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Domestic Regulation, Sovereignty, and Scientific Evidence Requirements: A Pessimistic View

Alan O. Sykes*

The World Trade Organization (“WTO”) and its predecessor, the General Agreement on Tariffs and Trade (“GATT”), have been extraordinarily successful at liberalizing trade in the global economy. The process of liberalization has entailed a series of negotiations resulting in reciprocal commitments to reduce or eliminate tariffs, quotas, and other traditional instruments of protectionism. To ensure the integrity of those commitments, it has been necessary since the inception of GATT to prohibit member nations from substituting other protectionist devices for those which they promise to forego.

Domestic regulations, in particular, can disadvantage or exclude foreign suppliers from export markets. Such regulatory obstacles to exports are known as “technical barriers to trade.” A number of legal principles have evolved in the WTO system to discipline technical barriers.¹ Regulations that discriminate against foreign suppliers are the most obvious source of undesirable technical barriers, and WTO law imposes an obligation on the regulators of member nations to avoid discrimination that disfavors foreign suppliers.² Facially nondiscriminatory regulations that impose

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1. The subject of technical barriers and associated disputes is also the source of a rich literature on WTO law. For a few notable examples, see Robert Howse, *Democracy, Science, and Free Trade: Risk Regulation on Trial at the World Trade Organization*, 98 Mich L Rev 2329 (2000) (arguing that WTO rules on technical barriers can promote deliberative democracy); David G. Victor, *The Sanitary and Phytosanitary Agreement of the World Trade Organization: An Assessment After Five Years*, 32 NYU J Intl L & Polit 865 (2000) (reviewing the history of disputes in the area). The question of what role science should play within the WTO is closely related to the “standard of review” employed by WTO dispute panels in assessing the judgments of national authorities. For an excellent reference on the standard of review generally, see Stephen P. Croley and John H. Jackson, *WTO Dispute Procedures, Standard of Review, and Deference to National Governments*, 90 Am J Intl L 193 (1996).
2. See General Agreement on Tariffs and Trade, as amended (“GATT”), art I, III(4), reprinted in John H. Jackson, William J. Davey and Alan O. Sykes, *2002 Documents Supplement to Legal Problems of International Economic Relations* 15 (West 4th ed 2002) (hereinafter *Documents Supplement*). This general nondiscrimination obligation applies more selectively in services markets, inasmuch as

relatively greater compliance costs on foreign suppliers can have the same effect as discriminatory regulations, however, and WTO law thus includes an array of constraints on domestic regulation that go beyond simple nondiscrimination requirements.³

One such constraint may be termed a “scientific evidence requirement”—a requirement that certain regulations, generally those enacted for the purpose of protecting health, safety, or the environment, be based on scientific evidence. The scientific evidence may go either to the existence of a risk, or to the efficacy of the regulation in reducing the risk.

The logic of scientific evidence requirements is obvious. If a regulation that is ostensibly aimed at protecting health, safety, or the environment nevertheless has the effect of restricting trade, and there is no scientific evidence of any danger to be avoided or of any reduction in risk as a result of the regulation, then the suspicion arises that the regulation is disguised protectionism. In effect, a scientific evidence requirement aids in motive review, and helps to sort regulations between those that are protectionist and those that seek to promote some legitimate, non-protectionist regulatory objective.⁴

But scientific evidence requirements can also create hurdles for regulators who sincerely pursue objectives other than protectionism. Depending on the context, scientific evidence may be inconclusive or its conclusions highly tentative or preliminary. Convincing scientific proof of certain types of risk, particularly low level risks, may be difficult to produce. And scientists may well disagree about the existence of a risk or the efficacy of various ways to reduce it. In the face of such scientific uncertainty, scientific evidence requirements may stand in the way of honest regulatory efforts to manage risk. These concerns are not merely hypothetical. As shall be seen below, they surface clearly in WTO disputes.

The uncomfortable interface between scientific evidence requirements and conditions of scientific uncertainty poses serious challenges for the WTO system, which has always billed itself as respectful of national regulatory “sovereignty.” The WTO agreements, as well as decisions pursuant to its dispute resolution process, are replete with references to the right of each member nation to decide on the level of risk that it wishes to tolerate within its jurisdiction. This deference to national sovereignty has played an essential political role in quieting opposition to the WTO

discriminatory domestic regulations are often the only sensible device for protecting domestic industries. Accordingly, nondiscrimination obligations apply only in sectors where members have agreed to them, and are subject to scheduled exceptions. See General Agreement on Trade in Services (“GATS”), art XVII, reprinted in *Documents Supplement* at 304.

