bioterrorist incidents are more likely to involve domestic persons using domestic food products to carry out attacks).

141. *See* § 306, 116 Stat. at 669-70 (codified as amended at scattered sections of 21 U.S.C.A. (West 2006)) (requiring any domestic individual, partnership or

this regulation is not an equivalent burden on domestic industry. Many companies keep such records in the normal course of business.¹⁴² Moreover, these records need only be documented, but not continually submitted, to the FDA and have no bearing on a domestic facility's ability to transport shipments between states.¹⁴³ In addition, while non-compliance with both prior notice and records maintenance is a prohibited act,¹⁴⁴ only failure to provide prior notice results in seizure and detainment of the food shipment.¹⁴⁵ Accordingly, Title III imposes a stricter level of protection on food imports than it does on corresponding domestic products.

Title III further applies different levels of protection to domestic and foreign food manufacturers in terms of communication requirements. While registration requires both domestic and foreign food facilities to designate an emergency contact,¹⁴⁶ the U.S. agent constraints are more burdensome than the domestic requirements.¹⁴⁷

corporation that manufactures, processes, packs, transports, distributes, receives, holds, or imports food to record the immediate source and recipient of all food goods).

142. See Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. 71,562, 71,566 (Dec. 9, 2004) (to be codified at 21 C.F.R. pts. 1, 11) (describing that the final rule merely requires what many businesses keep as records during normal business recordkeeping and that the Agency recognizes this as an attempt to minimize the burden of additional documentation).

143. See *id.* (reiterating that if a facility's existing recordkeeping system already contains the required information under records maintenance, no additional conditions are required and a facility need only keep such records available for a possible inspection).

144. See FDA Prior Notice of Imported Food, 21 C.F.R. § 1.284 (2006) (making failure to submit prior notice a prohibited act under § 301(ee) of the Federal Food, Drug and Cosmetic Act (codified at 21 U.S.C. § 331(ee) (2000))); FDA Establishment, Maintenance, and Availability of Records, 21 C.F.R. § 1.363 (2006) (designating failure to comply with records maintenance as a prohibited act as well).

145. See 21 C.F.R. § 1.283(a)(1)(i)-(iii) (explaining that imported food will be held within the port of arrival if prior notice is not provided). *But see* 21 C.F.R. § 1.363 (including no corresponding provision in the regulation of section 306 Records Maintenance).

146. See FDA Registration of Food Facilities, 21 C.F.R. § 1.232(e) (2006) (expecting a domestic facility to include the emergency contact phone number with the information submitted for FDA registration); *id.* § 1.232(d) (asking foreign facilities to include the emergency contact phone number of their U.S. agent in registration); *see also id.* § 1.233(e) (allowing foreign facilities to designate an emergency contact other than their U.S. agent, but explaining that the FDA will consider the agent the default emergency contact unless otherwise indicated).

147. Compare Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,894, 58,923, 58,927 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1, 20) (interim rule) (noting FDA changes in the interim rule that lessen the emergency contact information requirements and alleviate the burden for domestic facilities by allowing them to utilize "already established emergency procedures" in providing emergency contact information for FDA purposes), *with id.* at 58,915-16 (suggesting multiple changes in

Domestic facilities are permitted to use existing employees¹⁴⁸ in the role of emergency contact,¹⁴⁹ submit general contact information instead of the name of a specific individual,¹⁵⁰ and can further choose to designate an emergency contact at the corporate level.¹⁵¹ Quite the opposite, foreign firms are specifically constrained to choose an emergency contact for each facility who is physically present in the United States and who must be expressly named.¹⁵²

the U.S. agent requirements to minimize the burden on foreign entities, only to have each dismissed by the FDA).

148. The use of existing employees allows domestic facilities to rotate different employees internally through the role of emergency contact without updating registration information, while foreign facilities must update their registration to reflect any change in their designated U.S. agent most likely to be the default emergency contact under 21 C.F.R. § 1.283(d). *But see* Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. at 58,915 (allowing foreign facilities to use existing contacts in the United States as their U.S. agent, in response to a comment that the U.S. agent requirement is “onerous and potentially trade-restrictive”). However, only ten percent of foreign facilities are estimated to have such contacts readily available that would qualify as a U.S. agent. Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 70 Fed. Reg. 57,505, 57,507 (Oct. 3, 2005) (to be codified at 21 C.F.R. pt. 1, 20); *see* Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. at 58,943 (estimating that, at the time, ten percent of foreign facilities currently had U.S. representatives or existing business contacts within the United States who could function as the U.S. agent for that facility); *cf. id.* at 58,916 (limiting the ability of foreign facilities to use government officials in the United States to act as U.S. agents because of concerns that the duties of the U.S. agent may conflict with the duties of foreign government representation).

149. *See* Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 5,378, 5,384 (proposed Feb. 3, 2003) (to be codified at 21 C.F.R. pt. 1) (permitting domestic facilities latitude in determining how to comply with the domestic emergency contact requirement).

150. *See* Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. at 58,923 (modifying the emergency contact requirements so that domestic facilities do not need to designate an individual if the FDA can contact a live person representing the facility twenty-four hours a day, seven days a week).

151. *See id.* (consenting to a comment that proposed that domestic emergency contact information may be maintained at the corporate headquarters, if determined appropriate for that facility). Ironically, as a result of Title III’s definition of the term “domestic,” a facility located in the United States but owned by an international corporation could be allowed to maintain an emergency contact on foreign soil, at that facility’s headquarters, while foreign owned food facilities are forced to maintain such contacts within the United States. *See* Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 21 U.S.C.A. § 350d (West 2006) (defining a domestic facility by geographic location, as “a facility located in any of the States or Territories” of the United States, not by ownership of the facility).

152. *See* Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. at 58,923 (listing registration requirements for foreign facilities, making mandatory the inclusion of an agent located in the United States); FDA Registration of Food Facilities, 21 C.F.R. § 1.232(d) (2006) (explaining the requirements for a foreign facilities’ emergency contact); *see also supra* notes 48-50 and accompanying text (elaborating on the U.S. agent requirements for foreign facilities).

Additionally, registration requirements will be enforced exclusively against foreign facilities. Food offered for import from a foreign facility that is not registered correctly will be detained and refused entry,¹⁵³ but domestic facilities suffer no corresponding consequence for the same failure.¹⁵⁴ Registration therefore requires a stricter level of protection on foreign food producers by requiring a designated U.S. agent and by seizing and detaining foreign food products from unregistered or improperly registered facilities.

It is not sufficient to merely show Title III's imposition of different levels of protection. Under the three-part *EC-Hormones* test, these differences must also be arbitrary or unjustified and discriminate against foreign trade in order to violate the SPS Agreement.¹⁵⁵

The different levels of protection imposed by Title III are arbitrary because they are based solely on a superficial foreign/domestic distinction. Recent terrorist attacks on the United States have been perpetrated by both domestic and foreign individuals,¹⁵⁶ and previously documented bioterrorism attacks in the United States have largely been deployed against domestic food sources, by domestic persons.¹⁵⁷ There is little compelling evidence to suggest that foreign

153. See 21 U.S.C.A. §§ 331, 381 (West 2006); see also 21 C.F.R. § 1.241(c); *supra* note 47 (describing the various consequences of failing to register, including seizure and detention of the imported shipment or refusal of admission into the United States). As a result of FDA detention, perishable food may spoil or customers may be frustrated by late or canceled shipments, causing foreign facilities to incur incidental costs such as the loss of valuable business contracts.

154. See 21 U.S.C.A. § 381 (West 2006) (mandating consequences for failing to register only for imported food products).

155. See *supra* text accompanying note 136 (explaining the three-part test); see also *EC-Hormones*, *supra* note 25, ¶¶ 219-246 (describing the final two parts of the three-part test and applying the test to determine if the different EC levels of protection were arbitrary and unjustified and a violation of Article 5.5).

