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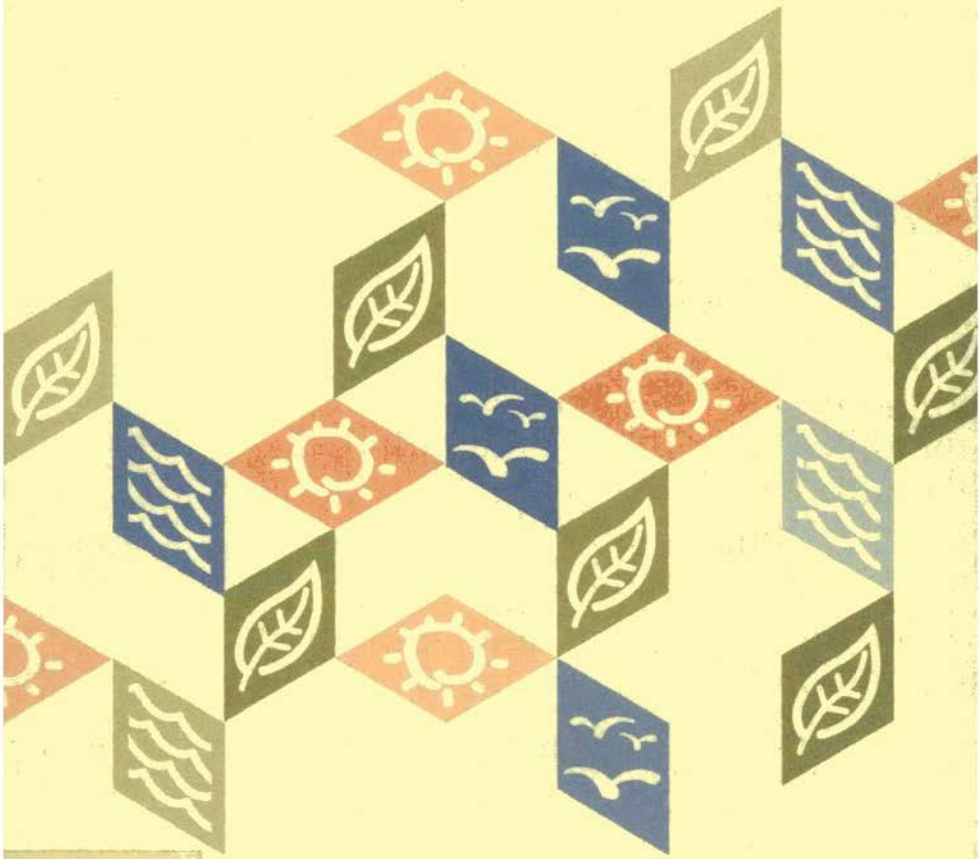
The Role of Science in the Uruguay Round and NAFTA Trade Disciplines

By David A. Wirth



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Series Coordinator: Scott Vaughan

ISSN: 1020-1610

Foreword

The 1992 "Earth Summit" found common ground upon which human development can be put on an environmentally sustainable footing. In 1993, completion of negotiations for the Uruguay Round set the course for a further liberalisation of international trade. One of the most pressing and complex challenges facing our generation is the search for a workable synthesis of the two, of economic relations and environmental realities.

We must embark upon this course, not because it is easy, but because it is necessary. Our planet's ecological vital-signs continue to warn us of an accelerating rate of degradation - depletion of the ozone layer that shields us from harmful solar radiation, erosion of productive soils needed to grow food, contamination of freshwater with hazardous wastes, depletion of fish stocks, the massive loss of biodiversity, the threat of climate change and global warming.

An important challenge identified at the Earth Summit is ensuring that trade and environment are "mutually supportive". It is hoped that this series, providing analysis on selected environmental issues of relevance to the environment - trade debate, will contribute to the search for solutions now under way.

Elizabeth Dowdeswell
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THE ROLE OF SCIENCE IN THE URUGUAY ROUND AND NAFTA TRADE DISCIPLINES

David A. Wirth*

This paper examines the increasingly important role of science in the structure and operation of international trade agreements. Indeed, under the recently completed Uruguay Round of Multilateral Trade Negotiations under the auspices of the General Agreement on Tariffs and Trade (Uruguay Round)[1] and the trilateral North American Free Trade Agreement (NAFTA)[2], the presence and integrity of scientific support is a principal touchstone for determining the legitimacy of many national regulatory efforts aimed at assuring environmental integrity or safeguarding public health. More particularly, the analysis in this paper is intended to highlight the quiescent issues at the interface between science and governmental regulatory policies that are raised by the emphasis on scientific validity in the Uruguay Round and the NAFTA.

