

ARTICLE: THE BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002 GOES TO GENEVA, OR, WOULD BIOTERROR GET THE SAME TREATMENT AS BIOTECH UNDER WTO RULES?

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Text

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Introduction

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ¹ ("the BT Act" or "the Act") was written and passed during the difficult, uncertain period of late 2001 and early 2002. This period saw a robust congressional response to the harrowing events of September 11 and to the anthrax mailings that followed: the PATRIOT Act, ² the Authorization for Use of Military Force, ³ and the BT Act all emerged from this era, and purportedly empowered various governmental institutions and agencies to guard against newly revealed threats. Of these, the BT Act, specifically Title III of the Act, responded most directly to the threat of contamination (terroristic or otherwise) in the food supply. ⁴

As with the several other attempts at legislative counterterrorism, questions have arisen regarding the efficacy of the BT Act and its [*500] compliance with the United States' international obligations. ⁵ In particular, a wide

¹ 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., [18 U.S.C., 21 U.S.C.](#), and 42 U.S.C.). Because Title III of the Act is the most problematic title with regard to international trade, and is therefore the focus of this Article, all references to "the BT Act" or "the Act" should be understood to refer to Title III of the Act.

² Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act of 2001, *Pub. L. No. 107-56, 115 Stat. 272* (codified in scattered sections in numerous titles of U.S.C.).

³ Authorization for Use of Military Force, *Pub L. No. 107-40, 115 Stat. 224* (2001).

⁴ See Public Health Security and Bioterrorism Preparedness and Response Act of 2002 §§301-315.

⁵ See, e.g., Claire S. Boisen, Comment, Title III of the Bioterrorism Act: Sacrificing U.S. Trade Relations in the Name of Food Security, *56 Am. U. L. Rev. 667 (2007)*; [Michael T. Roberts, Role of Regulation in Minimizing Terrorist Threats Against the Food Supply: Information, Incentives, and Penalties, 8 Minn. J.L. Sci. & Tech. 199, 218 \(2007\)](#) (suggesting that the BT Act is in

spectrum of commentators and actors both inside and outside of the international trade community has argued that the BT Act violates the United States' obligations under the World Trade Organization's ("WTO") Agreement on Sanitary and Phytosanitary Measures ("SPS" or "SPS Agreement").⁶ Most pointedly, it has been argued that Title III of the BT Act facially discriminates between foreign and domestic food producers and is not based on a risk [*501] assessment as the SPS Agreement requires.⁷ According to Claire Boisen's in-depth analysis and argument, because the BT Act saddles foreign producers with new and considerable administrative burdens and costs while allowing domestic producers to continue business under existing regulations,⁸ and because it does so without the scientific justification of a proper risk assessment,⁹ the BT Act would likely constitute an impermissible restriction on international trade under the SPS Agreement and the relevant WTO jurisprudence.¹⁰

The arguments of Boisen and related commentators, however, do not meaningfully consider the opposing possibility: that the BT Act might in fact comply with at least the letter (if not the spirit) of some of the SPS Agreement's requirements to the satisfaction of a WTO dispute settlement panel,¹¹ particularly in light of the

keeping with a "fragmented regulatory approach" that results in gaps, informational asymmetries, and insufficient incentives for regulators and producers); Ryan R. Kemper, Note, Responding to Bioterrorism: An Analysis of Titles I and II of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, *83 Wash. U. L.Q.* 385 (2005).

⁶ Boisen, *supra* note 5, at 672; Philip B.C. Jones, GM Foods: Treading Water in the Stream of Commerce, *Info. Sys. for Biotechnology News Rep.*, October 2003, <http://www.isb.vt.edu/news/2003/artspdf/oct0302.pdf> (noting that the BT Act contains traceability provisions similar to those in the European biotechnology regulations that the U.S. challenged under the SPS Agreement); 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" (internal quotation marks omitted)); Directorate-General for Health and Consumers, European Commission, Preliminary Comments from the European Commission on the USA Bioterrorism Act (2002), http://ec.europa.eu/food/international/trade/us_bio_act_prel_com_en.pdf (voicing initial concerns of the European Commission - the body that represents the European Union - that the BT Act is a major administrative and economic burden that creates a serious barrier to trade). Among additional comments on the new legislation received by the FDA from domestic and foreign trade representative groups, numerous 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; apart from the European Commission, representative embassies include Argentina, Australia, Canada, Chile, Germany, Hong Kong, India, Indonesia, Japan, Korea, Mexico, New Zealand, the Philippines, Switzerland, and the United Kingdom). Criticism of Title III's adverse trade effect is not limited merely to foreign entities. See, e.g., 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, 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) (reporting concerns of the Grocery Manufacturers of America, a trade association, about the prior notice regulation); Calum G. Turvey, Ben Onyango & Brian Schilling, Impact of the 2002 Bioterrorism Act on the New Jersey Food Industry (Food Policy Inst., Rutgers Univ., Working Paper No. WP-0603-010, 2003) (voicing domestic industry fears that, as a result of the BT Act's general restrictions, fewer foreign imports are likely and domestic business will suffer).

⁷ Boisen, *supra* note 5, at 672.

⁸ *Id.* at 668-69 (illustrating this effect with a hypothetical); *id.* at 671, 675-79 (describing the regulations).

⁹ *Id.* at 672, 702-04.

¹⁰ *Id.* at 715. Boisen states that Title III of the BT Act violates the WTO SPS Agreement because it discriminates against foreign food imports, and is not based on a sufficient risk assessment; she argues that if Title III cannot be implemented in a less restrictive manner, it should be abandoned to maintain uniformity with WTO trade obligations. *Id.*

¹¹ The Dispute Settlement Understanding ("DSU"), an annex to the Agreement Establishing the World Trade Organization, created the Dispute Settlement Body ("DSB"), comprised of all WTO members, and endowed the DSB with the authority to establish panels of three or five experts from member countries for hearing and issuing reports on disputes. Understanding on

relatively deferential holding issued by the panel in the recent case, *European Communities - Measures Affecting the Approval and Marketing of Biotech Products* ("EC-Biotech").¹²

In that case, the United States, Canada, and Argentina filed complaints before the WTO Dispute Settlement Body, claiming that various European Union restrictions on the importation and marketing of genetically modified ("GM") crops and food violated the EU's other treaty obligations under the SPS Agreement and General Agreement on Tariffs and Trade ("GATT") provisions. Of particular note, the United States claimed (1) that the EU, by failing to issue [*502] decisions regarding the approval or rejection of new GM crops and food, violated its obligation under Article 8 and Annex C of the SPS Agreement to avoid "undue delay" in approval procedures; (2) that this indefinite delay constituted a de facto moratorium on GM products, and that the EU failed to publish promptly a notification of this moratorium, in violation of SPS Agreement Article 7 and Annex B; (3) that this moratorium was not based on a risk assessment as required by SPS Agreement Article 5.1; and (4) that because no such moratorium applied to certain GM processing aids such as enzymes used in making European cheeses, the moratorium constituted an arbitrary or unjustifiable distinction in the level of protection applied to different GM products, in violation of SPS Article 5.5.¹³

Though the latter two claims were clearly the substantive crux of the United States' case, the panel ruled against the EU only with respect to the first claim, the procedural claim of undue delay in approvals.¹⁴ Importantly, however, the panel concluded that the EU practice of refusing to issue decisions on the approval of new GM products did not constitute an SPS measure at all, and was therefore not subject to the SPS Agreement's requirements.¹⁵ Because, according to the panel, the de facto moratorium was not a law, decree, regulation, requirement or procedure as defined by Annex A to the SPS Agreement, but was instead a "decision ... related to the application or operation of procedures,"¹⁶ the EU was under no obligation to base the moratorium on a risk assessment¹⁷ or to avoid arbitrary distinctions between the moratorium and any other treatment of GM products.¹⁸ By relying on this extraordinarily formalistic distinction, the panel largely sidestepped the fundamental but politically explosive question of the EU's right to balance health and safety as well as trade issues as it sees fit. Put another way, by contriving a means of avoiding substantive judgment of the EU moratorium under the SPS Agreement, the panel, however cautiously, deferred to the decisional authority of the EU.