156. Two visible attacks on the World Trade Center in New York demonstrate the acts of external, foreign terrorists. See Alexander, *supra* note 13, at 71-72 (describing the activities of foreign-based al-Qaeda and Osama bin Laden, including the 1993 attack on the World Trade Center); Christopher Drew & Judith Miller, *A Nation Challenged: Washington Concerned By Moves of Saudis*, N.Y. TIMES, Sept. 19, 2001, at B4 (reporting that the majority of the suspected September 11th hijackers were of Saudi Arabian descent). However, the United States also has a history of domestic terrorist attacks. See Elizabeth Gleick, *Who Are They? The Oklahoma Blast Reveals the Paranoid Life and Times of Accused Bomber Timothy McVeigh and his Right-Wing Associates*, TIME, May 1, 1995, at 44 (providing a history of the suspects in the Oklahoma City bombing—Timothy McVeigh, originally from New York, and the Nichols brothers, originally from Michigan—which has been described as the worst incident of domestic terrorism in the United States); Frank Rich, *Connect the Dots*, N.Y. TIMES, Apr. 30, 1995, at E15 (arguing that the domestic opposition to abortion clinics in the United States will join the Oklahoma City bombing in the chapter of the “history of home-grown American terrorism in the 1990’s”); see also Richard Lacayo, *How Safe is Safe? Americans Must Decide How Much Freedom They Are Willing To Trade For More Security*, TIME, May 1, 1995, at 68 (describing how Americans are now coping with the real threat of domestic terrorism).

157. *Infra* note 219.

imports are more susceptible than equivalent domestic food products for use as bioterrorist agents,¹⁵⁸ or that communication with foreign facilities in emergency situations would be significantly more problematic than similar domestic communication.¹⁵⁹

This mirrors the finding in *EC-Hormones*, where different levels of protection were applied based on a distinction between the intended purposes for administration of the hormone and whether the hormones present were naturally occurring or purposefully added.¹⁶⁰

158. The FDA is apparently most concerned with foreign food imports. See Frederick Golden, *What's Next? It Could Be Smallpox, Botulism, or Other Equally Deadly Biological Agents*, TIME, Nov. 5, 2001, at 44 (relaying the concerns of then Secretary of Health and Human Services, Tommy Thompson, about the susceptibility of the nation's food supply to contamination, focusing on imports in particular). If a bioterrorist attack is planned and carried out by a foreign bioterrorist, it is reasonable to assume that foreign food sources would be used because they are more accessible to the bioterrorist. However, the events of September 11th proved that foreign terrorists often plan attacks from within a targeted nation's border and utilize domestic resources. See Kevin Sack & Jim Yardley, *After the Attacks: U.S. Says Hijackers Lived in the Open with Deadly Secret*, N.Y. TIMES, Sept. 14, 2001, at A1 (reporting that several men suspected by the FBI to have carried out the September 11th attacks received flight training at the Flight Safety Academy in Vero Beach, Florida); see also Joel Achenbach, *'You Never Imagine' A Hijacker Next Door*, WASH. POST, Sept. 16, 2001, at A1 (detailing how some of the September 11th hijackers had lived in the United States for years prior to the attacks, seemingly "act[ing] like normal human beings, nothing abnormal"). The implicit FDA assumption that foreign imports carry a greater bioterrorism risk must, therefore, be premised upon a belief that the United States faces terrorism primarily perpetrated by foreign individuals using foreign, not domestic, sources. This is generally true given the United States' most recent experience with terrorism. Long-term, however, for both this country and most others, terrorist acts are carried out by dissent domestic groups. See Alexander, *supra* note 13, at 65-67 (describing both historical terrorism and contemporary terrorism, using examples from various regions of the world, as involving acts of domestic individuals uprising against a domestic government). Alexander explains that only recently has terrorism taken on an international dimension. *Id.* at 66. Additionally, the assumption that bioterrorists, as a particular subset of terrorists, are likely to be foreign individuals does not comport with the FDA's experience with bioterrorism thus far. See *supra* note 157 and accompanying text.

159. See Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,894, 58,952 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1, 20) (interim rule) (requiring more complete emergency contact information from foreign food facilities because of past difficulties contacting facilities due to incomplete information in agency records). However, presuming that communication to foreign facilities broke down as a result of difficulties in reaching the actual facility, not in contacting the foreign embassy, the same communication difficulties would just transfer to the U.S. agent. *Id.* The FDA could achieve the same communications objective by holding foreign facilities to the domestic requirements—allowing them to designate an internal emergency contact on call twenty-four hours a day, with the added proviso that the contact be fluent in English. This would eliminate any problems due to language barriers or time zone constraints.

160. See *EC-Hormones*, *supra* note 25, ¶ 218 (outlining five different levels of protection that the EC applied, as identified by the Panel). These levels of protection include:

Notably, the Appellate Body found the distinction maintained between the administration of growth hormones in cows, on the one hand, and the use of feed additives to enhance development in pigs, on the other hand, was “unjustifiable in the sense of Article 5.5.”¹⁶¹ Both substances had carcinogenic characteristics, and were therefore potentially harmful to human life and health.¹⁶²

Similarly, there is no fundamental difference between a food product, such as an apple, that is grown domestically and shipped within the United States and one that is produced internationally and shipped into the United States. The only distinguishing characteristic of the apples is the country of origin.¹⁶³ Because both apples have virtually identical composition, each is equally susceptible to biological contamination. Thus, similar to the finding in *EC-Hormones*, the maintenance of different levels of protection under Title III is not rationally justified, but rather arbitrary.

Additionally, Title III’s arbitrary imposition of different levels of protection discriminates against foreign industry and discourages trade. Despite its recognition of an arbitrary distinction, the Appellate Body in *EC-Hormones* determined that the EC’s prohibition of growth hormones was not discriminatory because it applied equally

-
- the level of protection in respect of natural hormones when used for growth promotion;
 - the level of protection in respect of natural hormones occurring endogenously [or naturally] in meat and other foods;
 - the level of protection in respect of natural hormones when used for therapeutic or zootechnical purposes;
 - the levels of protection in respect of synthetic . . . hormones when used for growth promotes; and
 - the level of protection in response of carbadox and olaquinox.

Id.

161. *Id.* ¶ 235.

162. *See id.* ¶¶ 226-235 (highlighting the parallel “genotoxic” and carcinogenic nature of carbadox, olaquinox and growth hormones and rejecting the EC’s various attempts to distinguish these substances or prove a justifiable distinction). The Panel found an arbitrary distinction between the maintenance of different standards for artificially injected hormones and naturally-occurring hormones, which the Appellate Body explicitly overturned. *Id.* ¶ 220. Unlike the Panel, the Appellate Body concluded there was a fundamental distinction between natural and synthetic hormones and stressed that the regulation of all naturally occurring hormones, present in virtually every animal producing subsequent meat products, would require an “absurd” level of administrative oversight. *Id.* ¶ 221 (describing that the oversight would “entail[] such a comprehensive and massive governmental intervention in nature” that it would impede upon the everyday, ordinary lives of the people). With respect to hormones administered for growth promotion purposes and therapeutic or zootechnical purposes, the Appellate Body held that there existed also an inherent and justifiable difference between these administration purposes. *Id.* ¶¶ 223-225.

163. *Cf. infra* note 219 and accompanying text (arguing that a distinction based on country of origin is unjustified).

to beef produced within the European Union and beef imports.¹⁶⁴ With respect to Title III, however, the different levels of protection are applied only according to the origin of the food product. This substantial difference in levels of protection demonstrates plain discrimination.¹⁶⁵ This discrimination, in turn, restricts trade by creating considerable costs for foreign exporters.¹⁶⁶ Therefore, Title III violates Articles 2.3 and 5.5 because it arbitrarily and unjustifiably discriminates against foreign industry and restricts international trade.

2. *Title III is not based on a proper risk assessment under Article 5.1*

Despite repeated demands for a risk assessment to support the Bioterrorism Act,¹⁶⁷ neither the United States nor the FDA has made such an assessment available for the purposes of the SPS

164. See *EC-Hormones*, *supra* note 25, ¶¶ 244-246 (concluding that the Panel erred in determining that there was an arbitrary or unjustifiable difference in the levels of EC protection that resulted in discrimination on foreign industry).

165. See Report of the Appellate Body, *Japan—Taxes on Alcoholic Beverages*, 18-31, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (Oct. 4, 1996) (exploring the different levels of taxation imposed on domestic and imported products and arguing, based on a parallel provision of the GATT, that significant differences in levels of protection may be sufficient to result in discrimination on trade); *cf.* *EC-Hormones*, *supra* note 25, ¶ 236 (considering and rejecting the Panel's conclusion, based on *Japan—Taxes on Alcoholic Beverages*, that different protection alone may prove discrimination under the SPS Agreement, but acknowledging that it is still an important factor). Indeed, this may have been the most important factor considered in *EC-Hormones*. See Victor, *supra* note 35, at 903 (reviewing the Appellate Body's findings with respect to the discrimination principle and arguing that the third factor, whether an arbitrary difference in protection harmed trade, was most relevant considering the SPS Agreement's objective to reduce trade barriers).