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At the outset, it is important to emphasise that international trade agreements, at least to the extent that they govern national regulatory measures in the areas of environment and public health, contain primarily "negative" obligations. That is to say, international trade agreements do not generally contain affirmative requirements directing national governments to achieve certain minimum criteria in these areas. Rather, under the Uruguay Round or the NAFTA, inadequate scientific support for a national environmental or public health standard may imply that that standard is unjustified. Consequently, tests of scientific validity in recent international trade agreements are intended to circumscribe the regulatory authority of national governments so as to limit the abuse of putatively "scientific" claims for protectionist purposes, and not to establish minimum benchmarks for protection of the environment and public health. In other words, the science-based trade disciplines in the Uruguay Round and the NAFTA are not just good practise standards. Instead, failure to satisfy those requirements, unless a regulatory measure is based on an international standard, implies inconsistency with the trade agreement, creating an obligation to remove or correct the offending measure.

As currently structured, these multilateral and regional trade agreements invite the application of science at the following principal junctures addressed in this paper:

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[1] Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, 33 I.L.M. 9 (1994) [hereinafter Uruguay Round Final Act].

[2] North American Free Trade Agreement, *opened for signature* Dec. 8, 1992, Can.-Mex.-U.S., 32 I.L.M. 296, 612 [hereinafter NAFTA].

- in establishing national regulatory standards; and
- in the quasi-adjudicatory panel dispute settlement process.

The application of science in both these contexts involves two principal tasks that pervade virtually all regulatory activity in the areas of environment and public health:

- the process of analysing experimental data to determine governmentally established regulatory requirements;
- the process of crafting national regulatory requirements in the face of scientific uncertainty.

Examination of these two tasks in both the contexts identified above then generates two central questions that this paper attempts to answer:

- What can reasonably be expected of science and scientists in the national regulatory process?; and
- In light of the answer to the previous question, what is a reasonable interpretation of the science-based trade disciplines in the Uruguay Round and the NAFTA?

The central theme of this paper is the necessity for deference to decision-making processes of national regulatory authorities in the application of these new trade disciplines and the need for trade-based review of national regulatory measures to operate within clearly defined limits. Accordingly, this paper first examines and summarises the relevant texts, including the original 1947 GATT, the Uruguay Round, and the NAFTA texts on standards. Next, the paper considers the role of science in

the standard-setting process with reference to the copious literature on this topic. Finally, the paper takes up the difficult question of the application of the science-based trade disciplines in the Uruguay Round and NAFTA texts in the context of the quasi-adjudicatory trade agreement dispute settlement process.

I. Basic Texts

From the point of view of the role of science in international trade, the potentially universal trade regime established in 1947 by the General Agreement on Tariffs and Trade (GATT 1947)[3] is of the greatest interest. The original 1947 instrument has been supplemented by a number of additional rounds of multilateral trade negotiations. Of particular importance to the subject of this paper are the Tokyo Round, which was completed in late 1979, and the Uruguay Round, which was completed in late 1993 and signed on April 15, 1994, but which, as of this writing, has yet to enter into force. As a result of this sequence of multilateral efforts, the GATT rules now govern an increasingly wide array of substantive issues, including in the Uruguay Round not only food safety laws but also intellectual property rights. Also relevant is the regional North American Free Trade Agreement (NAFTA), which entered into force for Canada, Mexico, and the United States on January 1, 1994.

A. GATT 1947

As a general matter, national measures directed at preservation of the environment and protection of public health are subject to the generic requirements of GATT 1947. Fundamental GATT obligations that apply in these areas, as in others, include the most-favoured-nation principle (non-discrimination among

[3]General Agreement on Tariffs and Trade, Oct. 30, 1947, as amended, Basic Instruments and Selected Documents [hereinafter BISD], vol. IV, 55 U.N.T.S. 188 [hereinafter GATT 1947].

imported products on the basis of their national origin), national treatment[4] (non-discrimination between foreign and domestic products)[5], and a prohibition on quantitative restrictions for imports or exports.[6]

Article XX of GATT 1947 contains a number of exemptions from the General Agreement for specific categories of national measures. Of particular importance in the fields of environmentand public health are two express exceptions in article XX of GATT 1947: one in paragraph (b) for measures "necessary to protect human, animal or plant life or health;" and another in paragraph (g) for measures "relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption."[7] The two exceptions are to be narrowly construed.[8] Moreover, in contrast to the usual

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[4] GATT 1947, *supra* note 3, art. I.

[5] *Id.* art. III.

[6] *Id.* art. XI.

[7] The relevant passage provides in full as follows:

Article XX

General Exceptions

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

(b) necessary to protect human, animal or plant life or health; [or]

(g) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption.