3. See generally Alan O. Sykes, *Regulatory Protectionism and the Law of International Trade*, 66 U Chi L Rev 1 (1999).

4. *Id.* at 17–18.

and thus in facilitating its core mission. Ideally, one might hope for an accommodation between scientific evidence requirements and “sovereignty” that allows both to be respected under WTO law.

My thesis in this essay, however, is that such an accommodation is exceedingly difficult if not impossible. Meaningful scientific evidence requirements fundamentally conflict with regulatory sovereignty in all cases of serious scientific uncertainty. WTO law must then choose between an interpretation of scientific evidence requirements that essentially eviscerates them and defers to national judgments about “science,” or an interpretation that gives them real bite at the expense of the capacity of national regulators to choose the level of risk that they will tolerate. The only middle ground lies in the rare cases where scientific uncertainty is remediable quickly at low cost. I further argue that “consistency” requirements cannot likely supplant scientific evidence requirements in a way that satisfactorily accommodates the tension between the desire to weed out protectionism on the one hand, and the desire to respect regulatory sovereignty on the other.

A close examination of pertinent WTO decisions to date, most importantly the decision in the “beef hormones” dispute and its unsuccessful effort to accommodate scientific evidence requirements with deference to domestic regulators, will provide the bulk of the argument. Section I provides some general background on WTO law, while section II considers the cases.

I. SOVEREIGNTY AND SCIENTIFIC EVIDENCE REQUIREMENTS IN WTO LAW

The only substantial constraints imposed on domestic regulation by the original GATT Agreement were nondiscrimination requirements, prohibiting discrimination among trading partners (the “most-favored-nation” obligation of article I) and between foreign suppliers and domestic suppliers (the “national treatment” obligation of article III). These obligations were subject to exceptions, such as in the case of measures “necessary” to protect human, animal or plant health, so long as they were not “applied in a manner which would constitute arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade” (article XX). Regulators were otherwise free to adopt whatever regulations they wished, even if the regulations raised the costs of foreign suppliers disproportionately and thus had the effect of insulating domestic firms from foreign competition.

The perceived inadequacy of this regime led to pressures for greater constraints on facially nondiscriminatory yet trade-distorting regulation. During the Tokyo Round of GATT negotiations in the 1970’s, some of the members of the GATT agreed to a “Standards Code” which introduced a number of new disciplines. Regulations governing product characteristics became subject to a least restrictive means requirement even if they were nondiscriminatory, and nations were required to

use performance standards rather than design standards where possible (for example, automobiles might be subject to emissions limits, but they could not be required to use a particular catalytic converter that might be more cheaply available to domestic manufacturers). Nations were encouraged to adopt international standards where appropriate to their goals. Some regulatory transparency requirements were also included, but scientific evidence requirements were not. Indeed, the Code failed to address a number of important issues in the view of some signatories. Among other things, it did not apply to regulations governing the way that products were produced, only to regulations governing the characteristics of the end product. As a result, a constituency for further negotiation on the subject emerged during the Uruguay Round of the 1980's.⁵

The resulting agreements, which formed the basis for the creation of the WTO, divided technical barriers issues between an Agreement on Technical Barriers to Trade ("TBT Agreement") and an Agreement on the Application of Sanitary and Phytosanitary Measures ("SPMs Agreement").⁶ Their coverage is mutually exclusive, with the TBT Agreement applicable to all regulations not covered by the SPMs Agreement.⁷ The SPMs Agreement defines SPMs, roughly, as measures by a member (a) to protect animal or plant life or health in its territory from the spread of pests or disease; (b) to protect human or animal life or health in its territory from risks arising from the presence of an additive, contaminant or disease-causing organism in a food, beverage or feedstuff; (c) to protect human life or health in its territory from risks arising from a disease-causing organism carried by an animal or plant; and (d) to prevent or limit other damage in its territory from the spread of a pest.

The substantive obligations differ between the two agreements in important ways. The TBT Agreement contains a tight prohibition on discrimination, for example,⁸ while the SPMs Agreement prohibits measures that "arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail."⁹ The permissibility of limited discrimination under the SPMs Agreement is aimed at situations where the risk is greater with goods from particular sources (for example, beef from England during the mad cow scare).

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5. For a detailed history of GATT rules in this area, and a discussion of the changes made by the WTO agreements, see Alan O. Sykes, *Product Standards for Internationally Integrated Goods Markets* 63–86 (Brookings 1995).
 6. These agreements are modeled on similar provisions in the NAFTA. See North American Free Trade Agreement, art 709–24, 901–15, 32 ILM 289, 377–383, 386–396 (1993), reprinted in *Documents Supplement* at 512, 573–83, 590–602 (cited in note 2).
 7. The division results from the way that negotiations were structured—technical barriers in general were entrusted to one negotiating group, but those of particular relevance to agriculture (the SPMs) were left to the agricultural negotiating group.
 8. TBT Agreement, art 2.1, reprinted in *Documents Supplement* at 150 (cited in note 2).
 9. SPMs Agreement, art 2.3, reprinted in *Documents Supplement* at 122 (cited in note 2).