[*503] As with the EU biotech measures challenged in the case described above, the BT Act is an example of an aggressive regulatory response to strongly felt threats, and one which may cross over the line between protection of health and safety on the one hand, and economic protectionism on the other. I suggest, therefore, that in light of this strong parallel between the EU biotech regime and the BT Act, and in the wake of the WTO panel ruling in the case of the former, a new treatment of the BT Act's status in the international trade arena is necessary. This Article

Rules and Procedures Governing the Settlement of Disputes, arts. 2, 8, Dec. 15, 1993, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Legal Instruments - Results of the Uruguay Round, [33 I.L.M. 112 \(1994\)](#).

¹² See Panel Report, *European Communities - Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R (Sept. 29, 2006) [hereinafter EC-Biotech]. The EC-Biotech panel report had not yet been circulated when Ms. Boisen's comment, *supra* note 5, was written; obviously she could not possibly have taken account of that report in composing her thorough and compelling analysis. See *infra* Part III for a discussion of deference generally, and in the EC-Biotech case specifically.

¹³ For a fuller, yet still concise recapitulation of the claims and issues in the case, see Gregory Shaffer, *A Structural Theory of WTO Dispute Settlement: Why Institutional Choice Lies at the Center of the GMO Case*, [41 N.Y.U. J. Int'l L. & Pol. 1, 27-28 \(2008\)](#), on which the summary contained here relies heavily.

¹⁴ EC-Biotech, *supra* note 12, PP 7.1570, 8.6.

¹⁵ *Id.* P 8.6.

¹⁶ *Id.* P 7.1326-7.1378, 7.1382.

¹⁷ *Id.* P 7.1393.

¹⁸ *Id.* P 7.1419.

attempts to provide that treatment, and implicitly to ask on a broader level whether a new balance between trade and health-safety issues may emerge in the WTO's dispute settlement jurisprudence after EC-Biotech.

Parts I and II of the Article analyze the primary claims that could be made against the BT Act, namely that it violates Articles 5.5 and 2.3, and Article 5.1 (respectively) of the SPS Agreement. Articles 5.5 and 2.3 require non-discrimination among products from countries in which comparable conditions prevail,¹⁹ while Article 5.1 requires that SPS measures be based on a risk assessment.²⁰ Included in the analysis of these primary claims against the BT Act is the possibility that the Act would be judged less harshly by a WTO dispute settlement panel applying a standard of implicitly greater deference to national decision-making in the wake of EC-Biotech. Part III then briefly considers whether the approach of the panel in EC-Biotech may lead to a more consistently deferential stance in future SPS disputes. Finally, Part IV concludes that should a complaint be brought against the United States claiming that the BT Act violates the aforementioned articles of the SPS Agreement, the WTO dispute settlement panel would likely engage in a process of interpretation similar to that undertaken by the panel in EC-Biotech in an attempt to reach a largely deferential result.

I. The BT Act's Compliance with Articles 5.5 and 2.3 of the SPS Agreement

The BT Act sets out new requirements for domestic and foreign facilities, two of which create significant, new procedural burdens for foreign facilities in particular. The Act requires facilities producing [*504] food for consumption in the United States to register extensive information with the FDA and to designate a U.S. agent for their company.²¹ It further requires foreign food producers to provide the FDA with prior notice of any food shipment sent to the United States.²² As implemented by the FDA in separate regulations,²³ these provisions require significant expenditures by foreign producers to ensure compliance,²⁴ and are therefore the crux of the claim that the BT Act violates U.S. trade obligations under the SPS Agreement.

As an initial matter, it must be shown that the SPS Agreement applies to these sections of the BT Act.²⁵ The SPS Agreement, by its terms, applies only to measures taken "to protect human or animal life or health ... from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs,"²⁶ and that "directly or indirectly, affect international trade."²⁷ These definitions are broad, and were interpreted to apply even in EC-Biotech, wherein the measures in question also arguably fell under other agreements.²⁸ For its

¹⁹ Agreement on the Application of Sanitary and Phytosanitary Measures, arts. 2.3, 5.5, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, Multilateral Agreement on Trade in Goods, 1867 U.N.T.S. 493 [hereinafter SPS Agreement].

²⁰ *Id.* art. 5.1.

²¹ Public Health Security and Bioterrorism Preparedness and Response Act of 2002, **Pub. L. No. 107-188**, sec. 305, § 415, **116 Stat. 594**, 667 (codified at [21 U.S.C. § 350d](#) (2006)).

²² *Id.* sec 307, § 801. For a thorough summary of § 305 and § 307, see Boisen, *supra* note 5, at 677-81.

²³ See 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) (codified at 21 C.F.R. pts. 1, 20) [hereinafter Registration of Food Facilities]; 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) (codified at 21 C.F.R. pt. 1) [hereinafter Prior Notice of Imported Food].

²⁴ See Registration of Food Facilities, *supra* note 23, at 58,949 tbl.12 (describing the costs associated with finding and retaining an agent); Prior Notice of Imported Food, *supra* note 23, at 59,061, 59,062 tbl.47 (describing the costs associated with the various options for regulating the importation of food using the prior notice rule).

²⁵ Though the extent to which the SPS Agreement applies was vigorously contested in the EC-Biotech case, the question is generally more straightforward; indeed, it is rarely a significant issue in dispute settlement proceedings.

²⁶ SPS Agreement, *supra* note 19, Annex A(1)(b).

²⁷ *Id.* art. 1.1.

part, then, the BT Act is on its face an SPS measure because it explicitly declares its intention "to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies." ²⁹ Just **[*505]** as clearly, the BT Act has a direct effect on international trade under the meaning of Article 1.1 of the SPS Agreement; by the United States' own estimates, the BT Act was likely to impose hundreds of millions of dollars of new costs per year on foreign food companies exporting products to the United States, ³⁰ potentially causing some sixteen percent of those foreign food companies to cease exporting to the United States. ³¹ The BT Act is, therefore, subject to the SPS Agreement's requirements. Chief among these are the requirements of non-discrimination (Articles 5.5 and 2.3) and scientific justification of SPS measures through risk assessment (Article 5.1).