GATT 1947, *supra* note 3.

[8] *See, e.g.*, United States—Restrictions on Imports of Tuna, BISD, Supp. No. 39, para. 5.22, at 155 (1993), 30 I.L.M. 1594, 1619 (1991) [hereinafter United States -Tuna Dolphin I Panel Report]. In response to a complaint

(contd.)

situation for resolving disputes over rights in GATT 1947, the burden is on the respondent whose measure is challenged, rather than on the complainant, to demonstrate the applicability of one of the enumerated exemptions.[9] The role of overtly scientific considerations in the jurisprudence of these two exceptions, as elaborated by GATT dispute settlement panels, is discussed in section III.B below.

Entirely apart from any consideration of scientific integrity, the "necessary" requirement with respect to measures to protect human, animal, or plant life or health has been interpreted by panels as implying a test that turns on the trade effect of the

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8. (contd.)

lodged by Mexico, this panel report addressed an embargo on importation of yellowfin tuna into the United States. The embargo was designed to encourage foreign states to ensure that vessels under their jurisdiction conduct tuna fishing operations so as not to kill or injure dolphins. A second challenge, initiated by the European Union and the Netherlands, addressed a secondary import ban designed to discourage "tuna laundering" by intermediary nations which purchase yellowfin tuna abroad and export it to the United States. United States—Restrictions on Imports of Tuna, 33 I.L.M. 842 (1994) [hereinafter United States—Tuna Dolphin II Panel Report]. Both panels concluded that the import prohibitions in question were inconsistent with the United States' obligations pursuant to the GATT. The GATT Council rejected a request by the European Union to adopt the first panel report, in which Mexico was the complainant. *See GATT Council Refuses EC Request to Adopt Panel Report on U.S. Tuna Embargo*, 9 INT'L TRADE REP. (BNA) 353 (Feb. 26, 1992). In a discussionof the second report, the GATT Council is reported to have rejected a proposal from the United States that would have opened further Council meetings on that case to the public, and Mexico was said to consider requesting adoption of the first report. Frances Williams, *GATT Shuts Door on Environmentalists*, FIN. TIMES, July 21, 1994, at 6. As of this writing, neither report has been adopted by the GATT Council and hence neither has yet acquired legal force. *See* William J. Davey, *Dispute Settlement in GATT*, 11 FORDHAM INT'L L.J. 51, 94 (1987).

[9] *See, e.g.*, United States—Section 337 of the Tariff Act of 1930, BISD, Supp. No. 36, para. 5.27, at 345, 393 (1990).

measure.[10] Similarly, the exception for trade measures to protect exhaustible natural resources has been interpreted to require that the standards in question are "primarily aimed at conservation."[11] Only one of the environmental, conservation, or public health measures examined by dispute settlement panels whose

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[10] *E.g.*, United states - Taxes on Automobiles, GATT Doc. DS31/R para. 5.64-65 (Sept. 29, 1994) (regulatory scheme requiring manufacturers and importers to meet minimum average fuel efficiency for all automobiles is intended to promote energy conservation and therefore is primarily aimed at conservation);United States –Tuna Dolphin I Panel Report, *supra* note 8, para. 5.28 (failure to "exhaust[] all options reasonably available . . . through measures consistent with the General Agreement" implies lack of necessity pursuant to article XX(b)); Thailand –Restrictions on Importation of and Internal Taxes on Cigarettes, BISD, Supp. No. 37, paras. 74-81, at 200 (1991), 30 I.L.M. 1122 (1991) (import restrictions not justified by article XX(b) in light of availability of GATT-consistent or less GATT-inconsistent measures). *Cf.* United States– Measures Affecting Alcoholic and MaltBeverages, BISD, Supp. No. 39, paras. 5.41-43 & 5.52, at 206 (1993) (measures relating to import of beer are not the least trade-restrictive and therefore not "necessary" within meaning of article XX(d), which exempts "measures necessary to secure compliance with laws or regulations which are not inconsistent with" GATT); United States—Section 337 of the Tariff Act of 1930, *supra* note 9, at paras. 5.25-.35 (availability of GATT-consistent or less GATT-inconsistent alternatives implies that challenged measures are not "necessary" under article XX(d)). *See generally* Steve Charnovitz, *GATT and the Environment: Examining the Issues*, 4 INT'L ENVTL. AFF. 203, 212-14 (1992) (criticising "the mutating 'necessary' test").