By contrast, the SPMs Agreement contains significantly tighter scientific evidence requirements. The TBT Agreement merely requires that regulations “not be more trade-restrictive than necessary to fulfill a legitimate objective,” which can include the “protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information”¹⁰ Seemingly, the only obligation under the TBT Agreement with respect to scientific evidence is that it be “considered.”

Under the SPMs Agreement, however, “[m]embers shall ensure that any sanitary or phytosanitary measure ... is based on scientific principles and is not maintained without sufficient scientific evidence.”¹¹ Measures which conform to relevant international standards are presumptively in conformity with the requirements of the Agreement, and Members may only introduce or maintain measures “which result in a higher level of ... protection than would be achieved by measures based on the relevant international standards ... if there is a scientific justification, or as a consequence of the level of ... protection a Member determines to be appropriate” in accordance with other provisions of the Agreement governing the assessment of risks.¹² The risk assessment provisions state that “[m]embers shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations. In the assessment of risks, Members shall take into account available scientific evidence”¹³ An exception exists for cases “where relevant scientific evidence is insufficient.” Then, “a Member may provisionally adopt ... measures on the basis of available pertinent information,” provided that they “shall seek to obtain the additional information necessary for a more objective assessment of risk and review the ... measure accordingly within a reasonable period of time.”¹⁴ As indicated in the next section, these scientific evidence requirements of the SPMs Agreement have served as a basis for holding that several challenged regulations violate WTO obligations.

As the TBT and SPMs Agreements created important new obligations, however, they also purported to ensure that member nations could continue to regulate to avoid risks that they did not wish to tolerate. The SPMs Agreement recites at its outset that “no Member should be prevented from adopting or enforcing

10. TBT Agreement, art 2.2, reprinted in *Documents Supplement* at 150 (cited in note 2).

11. SPMs Agreement, art 2.2, reprinted in *Documents Supplement* at 122 (cited in note 2).

12. SPMs Agreement, art 3.3, reprinted in *Documents Supplement* at 123 (cited in note 2).

13. SPMs Agreement, arts 5.1–5.2, reprinted in *Documents Supplement* at 123–24 (cited in note 2).

14. SPMs Agreement, art 5.7, reprinted in *Documents Supplement* at 124 (cited in note 2).

measures necessary to protect human, animal or plant life or health”¹⁵ Likewise, the TBT agreement insists that “no country should be prevented from taking measures necessary ... for the protection of human, animal or plant life or health, of the environment ... at the levels it considers appropriate”¹⁶ The evident purpose of these statements is to reassure member nations that the WTO is not in the business of deciding which risks are acceptable and which are not. WTO law simply aims to ensure that the regulation of genuine risks is not more deleterious to trade than necessary. In this respect, both agreements promise to respect regulatory sovereignty regarding risk tolerance. The next section will suggest that the scientific evidence requirements of the SPMs Agreement, as interpreted by the WTO Appellate Body, have rendered this promise in no small part illusory.

II. SCIENTIFIC EVIDENCE REQUIREMENTS IN WTO DISPUTE RESOLUTION

As noted, the role of scientific evidence requirements is much greater in situations that implicate the SPMs Agreement. Accordingly, they are the focus of attention here.

A. THE SPMS CASES

The scientific evidence requirements of the SPMs Agreement have played a significant role in three reported WTO decisions to date involving European imports of beef, Australian imports of salmon, and Japanese imports of certain agricultural products. In each case, the regulation in question was held to violate WTO law.

1. European Community/Beef Hormones

The beef hormones dispute is one of the longest running trade disputes in the modern trading system. It stems from a decision by the European Union to prohibit the administration of certain growth hormones (including estrogen, progesterone and testosterone) to cattle. Europe not only prohibited the use of these hormones domestically, but banned the importation of meat and meat products from cattle that had received these hormones abroad. These growth hormones are widely used by ranchers in the United States and Canada. After the entry into force of the agreements creating the WTO, the United States and Canada quickly brought a case alleging violations of the SPMs Agreement. A dispute panel found for the complainants on a number of grounds, some of which were reversed by the WTO Appellate Body. But the Appellate Body ultimately agreed with the panel that the European regulation violated WTO law and, in particular, the scientific evidence

15. SPMs Agreement, Preamble, reprinted in *Documents Supplement* at 121 (cited in note 2).

16. TBT Agreement, Preamble, reprinted in *Documents Supplement* at 149 (cited in note 2).

requirements of the SPMs Agreement. It is instructive to examine the Appellate Body's analysis in some detail.