166. See *supra* Part II.A (concluding that Title III has an adverse impact on international trade because it imposes considerable costs on foreign facilities alone); see also *supra* notes 120, 124 (explaining the difference between the total cost of foreign compliance with registration and the separate cost for the U.S. agent requirement and providing an estimate of total annual costs to comply with registration and prior notice). Compare Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. 71,562, 71,612, tbl.1 (Dec. 9, 2004) (to be codified at 21 C.F.R. pts. 1, 11) (predicting recurring annual costs on domestic facilities for records maintenance, in addition to normal business recordkeeping, at \$123 million), with Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,974, 59,046, tbl.25 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1) (interim rule) (forecasting recurring annual costs of \$260 million on foreign facilities for prior notice; thus demonstrating that prior notice is more than twice as costly as the domestic records maintenance requirement).

167. See, e.g., European Commission, Comments of the European Commission on implementing rule of US Bioterrorism Act, Registration of Food Facilities, Apr. 4, 2003, at 1, http://ec.europa.eu/food/international/trade/reg_food_fac_en.pdf ("The U.S. should provide such a risk assessment as requested by the SPS Agreement to both justify the proposed measure and ensure that any potential risks are addressed in an effective and proportionate manner.").

Agreement.¹⁶⁸ The importance of a valid, supportive risk assessment cannot be overstated. All four cases disputed under the SPS Agreement focused on the need for, and the lack of, a proper risk assessment in finding against the domestic legislation under consideration.¹⁶⁹

The FDA has published a risk assessment concerning food terrorism.¹⁷⁰ However, the purpose of this assessment is to communicate the risk of foodborne illness from acts of food terrorism and incidents of unintentional contamination to the American public, not to comply with the SPS Agreement.¹⁷¹ Thus, the United States has failed to comply with Article 5 of the SPS Agreement because it has produced no specific risk assessment, or, to public knowledge, performed an assessment,¹⁷² for the express purpose of supporting the Bioterrorism Act.¹⁷³

168. See SPS Agreement, *supra* note 19, art. 5.8 (requiring WTO members to respond to requests for justification of trade restrictive measures by providing supportive risk assessments).

169. See *Japan-Apples*, *supra* note 22, ¶¶ 189-216, 243(d) (discussing arguments that Japan violated Article 5.1 and concluding that the analysis presented by Japan failed to satisfy the definition of “risk assessment” established in Annex A, paragraph 4 of the SPS Agreement); *Japan-Testing*, *supra* note 88, ¶¶ 109-117, 143(f) (evaluating arguments that Japan’s testing requirement for certain fruits (apricots, pears, plums, and quinces) violated Article 5.1 and finding the measure was not based on a risk assessment, therefore breaching the SPS Agreement); *Australia-Salmon*, *supra* note 85, ¶¶ 42-54, 112-178, 279(c)-(d) (reviewing claims that Australia’s salmon import violated Article 5.1 and 5.5 of the SPS Agreement and finding that Australia breached both Articles due to the lack of proper risk assessment); *EC-Hormones*, *supra* note 25, ¶¶ 82-96, 178-246, 253 (considering the Panel’s finding that the EC had violated numerous provisions of Article 5 and ultimately deciding that the EC violated only Article 5.1 because its measure was not substantively based on a risk assessment of hormone-treated beef); see also Davey, *supra* note 90, at 92 (stating that “the major issue in SPS cases so far has been a failure to conduct a risk assessment or base a measure on the assessment”).

170. See Risk Assessment for Food Terrorism and Other Food Safety Concerns, 68 Fed. Reg. 59,078 (Oct. 10, 2003) (notice) (announcing the availability of the FDA Risk Assessment concerning food terrorism in an effort to inform the public and improve the Agency’s “ability to prevent, prepare for, and respond to an incident of food sabotage”).

171. See FDA RISK ASSESSMENT, *supra* note 13, pt. I (stating that the purpose of the FDA Risk Assessment is to educate the public of the risks inherent in acts of food terrorism).

172. *But see* Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,894, 58,952 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1, 20) (interim rule) (stating that the FDA commissioned two threat assessments, one by the Batelle Memorial Institute and a second by the Institute of Food Technologists, to evaluate the vulnerability of the U.S. food supply). However, the results of these assessments are classified. *Id.* As such, neither has been made available to the public, nor submitted in support of Title III’s compliance with the SPS Agreement.

173. See SPS Agreement, *supra* note 19, art. 5 (describing the need for a risk assessment to determine that a member’s adopted level of protection is appropriate); see also *EC-Hormones*, *supra* note 25, ¶ 190 (explaining that Article 5.1 does not insist that a member carry out its own risk assessment, only that a measure be based on

Assuming arguendo that the FDA Risk Assessment is offered for the purposes of the SPS Agreement, it is still not sufficient to support Title III. The assessment is too redacted to provide useful information or inform an independent review of the threat of bioterrorism,¹⁷⁴ and it addresses the broad category of food contamination without adequate focus on the specific incident of food bioterrorism.¹⁷⁵ More significantly, it fails by the letter of Article 5 to fulfill the procedural and substantive requirements of a supportive risk assessment. Finally, it is possible that no risk assessment could adequately support Title III as currently implemented because Title III's ability to provide sufficient protection against bioterrorism is weakened by the number of direct-to-consumer food sources that are exempted from the regulation.¹⁷⁶

a. General deficiencies of the FDA Risk Assessment

The FDA Risk Assessment is generally deficient as an evaluation of the risk of bioterrorism because it fails to address the particular threat or effect of intentional food contamination.¹⁷⁷ The FDA relies primarily upon classified information to evaluate the vulnerability of the food supply and the risk of bioterrorism, leaving many aspects of its analysis obscurely unexplained.¹⁷⁸ While the Agency identifies

some risk assessment, and that a measure "might well find its objective justification in a risk assessment carried out by another Member, or an international organization"). The requirements that the measure be "based on" a risk assessment, and that a member must produce an assessment to justify a disputed measure under Article 5.8 remain regardless of who performs the assessment. See *infra* notes 199-201 and accompanying text (concluding that Title III is *not* "based on" any published risk assessment available; thus, the United States has violated Article 5.1).

174. See FDA RISK ASSESSMENT, *supra* note 13 pt. I, ¶ 5 ("This Risk Assessment uses scientific evidence on food terrorism to the extent that it exists and is available, but balances this disclosure with the need to maintain the integrity of classified information."). This paragraph goes on to note that the assessment is based "solely on unclassified information." *Id.*

175. See, e.g., *id.* at pt. II.B (analyzing the likely magnitude of the risk, in terms of severity and duration of effect, by equating accidental and deliberate contamination and relying on reports of the spread of foodborne disease caused by unintentional contamination).

176. See *infra* Part II.B.2.c.

177. See *EC-Hormones*, ¶¶ 182-184 (interpreting the treaty definition of a risk assessment to require a two-step process, as laid out in paragraph four of Annex A of the SPS Agreement). This process requires a risk assessment to first "identify the adverse effects on human health (if any) arising from the [specific risk at issue]" and "if any such adverse effects exists, evaluate the potential or probability of occurrence of such effects." *Id.* ¶¶ 183-184 (alteration in original).

178. See FDA RISK ASSESSMENT, *supra* note 13, pt. I (disclosing at the outset that the assessments performed by the FDA to assess the risk of food terrorism are largely classified in nature); see also *supra* text accompanying note 174.

biological agents that could be used as bioterrorist weapons,¹⁷⁹ and suggests the threat to the U.S. food supply is “more than theoretical,”¹⁸⁰ it also admits the difficulty of predicting with any certainty the likelihood that a bioterrorist attack will actually occur.¹⁸¹

Understandably, no one is able to predict precisely the threat of bioterrorism. Indeed, as a precautionary measure, other nations have reported heightened states of alert for biological attacks via air, food, or water.¹⁸² However, if the FDA possesses information that more specifically identifies the bioterrorism threat to the food supply, such materials should be made available in a more detailed and transparent assessment to other WTO members.¹⁸³

In addition, the FDA relies heavily on reports of foodborne disease caused by *unintentional* contamination to demonstrate the potential reach of food outbreaks,¹⁸⁴ but fails to identify the consequences of a

179. See, e.g., FDA RISK ASSESSMENT, *supra* note 13, pt. II.A (listing *Bacillus anthracis* (anthrax) and *Clostridium botulinum* (botulism) as deadly Category A agents, which are high-priority agents because of their potential impact on human life and health).