[11] *E.g.*, United States—Tuna Dolphin II Panel Report, *supra* note 8, para. 5.27 (measures taken so as to force other countries to change their policies, and that are effective only if such changes occur, are not primarily aimed at conservation); United States – Tuna Dolphin I Panel Report, *supra* note 8, para. 5.33 (limitations on taking marine mammals by foreign fleets established with reference to dolphin kills by U.S. vessels not primarily aimed at conservation); Canada – Measures Affecting Exports of Unprocessed Herring and Salmon, BISD, Supp. No. 35, paras. 4.6-.7, at 98 (1989) (requirement that fish be processed domestically before export is not primarily aimed at conservation and therefore not justified by article XX(g)). *See* text accompanying notes 104-117 *infra* (discussing panel report under Canada-United States Free-Trade Agreement which concluded that Canadian "landing" requirement for salmon and herring caught in Canadian waters was not primarily aimed at conservation).

consistency with GATT turned on the availability of these exceptions has ever met these tests.[12]

B. Tokyo Round Standards Code

In response to the generally perceived failure of the GATT regime to respond to the problem of non-tariff barriers, an Agreement on Technical Barriers to Trade[13], often known as the "Standards Code," was adopted in 1979 as part of the Tokyo Round of Multilateral Trade Negotiations. The Standards Code, which governs mandatory governmentally established specifications for industrial and agricultural products, is intended to minimise trade distortions that arise from disparate national regulatory requirements.

The Standards Code, which applies only to the thirty-nine parties to GATT, including the European Union (EU), that currently accept it, requires parties to use multilaterally agreed standards, where they exist, as a basis for national measures.[14] The Standards Code also clearly establishes a requirement of non-discrimination in standards and their application, both among imported products on the basis of their national origin and between foreign and domestic products.[15]

The central criterion for determining the validity of a standard under the Standards Code is whether that standard constitutes an "unnecessary obstacle to international trade." Although the

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[12] United States - Taxes on Automobiles, *supra* note 11. *But cf.* United States - Tuna Dolphin II Panel Report, *supra* note 8; United States—Tuna Dolphin I Panel Report, *supra* note 8; Thailand—Restrictions on Importation of and Internal Taxes on Cigarettes, *supra* note 10;Canada—Measures Affecting Exports of Unprocessed Herring and Salmon, *supra* note 11; United States—Prohibition of Imports of Tuna and Tuna Products from Canada, BISD, Supp. No. 29, at 91 (1983).

[13] Agreement on Technical Barriers to Trade, Apr. 12, 1979, 1186 U.N.T.S. 276, BISD, Supp. No. 26, at 8 (1980) [hereinafter Standards Code].

[14] *Id.* art. 2.2.

[15] *Id.* art. 2.1.

Standards Code may have helped in reducing the potential for divergent national regulatory standards to distort trade as non-tariff barriers, the core test for an "unnecessary obstacle"—i.e., an unacceptable standard—was not clearly articulated. Unlike other key terms like "standard," "unnecessary obstacle" is not defined in the Standards Code. The text does not expressly distinguish between unnecessary and necessary regulations, but instead:

> recognizes implicitly that there may be "necessary" obstacles. Much time was spent on this formulation, and the end result is not entirely satisfactory. While subsequent provisions in the Code may be taken as providing guidance on what may be considered as "necessary" the fact remains that these provisions are likely to give rise to considerable difficulties of interpretation in practice: the complaining party will have either to prove deliberate protectionist intent, or to demonstrate that the measure went beyond what was "necessary[.]"[16]

The Standards Code contains special dispute resolution procedures that anticipate the establishment of technical expert groups, which are created by and advise dispute settlement panels.[17]

As of this writing, there is no panel jurisprudence interpreting the meaning of "unnecessary obstacle" within the meaning of the Standards Code.[18]

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[16] R.W. Middleton, *The GATT Standards Code*, 14 J. WORLD TRADE L. 201, 206 (1980).

[17] Standards Code, *supra* note 13, paras. 14.9-14.12, Annex 2.

[18] *See, e.g.*, Eliza Patterson, *International Efforts to Minimize the Adverse Trade Effects of National Sanitary and Phytosanitary Regulations*, 24 J. WORLD TRADE, Apr. 1990, at 91, 95. In a domestic proceeding in the United

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C. Uruguay Round of Multilateral Trade Negotiations

The Uruguay Round of Multilateral Trade Negotiations in GATT, completed in December 1993, contains two new texts addressing standards relevant to the protection of environment and public health: (1) an Agreement on the Application of Sanitary and Phytosanitary Measures (Uruguay Round SPS Agreement)[19] addressing such domestic regulations as those designed to protect the food supply from contamination; and (2) an Agreement on Technical Barriers to Trade (Uruguay Round TBT Agreement),[20] which elaborates the earlier Tokyo Round Standards Code for standards other than sanitary and phytosanitary measures.

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18. (contd.)