Articles 5.5 and 2.3 enshrine the laudable principle that WTO member nations should not enact SPS measures that effectively disadvantage the products of other nations unless there is a genuine SPS reason to do so. ³² Perhaps not surprisingly, the two articles are closely related in the WTO's dispute settlement jurisprudence, with Article 5.5 having been interpreted as a specific instance of the more general non-discrimination requirement contained in Article 2.3. ³³ Thus, a violation of Article 5.5 will necessarily entail a violation of Article 2.3. ³⁴ This construction is a great aid to the cause of judicial economy, and generally leads to an examination of Article 5.5 prior to Article 2.3, given that a finding that the measure in question violates the former could obviate the need for an extensive analysis regarding the latter. ³⁵

In 1998, the WTO's Appellate Body decision in *European Communities - Measures Concerning Meat and Meat Products (Hormones)* ("EC-Hormones"), established a three-part test for **[*506]** determining whether a challenged SPS measure violates Article 5.5. ³⁶ A measure violates Article 5.5, and, by implication, Article 2.3 if: (1) the measure creates distinct levels of protection in different (but comparable) situations, (2) those distinct levels of protection are arbitrary or unjustifiable, and (3) those arbitrarily or unjustifiably distinct levels of protection result in discrimination or a disguised restriction on trade. ³⁷

²⁸ EC-Biotech, supra note 12, PP 7.393-7.433 (concluding that the SPS Agreement should apply to measures affecting the approval of biotech products even though those measures had purposes other than the protection of human life or health and could therefore be subject to the strictures of other agreements to a greater or lesser degree).

²⁹ Public Health Security and Bioterrorism Preparedness and Response Act of 2002, **Pub. L. No. 107-188, 116 Stat. 594**, 594. But see Hal S. Shapiro, *The Rules That Swallowed the Exceptions: The WTO SPS Agreement and Its Relationship to GATT Articles XX and XXI: The Threat of the EU-GMO Dispute*, [24 Ariz. J. Int'l & Comp. L. 199, 218 \(2007\)](#) (noting that the BT Act was almost certainly not intended to be an SPS measure, but was conceived as a national security measure).

³⁰ See *Registration of Food Facilities*, supra note 23, at 58,949 tbl.12; *Prior Notice of Imported Food*, supra note 23, at 59,061, 59,062 tbl.47.

³¹ *Registration of Food Facilities*, supra note 23, at 58,943.

³² See SPS Agreement, supra note 19, arts. 2.3, 5.5.

³³ Appellate Body Report, *Australia - Measures Affecting Importation of Salmon*, PP 244-52, WT/DS18/AB/R (Oct. 20, 1998) [hereinafter *Australia-Salmon*] (implicitly affirming the panel's characterization of the relationship between Articles 5.5 and 2.3).

³⁴ Id. P 252. Note, however, that the converse of this proposition does not hold true. See id. P 248 (affirming the panel's recognition that "not all violations of Article 2.3 are covered by Article 5.5"); Appellate Body Report, *European Communities - Measures Concerning Meat and Meat Products (Hormones)*, P 212, WT/DS26/AB/R, WT/DS48/AB/R (Jan. 16, 1998) [hereinafter *EC-Hormones*] (noting that Article 5.5 is essentially a particularized application of Article 2.3, implying that Article 2.3 has a broader scope than Article 5.5).

³⁵ See, e.g., *Australia-Salmon*, supra note 33, PP 243-55.

³⁶ *EC-Hormones*, supra note 34, P 214.

³⁷ Id.

Importantly for an analysis of the BT Act, however, it is not clear whether, in construing Articles 5.5 and 2.3 to overlap so extensively, the Appellate Body in EC-Hormones read Article 5.5's "different situations" language to cover distinct levels of protection across comparable countries as well as across comparable risk-generating products or mechanisms. In no case has a complainant charged an Article 5.5 violation on the theory that distinctions based solely on different products' country of origin constitute "distinctions in the levels [of protection] it considers appropriate in different situations" under the meaning of that article.³⁸ Rather, claims of Article 5.5 violations have invariably been based on assertions of distinct levels of protection between products presenting a comparable risk, regardless of the country of origin for those products. For example, in EC-Hormones, the Appellate Body considered the different levels of protection at issue to be:

- (i) the level of protection in respect of natural hormones when used for growth promotion;
- (ii) the level of protection in respect of natural hormones occurring endogenously in meat and other foods;
- (iii) the level of protection in respect of natural hormones when used for therapeutic or zootechnical purposes;
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- (iv) the level of protection in respect of synthetic hormones (zeranol and trenbolone) when used for growth promotion; and
- (v) the level of protection in respect of carbadox and olaquinox.³⁹

These distinct levels of protection were applied to products containing the relevant hormones, irrespective of where those products originated.

Similarly, in Australia - Measures Affecting Importation of Salmon ("Australia-Salmon"), distinct levels of protection were applied with respect to different fish, regardless of country of origin.⁴⁰ And again in EC-Biotech, the distinct levels of protection complained of were those applied, regardless of country of origin, to (1) biotech products pending approval, (2) previously approved biotech products, and (3) novel non-biotech products.⁴¹ By contrast, the BT Act's distinct levels of protection are those applied to foreign products on the one hand, and domestic products on the other.

Thus, there is at least some cognizable doubt regarding the applicability of Article 5.5 to the BT Act. Particularly if a WTO dispute settlement panel were inclined to employ, however covertly, a more deferential standard of review (à la EC-Biotech), it could find that the first prong of the Article 5.5 test has not been met. That is, a panel might reasonably conclude that Article 5.5 does not apply to the BT Act because the language of Article 5.5 does not envisage and has never before been applied to measures - such as the BT Act - that create distinctions based solely on product origin rather than on product features or characteristics.⁴² Bolstering this conclusion is the

³⁸ SPS Agreement, supra note 19, art. 5.5. Though any number of requests for consultation under the WTO Dispute Settlement Understanding have included conflicts that would be covered by the SPS Agreement, only five panels have ever issued a report in disputes to which the SPS Agreement applied: Australia-Salmon, supra note 33; and EC-Hormones, supra note 34; EC-Biotech, supra note 12; Panel Report, Japan - Measures Affecting the Importation of Apples, WT/DS245/R (July 15, 2003) [hereinafter Japan-Apples]; Panel Report, Japan - Measures Affecting Agricultural Products, WT/DS76/R (Oct. 27, 1998) [hereinafter Japan-Agricultural Products].

³⁹ EC-Hormones, supra note 34, P 218 (footnotes omitted).

⁴⁰ Australia-Salmon, supra note 33, P 144.

⁴¹ EC-Biotech, supra note 12, P 4.212.

⁴² In fact, this scenario resulting from the BT Act's country-based distinction in protection levels may be one example of a case in which there exists a route to Article 2.3 that does not run through Article 5.5. See Australia-Salmon, supra note 33, P 252 (discussing "routes" to Article 2.3). By establishing a clear separation between which measures are best handled by one article or the other, the WTO could answer calls to determine "what, if anything, Article 5.5 adds to what is already covered by Article

difference in the text of Articles 2.3 and 5.5: Article 2.3 directly proscribes discrimination based on product origin, whereas Article 5.5 prohibits distinctions based on product characteristics without reference to product origin, if those distinctions then result in [*508] discrimination.⁴³ Because a panel would rightly assume that the drafters of the SPS Agreement did not intend redundancy regarding these two articles,⁴⁴ the panel could justifiably deduce from their differing language an intent that Article 2.3 should apply to cases of direct, facial discrimination between foreign and domestically produced products, and that Article 5.5 should apply to cases of indirect discrimination resulting from distinct levels of protection being applied to comparable products.

This construction of Article 5.5 would not absolve the BT Act of the requirement to avoid non-discrimination, of course. Rather, it would shift the analytical focus to Article 2.3's more general requirement to avoid discriminating between products from countries where identical or similar conditions prevail.⁴⁵ The effect of such a shift could be momentous. Because no previous SPS dispute has resulted in a consideration of Article 2.3's requirements independent of a concomitant finding with regard to Article 5.5,⁴⁶ a panel or the Appellate Body would have a blank jurisprudential slate on which to engrave Article 2.3's inner dictates.