Note first that the European regulation was nondiscriminatory, and thus beyond the reach of the basic nondiscrimination obligations that have existed since the inception of the GATT system. But it is the type of nondiscriminatory regulation that has a disparate impact on foreign trade. Meat packers in nations that permit the use of hormones cannot export to Europe unless they deal with ranchers who segregate part of their herds to be raised as hormone free, and generate the supporting evidence of that practice necessary to satisfy European regulators. These added costs may not be worth the bother to packers who anticipate that only a modest portion of their business will involve European exports, and indeed we know that the initial impact of the hormone beef regulation was to reduce US exports from about \$100 million annually to zero.¹⁷ Whether intended as a protectionist measure or not, therefore, the effect of such a regulation is to disadvantage foreign suppliers relative to domestic suppliers, and it affords a nice example of why nondiscrimination obligations alone are perceived as inadequate to address technical barriers.

But is the regulation disguised protectionism that the system should condemn? Its history suggests not. The first version of the regulation was enacted following widely publicized adverse reactions to the ingestion of beef from cattle treated with the hormone DES, such as the development of breasts in young children. The European Council of Agricultural Ministers responded with a zero risk policy, banning all growth hormones whether or not they had been shown to produce adverse reactions in humans.¹⁸ Although there is little doubt that the regulation improved the competitive position of European beef producers and they no doubt welcomed it in part on that basis, the impetus for the measure can be traced clearly to an episode that raised bona fide concerns about the safety of growth hormones.

But the central issue before the WTO was whether the measure rested on an acceptable scientific footing, and in particular whether it was "based on" a risk assessment as required by article 5.1 of the SPMs Agreement. In addressing this question, the WTO Appellate Body tipped its hat often to the notion that national regulators have the right to regulate low level risks. It noted that the requirement of a risk assessment does not mean that "a certain magnitude or threshold level of risk be demonstrated"—"such a quantitative requirement finds no basis" in the Agreement.¹⁹ Further, "Article 5.1 does not require that the risk assessment must necessarily embody only the view of a majority of the relevant scientific community. ...

17. See Alan O. Sykes, *Product Standards for Internationally Integrated Goods Markets* 17 (Brookings 1995).

18. *Id.* at 16–17.

19. World Trade Organization, Report of the Appellate Body, *EC Measures Concerning Meat and Meat Products (Hormones)*, ¶ 186, WTO Doc No WT/DS26/AB/R (Feb 13, 1998) (hereinafter *Hormones Report*) (emphasis omitted).

[R]esponsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion²⁰ The requirement that a measure be “based on” a risk assessment is simply “a substantive requirement that there be a rational relationship between the measure and the risk assessment.”²¹

Nevertheless, the regulation failed to pass muster. The Appellate Body pointed to studies of the safety of growth hormones done for the Codex Alimentarius, an international standard-setting body connected to the World Health Organization, which concluded that the use of the hormones in question was “safe” if they were used in accordance with good veterinary practice.²² Hence, these scientific studies did not “rationally support” the European measure.²³

Europe pointed to a number of studies that document a relationship between hormone ingestion and cancer, a linkage that has recently been confirmed by studies of women undergoing hormone replacement therapy, but these were deemed inadequate because “[t]he Monographs and the articles and opinions of individual scientists have not evaluated the carcinogenic potential of those hormones when used specifically for growth promotion purposes. Moreover, they do not evaluate the specific potential for carcinogenic effects arising from the presence in ‘food’, more specifically, ‘meat or meat products’ of residues of the hormones in dispute.”²⁴

Europe also produced an expert witness before the dispute panel, one Dr. Lucier, who opined that the ingestion of growth hormone residues in meat would indeed cause some small number of additional cancers. He stated that of every one million women, 110,000 would contract breast cancer, of which several thousand cases would likely result from the intake of exogenous estrogens from all sources. “And by my estimates one of those 110,000 would come from eating meat containing oestrogens as a growth promoter, if used as prescribed.”²⁵ The Appellate Body might have simply noted that Dr. Lucier’s opinion was not available to the European Union at the time the regulation was promulgated, and hence that the regulation could not be “based on” it. But that would have left Europe the opportunity simply to repromulgate the regulation in reliance on Dr. Lucier’s analysis. Instead, the Appellate Body noted “that this opinion by Dr. Lucier does not purport to be the result of scientific studies carried out by him or under his supervision focusing specifically on residues of hormones in meat from cattle fattened with such hormones. Accordingly, ... the single divergent opinion expressed by Dr. Lucier is not reasonably sufficient”²⁶