180. *Id.* pt. II.C, ¶ 5; see *id.* at pt. II.C, ¶¶ 6-7 (documenting some unclassified reports of terrorist organizations' attempts to acquire biological materials, such as a Federal Bureau of Investigation (“FBI”) report that documents recovered in Afghanistan mentioned the use of nicotine and solanine, two naturally occurring toxins, as poisons in terrorist activities); see also WORLD HEALTH ORG., TERRORIST THREATS TO FOOD: GUIDANCE FOR ESTABLISHING AND STRENGTHENING PREVENTION AND RESPONSE SYSTEMS 1 (2002) (warning that “[t]he malicious contamination of food for terrorist purposes is a real and current threat”).

181. See FDA RISK ASSESSMENT, *supra* note 13, pt. II.C, ¶ 2 (noting that “it is difficult for FDA to predict with any certainty the likelihood that an act of food terrorism will occur”); see also Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,894, 58,952 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1, 20) (interim rule) (describing that because the probability of a bioterrorist attack occurring and the exact reduction of risk as a result of the new registration provisions is unknown, the FDA has analogized to past outbreaks resulting from domestic incidents of accidental and intentional food contamination to illustrate the cost of foodborne public health emergencies); Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,974, 59,064 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1) (interim rule) (admitting that because the FDA “lacks data to estimate the likelihood of a strike occurring,” the agency again used a comparison to the risk associated with accidentally contaminated imported foods).

182. WORLD HEALTH ORG., *supra* note 180, at 2.

183. If the U.S. government does disclose other classified information that was used as the basis for the FDA Risk Assessment, or another assessment otherwise supporting Title III, this Comment's analysis that the United States violated Article 5.1, *infra* Part II.B.2.b, could change, as classified information may tend to show that the measure is in fact amply supported. Without such information, however, and in light of the fact that the U.S. has not yet provided any information of a risk assessment despite many requests from international trading partners, this Comment's current analysis holds true.

184. See FDA RISK ASSESSMENT, *supra* note 13, pts. II.B-D (assessing the effect, exposure, and risk of a successful bioterrorist attack by analogizing to unintentional food contamination, instead of providing information pertaining specifically to *intentional* contamination); see also *supra* note 181 (describing how the FDA

successful and *intentional* food attack.¹⁸⁵ Although “risk assessments need not be based entirely on research in the physical sciences[,] nor . . . examine only quantitative risks,”¹⁸⁶ an assessment must be applied to the particular risk that the disputed sanitary measure is designed to prevent.¹⁸⁷ The FDA Risk Assessment, which does not provide an analysis of the effect a specifically targeted bioterrorism attack would have on the food supply, is lacking in this respect.

b. The FDA Risk Assessment fails to satisfy the procedural and substantive requirements of Article 5.1 and does not demonstrate reasonable support for Title III

In addition to these general problems, the FDA Risk Assessment also fails to satisfy the specific procedural and substantive requirements of Article 5.1. The Appellate Body in *EC-Hormone* derived a procedural and substantive requirement from two important words in Article 5.1: “Members shall ensure that their sanitary . . . measures are *based on* a[] [risk] assessment. . . .”¹⁸⁸

The procedural element requires that a member initially obtain a risk assessment, which serves as the basis for an enacted measure.¹⁸⁹ The *EC-Hormones* Panel construed the term “based on” to establish a “minimum procedural requirement” that a member actually “took into account”¹⁹⁰ certain studies and assessments in forming the measure in dispute.¹⁹¹ While the Appellate Body in *EC-Hormones*

analogizes to events of unintentional contamination to assess the risks of bioterrorism and the costs of the new regulations, under both registration and prior notice interim rules).

185. See FDA RISK ASSESSMENT, *supra* note 13, pt. II.B (describing illness and death, economic effects, and sociological and political implications such as public fear and anxiety as the consequences of accidental food outbreaks, but failing to account for any consequences of intentional contamination).

186. See Victor, *supra* note 35, at 901 (highlighting that the Appellate Body in *EC-Hormones* stressed that risk assessments need not be fully and completely supported by scientific information).

187. See *EC-Hormones*, *supra* note 25, ¶¶ 204-209 (emphasizing that a risk assessment must support the specific risk targeted in the domestic measure at issue, and finding that because the EC risk assessments only generally addressed the risk of growth hormones without specifically addressing the risk of improper administration of hormones (the impetus of the EC ban), the EC measure was not supported).

188. See *id.* ¶ 179 (emphasis added) (alteration in original) (quoting SPS Agreement, *supra* note 19, art. 5.1).

189. See SPS Agreement, *supra* note 19, art. 5.1 (listing the basic risk assessment principle); see also *EC-Hormones*, *supra* note 25, ¶¶ 188-191 (discussing the procedural requirement of Article 5.1); *supra* note 85 and accompanying text (explaining Article 5 in detail).

190. *EC-Hormones, Complaint by Canada*, *supra* note 93, ¶ 8.116; *EC-Hormones, Complaint by the United States*, *supra* note 97, ¶ 8.113.

191. See *EC-Hormones*, *supra* note 25, ¶¶ 188-189 (relaying and discarding the Panel’s textual interpretations of Article 5).

rejected the Panel's textual construction,¹⁹² it embraced the Panel's underlying legal reasoning.¹⁹³ The Appellate Body re-affirmed that the term "based on" requires that a member, at a minimum, obtain a risk assessment that forms the basis for the disputed measure.¹⁹⁴

Next, the assessment must substantively support the measure.¹⁹⁵ This substantive element involves a two part inquiry: first, an examination of the scientific conclusions reached in the assessment and implicit in the enacted measure and, second, an evaluation of the relationship between the two sets of scientific conclusions.¹⁹⁶ Ultimately, the risk assessment must demonstrate reasonable support for the disputed measure.¹⁹⁷ Thus, "there is not only a procedural requirement to obtain a risk assessment," but also a "substantive requirement that there be a *rational relationship* between the measure and the risk assessment."¹⁹⁸

Title III is not procedurally "based on" the FDA Risk Assessment. The Bioterrorism Act was enacted on June 12, 2002, well before the publication of this assessment.¹⁹⁹ Furthermore, nothing in the Act acknowledges the FDA Risk Assessment, or any other risk assessment, in support of the measure.²⁰⁰ It is also unclear how the FDA Risk Assessment may have shaped the registration or prior notice regulations implementing Title III, which were published

192. *See id.* ¶ 189 (preferring to retain the language specifically used in the Agreement to remain consistent with the principle of plain language interpretation, rather than adopt the "take into account" language employed by the Panel, for which no textual basis exists in Article 5).

193. *Id.* (rejecting the Panel's textual interpretations, but rearticulating the Panel's basic legal argument that there is an inherent procedural requirement in Article 5).

194. *Id.* (announcing the term "based on" compels a "certain *objective relationship* . . . that persists and is observable between an SPS measure and a risk assessment").

195. *See id.* ¶ 193 (requiring that the results of the obtained risk assessment also "reasonably support" the measure as a substantive matter).

196. SPS Agreement, *supra* note 19, art. 5.1; *see EC-Hormones*, *supra* note 25, ¶¶ 192-209 (explaining the substantive requirement of Article 5.1).

197. *EC-Hormones*, *supra* note 25, ¶ 193.

198. Victor, *supra* note 35, at 901 (quoting, in part, *EC-Hormones*, *supra* note 25, ¶ 193).

199. *See* Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, pmb., 116 Stat. 594, 594 (noting the date of enactment as June 12, 2002).