States,Canada filed a brief *amicus curiae* supporting a Canadian mining company and a number of Canadian trade unions that challenged a United States regulation banning the manufacture, importation, processing, and distribution in commerce of most asbestos-containing products. Canada argued that, because it was not supported by sufficient scientific evidence, the regulation was an unnecessary obstacle to trade within the meaning of the Standards Code. Brief for Amicus Curiae Government of Canada at 16-19, Corrosion Proof Fittings v. Environmental Protection Agency, 947 F.2d 1201 (5th Cir. 1991). Although concluding that the regulation was not valid on domestic legal grounds, the court in the United States determined that Canada's arguments based on the Standards Code could not be entertained in the domestic tribunal. Corrosion Proof Fittings v. Environmental Protection Agency, 947 F.2d 1201, 1211 n.8 (5th Cir. 1991). *See generally* Kyle E. McSlarrow, *International Trade and the Environment: Building a Framework for Conflict Resolution*, 21 ENVTL. L. REP. 10,589 (1991) (discussing Canadian challenge to U.S. asbestos regulation).

[19] Agreement on the Application of Sanitary and Phytosanitary Measures, Uruguay Round Final Act, *supra* note 1, at II-A1A-4 [hereinafter Uruguay Round SPS Agreement].

[20] Agreement on Technical Barriers to Trade, Uruguay Round Final Act, *supra* note 1, at II-A1A-6 [hereinafter Uruguay Round TBT Agreement].

1. Agreement on the Application of Sanitary and Phytosanitary Measures

The Uruguay Round SPS Agreement governs a particular and specific category of measures known as "sanitary and phytosanitary standards,"[21] defined by the objective of the measure and the type of product regulated. The principal regulations of concern regarding human health are those that restrict additives, pesticides, and other contaminants to protect the integrity of the food supply. Unlike the earlier Tokyo Round Standards Code, the new text on sanitary and phytosanitary measures must be accepted by contracting parties as part of the overall Uruguay Round package, including the newly created World Trade Organisation (WTO).[22]

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[21] Paragraph 1 of Annex A of the Uruguay Round SPS Agreement defines "sanitary or phytosanitary measure" as:

Any measure applied:

- to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
- to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
- to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
- to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

Uruguay Round SPS Agreement, *supra* note 19.

[22] *See* Agreement Establishing the World Trade Organization, 33 I.L.M. 15 (1994).

A serious disagreement between the United States and the European Union over hormone-treated beef, now nearly a decade in duration, motivated much of this text, which is designed to prevent the abuse of sanitary and phytosanitary measures as non-tariff barriers to trade. As of January 1, 1988, the European Union banned the use of growth hormones in the breeding of cattle and the sale of beef, including imported beef, treated with growth hormones. The United States, where those hormones are permitted, has strongly objected to the bar as a non-tariff barrier to trade unsupported by scientific evidence.[23] The conflict consequently turns on the risk to human health, if any, from consumption of hormone-treated beef. This controversy has never reached a GATT dispute settlement panel.

Although formally governed by the 1979 Tokyo Round Standards Code, the sub-category of sanitary and phytosanitary measures received particular attention in the Uruguay Round. One important motivation for this segmentation appears to have been the prominence of the U.S.-EU beef hormone dispute. Another was the close nexus between broader agricultural issues and sanitary and phytosanitary standards, which led to the treatment of the latter within the broader context of agriculture in the Uruguay Round.[24] Finally, sanitary and phytosanitary

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[23] *See, e.g.*, 19 U.S.C. § 2901(b)(7)(C) (1988) (identifying as a principal negotiating objective of the United States in the Uruguay Round and the NAFTA "eliminating and reducing substantially . . . unjustified phytosanitary and sanitary restrictions"). *See generally* Steven J. Rothberg, Note, *From Beef to BST: Circumventing the GATT Standards Code's Prohibition on Unnecessary Obstacles to Trade*, 75 MINN. L. REV. 505 (1990); Michael B. Froman, Recent Developments, *The United States-European Community Hormone Treated Beef Conflict*, 30 HARV. INT'L L.J. 549 (1989); Adrian Rafael Halpern, *The U.S.-EC Hormone Beef Controversy and the Standards Code: Implications for the Application of Health Regulations to Agricultural Trade*, 14 N.C. J. INT'L L. & COM. REG. 135 (1989).

[24] *See* 1 THE GATT URUGUAY ROUND: A NEGOTIATING HISTORY (1986-1992) 141-42 (Terence P. Stewart ed. 1993).

measures were thought to raise difficulties distinct from those associated with technical standards generally, including the greater importance of scientific assessment of risk, a wide variety of national approaches to standard setting in the area of health, and the crucial role of national regulatory authorities in determining the need for action and in choosing preventive or remedial measures in this area.[25] As a consequence, sanitary and phytosanitary standards have been "split off" from the larger generic issues associated with technical standards and are treated in a separate agreement in the Uruguay Round that emphasises scientific validity to a considerably greater extent than the broader new Agreement on Technical Barriers to Trade.