20. Id at ¶ 194.

21. Id at ¶ 193.

22. Id at ¶ 196.

23. Id at ¶ 197.

24. Id at ¶ 199 (emphasis in original).

25. Id at ¶ 198 n 181.

26. Id at ¶ 198.

Europe's final line of defense was to point to the dangers of hormone abuse by cattle ranchers. Even if the Codex studies were right that hormones are "safe" when used in accordance with good veterinary practice, some ranchers might be tempted to overuse them, leaving higher and more dangerous residues. To this argument, the Appellate Body responded in essence that Europe had produced no empirical study of the risks of hormone abuse that demonstrated the magnitude or severity of the problem. Accordingly, if the justification for the regulation lay in the fear of excess residues attributable to hormone abuse, it still was not "based on" a risk assessment.²⁷

2. Australia/Salmon

Australia has developed a successful salmon industry, and insists that the importation of uncooked salmon from other nations creates a risk that certain diseases of salmon prevalent elsewhere will be introduced into the Australian fish population. Accordingly, it enacted a ban on the importation of salmon from various places, including Canada. Canada brought a challenge to the ban contending, inter alia, that the ban was not "based on" a risk assessment.

In reviewing this claim, the Appellate Body again tipped its hat to the right of member nations to set their own risk levels, indicating that a Member may permissibly elect a zero risk policy.²⁸ But the regulation must nevertheless be based on a "risk assessment." The requirements of a "risk assessment" can be found in the definition of the term in Annex A to the SPMs Agreement. A risk assessment must:

- (1) identify the diseases whose entry, establishment or spread a Member wants to prevent within its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these diseases;
- (2) evaluate the likelihood of entry, establishment or spread of these diseases, as well as the associated potential biological and economic consequences; and
- (3) evaluate the likelihood of entry, establishment or spread of these diseases according to the SPS measures which might be applied.²⁹

In interpreting these requirements, the Appellate Body held that

it is not sufficient that a risk assessment conclude that there is a possibility of entry, establishment or spread of diseases and associated biological and economic consequences. A proper risk assessment of this type must evaluate the 'likelihood', i.e., the 'probability', of entry, establishment or spread of diseases and associated biological and economic consequences as well as the 'likelihood', i.e., 'probability', of entry, establishment or spread of diseases according to the SPS measures which might be applied.³⁰

"The likelihood may be expressed either quantitatively or qualitatively."³¹

27. Id at ¶ 207.

28. World Trade Organization, Report of the Appellate Body, *Australia—Measures Affecting Importation of Salmon*, ¶ 125, WTO Doc No WT/DS18/AB/R (Oct 20, 1998) (hereinafter *Salmon Report*).

29. Id at ¶ 121 (emphasis in original).

30. Id at ¶ 123 (emphasis in original).

31. Id at ¶ 124.

Australia produced a government report that noted the possibility of twenty-four diseases being spread through imports of uncooked salmon, and offered it as the “risk assessment” on which the regulation was based. The Appellate Body found the report adequate as to the first criterion above—it identified the diseases at issue and their potential consequences. But as to the second criterion, the Appellate Body found that the report did not adequately “evaluate the likelihood” of the spread of disease through importation of salmon. It based that conclusion on the dispute panel’s finding that the report contained “general and vague statements of mere possibility of adverse effects occurring; statements which constitute neither a quantitative nor a qualitative assessment of probability.”³² Likewise, the Appellate Body found the report inadequate under the third criterion because, although it identified various options for reducing the risks in question, it “d[id] not, in any substantial way, evaluate or assess their relative effectiveness in reducing the overall disease risk.”³³

In short, even though a zero risk policy is acceptable according to the Appellate Body, an adequate risk assessment must nevertheless evaluate the probability of the spread of disease, and must do so for the various alternative regulatory options as well as for the status quo ante in the absence of regulation. The probability may be assessed “qualitatively,” but a conclusion that a mere “possibility” exists that disease may spread apparently falls short of a “qualitative” assessment of “probability.”

3. Japan/Agricultural Products

Coddling moth is a pest that lowers the yield for a variety of fruit products, but it has not yet been detected in Japan. To prevent the introduction of the pest into Japan, the government imposes strict regulations on imported fruit, requiring that it be treated effectively with some combination of fumigation and cold storage to kill the moth at any stage of its life cycle. The United States objected to one important feature of the regulatory scheme, which in essence required an elaborate scientific investigation of the efficacy of measures to kill the moth for every individual variety of a given product (for example, a separate study would have to be conducted for Macintosh apples and Granny Smith apples). Unless a study had been conducted for a particular variety that proved the efficacy of pest control measures to the satisfaction of Japanese regulators, that variety could not be imported into Japan.