200. *See id.* (failing to mention any supportive risk assessment or other scientific study to justify the legislative act); *see also EC-Hormones*, *supra* note 25, ¶ 191 (pointing out that preambles of legislative acts or administrative regulations commonly fulfill requirements of WTO members, such as identifying scientific support for a measure under the SPS Agreement). The Appellate Body does acknowledge, however, that the absence of reference to a scientific study is not dispositive proof that no scientific support exists because such preambles are not a requirement of any WTO Agreement, including the SPS Agreement. *EC-Hormones*, *supra* note 25, ¶ 191.

simultaneously with the FDA Risk Assessment.²⁰¹ Therefore, the FDA Risk Assessment could not logically have formed the basis for Title III because it was published after the Act's passage and simultaneously with the implementation of the regulations.²⁰²

Title III is also not substantively "based on" the FDA Risk Assessment because the scientific conclusions contained in the risk assessment fail to justify the conclusions implicit in the regulation. The FDA Risk Assessment concludes that there is a hazard that deadly pathogens could be used as bioterrorist agents²⁰³ and that a successful attack could impact human life and the nation's economic vitality or cause sociological and political ramifications.²⁰⁴ The assessment repeatedly stresses the uncertain nature of bioterrorism and correspondingly, the Agency's inability to fully assess the threat of

201. See *supra* notes 7, 17, 170 (listing October 10, 2003 as the date of notification in the Federal Register of the availability of the FDA Risk Assessment, as well as the publication date for the FDA interim rules on registration and prior notice, respectively).

202. This argument assumes that the FDA Risk Assessment is the only assessment FDA or Congress could have consulted in the formation of Title III and its regulations. This assumption is warranted because as of yet, no other risk assessment has been identified by either party. However, it is important to note, as the Appellate Body did, that Article 5 does not require that the member in question have performed the risk assessment upon which the measure is based. Instead, the member must clearly offer any designated, "substitute" risk assessment in support of its measure. *EC-Hormones, supra* note 25, ¶¶ 41, 190; see *supra* text accompanying note 173.

203. See FDA RISK ASSESSMENT, *supra* note 13, pt. II.A, ¶ 1-2 (describing activities of the CDC, even before the 2001 anthrax attacks, to identify and rank several food pathogens as critical agents for possible terrorist attacks, among which anthrax and botulism ranked as "Category A" high-priority substances). However, the assessment further notes that the majority of biological agents identified by the CDC were classified as "Category B" agents because they are moderately easy to disseminate and cause moderate to low morbidity, which is the ratio of observable deaths to total population. *Id.*

204. See Joseph A. Levitt, *CFSAN's Program Priorities: From Food Safety to Food Security*, 58 FOOD DRUG L.J. 19, 20 (2003) (cautioning that if a bioterrorist attack is successful, "the result could be significant morbidity and mortality [human health effects] as well as significant economic loss"); see also FDA RISK ASSESSMENT, *supra* note 13, pt. II.B.1 (considering the possible impact of bioterrorism on human life and health by using CDC data documenting the annual effect of accidental contamination in the United States at 76,000,000 illnesses, 325,000 hospitalizations, and 5,000 deaths); *id.* pt. II.B.2 (describing at least three types of economic effects generated by food terrorism: direct economic loss from the cost of response, indirect effects suffered by industry, and international ramifications, such as trade embargoes or other trade reactions to contaminated U.S. products); *id.* pt. II.B.3 (highlighting the potential social impact of bioterrorism as parallel to the public hysteria experienced in the United States when Bovine Spongiform Encephalopathy ("BSE") or "mad cow disease" was discovered in British cattle in the late 1980s). The assessment also explains that societal fears and anxieties produced by such an event could reduce confidence in the political system and governing bodies or result in political destabilization, as was experienced by Great Britain during the mad cow crisis. *Id.*

future attacks.²⁰⁵ However, the FDA documents some evidence of terrorist plans to acquire biological contaminants²⁰⁶ and notes the “unique susceptibility” of food products generally.²⁰⁷ Implicit in Title III and its implementing regulations are three conclusions: (1) increased oversight of food suppliers can deter deliberate food contamination;²⁰⁸ (2) advanced notice of the entry of foreign foods into the United States will enable the FDA to investigate reported threats;²⁰⁹ and (3) increased avenues of communication can reduce the spread of any successful attack.²¹⁰

The fatal flaw of the FDA Risk Assessment is that it fails to demonstrate reasonable support for Title III or show that the measure is substantively “based on” the assessment’s scientific

205. See FDA RISK ASSESSMENT, *supra* note 13, pt. II.C (acknowledging that uncertainty must factor into the risk assessment); see also *supra* note 181 and accompanying text (describing repeated instances where the FDA admits it lacks the information and capability to fully assess the threat, likelihood, or magnitude of a bioterrorism attack).

206. See FDA RISK ASSESSMENT, *supra* note 13, pt. II.C (pointing out the seizure of U.S. agricultural documents that had been translated into Arabic from an Al Qaeda location in Afghanistan, and a report from the U.S. Central Intelligence Agency that in 2003, the British investigated a suspected Al Qaeda plot to poison their troops’ food supplies).

207. See *id.* at pt. II.C, ¶ 4 (relying on information from CDC experts that describes how the relative centralization of food production in the United States, and the distribution of food products on a global scale, creates a vulnerability in the food supply to wide-scale sabotage).

208. See Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,894, 58,951-52 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1, 20) (interim rule) (listing the FDA’s expectation that registration will deter bioterrorists by making their activities traceable).

209. See Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,974, 59,064 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1) (interim rule) (presuming that increased information about imported foods will help the FDA match bioterrorism intelligence to imported food shipments and therefore enhance containment of food products that are in fact adulterated at port); see also Matthew T. McGrath & Cortney O’Toole Morgan, *Business Regulation: Customs Law*, 37 INT’L LAW. 245, 253-54 (2003) (describing how the Prior Notice of Imported Food rule provides the FDA with increased inspection authority).

210. See Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. at 58,952 (expecting that updated registration contact information and the specific designation of a U.S. agent will accelerate the FDA’s communication with food facilities post-incident, so that the effects of a potential bioterrorist attack could be contained through quick, coordinated agency and facility reaction to the outbreak); see also Levitt, *supra* note 204, at 24 (stressing the need for improved communication and coordination to limit biological contamination’s effects and praising Title III’s registration provisions that allow the FDA to quickly conduct trace-back investigations to map out the contamination route).

conclusions.²¹¹ This mirrors the specific finding in *EC-Hormones*.²¹² Although the EC submitted various risk assessments in support of its measure, the scientific conclusions contained therein revealed that the banned growth hormones generally did not pose a threat to human life or health.²¹³ Accordingly, the Appellate Body concluded that the EC import ban was not warranted.²¹⁴ Similarly, nothing in FDA's Risk Assessment establishes that requiring foreign importers to provide prior notice before importing food into the United States, or to designate a U.S. agent, will protect human life or health from potential acts of bioterrorism.²¹⁵

There are two reasons why the FDA Risk Assessment substantively fails to provide reasonable support for Title III. First, it is far too broad in scope. All food, from both domestic and foreign sources, and all types of contamination, both accidental and deliberate, are lumped together,²¹⁶ despite the fact that intentional contamination is a distinct danger.²¹⁷ Title III unilaterally imposes increased regulation on foreign imports, but the assessment fails to sufficiently

211. See *infra* notes 217-227 and accompanying text (arguing that there is no rational relationship between the FDA Risk Assessment and Title III and its regulations, and explaining why the assessment fails the substantive requirement).

212. See *EC-Hormones*, *supra* note 25, ¶ 208 (concluding that “no risk assessment . . . reasonably supports or warrants” the EC import prohibition).

213. See *id.* ¶ 206 (concluding that most if not all of the scientific studies referred to the Panel by the EC found that the use of the banned hormones for growth promotion in animals was safe); see also Victor, *supra* note 35, at 899 (declaring that “[u]nfortunate for the EC’s position, however, was the fact that every risk assessment of these hormones had shown that growth hormones applied according to good veterinary practices would result in no significant harm to humans,” including at least two reviews commissioned by the EC itself).

214. See *EC-Hormones*, *supra* note 25, ¶ 207 (reviewing the EC’s scientific reports and data and concurring with the Panel decision that this evidence presented a “theoretical framework” for the analysis of the effect of growth hormones, but did not “investigate and evaluate” the actual problems the EC claimed to be experiencing as a result of hormone-treated meat).

215. See *supra* notes 208-09.

216. See FDA RISK ASSESSMENT, *supra* note 13, pt. II.B (analyzing all types of contamination, including some deliberate acts, as well as data from accidental outbreaks originating from domestic and foreign sources to assess the risk of bioterrorism).