Accordingly, scientific tests lie at the core of the trade disciplines established in the new Uruguay Round SPS Agreement. The final Uruguay Round text specifies that sanitary and phytosanitary measures must be "based on scientific principles and . . . not maintained without sufficient scientific evidence."[26] National measures that conform to international standards, such as those established by the Codex Alimentarius Commission, are presumptively valid.[27]

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[25] *See* Patterson, *supra* note 18, at 95-96.

[26] Uruguay Round SPS Agreement, *supra* note 19, para. 6.

[27] *Id.* para. 10. The new agreement specifically references a number of international standard setting bodies, of which the most important from the point of view of protecting human health is the Codex Alimentarius Commission. The Codex Alimentarius Commission was created in 1962 as a joint undertaking of the UN Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO). The Commission, membership in which is open to all FAO and WHO member states and now numbers more than 130, has a dual function: "protecting the health of the [*sic*] consumers and ensuring fair practices in the food trade." Statutes of the Codex Alimentarius Commission, art. 1, para. a, *reprinted in* CODEX ALIMENTARIUS COMMISSION, PROCEDURAL MANUAL 5 (8th ed. 1993). To this end, the Commission is specifically charged with adopting advisory multilateral "good practise" standards on such matters as the composition of food products, food additives, labelling, food processing techniques, and

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inspection of foodstuffs and processing facilities. As of 1993, Codex had evaluated 187 pesticides, 523 food additives, and 57 food contaminants and established 3,019 maximum residue limitations for pesticides. ROGER W. MILLER, THIS IS CODEX ALIMENTARIUS (1993).

From the point of view of this paper, Codex activities fall in the realm of harmonisation and international standard setting and involve both risk assessment and risk management functions. *See* text accompanying notes 60-64 *infra*. The Commission's Secretariat recently released a paper on the role of science in the Codex decision making process. That paper recommends

- clearly distinguishing between risk assessment and risk management in the Codex process and regularising data analysis and risk assessment methodologies;
- improving the transparency of the Codex decision making process by identifying publicly available scientific data, clearly explaining the methodology used to evaluate risk, plainly identifying social policy choices such as the acceptable level of protection underlying a particular standard, and providing a narrative statement of scope and purpose to accompany each standard;
- distinguishing between those standards intended for the protection of public health and those for other purposes, including prevention of unfair trade;
- adopting a "sunset" rule specifying that Codex standards are valid for no less than 20 years to assure reevaluation of Codex standards in light of new scientific developments. Existing Codex standards would expire within 10 years; and
- ensuring that Codex standards are "no more restrictive of trade than necessary to achieve legitimate interests, taking into account technical and administrative aspects of implementation."

Codex Alimentarius Commission Doc. CX/GP 94/4. An earlier paper on risk assessment procedures used by the Codex Alimentarius Commission and its subsidiary and advisory bodies, Codex Alimentarius Commission Doc. ALINORM 93/37, prepared by a consultant, documented variability in risk assessment methodologies within Codex and recommended standardisation of Codex's overall approach to formal risk assessment.

Codex's treatment of carcinogenic pesticides has been compared to the system employed in the United States at the national level as follows:

> The EPA [U.S. Environmental Protection Agency] employs a quantitative risk procedure for evaluating pesticides that may be carcinogenic. With noncarcinogenic pesticides, a threshold level (no observed effects level) is identified which then serves as the basis for establishing an ADI [acceptable daily intake]. With carcinogenic pesticides, the EPA assumes that there is no threshold level but rather, a probability of risk exists at any level of exposure.

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The Uruguay Round SPS Agreement introduces the concept of a WTO member's appropriate level of sanitary or phytosanitary protection.[28] Although the choice of appropriate level of protection appears to be the unilateral prerogative of each WTO member state, the level of protection must "take into account the objective of minimizing negative trade effects."[29] Moreover, each party is to "avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade."[30] In a somewhat obscure passage, guidelines for implementing this requirement to be considered subsequently by the WTO members "shall take into account . . . the exceptional character of human health risks

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27. (cont'd.)

> The focus of the EPA's assessment is to determine if an acceptable level of risk exists for the pesticide. This is accomplished by applying multistage mathematical models to available dose/response test data and taking into account the weight of evidence concerning carcinogenicity. The result is the calculation of human risk probabilities. A risk of one in a million is considered acceptable under certain conditions.
>
> The [Codex] uses basically the same procedures for interpreting carcinogenic data as in evaluating other toxic effects of pesticides. It may use a larger safety factor when recommending an ADI level for pesticides where carcinogenic risk is apparent. In cases where a no observed effects level cannot be clearly established and the carcinogenic risk is high, there would be cause for not recommending an ADI.