The United States challenged the evidence on familiar grounds—that it was not “based on” a risk assessment and was maintained without sufficient scientific evidence. The Appellate Body affirmed the panel’s ruling that the language in article 2.2, prohibiting measures that are “maintained without sufficient scientific evidence,” requires a rational relationship between the measure and the scientific evidence

32. Id at ¶ 129.

33. Id at ¶ 133.

presented.³⁴ The dispute panel's factual determination (not appealable) that no rational relationship existed to the available scientific evidence turned heavily on the fact that Japan could not point to a single instance in which an approved method for killing the moth on one variety of fruit had not proven effective when used on another variety of the same fruit.³⁵ Although Japan could produce some scientific evidence of possible differences across varieties that might make treatments less effective for one variety than another, the mere possibility of a difference was not enough—the panel apparently wanted some affirmative evidence of differences in the efficacy of treatment measures across varieties to justify Japan's policy.

Japan also attempted to justify the policy as “provisional” pursuant to article 5.7 governing conditions where “scientific evidence was insufficient.” This defense failed because Japan could not show that it was engaged in an active research program “to obtain the additional information necessary for a more objective assessment” or that it had reviewed its provisional measures within a “reasonable period of time.”³⁶

B. ANALYSIS AND IMPLICATIONS

Beginning with the hormones decision, the factual propositions that underlie the Appellate Body's conclusions are surely correct. No empirical scientific analysis was presented to the WTO that specifically examined the human health risks from the ingestion of beef containing growth hormone residues, and that concluded that a risk to human health was present. Dr. Lucier's opinion did not rest on any such study that he had conducted, but was simply an extrapolation from the now well-known fact that estrogen ingestion causes an increase in the incidence of breast cancer. And no empirical scientific analysis was presented that examined the risks associated with the possible failure of ranchers to observe good veterinary practice.

Yet, one must ask what the European Union could reasonably have done to bolster the scientific case. Precisely how does one conduct a study of “the specific potential for carcinogenic effects arising from the presence in ‘food’, more specifically, ‘meat or meat products’ of residues of the hormones in dispute”?³⁷ In theory, one might conduct cross-sectional studies comparing cancer rates in nations that permit growth hormones with rates in nations that ban them. But there are innumerable sources of external estrogens besides residues in meat, and innumerable other factors that may affect cancer rates. Can one hope to control for all these factors convincingly?

34. World Trade Organization, Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products*, ¶ 84, WTO Doc No WT/DS76/AB/R (Feb 22, 1999).

35. World Trade Organization, Report of the Panel, *Japan—Measures Affecting Agricultural Products*, ¶ 8.42, WTO Doc No WT/DS76/R (Oct 27, 1998).

36. World Trade Organization, Report of the Appellate Body, *Japan—Measures Affecting Agricultural Products* at ¶¶ 92–93 (cited in note 34).

37. *Hormones Report* at ¶ 199 (cited in note 19) (emphasis in original).

And even if one could, everyone (including Europe) agrees that the marginal contribution to cancer rates from meat hormone residues is likely to be small—could one ever hope to identify such small effects at conventional statistical confidence levels?

Are animal studies the answer? Would studies of low dose hormone administration to lab rats satisfy the Appellate Body? How could one be confident that any results from such studies carry over to humans, whichever way the result came out? And if the issue is the effect of the low residues in meat that might cause cancer at the rate of one case per million population (Dr. Lucier's estimate), how large would the population of test rats have to be for statistically convincing results to be observed?

Finally, if the concern is the risk of hormone misuse, how precisely does one study that risk? One suspects that a questionnaire to a random sample of US ranchers, asking them whether they abuse growth hormones in violation of sound veterinary practice, might yield a negative response regardless of the truth. Could random samples of meat entering Europe at the border be tested for excessive residues? Would excessive residues found on occasion demonstrate an important problem of abuse? How would one determine the risks to human health of those excessive residues, any more than one could empirically assess the risks from the low level residues associated with sound veterinary practice?

Although I am not a toxicologist, I can claim to know enough about empirical research to say that statistically convincing studies demonstrating the existence of a small health risk from hormone residues in meat are likely to be exceedingly difficult to generate. One can observe that the hormones in question are known carcinogens, and that some residue of these hormones exists in the meat. But it is likely impossible to know with any degree of statistical confidence whether these small residues, when added to the diets of people who are exposed to the same hormones from many other sources (not to mention numerous other carcinogens), do or do not cause a few more cases of cancer at the margin.