217. Bioterrorism, by definition, is specifically targeted to cause maximum human casualties and thus can be significantly different from accidental food outbreaks in terms of exposure and spread of the contamination. See Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,894, 58,952 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1, 20) (interim rule) (admitting that an intentional attack on the food supply would probably be significantly more costly, and sicken many more U.S. citizens, than an act of accidental food contamination). But see FDA RISK ASSESSMENT, *supra* note 13, pt. II.B, ¶ 1 (defending the analogy to unintentional contamination, calling attention to the similarities between the two forms of contamination, and describing the risk to consumers as “comparable, regardless of whether the contamination was deliberate or accidental”).

demonstrate that imported foods carry a higher risk of use in biological attacks or are more susceptible to deliberate contamination.²¹⁸ In fact, the exact opposite appears to be true. Past incidents of food bioterrorism in the United States, targeted at Americans themselves or specific American food sources, have all been perpetrated by individuals living in the country and using *domestic* food sources.²¹⁹

A risk assessment must evaluate the specific risk mitigated by the establishment of the sanitary measure; it should not simply demonstrate a cognizable threat.²²⁰ The EC hormone ban was rejected because its risk assessments considered only the general effects of hormone use, without appropriate focus on the six banned hormones or the hormones' potential to negatively affect meat products in particular.²²¹ In similar fashion, the FDA Risk Assessment pertains to the entire category of food contamination, without appropriate concentration on the actual threat of purposeful, biological contamination of imported food products.²²²

218. See FDA RISK ASSESSMENT, *supra* note 13, pt. II.A (characterizing the risk of certain biological agents, but failing to identify any distinction between the threat of bioterrorism attempted on domestic versus foreign food products).

219. See Hodge, *supra* note 2, at 255 (reciting past incidents of bioterrorism, which were all domestic incidents). Hodge describes bioterrorism events dating back to the American colonial period, when British and French troops exchanged dry goods intentionally contaminated with smallpox with Native Americans. He also lists two major bioterrorism attempts on U.S. soil in the late twentieth century: a foiled plot to poison water supplies in Midwestern cities with typhoid bacteria, resulting in the arrests of several Chicago citizens; and the 1982 contamination of local salad bars with salmonella to disrupt a local Oregon election. *Id.* In closing, Hodge notes that the FBI, the federal agency responsible for, inter alia, investigations of domestic threats of terrorism, has investigated hundreds of claims of bioterrorism threats in the years after the 2001 anthrax attacks. *Id.* Note, however, that each of these attacks occurred by *domestic* persons who used *domestic* food products already in the United States. *Id.*; see FDA RISK ASSESSMENT, *supra* note 13, pts. I-II.A (listing past acts of domestic deliberate food contamination, including those reported in the Hodge article, but failing to identify any past acts of deliberate food contamination originating from foreign sources); cf. Alexander, *supra* note 13, at 81-82 (describing the endeavors of the Aum Shinrikyo Japanese cult to release numerous biological and chemical agents on the people of Japan over the last thirty years, including a highly publicized successful attack on the Tokyo subway system using the nerve gas sarin, thus revealing that other countries grappling with bioterrorism concerns also face a demonstrated risk from domestic persons using domestic means of attack).

220. See *EC-Hormones*, *supra* note 25, ¶ 203 (stating that the risks articulated by the EC did not address the specific substances at issue because they merely pronounced general problems with control over the hormones, and finding that the EC's articulated risks were insufficient to show that the hormones in dispute actually posed a real threat to human life and health).

221. *Id.* ¶ 199 (noting that the EC risk assessments applied to entire *categories* of hormones, rather than narrow application to the specific risk of growth hormones and that the assessments further failed to evaluate the carcinogenic effects of hormones in food, specifically meat products).

222. FDA RISK ASSESSMENT, *supra* note 13, pt. I.

Second, the scientific conclusions implicit in Title III and the FDA's regulations focus on the need for increased communication, whereas the conclusions derived from the FDA Risk Assessment support increased controls on biological agents, but not post-attack response mechanisms.²²³ The FDA document contains no specific assessment of the magnitude, effect, or potential reach of a bioterrorist attack,²²⁴ yet Title III purports to minimize the risk of bioterrorism by reducing the spread of an outbreak.²²⁵ Because the risk assessment fails to explore the effect or potential spread of a deliberate food attack, it likewise fails to justify responsive measures.²²⁶ This is comparable to the *EC-Hormones* finding that the EC's responsive measure to prevent the consumption of harmful growth hormones was not scientifically justified because its risk assessments failed to consider the particular risk in the administration of the banned growth hormones in cattle and instead, merely asserted generalized claims of the hormones' carcinogenic properties.²²⁷ In conclusion, because Title III is neither procedurally nor substantively "based on" the FDA Risk Assessment, it violates Article 5.1 of the SPS Agreement.²²⁸

223. Compare *id.* pt. II.A (characterizing the likelihood of bioterrorist targeting of certain biological agents as weapons), with Public Health Security and Bioterrorism Preparedness and Response Act of 2002, tit. 2, Pub. L. No. 107-188, 116 Stat. 594 (codified as amended in scattered sections of 7 U.S.C.A., 18 U.S.C.A., 21 U.S.C.A., and 42 U.S.C.A. (West 2006) (increasing federal controls over biological agents). Title II of the Bioterrorism Act is clearly warranted by the scientific findings in the FDA Risk Assessment, which demonstrate that certain biological agents are in fact very harmful to human life and health, namely, anthrax and botulism, which are identified in the FDA Risk Assessment as "Category A" agents, and supplies of such toxins should be properly protected). FDA RISK ASSESSMENT, *supra* note 13, pt. II.A.

224. See FDA RISK ASSESSMENT, *supra* note 13, pt. II.B (characterizing the magnitude of the risk based on unintentional contamination only).

225. See *supra* text accompanying note 46 (listing the communication benefits of registration and how they are designed to limit the effective spread of biocontaminants).

226. See FDA RISK ASSESSMENT, *supra* note 13, pt. II.B (limiting the assessment explicitly to unintentional food contamination).

227. See *EC-Hormones*, *supra* note 25, ¶ 200 (holding that the studies, articles, and opinions submitted by the EC failed to address the particular risk at stake, as required by paragraph four in the Annex of the SPS Agreement, which describes the purpose of a risk assessment and what it should achieve); see also *supra* note 85 (detailing the SPS Agreement requirements in Annex A).

228. Cf. *EC-Hormones*, *supra* note 25, ¶ 209 (concluding that the EC violated Article 5.1 and finding that because the import ban was more stringent than the relevant international standard, and as a result of the interrelation between the harmonization and risk assessment principles, the EC measure was also inconsistent with Article 3.3 (harmonization) by failing to comply with Article 5.1.). Compare this to the above finding that Title III violates Article 5.1 and the inference that, by implication, Title III thus violates Article 3.3. Consider also the author's assessment that Title III independently violates the harmonization principle. *Supra* note 133 and accompanying text.

c. Title III exempts a number of significant food sources and fails to achieve its stated level of bioterrorism protection

Although most domestic and foreign facilities are required to register with the FDA, Title III exempts a large number of domestic direct food-to-consumer sources from registration that would have equal, if not greater, adverse impacts on the food supply if deliberately contaminated.²²⁹ While practical for other regulatory purposes, these exemptions critically undermine the Act's overall ability to achieve bioterrorism protection, especially with regard to its goal of deterrence.²³⁰ Most importantly, these exemptions make the possibility of conformity to Article 5 even more unfeasible because no risk assessment can support imposition of the measure if the sanitary measure will not achieve its stated level of protection.²³¹

Title III excludes over two million American farms²³² from registering with the FDA,²³³ any of which would each make an easy target for bioterrorists.²³⁴ While subsequent food processing would

229. See 21 U.S.C.A. § 350d(b)(1) (West 2006) (describing that the term "facility" does not include: "farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels"); FDA Registration of Food Facilities, 21 C.F.R. § 1.226 (2006) (explaining which facilities are not required to register with the FDA); see also *supra* note 43 and accompanying text (describing the above, and other, exemptions from registration requirements).