UNITED STATES GENERAL ACCOUNTING OFFICE, INTERNATIONAL FOOD SAFETY: COMPARISON OF U.S. AND CODEX PESTICIDES STANDARDS 24 (1991) (footnote omitted) [hereinafter INTERNATIONAL FOOD SAFETY].

[28] Uruguay Round SPS Agreement, *supra* note 19, Preamble para. 6, paras. 11, 14, 18, 19, 20, 21, 29, 32, 41 & Annex B, para. 2.1(c). Noting that "[m]any Members . . . refer to this concept as the 'acceptable level of risk,'" paragraph 5 of Annex A defines "[a]ppropriate [l]evel of [s]anitary or [p]hytosanitary [p]rotection" as "[t]he level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory."

[29] *Id.* para. 19.

[30] *Id.* para. 20.

to which people voluntarily expose themselves,"[31] a category which presumably includes tobacco. Somewhat incoherently, this requirement appears to imply that the level of protection from involuntary or unknowing exposures to contaminants in food that a WTO member country decides to provide to all its citizens should be determined by reference to the level of risk to which certain individuals, such as smokers, voluntarily and knowingly choose to expose themselves.

A WTO member state may adopt measures more stringent than international standards to achieve its appropriate level of sanitary or phytosanitary protection, so long as those measures are supported by "a scientific justification."[32] This passage apparently is intended to assure that WTO member states may adopt measures more stringent than harmonised international standards, but only so long as those national measures are grounded in sound science. It is by no means obvious, however, that "good science" can be defined with precision in the abstract.

The text of the Uruguay Round SPS Agreement mirrors this deeply rooted difficulty. The use of the term "scientific justification" in the so-called "Dunkel Draft," an interim negotiating text of the Uruguay Round produced in December 1991,[33] was controversial in some quarters because of its potential implication of a rigorous cause-and-effect nexus between empirical scientific evidence and the national regulatory measure chosen.[34] The final Uruguay Round SPS Agreement elaborates the meaning of this term, as the Dunkel Draft did not, by explaining that,

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[31] *Id.* para. 20. *Cf. infra* text accompanying note 127 (GATT panel finding the "smoking constitute[s] a serious risk to human health").

[32] Uruguay Round SPS Agreement, *supra* note 19, para. 11.

[33] Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, G.A.T.T. Doc. MTN.TNC/W/FA, sec. L, pt. C, para. 11, at L.37 (1991).

[34] *See* section II.B *infra* (discussing precautionary approaches).

> there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations arenot sufficient to achieve its appropriate level of protection.[35]

Although apparently intended to clarify the text, this insertion adds another layer of interpretational difficulty. This passage links a party's appropriate level of sanitary or phytosanitary protection with the concepts of "scientific justification" and "available scientific information." The footnote consequently might be taken to suggest, as the rest of the text does not, that there are scientific constraints on the choice of appropriate level of protection, a risk management decision that reflects social value choices distinct from the scientific process of risk assessment.[36]

Contracting parties are required to assure that sanitary and phytosanitary measures are "based on" a risk assessment.[37] In performing this risk assessment, governments must "tak[e] into account risk assessment techniques developed by the relevant

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[35] Uruguay Round SPS Agreement, *supra* note 19, para. 11 n.2.

[36] *See infra* text accompanying note 64.

[37] Uruguay Round SPS Agreement, *supra* note 19, para. 16. Paragraph 4 of Annex A to the agreement defines "risk assessment" as

> 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 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, feedstuffs and beverages.
>
> *Id.*

international organizations"[38] and "take into account available scientific evidence."[39] In cases of scientific uncertainty or inadequate data "where relevant scientific evidence is insufficient," WTO member states "may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information".[40]