It is difficult to say exactly where a panel might turn for models in developing the analytical structure and content of Article 2.3. One source, however, might be GATT Article XX.⁴⁷ Article XX generally prohibits "arbitrary or unjustifiable discrimination ... or a disguised restriction on international trade" that would prevent the adoption or enforcement of any measure necessary to protect the health of human, animal, or plant life.⁴⁸ Although the Appellate Body in EC-Hormones warned against the "casual" importation of GATT Article XX standards, EC-Hormones was interpreting Article 5.5, not Article 2.3.⁴⁹ Specifically, the Appellate Body cited the "structural differences [*509] between the standards of the chapeau of Article XX of the GATT 1994 and the elements of Article 5.5" as reasons why an analogy to Article XX was inappropriate in that case.⁵⁰ However, the Appellate Body never delineated those structural differences, and in any case, SPS jurisprudence has clearly established that Article 2.3 is different in scope and nature from Article 5.5. Moreover, the language of Article 2.3 tracks that which is contained in the chapeau of GATT Article XX much more closely than does the language of Article 5.5, thus making Article 2.3 a more natural candidate to be informed by the meaning of Article XX. Finally, the SPS Agreement as a whole was intended to be a clarification of the particular exception to GATT rules contained in GATT Article XX(b).⁵¹ Therefore, the chapeau of Article XX would seem to possess a direct if indeterminate interpretive relevance in relation to the various SPS articles.

2.3." 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, 92 (2001).

⁴³ Compare SPS Agreement, *supra* note 19, art. 2.3, with *id.*, art. 5.5.

⁴⁴ Appellate Body Report, *United States - Standards for Reformulated and Conventional Gasoline*, 23, WT/DS2/AB/R (Apr. 29, 1996) [hereinafter *U.S.-Gasoline*] ("One of the corollaries of the 'general rule of interpretation' in the Vienna Convention is that interpretation must give meaning and effect to all the terms of a treaty. An interpreter is not free to adopt a reading that would result in reducing whole clauses or paragraphs of a treaty to redundancy or inutility.").

⁴⁵ SPS Agreement, *supra* note 19, art. 2.3.

⁴⁶ See *supra* note 38 (listing the previous SPS cases to come before WTO dispute settlement panels). In none of these cases did the panel deal with a charged violation of Article 2.3 independently of Article 5.5.

⁴⁷ General Agreement on Tariffs and Trade, art. XX, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194.

⁴⁸ *Id.*, 61 Stat. at A-60 to -61, 55 U.N.T.S. at 262.

⁴⁹ EC-Hormones, *supra* note 34, P 239.

⁵⁰ *Id.*

⁵¹ SPS Agreement, *supra* note 19, at 493.

An invocation of Article XX is not, as it may initially seem, an invitation to imprecision or lack of clarity in WTO panel or Appellate Body decisions.⁵² In *United States - Standards for Reformulated and Conventional Gasoline* ("U.S.-Gasoline"), one of the earliest cases to come before the WTO dispute settlement system, the Appellate Body considered what the contours of an inquiry under the chapeau of Article XX should be:

The chapeau by its express terms addresses, not so much the questioned measure or its specific contents as such, but rather the manner in which that measure is applied. It is, accordingly, important to underscore that the purpose and object of the introductory clauses of Article XX is generally the prevention of "abuse of the exceptions of [what was later to become] Article [XX]." ⁵³

The report continues:

The kinds of considerations pertinent in deciding whether the application of a particular measure amounts to "arbitrary or unjustifiable discrimination", may also be taken into account in determining the presence of a "disguised restriction" on international **[*510]** trade. The fundamental theme is to be found in the purpose and object of avoiding abuse or illegitimate use of the exceptions to substantive rules available in Article XX.⁵⁴

Though broad, Article XX's "theme ... of avoiding abuse" in crafting and enacting trade policies provides a coherent analytical thrust in determining an SPS measure's compliance with Article 2.3. The GATT Article XX standard is not without content,⁵⁵ yet it retains the kind of flexibility that would allow a panel to take a more straightforward, less legalistic path toward a deferential ruling than that taken by the panel in *EC-Biotech*.

Regarding the BT Act, a panel searching for ways to avoid intruding unduly into spheres of national decision-making could find that, despite other potential infirmities, the BT Act does not constitute an "abuse or illegitimate use" of an SPS measure under the meaning of Article 2.3 (as informed by the chapeau of GATT Article XX). A panel could employ a number of judicial tools to reach this conclusion: First, it could hold that the U.S.-Gasoline approach of asking whether other less trade-restrictive measures were available more properly belongs under SPS Articles 2.2 and 5.6. Second, it could take a firm position in support of the precautionary principle⁵⁶ and decide that that principle justifies the BT Act's otherwise problematic distinctions between foreign and domestically produced goods. Third, it could recall that the complainant (whoever it might **[*511]** be) has the burden of proving that the BT Act discriminates between countries where identical or similar conditions exist. But in light of the numerous cross-border terrorism acts in recent years, it would seem all but impossible to disentangle the complex threads of inquiry regarding the relevant "conditions" in countries around the globe. Finally, it could hew closely to the Appellate Body's approach in *U.S.-Gasoline* and inquire whether less trade-restrictive alternatives to the BT Act

⁵² See generally Shapiro, *supra* note 29 (lamenting the confusing relationship between the SPS Agreement and GATT art. XX).

⁵³ *U.S.-Gasoline*, *supra* note 44, at 22 (alterations in original) (footnote omitted).

⁵⁴ *Id.* at 25.

⁵⁵ See *id.* at 22-24. Following the formulation of its "avoiding abuse" standard, *id.* at 25, the Appellate Body weighed the extent to which the United States' failure to pursue alternative, less trade-restrictive measures should preclude the United States from claiming an Article XX exception. The Appellate Body found that indeed the U.S. measures in question "are not entitled to the justifying protection of Article XX as a whole." *Id.* at 30. Though perhaps out of political restraint, the Appellate Body never explicitly labeled the U.S. measure in question an "abuse" of Article XX's protection. See *id.* at 30-31.

⁵⁶ The precautionary principle is a general principle of customary international law, the exact contours of which are much debated. Perhaps the most common iteration of the principle is something like the following, from the Rio Declaration on Environment and Development: "lack of full scientific certainty shall not be used as a reason for postponing ... measures to prevent environmental degradation." U.N. Conference on Environment and Development, June 3-14, 1992, Rio Declaration on Environment and Development, princ. 15, U.N. Doc. A/CONF.151/5/Rev.1 (June 13, 1992), reprinted in [31 I.L.M. 874, 879 \(1992\)](#). The principle is invoked in many different contexts other than environmental regulation, and the EU in particular is widely perceived to have "endorsed the general idea that regulatory action should be taken even when harm cannot be established, and indeed even when it is highly speculative." Robert W. Hahn & Cass R. Sunstein, *The Precautionary Principle as a Basis for Decision Making*, 2:2 *The Economists' Voice*, Article 8, at 1 (2005), <http://www.bepress.com/ev/vol2/iss2/art8/>.

were available to the United States, but find in the end that the United States had persuasively shown the BT Act's discrimination to be "merely inadvertent or unavoidable." ⁵⁷

Without knowing the details of the justifications the United States might put forth in defense of the BT Act, or even what potentially justificatory information the United States would choose to reveal before a panel, ⁵⁸ it is difficult to speculate on which mechanism a panel would ultimately prefer. The broader point is that by separating the analyses under Articles 2.3 and 5.5, and incorporating GATT Article XX (the standard of avoiding abuse in the application of SPS measures), a panel could engage in, and thereby effectively endorse, the less intrusive mode of analysis pioneered by the panel in EC-Biotech. That analysis, as discussed above, could lead to a conclusion that the BT Act does not violate either Article 5.5 or 2.3 of the SPS Agreement.