Consequently, the Appellate Body's insistence that Europe point to highly particularized studies showing a risk from hormone residues in meat likely presents an insurmountable hurdle. The effect is to make it impossible for national regulators to elect to eliminate low level risks that are not susceptible to rigorous demonstration. That may not be bad policy, and indeed it might well be the case that Europe's ban on growth hormones would flunk any sort of careful cost-benefit analysis. But if scientific evidence requirements are construed in a way that makes it impossible to regulate risks that are not demonstrable through particularized scientific studies, they surely clash with the notion that WTO law is not meant to tell member states which risks they must tolerate and which risks they may elect to avoid.

The Australian Salmon case, in my view, is similar in this regard. While pretending to permit nations to embrace a zero risk policy, it simultaneously holds that a credible scientific opinion affirming the possibility of a risk is not enough for

even a “qualitative” assessment of “probability” as required by article 5.1. To some readers, as well as this writer, the Appellate Body’s position on this issue borders on the incoherent. And whatever it is that must be done to count as an acceptable assessment of “probability,” it must be done for all of the regulatory options under consideration. One again wonders exactly what it would take in the way of additional research for Australia to satisfy the Appellate Body—how can one assess the “probability” of disease spreading through imported goods if that unfortunate eventuality has (thankfully) not yet transpired? Would it suffice to demonstrate that live disease organisms reside in the carcasses of uncooked salmon? Seemingly not, as that demonstration should not be a difficult one. And if that is not enough, how does one proceed to isolate the “probability” that such organisms might spread to the live fish population in Australia?

The Japanese measures at issue in the agricultural products case were similarly predicated on unproven risks, but at least that case hinted at a roadmap for further research. In particular, the panel decision implied that if Japan could convincingly identify one instance in which coddling moth treatment effective on one variety of fruit was ineffective on another, it might be able to justify its varietal testing requirements. And had Japan been actively engaged in research on possible varietal differences in treatment efficacy, it might have been able to justify its measures for the short term as provisional. But this decision too seems to stand for the proposition that over the long term, affirmative and convincing scientific evidence must be adduced to establish the presence of the risk in question. *Bona fide* concerns about possible risks are not enough.

Consider, however, the alternative. In the hormones case, the Appellate Body might have written an opinion that would permit Europe to rely on minority opinions like those of Dr. Lucier going forward, simply insisting that such an opinion be in place at the time that a regulation is enacted so that the regulation can fairly be said to have been “based on” it. An adequate “risk assessment” would exist whenever a consultant could colorably extrapolate from a known risk to suggest that a smaller risk was present though not statistically demonstrable—minimal exposure to a substance known to be dangerous in large quantity could always be regulated, for example, as might exposure to substances bearing chemical similarity to those known to be dangerous. Indeed, if experience with the American tort system teaches us anything, it is that determined parties can almost always find consultants willing to opine that risk is present, whether from Bendectin, Agent Orange, silicone breast implants, electromagnetic radiation from cell phones, or any number of other sources. An interpretation that accepts the minority opinions of consultants as “risk assessments” effectively converts scientific evidence requirements into minimal procedural hurdles that can be met easily by any determined regulators, high-minded and protectionist alike. The right of member nations to refuse risks that they do not wish to tolerate would be preserved, but the opportunities for mischief would surely be enhanced as well.

Of course, the problem here is limited to cases of genuine scientific uncertainty. Cases surely arise in principle where the science is so clear that no doubts exist, but I suspect that these cases will rarely make it so far as to trigger a WTO dispute, and certainly that type of case is not what the WTO has seen in practice so far.

The only other class of cases in which the Appellate Body's insistence on hard supporting evidence might not intrude importantly on regulatory sovereignty are those in which scientific uncertainty can be laid to rest reasonably cheaply and quickly. A nation that eschews obvious and inexpensive opportunities for research that will confirm or deny the wisdom of its regulatory policy can hardly complain very loudly if WTO law requires those opportunities to be pursued. But again, these cases are perhaps unlikely to be the ones that provoke international disputes. It is also noteworthy that nothing in WTO treaty text or in WTO decisions to date seems to condition the stringency of the scientific evidence requirement on the technical and economic feasibility of the research program to eliminate scientific uncertainty. Technical and economic feasibility is indeed a factor to be considered in deciding whether a regulatory measure represents the least restrictive means,³⁸ but WTO jurisprudence does not yet bring similar ideas to bear in judging the acceptability of a national "risk assessment."

C. CONSISTENCY REQUIREMENTS AS AN ALTERNATIVE

Before concluding, one might reasonably ask whether alternative devices exist for policing regulatory mischief that would perform reasonably well and that would pose less of a threat to regulatory sovereignty than tight scientific evidence requirements. One option deserving of careful consideration in this regard is a consistency requirement, which also finds expression in WTO law. Article 5.5 of the SPMs Agreement provides that "[w]ith the objective of achieving consistency in ... sanitary or phytosanitary protection ... , each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate for different situations, if such distinctions result in discrimination or a disguised restriction on international trade."