230. See Lovett, *supra* note 3, at 477-81 (claiming that the Bioterrorism Act "curiously exempts" multiple facilities in which foods are prepared for or served directly to the consumer with little explanation or justification). Lovett hypothesizes that terrorist groups could easily tamper with food in these exempted establishments all over the country and create havoc in the food supply. *Id.*

231. See SPS Agreement, *supra* note 19, art. 5. A risk assessment must explain the reasons for a sanitary measure designed to achieve a given level of protection. See *id.* art. 5.8. If, however, flaws in the application or coverage of the sanitary measure mean that it will not achieve that level, a risk assessment purportedly supporting the measure will also fail. This is because a risk assessment cannot support what the measure cannot do; that is, if the exemptions to Title III so critically weaken the assessment's ability to provide protection from the risk of intentional food contamination, no risk assessment submitted in support of Title III can demonstrate that it will, in fact, protect against bioterrorism. *Id.*

232. See United States Department of Agriculture Homepage, Data and Statistics, http://www.nass.usda.gov/Census/Create_Census_US.jsp (in "Step 2," select "Farms (number);" in "Step 3," select "All States, United States;" click "Add;" click "Get Data") (last visited Nov. 10, 2006) (documenting the U.S. Department of Agriculture's account of the total farms in the United States, per 2002 census data, at approximately 2,100,900).

233. See 21 U.S.C.A. § 350d(b)(1) (exempting farms from registration).

234. See Radford B. Davis, *Agroterrorism: Need for Awareness*, in PERSPECTIVES IN WORLD FOOD AND AGRICULTURE 353-416 (Colin G. Scanes & John A. Miranowski eds., 2004), available at <http://www.actionbioscience.org/newfrontiers/davis.html> (describing agriculture as the "perfect target" for bioterrorists, also called agroterrorism). Radford explains that the agriculture industry is unmatched in revenue and scope, as more than twenty-four million Americans are employed directly in the agriculture industry and food accounts for over thirteen percent of the

likely limit the effects of deliberate contamination of farm animals or crops, accidental foodborne diseases from farm products have severely impacted human health and the vitality of the U.S. food market in the past.²³⁵ Despite the fact that forty percent of Americans eat two to three meals weekly at restaurants and fast food establishments,²³⁶ Title III also exempts restaurants and other retail establishments.²³⁷ Since these types of establishments are generally a responsibility of the states,²³⁸ Congress may have lacked jurisdiction to regulate them, or determined that their registration was unnecessary to the effectiveness of the Act.²³⁹ There is, however, no assurance that the food supply is fully safe from bioterrorism while the Bioterrorism Act exempts from its protective measures facilities that deliver food directly to American consumers.

In light of these significant exemptions, which weaken the Bioterrorism Act's protective purpose, Title III may never be supported as a valid sanitary measure under the SPS Agreement. Article 5 requires a risk assessment to show that a sanitary measure is necessary to achieve the level of protection deemed appropriate by a certain member, in this case protection against intentionally contaminated foods.²⁴⁰ Here, gaping holes in the application of Title

U.S. Gross Domestic Product ("GDP"), one measurement of the size of an economy. As the United States is a world leader in food production, if any one of its major food products, including corn, soy, cattle, or poultry, were significantly affected by a bioterrorist act, the result could be "catastrophic." Consequently, agroterrorism should not only concern the farmer, but also businesses such as suppliers, transporters, grocery stores, or restaurants, as well as the end consumer, who could all expect to suffer from bioterrorism's effects. *Id.*

235. See, e.g., FDA RISK ASSESSMENT, *supra* note 13, pt. II.B.1, ¶ 3 (detailing how one of the largest reported food outbreaks involved unintentional biological contamination of milk with *Salmonella typhimurium*, during the pasteurization process at a farm facility that resulted in the hospitalization of nearly 170,000 Americans).

236. See *How and Where America Eats*, CBS Poll, Nov. 20, 2005, <http://www.cbsnews.com/stories/2005/11/20/opinion/polls/main1060315.shtml> (providing poll data that reveals twenty-one percent of Americans ate at a restaurant for at least two or three meals in a week, and that seventeen percent of the same group polled for the same time frame had eaten at fast food establishments).

237. 21 U.S.C.A. § 350d(b)(1).

238. See Lovett, *supra* note 3, at 478 n.121 (citing *Kellogg Co. v. Mattox*, 763 F. Supp. 1369 (N.D. Tex. 1991), for the proposition that the oversight and administration of these facilities falls under the jurisdiction of the individual states, not the federal government, to provide one reason for the exemption in section 305 registration).

239. See *id.* at 478 n.120 (noting from her research of the legislative history of the Bioterrorism Act that there is little clarification as to why the exemptions are in place, but at least some indication that Congress members may have considered registration of these facilities "unnecessary" for the Bioterrorism Act as a whole to be effective). Lovett cites to a public document recording part of the Senate amendments to the Act in its initial stages in support. *Id.* (citing H.R. REP. NO. 107-3448 (2001)).

240. See *supra* note 231 and accompanying text.

III allow various avenues for bioterrorists to strike the food supply. Therefore, no risk assessment may ever adequately support the need for Title III as a sanitary measure because of the inherent flaws that render it ineffective.

III. LOOKING TO THE FUTURE: IMPLICATIONS OF THE WTO VIOLATION AND RECOMMENDATIONS FOR A FUTURE BIOTERRORISM PLAN THAT IS BOTH EFFECTIVE AND INTERNATIONALLY SENSITIVE

As demonstrated above, persuasive arguments can be made that Title III of the Bioterrorism Act violates the WTO SPS Agreement. First, Title III discriminates against foreign food imports in violation of Articles 2.3 and 5.5 of the Agreement and erects administrative barriers to trade.²⁴¹ Moreover, the measure is unsupported by an assessment of risk as required under Article 5.1.²⁴² These violations are significant: the majority of disputes under the SPS Agreement have focused on either a failure to conduct or sufficiently base a measure on a risk assessment, or a breach of the Agreement's non-discrimination principles.²⁴³

The Bioterrorism Act as written specifically requires both of the trade-restrictive measures in question.²⁴⁴ Consequently, the FDA cannot be less trade-restrictive in implementing the title because it is constrained by the language Congress selected.²⁴⁵ If Title III cannot be changed or implemented in a less trade-restrictive manner through agency regulation, it should be abandoned in order to remain consistent with WTO trade obligations.

241. See *supra* Part II.B.1 (analyzing Title III under the three-part discrimination framework and concluding that because the measure arbitrarily imposes different levels of sanitary protection on domestic versus foreign-produced food products and the restriction negatively impacts foreign trade, it violates Article 5.5, and by implication Article 2.3, of the SPS Agreement).

242. See *supra* Part II.B.2 (evaluating the FDA Risk Assessment under a presumption that it would be offered in support of Title III, and determining that Title III is neither procedurally nor substantively based on the FDA assessment and therefore violates the risk assessment requirement of Article 5.1 of the SPS Agreement).

243. Davey, *supra* note 90, at 90.

244. See Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 21 U.S.C.A. §§ 331, 350d, 381 (West 2006) (applying the registration and prior notice requirements by the letter of the legislation to all foreign manufacturers).

245. See, e.g., Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,894, 58,915 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1, 20) (interim rule) (responding twice to suggestions to modify the U.S. agent requirements and recognizing that the FDA has acted consistently to structure the agent requirements by the plain language of the Bioterrorism Act, as Congress intended).

Should the legislation be retained, there is a significant risk that a dispute lodged against the United States in the WTO system would be successful.²⁴⁶ The “one very powerful, central element of the WTO . . . is its ability to deliver equity’ through dispute settlement.”²⁴⁷ Overall, WTO members express overwhelming support for the dispute settlement system,²⁴⁸ despite a somewhat varied history with respect to enforcement of decisions.²⁴⁹ Generally, the United States has complied with WTO decisions²⁵⁰ and in this case, should an

246. See *supra* Parts II.B.1-II.B.2 (making the case that Title III violates two articles of the SPS Agreement, either of which would support an adverse finding against the United States).