II. The BT Act's Compliance with Article 5.1 of the SPS Agreement

Having engineered a plausible means of finding that the BT Act does not violate Articles 5.5 and 2.3 of the SPS Agreement, a panel would next face the question of whether the Act is justified by a risk assessment as required by Article 5.1. ⁵⁹ The inquiry into Article 5.1's **["*512"]** requirement of a risk assessment, as distilled by the panel in EC-Biotech, breaks down into "two distinct issues: (i) whether there is a 'risk assessment' within the meaning of the SPS Agreement; and (ii) whether the measure is 'based on' this risk assessment." ⁶⁰

A. Does a Risk Assessment Exist to Support the BT Act?

The FDA has conducted and published what it considers to be a risk assessment in support of the BT Act. ⁶¹ However, whether the FDA's risk assessment would be considered sufficient for Article 5.1 purposes turns on the answer to the question of what constitutes a risk assessment. In EC-Hormones, the Appellate Body dealt with this issue by turning to paragraph 4 of Annex A to the SPS Agreement. ⁶² This paragraph contains two alternative definitions of "risk assessment":

[(1)] The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or [(2)] the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs. ⁶³

⁵⁷ See U.S.-Gasoline, *supra* note 44, at 29.

⁵⁸ See Boisen, *supra* note 5, at 703 n.172 (noting that risk assessments conducted to evaluate the vulnerability of the U.S. food supply have been classified).

⁵⁹ In EC-Hormones, the Appellate Body approved the panel's conclusion that "Article 5.1 may be viewed as a specific application of the basic obligations contained in Article 2.2 of the SPS Agreement," and went on to "stress that Articles 2.2 and 5.1 should constantly be read together. Article 2.2 informs Article 5.1: the elements that define the basic obligation set out in Article 2.2 impart meaning to Article 5.1." EC-Hormones, *supra* note 34, P 180 (footnote omitted). This would seem to indicate that an analysis parallel to that undertaken with respect to Articles 5.5 and 2.3 is appropriate here. However, after the initial endorsement of Article 2.2's importance for Article 5.1, the Appellate Body hardly mentions the former article, and the analytical focus in each case involving the SPS Agreement to come before a dispute settlement panel has been fully on Article 5.1. Thus, I do not here offer a treatment of Article 2.2.

⁶⁰ EC-Biotech, *supra* note 12, P 7.3019.

⁶¹ See U.S. Food and Drug Administration, Risk Assessment for Food Terrorism and Other Food Safety Concerns (2003), <http://www.cfsan.fda.gov/dms/rabtact.html#ftnref15> [hereinafter FDA Risk Assessment]. The FDA provided this publicly available report in an effort to "promote transparency" since the assessments evaluating risk to the U.S. food supply contain classified information and are not otherwise available. *Id.*

⁶² EC-Hormones, *supra* note 34, P 182.

⁶³ SPS Agreement, *supra* note 19, Annex A(4).

Because growth hormones are clearly additives in food, and not a pest or disease, the Appellate Body considered whether a risk assessment of the kind described in the second clause of Annex A(4) had been conducted.⁶⁴ In doing so the Appellate Body affirmed two requirements set out by the panel in that case:

[*513]

The Panel elaborates risk assessment as a two-step process that "should (i) identify the adverse effects on human health (if any) arising from the presence of the [additives in question] ... , and (ii) if any such adverse effects exist, evaluate the potential or probability of occurrence of such effects."⁶⁵

Applying these requirements, the Appellate Body ultimately concluded that although the European Communities had assessed the possibility of excess or abuse in the largely unmonitored process of administering hormones, it had not gone further and conducted or taken into account any "assessment of the potential adverse effects" of this excessive hormone use, as the above formulation of the Annex A(4) definition of risk assessment required.⁶⁶ In other words, the European Communities had not identified any threat to health that might arise even if its allegations of excessive hormone use were true.

This analysis by the Appellate Body in EC-Hormones remains the only treatment of the meaning of risk assessment under the second clause of Annex A(4). As the panel in EC-Biotech noted, only the Appellate Body's decision in Australia-Salmon provides any further reasoning on the issue:

Unlike for the definition of risk assessment contained in the first clause of Annex A(4), WTO jurisprudence provides little guidance on the meaning of key concepts contained in the definition provided in the second clause. The Appellate Body [in Australia-Salmon] merely observed in this respect that the first clause is substantially different from the second clause, and that the second clause requires "only" the evaluation of the "potential" for adverse effects on human or animal health arising from the presence of certain substances in foods, whereas the first clause requires an evaluation of the "likelihood" of entry, establishment or spread of a pest or disease and of the associated biological and economic consequences.⁶⁷

[*514] Thus, a panel seeking to determine whether a risk assessment exists to support the BT Act would be left to apply the definitional framework of EC-Hormones in light of Australia-Salmon's modest gloss. In so doing, a panel would encounter at least two difficulties.

First, the "potential adverse effects" of the additives, contaminants, toxins, or disease-causing organisms against which the BT Act is designed (at least in part) to guard, are not merely potential.⁶⁸ Rather, the agents of bioterrorism are well-known pathogens, and in fact would be selected precisely because of their capacity to do harm. Thus, their nature and adverse effects are not the "risk" in question. The risk in question is either that foods

⁶⁴ EC-Hormones, supra note 34, P 182. It should be noted that although a novel argument might be made in favor of analyzing the FDA's risk assessment under Annex A(4)'s first definition, the argument would be just that - novel. To date, Annex A(4)'s first definition of risk assessment has only been applied in cases concerning the threat that imported products could infect domestic plant or animal populations with a pest or disease that could decimate domestic producers' crops or animal stocks: Japan-Apples, supra note 38; Japan-Agricultural Products, supra note 38; and Australia-Salmon, supra note 33. Though previous panel or Appellate Body decisions have no formal precedential value, complainants, respondents, panels and the Appellate Body seem thus far to have presumed that Annex A(4)'s first definition is intended to cover threats from animal or plant pests or diseases to non-human populations. The BT Act, of course, is intended to prevent harm to humans, and the FDA's risk assessment clearly focuses on threats to human health. FDA Risk Assessment, supra note 61.

⁶⁵ EC-Hormones, supra note 34, P 183.

⁶⁶ Id. P 207.

⁶⁷ EC-Biotech, supra note 12, P 7.3048.

⁶⁸ FDA Risk Assessment, supra note 61, pt. II(A) (listing foodborne pathogens identified by the U.S. Centers for Disease Control and Prevention as likely agents of bioterrorism, including anthrax, botulism, salmonella, E. coli 0157:H7, and other biological and chemical substances).

produced in a foreign facility will be intentionally contaminated with a harmful substance or that foods thus contaminated will enter the U.S. food supply.

The BT Act is not generally the kind of measure envisioned by the SPS Agreement.⁶⁹ In its veneration of scientific means, techniques, and processes, the SPS Agreement is primarily structured to deal with physical, biological, and chemical uncertainties or risks, not the risk of intentionally harmful human action. An assertion, even if backed by meaningful evidence, that foreign individuals bear ill will against a country and possess the means to act on that ill will is difficult to characterize as a risk assessment of the type codified in the SPS Agreement. Yet if the relevant risk is defined - as it rightly must be in the case of the BT Act - as the risk that foods destined for the U.S. market will be intentionally contaminated, how can the potential of that occurrence be scientifically assessed?