A nice application of this principle may be found in the Australian Salmon case, in which the Appellate Body affirmed an alternative basis for declaring that Australia's ban on salmon imports was impermissible. In particular, the evidence seemed to be quite clear that the risk to the Australian salmon population from the spread of disease was considerably greater from certain activities that Australia did not regulate at all—in particular, the importation of ornamental aquarium fish that might be released into local waters (recall the Asian carp and Northern snakehead problems in the United States presently) and the importation of live herring to use as a baitfish—than it was from the importation of uncooked salmon. Because the evidence of a

38. SPMs Agreement, art 5.6, reprinted in *Documents Supplement* at 124 (cited in note 2).

greater hazard from these activities seemed compelling and Australia had no persuasive justification for ignoring these other hazards on the one hand, while regulating a lesser hazard from a product that just happened to compete with an important domestic industry on the other, the distinction was found to be arbitrary or unjustifiable and a disguised restriction.³⁹

The virtue of resting the decision on the consistency issue alone is at first blush considerable. No longer would the WTO seemingly be telling nations that they could not regulate in the face of potentially intractable scientific uncertainty. Rather, nations would be free to regulate a hazard that was somewhat speculative, but only if they did so evenhandedly without regard to which sources of hazard were competitive irritants to domestic producers. In a circumstance like the Australian case, a weakened scientific evidence requirement would not prevent suspicious regulatory behavior from being policed.

One difficulty, of course, is that regulators will often be able to offer plausible reasons why one type of hazard is regulated and one is not. The costs of regulation may be much higher in one case than another, for example, or differences in the efficacy of regulatory options may make some types of regulation futile. If such arguments are rejected in favor of a finding of an "arbitrary and unjustifiable" distinction, the perceived intrusion on regulatory sovereignty may be no less than before.

There is also the difficult issue of which regulatory distinctions are comparable for consistency purposes. The Australian case was unusual in that one could look to the identical risk to the identical fish population from multiple sources. In the beef hormones case, by contrast, what regulations (or non-regulations) would one examine for consistency? In fact, the dispute panel examined several, including the policy of the European Community to permit certain carcinogenic medications to be used for growth promotion in piglets, and the policy of doing nothing to regulate the ingestion of naturally occurring hormones, such as those present in eggs. In the end, the Appellate Body found no violation of article 5.5 because some of the distinctions were not arbitrary or unjustifiable (such as ignoring the hormones that occur naturally), and others could not be said to be a disguised restriction on trade (the medication used on piglets).⁴⁰

A serious requirement of consistency in regulation probably could not be met by any nation—it is well known, for example, that the cost per life saved varies hugely across public safety and health regulations in the United States.⁴¹ The only way to

39. *Salmon Report* at ¶¶ 234–40 (cited in note 28).

40. *Hormones Report* at ¶ 246 (cited in note 19).

41. See, for example, Lisa Heinzerling, *Regulatory Costs of Mythic Proportions*, 107 *Yale L J* 1981, 2042–64 (1998); Eric A. Posner, *Controlling Agencies with Cost-Benefit Analysis: A Positive Political Theory*

avoid the appearance of rampant inconsistencies will be to narrow the comparisons to regulations that appear similar in some superficial way (in the hormones case, other food regulation, other meat regulation, etc.). Alternatively, one can simply tolerate inconsistencies by recognizing that they are pervasive and rarely motivated by protectionism, as the Appellate Body essentially so found in the hormones case when it addressed the use of carcinogenic medication in piglets. Either way, one quickly becomes pessimistic about the ability of consistency requirements to step into the breach should scientific evidence requirements become more deferential.

III. CONCLUSION

The battle between the proponents of open trade and the proponents of national “sovereignty” has been central to the political fortunes of the World Trade Organization since its inception. Defenders of the system regularly insist that the tension is illusory, and that WTO rules do not intrude on proper national prerogatives. Without taking any normative position on the matter, this essay has argued that in some contexts a serious tension indeed arises, and that the goals of open trade and respect for national sovereignty can be irreconcilably at odds to the point that one must give way. With particular regard to the scientific evidence requirements of the WTO Agreement on Sanitary and Phytosanitary Measures, the WTO Appellate Body has embarked on a course that unmistakably elevates the policing of trade restrictive measures above the ability of national governments to address risk in the face of scientific uncertainty. There is little alternative to such a policy if scientific evidence requirements are to serve as more than window dressing.

Perspective, 68 U Chi L Rev 1137 (2001); Richard J. Zeckhauser and W. Kip Viscusi, *The Risk Management Dilemma*, 545 Annals Am Acad Polit & Soc Sci 144 (1996).