247. Daniel Pruzin & Christopher S. Rugaber, *Officials Predict Rise in Dispute Cases at WTO After Collapse of Doha Trade Talks*, 23 INT’L TRADE REP. 1124, 1124 (2006) (quoting Australia’s Trade Minister, Mark Vaile); see Daniel Kalderimis, *Problems of WTO Harmonization and the Virtues of Shields Over Swords*, 13 MINN. J. GLOBAL TRADE 305, 311-12 (2004) (asserting that the dispute settlement mechanism is the most important instrument in the WTO’s arsenal and has helped it to achieve a level of institutional power that sets it apart from other international organizations). Kalderimis calls the system an “important success” and praises its mandatory, legalistic, and binding resolution of international trade disputes. *Id.*

248. See Van der Borgh, *supra* note 90, at 1225 (“If there is one point of agreement among the WTO [m]embers . . . it is their general satisfaction with the [dispute settlement] system.”); see also EPPING, *supra* note 92, at 49 (noting that even if a country does not agree with a decision of the WTO, it is always in the country’s best interest to remain within the WTO framework). Van der Borgh conveys numerous praises of the system. She notes that the dispute settlement mechanism has strengthened the multilateral system as a whole, acting as a neutral and impartial body in which positive and satisfactory solutions are rendered. Van der Borgh, *supra* note 90, at 1225. Its most frequent praise is that it provides a predictable, rules-based forum for resolution of disputes. *Id.* Additionally, complainants in the system are generally satisfied by successful rulings. See Davey, *supra* note 90, at 80-81 (reviewing all 38 Panel and 28 Appellate Body reports from 1994 until 2000 to analyze member countries’ satisfaction with the system and its impact on members’ national powers); Pruzin & Rugaber, *supra* note 247, at 1124 (relaying comments that the dispute settlement process has increasingly worked well to resolve disagreements between WTO members).

249. For example, the EC hormone dispute is still raging. See Daniel Pruzin & Gary G. Yerkey, *WTO Approves U.S., Canada Sanctions on EU of \$124.5 Million in Beef Hormone Dispute*, 16 INT’L TRADE REP. 1158, 1158 (1999) (conveying the WTO approval of trade sanctions imposed upon the EC by the United States and Canada because of the EC’s refusal to remove the import ban on hormone-treated beef). In the most recent development, the EC has attempted to support its continued ban on hormone-treated meat imports with a new risk assessment. See Daniel Pruzin, *U.S., Canada Fault EU Risk Assessment in WTO Dispute Over Hormone-Treated Beef*, 23 INT’L TRADE REP. 1455, 1455 (2006) (reporting arguments that the European Union has once again failed to produce scientific evidence in the form of a risk assessment sufficient to support its ban).

250. *E.g.*, Esther Lam, *U.S. to Implement WTO Decision that Rejected Use of Zeroing Method*, 23 INT’L TRADE REP. 1203 (2006); see Esther Lam, *EU Will Not Appeal WTO DRAMs Ruling; U.S. Will Implement Korea CVD Decision*, 22 INT’L TRADE REP. 1305 (2005) (stating that both the European Union and the United States will comply with WTO rulings in favor of Korea’s free export of dynamic random access memory semiconductors (DRAMs)); see also Raj Bhala & David A. Gantz, *WTO Case Review 2004*, 22 ARIZ. J. INT’L & COMP. L. 99, 110-11 (2004) (reporting that in 2004 the United States made “significant progress towards compliance in several outstanding

adverse ruling on Title III be rendered, there are strong motivations to compel continued U.S. compliance with the Agreement.

Foremost, the United States is currently engaged in ongoing disputes over important U.S. products and needs support from the WTO system to pursue favorable trade remedies in these cases.²⁵¹ The United States has a strong interest in ensuring that other WTO members comply with adverse rulings and respect the authority of the system as a whole and should, therefore, set the example by its own compliance. Furthermore, the WTO allows members to impose sanctions against countries who fail to reduce barriers to trade after an unsuccessful dispute.²⁵² Given the broad scope of Title III, which is applicable to all foreign nations that import food products into the United States, retaliatory sanctions in aggregate could be crippling.

In addition, the option of diplomacy always remains. The United States can mend bridges, broken by the restrictive Title III, by approaching food security in the future on an international level. International cooperation that takes both bioterrorism and trade concerns into account may ease tensions between the United States and trading partners and prevent a dispute from being lodged in the dispute settlement system. This is not only a cooperative and diplomatic solution, but also an effective one. The most efficient way to truly achieve global bioterrorism awareness, prevention, and preparedness, for both the United States and the world, is through

cases”). *But see* Yerkey, *supra* note 15, at 19 (quoting EC allegations that “the U.S. record of ‘prompt compliance’ with dispute settlement rulings issued by the World Trade Organization has been poor”). Yerkey notes, however, that of the seventeen adverse WTO rulings, the United States has only failed to comply, or been forced to comply after subsequent proceedings, with six of those decisions. *Id.*

251. *See* Bhala & Gantz, *supra* note 250, at 178-98 (discussing the most recent decision, favoring the United States, by the Appellate Body in the United States-Canada softwood lumber dispute, the longest-running trade dispute between the two nations that has persisted for twenty-three years). Another example is clearly depicted in the EC hormone dispute. While the United States has secured approval for sanctions against the EC, continued support from the WTO system is needed to maintain such measures. *See* Pruzin, *supra* note 249, at 1455-56 (describing how the EC has recently initiated proceedings against the United States and Canada, attempting to force these countries to lift the punitive sanctions in place against the EC); *see also* Bhala & Gantz, *supra* note 250, at 114-16 (noting that the principal issue with the EC’s compliance in the WTO system is still the hormone problem, and that the United States remains unconvinced that it should terminate its efforts against the EC ban).

252. *See* EPPING, *supra* note 92, at 49 (explaining that the system of punishment under the WTO is in the form of punitive tariffs, intended to compensate damaged countries for losses caused by trade-restricting member); Pruzin & Yerkey, *supra* note 249, at 1158 (describing the details of the WTO-approved sanctions against the European Union for its continued maintenance of a beef import ban).

intergovernmental organizations.²⁵³ In Europe, progress is already underway to pool available resources and knowledge and unite the many nations with bioterrorism concerns.²⁵⁴ The United States should cooperate with the governments of other nations and intergovernmental agencies to form any future plans for future bioterrorism prevention and achieve an efficient and internationally-sensitive strategy.

253. See Fidler, *supra* note 2, at 13-14 (predicting that the anthrax attacks may bring “back from the dead” the former international attempts to negotiate a Biological Weapons Convention to create protocol for responding to bioterrorist incidents globally and synchronize efforts to prepare for catastrophic terrorism using biological weapons); Interpol Media Release, *Bio-Terrorism Conference Opens with Warning of Major Threat: Interpol Member Countries Seek Co-ordinated Global Response*, Mar. 1, 2005, <http://www.interpol.int/Public/ICPO/PressReleases/PR2005/PR200510.asp> (quoting the Interpol Secretary General Ronald K. Noble, who describes bioterrorism as “[a] global threat that requires a global response”). Interpol is the world’s largest international police organization and boasts membership from over 184 countries worldwide. The organization aims to facilitate international police cooperation even where diplomatic relations between nations are not particularly strong, in the interest of preventing international acts of crime. See Interpol Website, About Interpol, <http://www.interpol.int/public/icpo/default.asp> (last visited Nov. 10, 2006). But see Alexander, *supra* note 13, at 88-89 (maintaining that it is “generally easier to take steps at home than it is to promote international action”). Alexander questions the immediate efficiency of international efforts, but does not discount the advantages of international bioterrorism cooperation. *Id.* Indeed, he ultimately notes that many governments have pursued international measures to deal with acts of terrorism and bioterrorism alike. *Id.* at 88.

254. See Interpol Media Release, *supra* note 253 (describing recent efforts in 2005 to organize a global solution to the global problem of bioterrorism). The Global Bioterrorism Conference, held by Interpol, saw over 150 countries in attendance to learn more about the growing problem of bioterrorism and to discuss how to attack bioterrorism on domestic levels, but also as part of an international team. Preventing and fighting bioterrorism worldwide is one of Interpol’s highest priority concerns, and the Bioterrorism Conference was a part of its most public ventures to increase international cooperation and work towards a global prevention plan. At a press conference following the Bioterrorism Conference, Interpol President Jackie Selebi declared, “[w]e must build bridges . . . [to] prevent bio-terrorism through sustained communication with international law enforcement to mitigate the risks we are facing. Interpol and police services around the world must be part of a broader integrated response to combat the threat of biological weapons.” Interpol Media Release, *Interpol Conference Agrees on Measures to Fight Bio-Terrorism: Emphasis on Training Police, Better International Cooperation*, Mar. 2, 2005, <http://www.interpol.int/Public/ICPO/PressReleases/PR2005/PR200511.asp>.