Faced with this quandary, a panel's choices would seem stark. First, the panel could hold that the FDA's proffered risk assessment does not constitute a risk assessment at all, due to the fact that it does not scientifically assess the potential or probability that the actual threat, a bioterror attack originating outside the United States, could occur. Alternatively, the panel could conclude that the assessment at least passes its initial test because it does conform to the EC-Hormones definition of a risk assessment, even if it assesses a risk that is not actually the uncertainty or threat at issue. Because a panel in search of a compromise that respects national decision-makers **[*515]** would presumably hesitate to find a clear violation at this advanced stage of its analysis, the only real choice is to find that the FDA's assessment of the risks posed by bioterrorism is a risk assessment under the meaning of Article 5.1 and Annex A(4).

To accomplish this result, the panel would have to proceed as if the pertinent risk is the risk that contaminated foods will cause harm, not the risk that foods produced for the U.S. market will be contaminated in an act of bioterrorism. Beginning with this admittedly artificial presumption, however, a panel would have no difficulty concluding that the FDA's risk assessment "identifies the adverse effects on human health" and "evaluates the potential or probability of occurrence of such effects."⁷⁰ The FDA rehearses a litany of known ills arising from the consumption of contaminated foods, and duly notes the virtual certainty that consumption of such contaminated foods will lead to the occurrence of these ills,⁷¹ thereby satisfying, at least formally, the requirements of Article 5.1 and Annex A(4).

The second obstacle in determining whether a state has properly complied with the risk assessment requirement involves the timing of the risk assessment. The BT Act seems to raise a question regarding at what point in the process leading to the creation of an SPS measure a risk assessment must emerge on the policy-making scene; the FDA's designated risk assessment regarding bioterrorism was made available well after the BT Act was passed, and notice that the risk assessment was available was given on the same day as the FDA regulations implementing the BT Act's provisions.⁷² At least one commentator has suggested that this sequence of events would render the

⁶⁹ See Shapiro, *supra* note 29, at 218 (noting that the BT Act was surely conceived of by its authors as a piece of national security legislation, not as an SPS measure).

⁷⁰ EC-Hormones, *supra* note 34, P 183 (internal quotation marks omitted) (quoting Panel Report, European Communities - Measures Concerning Meat and Meat Products (Hormones), Complaint by the United States, P 8.98, WT/DS26/R/USA (Aug. 18, 1997); Panel Report, European Communities - Measures Concerning Meat and Meat Products (Hormones), Complaint by Canada, P 8.101, WT/DS48/R/CAN (Aug. 18, 1997)).

⁷¹ FDA Risk Assessment, *supra* note 61, pt. II(A).

⁷² See Registration of Food Facilities, *supra* note 23, at 58,894 (published on October 10, 2003); Prior Notice of Imported Food, *supra* note 23, at 58,974 (published on October 10, 2003); Risk Assessment for Food Terrorism and Other Food Safety Concerns, [68 Fed. Reg. 59,078](#) (Oct. 10, 2003) (notice). But see FDA Risk Assessment, *supra* note 61 (indicating that the document was available on October 13, 2003).

risk assessment logically incapable of assessing potential adverse effects in the prospective manner that Article 5.1 and Annex A(4) envision.⁷³

[*516] Before EC-Biotech, the FDA's late-in-coming risk assessment supporting the BT Act might have posed a problem. However, EC-Biotech appears to have resolved this issue definitively when the panel stated that "in [its] view, both a risk assessment carried out before the adoption of a particular safeguard measure and a risk assessment carried out after its adoption could "sufficiently warrant,' or "reasonably support,' the maintenance of that measure."⁷⁴

Turning to the BT Act, the provisions of the Act itself would never have been applied without the FDA's implementing regulations. Those regulations were issued simultaneously with the FDA's risk assessment, and there is no reason to believe that the risk assessment was not conducted in concert with the crafting of the regulations, informing and helping to shape them.⁷⁵ Thus, reading the Act together with its implementing regulations, and in light of the above ruling by the EC-Biotech panel, the timing of the FDA's risk assessment does not appear to threaten its status as a valid risk assessment under Article 5.1 and Annex A(4). In fact, given the panel's strong statement in EC-Biotech, it is probably not necessary to read the FDA's subsequent implementing regulations as integral to the Act in this way. Nevertheless, it is an eminently sensible mode of construction: because most policy-making in the major trading nations of the world today involves both legislative and administrative or regulatory elements, it would hardly be a stretch for a panel to construe the BT Act and its implementing regulations as a single, multifaceted process, resulting in a cohesive legal structure (or measure). Taking this view would not only allow the panel to solve the temporal problem (to the extent there is one after EC-Biotech) by concluding that the entire juridical unit consisting of the BT Act and its implementing regulations was informed and shaped by an FDA risk assessment, but would also more fully account for the complex nature of national rule-making generally.

Ultimately, with the temporal question minimized, and the risk in question presumed to be the risk of illness resulting from additives in the food supply, the FDA's risk assessment appears to fit, at least **[*517]** formally, the definition of a risk assessment set out in Annex A(4) and developed further in EC-Hormones. Accordingly, a panel could reasonably find that a risk assessment exists to support the BT Act as required by Article 5.1.

B. Is the BT Act "Based on" a Risk Assessment?

Questions regarding the mere existence of a risk assessment are, of course, distinct from the question of whether the BT Act (as construed to include its implementing regulations) is "based on" the risk assessment as required by Article 5.1. In EC-Hormones the Appellate Body took up the question of what it means for a measure to be "based on" a risk assessment, holding that the phrase, as used in Article 5.1, "is appropriately taken to refer to a certain objective relationship between two elements, that is to say, to an objective situation that persists and is observable between an SPS measure and a risk assessment."⁷⁶ Beyond this, according to the Appellate Body, for an SPS measure to be based on a risk assessment, "the results of the risk assessment must sufficiently warrant" or "reasonably support" the SPS measure in question; that is, there must be not merely an objective relationship, but also a "rational relationship between the measure and the risk assessment."⁷⁷

⁷³ Boisen, *supra* note 5, at 707-08 (asserting the impossibility of Title III being based on the FDA Risk Assessment because the BT Act had been published on June 12, 2002 - well before the FDA Risk Assessment had been published - and, for further proof, the BT Act never mentions the FDA Risk Assessment or any other risk assessment).

⁷⁴ EC-Biotech, *supra* note 12, P 7.3030.

⁷⁵ Recall that the burden of proof lies with the complainant charging a violation of the SPS Agreement, meaning, in this case, that the complainant would have to make out a *prima facie* case that no risk assessment existed at any relevant point in time. See, e.g., EC-Hormones, *supra* note 34, P 98.

⁷⁶ *Id.* P 189.

⁷⁷ *Id.* P 193.

In practice, the "rational relationship" question is usually less about whether the disputed SPS measure would actually work to limit the harm to human or animal life or health resulting from a known threat, and more about whether there is any genuine threat to human or animal life or health from the onset. For example, banning the sale of meat from animals that were fed hormone supplements would clearly eliminate any risk of harm resulting from consumption of such meat. But the real question (and the focus of the rational relationship test) is whether consumption of such meat poses any threat of harm in the first place. Thus, the analytical focus is on what the risk assessment actually says, and how the assessing country has interpreted that risk assessment.⁷⁸ Put another way, the rational relationship question is usually a question as to whether a country has trumped-up the seriousness of a threat in order to make a restrictive SPS measure appear necessary.

[*518] In the case of the BT Act, however, the issue is not whether the United States overstated the severity of the harm that could result from a bioterror attack on the U.S. food supply. There is instead a series of interrelated doubts about the likelihood of a bioterror attack taking place at all, the likelihood of such an attack being launched from outside the United States, and the efficacy of the BT Act's provisions in preventing or containing such an attack. In evaluating the BT Act, therefore, it would seem that the focus of the inquiry should be not on the contents of the risk assessment, as it commonly is, but on the contours of the Act itself. Because the harm that could be done by an act of bioterrorism is clear, the question becomes what, if anything, the BT Act does to prevent that harm.

Here again, though, we encounter the fact that the risk of a bioterror attack originating outside the United States, and the ability of regulatory procedures to mitigate that risk, are not the kinds of problems susceptible to the scientific investigation and estimation seemingly required by the SPS Agreement. In EC-Hormones, the lengthy discussion of what constitutes a rational relationship between a risk assessment and an SPS measure refers to "the scientific conclusion" of the risk assessment, "the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view," and "qualified scientists who have investigated the particular issue at hand."⁷⁹ Yet, because national security advisors, not scientists, are the ones to investigate the likelihood of attacks and the likely efficacy of regulatory protections against such attacks, and because there is scant applicable precedent in the previous SPS cases, the panel in a dispute over the BT Act would again be faced with the prospect of improvising an evaluation of the relationship between the FDA's risk assessment and the BT Act.

In doing so, a panel might do well to rely upon these problematic factual distinctions between the BT Act and the previously challenged SPS measures. However much these factual distinctions muddy the analytical waters, they could also provide a panel seeking to craft more measured responses to national policies with a means of distinguishing the BT Act from those previous cases, all of which ended badly for the country maintaining the SPS measure in question.

[*519] In EC-Hormones, the Appellate Body found that the SPS measures in question were not based on proper risk assessments.⁸⁰ In that case, the Appellate Body concluded that the proffered risk assessments failed primarily because they did not identify any genuine threat to human or animal life or health.⁸¹ The FDA's risk assessment, on the other hand, clearly delineates the harm and adverse effects that could result from a bioterror attack.⁸² The

⁷⁸ See, e.g., *id.* PP 195-203 (evaluating the contents of the various documents submitted as risk assessments).

⁷⁹ *Id.* P 194 (emphasis added). Though the Appellate Body went out of its way to declare that the concept of a risk assessment does not exclude "matters not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences," it nevertheless proceeded to focus exclusively on the "scientific" concerns mentioned above. *Id.* P 187.

⁸⁰ *Id.* P 208.

⁸¹ See *id.* PP 207-08 (indicating that the assessments failed to provide an analysis of potential adverse effects).

⁸² FDA Risk Assessment, *supra* note 61, pt. II(A).

FDA's risk assessment also identifies particular cases in which terrorist groups have been found to be contemplating an attack on food and agricultural systems in the United States.⁸³

By noting these two aspects of the FDA's risk assessment (the identified harm that would result from a bioterror attack plus verified bioterror plots), and by further noting that the previous SPS cases (specifically EC-Hormones) dealt with risks more amenable to scientific investigation, the panel would essentially be applying an alternate mode of analysis for SPS measures, such as the BT Act, that guard against risks that cannot truly be scientifically estimated. In such cases the panel could focus less on risk assessment as defined in previous cases, and more on evidence, broadly conceived, of specific, genuine threats, as opposed to vaguely asserted dangers. This type of analysis would be in perfect accord with the Appellate Body's instruction in EC-Hormones that

it is essential to bear in mind that the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory ... , but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.⁸⁴

Applying this alternate framework, the panel could conclude that the FDA's risk assessment does sufficiently address, in ways that previously challenged SPS measures did not, the harm that could result from a bioterror attack even though the risk of that harm is not actually the risk in question, and that the FDA's risk assessment goes [*520] further by demonstrating that bioterror attacks from non-U.S. sources are a specific, genuine threat. The evidence adduced, though unavoidably limited, removes this threat of bioterror attacks originating outside the United States from the realm of mere assertion of a vaguely conceived danger. The panel could therefore find that the assessment as a whole is a "systematic, disciplined and objective enquiry"⁸⁵ despite its otherwise unscientific nature.

This still leaves the question of whether the BT Act and its implementing regulations respond reasonably to the threats identified in the FDA's risk assessment, or go further than necessary in responding to those threats, thereby unnecessarily restricting trade. In essence, this is a type of independent Article 2.2 question, which, as mentioned above, has never been addressed by a panel or by the Appellate Body. In finding that the disputed measures in the previous SPS cases were not based on a risk assessment, the panels and the Appellate Body found each time that the proffered risk assessment was insufficient per se to support an SPS measure.⁸⁶ Thus, those cases provide virtually no guidance regarding how narrowly an SPS measure must be tailored to respond to the threat identified in a valid risk assessment.

In the absence of any such precedential guidance, a panel may find its analytical footing in the terms of the BT Act itself. The Act's stated aims are to deter a bioterror attack, prevent contaminated foods from entering into the supply chain, and mitigate or contain the damage done by any successful attack.⁸⁷ Because these aims invoke the threats identified in the risk assessment, the Act's capacity to achieve those aims could provide a rough measure of the extent to which the Act is reasonably responsive to its own risk assessment. Put another way, if the Act's stated aims are to prevent the threats set out in the risk assessment, and the Act rationally furthers the achievement of those stated aims, then, logically, it must bear a rational relationship to the risk assessment as well, thereby satisfying Article 5.1.

American jurists might recognize in this maneuver some similarity to certain elements of "rational basis" review under the Equal Protection Clause of the Fifth and [Fourteenth Amendments to \[*521\] the U.S. Constitution](#). There,

⁸³ Id.

⁸⁴ EC-Hormones, supra note 34, P 187.

⁸⁵ Id.

⁸⁶ See Australia-Salmon, supra note 33, PP 129-35; EC-Hormones, supra note 34, PP 208-13; Japan-Apples, supra note 38, P 9.1.

⁸⁷ See Public Health Security and Bioterrorism Preparedness and Response Act of 2002, *Pub. L. No. 107-188, 116 Stat. 594*, 594, 662.

as here, the judicial body essentially requires that the statute (or SPS measure, in our case) possess an internal coherence: "if there is any reasonably conceivable" set of circumstances under which the provisions of the measure might work to further the measure's stated aims, then the measure will survive scrutiny.⁸⁸

Whether the BT Act actually furthers the achievement of its own stated aims is, of course, a factual question, albeit one on which there will likely be a dearth of evidence. After all, short of catching a terrorist red-handed, how might the United States demonstrate that it has successfully deterred a bioterror attack? Recall, however, that the Equal Protection Clause's rational basis test would allow a panel to accept as "evidence" any "reasonably conceivable" set of circumstances that would tend to show that the BT Act could achieve its goals of deterrence, prevention, and containment. In the end, this would seem perfectly plausible content for a "rational relationship" test such as exists under Article 5.1: if there is some rationally determinable way in which the BT Act could prevent the threats covered in the FDA's risk assessment, then it is not an unreasonable response to that risk assessment, but instead stands in a rational relationship to the assessment.

There is no question that to allow the Equal Protection Clause's rational basis jurisprudence to inform Article 5.1's rational relationship test in this way is to employ an extraordinarily deferential standard. However, in the absence of meaningful precedent regarding the necessary consonance between a valid risk assessment and the SPS measure which it supports, a "rational basis" style of review focused on the internal coherence of the measure provides a satisfyingly concrete rubric. Furthermore, the degree of deference that the test entails is unlikely to be objectionable to the kind of panel posited in this Article: that is, a panel inclined to grant precisely this kind of increased leeway to national decisions.

III. What Does EC-Biotech Really Portend for Future SPS Disputes?

What is behind this talk of deference? What does it mean to imagine, as this Article has, that a WTO dispute settlement panel may seek to "apply a standard of implicitly greater deference to national [*522] decision-making?" What would such a panel really be doing? And what would it all have to do with the EC-Biotech case?

As Gregory Shaffer suggests, WTO panels, whether consciously or unconsciously, "effectively allocate[] power from one institution to another, thus affecting who participates and how they participate in deciding which substantive goals to pursue."⁸⁹ In other words, panel and Appellate Body decisions determine who decides. Strict scrutiny of a product ban, for instance, may invalidate the ban, thereby allowing the previously banned product to compete with domestic products and allowing the market to decide the product's place in society; alternatively, a lesser degree of scrutiny may uphold the ban, thereby affirming the national political body's right to decide that the banned product has no place in its society.⁹⁰ Thus, to speak of deference is to invoke this latter state of affairs in which a panel or the Appellate Body, by whatever interpretive means, leaves undisturbed the status of the national political body as the appropriate decision-maker in the case.

What is remarkable about the operation of this phenomenon in the EC-Biotech case is not that the panel achieved such a comprehensively deferential result; indeed, using the above institutional choice framework, one might say the panel did in fact remove the procedural decision-making prerogatives from the European Communities, and thereby technically ruled against the EC.⁹¹ Rather, what the case seems to demonstrate is the extent to which a panel may be willing to strain the meaning of the SPS Agreement's terms in order to leave substantive decisional authority in the hands of a domestic (or in the case of the EU, a regional) political institution.

Of course, this interpretation of the EC-Biotech result presumes that the panel intentionally set out to find a way to affirm the European Commission's right to decide the place of genetically modified organisms in European society.

⁸⁸ [FCC v. Beach Commc'ns, Inc., 508 U.S. 307, 313 \(1993\)](#).

⁸⁹ Shaffer, *supra* note 13, at 5.

⁹⁰ See *id.* at 42-45.

⁹¹ EC-Biotech, *supra* note 12, P 7.1570.

Institutional choice theory, which posits that institutions take into account how their decisions will affect the allocation of power, clearly does not require such intentionality.⁹² However, it is difficult both to understand the EC-**[*523]** Biotech panel decision in purely textualist terms, and to imagine that the panel was unaffected by the pressure to balance competing legitimacy concerns. Put another way, the most ready explanation for the "convoluted,"⁹³ "tortuous,"⁹⁴ even "casuistic"⁹⁵ reasoning employed by the panel is that such reasoning was necessary to achieve the extra-textual goal of balancing institutional demands.

It should be noted that these institutional demands include not only the need to accommodate the views and values of the various parties to the dispute, but also the need for the WTO as a dispute settlement body itself to maintain legitimacy. As Andrew Guzman points out, because "health and safety [measures] implicate deeply held notions of sovereignty and autonomy," to invalidate such measures is to "invite non-compliance."⁹⁶ Thus, though the dispute resolution system has not drifted toward irrelevance despite protracted bouts of non-compliance in some high-level cases such as EC-Hormones, the prospect of removing another politically explosive health and safety decision from the hands of European Community policy-makers must have given the EC-Biotech panel pause.

One might reasonably expect the same would be true in the case of a national security decision such as that reflected in the BT Act. National security concerns, no less than those over health and safety, evoke powerful instincts of self-determination. Subjugating those concerns to the imperatives of liberalized trade, especially after having bent over backwards to leave substantive regulatory authority over health measures unaffected by trade demands in EC-Biotech, could conceivably be viewed as courting the kind of non-compliance conflict that may finally loosen the foundations of the dispute resolution system's legitimacy.

So, what is a panel to do? Barring a radical renegotiation of the SPS Agreement to include national security and other exceptions to SPS rules, as some have called for,⁹⁷ a panel is left with its familiar judicial or interpretive tools for balancing the competing interests and values of stakeholders in the world trading system. This arsenal **[*524]** could - and perhaps should - include a lessened standard of review for SPS measures,⁹⁸ or some of the judicial avoidance techniques deployed by the domestic courts of the world, such as standing, ripeness, and political question doctrines. However, almost a decade and a half into the life of the WTO dispute settlement system, these techniques have not found favor with panels or the Appellate Body, and to introduce them at this stage would be to swim against a strong current of judicial inertia. Thus, as the only apparent route to deference available, the EC-Biotech panel's method of ad hoc creative interpretation is likely to persist, and I have tried to imagine in this Article some of the shapes that creative interpretation might take with respect to the BT Act.

Conclusion

The particular difficulties faced by the panel in the EC-Biotech case regarding the proper extent to which the requirements of the WTO's SPS Agreement should displace domestic (or regional) decisions regarding the proper

⁹² Nor, however, does it preclude such intentionality on the part of judicial bodies such as WTO panels. See Shaffer, *supra* note 13, at 9-10 (hypothesizing that judicial decision-makers may implicitly construct their textual analysis so as to achieve a result that will allocate decisional authority to a particular institution).

⁹³ Shapiro, *supra* note 29, at 230.

⁹⁴ Shaffer, *supra* note 13, at 33.

⁹⁵ *Id.* at 86.

⁹⁶ Andrew T. Guzman, Food Fears: Health and Safety at the WTO, [45 Va. J. Int'l L. 1, 4 \(2004\)](#).

⁹⁷ See, e.g., Shapiro, *supra* note 29, at 225-28.

⁹⁸ See Guzman, *supra* note 96, at 28. As I understand Professor Guzman's proposed standard of review, it would be one of near total deference to the substance of national decisions. Presumably this would go one slight step beyond the framework put forth above in which a rational relationship test is maintained but informed by the extremely deferential standard embodied in the U.S. Equal Protection Clause jurisprudence. In practice, there may be little or no difference between the two approaches.

method of identifying and responding to health and safety risks in the food supply are not confined to that case. The U.S. Bioterrorism Preparedness and Response Act of 2002 is another measure that, like the European regime governing genetically modified products, fits imperfectly within the boundaries of the SPS Agreement despite clearly being covered by the terms of that Agreement. As such, it raises similar questions regarding a dispute settlement panel's need to balance all involved parties' (including its own) claims to decisional authority.

In order to accomplish this balance, a panel must find some way of interpreting the SPS Agreement so that it does not intrude too far into spheres of national policy-making. In this Article, I have tried to imagine some of the ways in which a panel reviewing the BT Act might do just that, particularly in light of some of the rather extraordinary reasoning undertaken in the EC-Biotech case. Like the panel's decision in EC-Biotech, I believe the Article reveals just how difficult this process of deferential interpretation can be; at times the [*525] required interpretive maneuvers can feel particularly unsatisfying even to the one making them.

Even so, fears that such creative interpretation will undermine the legitimacy of WTO dispute settlement proceedings may be unfounded. Members of the WTO continue to turn to the dispute settlement system with great regularity, and despite the EC-Biotech decision's much-belabored problems, it was not appealed by either party. As illustrated in this Article, there would seem to be no immediately apparent reason to expect that a challenge to the BT Act would bring about different results, either in the decisional process of a panel, or in the overall impact of the case on the dispute settlement system.

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