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[38] *Id.* para. 16. Partially because of lack of standardisation in the definitions of "risk assessment" and "risk management," as discussed in section II.A *infra*, harmonisation of risk assessment methodologies has not proceeded especially quickly. For chemical risks, the Organisation for Economic Co-operation and Development (OECD) has undertaken to harmonise risk assessment methodologies, particularly with respect to pesticides, and has published guidelines for the testing of chemicals. The International Programme on Chemical Safety, a joint project of the World Health Organisation (WHO), the International Labour Organisation (ILO), and theUnited Nations Environment Programme (UNEP), has also undertaken work in this area. Although not strictly international, there is also a considerable body of experience with risk assessment in the European Union, which has recently resulted in the adoption of common principles and methodologies as applied to certain dangerous substances. *See, e.g.*, Commission Directive 93/67/EEC of 20 July 1993 Laying Down the Principles for Assessment of Risks to Man and the Environment of Substances Notified in Accordance with Council Directive 67/548/EEC, 1993 O.J. EUR. COMM. (L 227) 9. For a comparison of risk assessment methodologies in OECD countries, *see generally* UNITED STATES GENERAL ACCOUNTING OFFICE, PESTICIDES: A COMPARATIVE STUDY OF INDUSTRIALIZED NATIONS' REGULATORY SYSTEMS 58-69 (1993) [hereinafter PESTICIDES: A COMPARATIVE STUDY OF INDUSTRIALIZED NATIONS' REGULATORY SYSTEMS].

[39] Uruguay Round SPS Agreement, *supra* note 19, para. 17.

[40] *Id.* para. 22. Other salient disciplines include a requirement that sanitary and phytosanitary measures be "necessary for the protection of human, animal or plant life or health," *id.* para. 5, and that such measures are "applied only to the extent necessary to protect human, animal or plant life or health." *Id.* para. 6. Sanitary and phytosanitary measures must not "arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail" and must not "be applied in a manner which would constitute a disguised restriction on international trade." *Id.* para. 7. Particular sanitary and phytosanitary measures may not be "more trade restrictive than required to achieve [a WTO member's] appropriate level of protection, taking into account technical and economic feasibility." *Id.* para.

(contd.)

2. Agreement on Technical Barriers to Trade

The Uruguay Round also contains an Agreement on Technical Barriers to Trade (Uruguay Round TBT Agreement) which elaborates the requirements of the Tokyo Round Standards Code for technical regulations and standards,[40] with the exception of sanitary and phytosanitary measures, which are covered under the Uruguay Round agreement on that subject. Unlike the earlier Standards Code, this new agreement is an integral component of the Uruguay Round that must be accepted by all GATT contracting parties that adhere to the new Round. As in the case of the Tokyo Round Standards Code, the new agreement establishes trade disciplines to distinguish those domestic standards, including those designed to preserve the environment and to protect public health, that could act as non-tariff barriers to trade.

Anecdotal reports suggest that one motivation for the Uruguay Round TBT Agreement is the increasing "internationalisation" of manufacturing processes. For example, component parts of such products as automobiles may be manufactured by, or to the specifications of, multinational corporations in a variety of countries and cross national boundaries any number of times before the finished goods are placed on the market. The new TBT Agreement could potentially apply to a wide variety of regulatory requirements that haveenvironmental or public health implications, but that are

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40. (contd.)

21 (footnote omitted). The choice of sanitary or phytosanitary measure must also reflect economic considerations for measures intended to protect animal or plant life or health. *Id.* para. 18.

[41] The Uruguay Round TBT Agreement is somewhat broader in coverage than that of the Tokyo Round Standards Code. The new agreement specifies that it applies to both mandatory and advisory requirements not only for products, but also for "related processes and production methods." Uruguay Round TBT Agreement, *supra* note 20, Annex 1, paras. 1-2

not sanitary or phytosanitary standards. Specifications for consumer products and children's toys, appliance efficiency criteria, and vehicle fuel efficiency standards might all be governed by the Uruguay Round TBT Agreement.

As discussed above, unlike the Uruguay Round SPS Agreement, the new technical barriers agreement contains no scientifically-based trade disciplines. Like the Tokyo Round Standards Code, the Uruguay Round TBT Agreement articulates a basic test of non-discrimination and retains the central notion of an unnecessary obstacle to international trade. This latter concept is elaborated by the requirement that product standards "shall not be more trade-restrictive than necessary to fulfil a legitimate objective," such as protection of the environment or public health.[42] Also like the earlier Standards Code, the new text encourages the use of international standards where they exist.[43] Because of the much broader range of legitimate objectives, such as consumer protection, in standards covered by the new TBT Agreement, and in distinct contrast to the Uruguay Round SPS Agreement, national regulations that are more stringent or rigorous than comparable international standards need not meet a scientific test.

D. The North American Free Trade Agreement

The trilateral North American Free Trade Agreement[44] entered into force for Canada, Mexico, and the United States on January 1, 1994. An earlier bilateral agreement between Canada and the United States entered into force on January 1, 1989.[45]

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[42] *Id.* art. 2, para. 2.2.

[43] *Id.* art. 2, para. 2.4 & Annex 3, para. F. The Uruguay Round TBT Agreement, like the Uruguay Round SPS Agreement, articulates the concept of a "level of protection" chosen by each state member. *Id.* preamble para. 5 & Annex 3, para. F.

[44] *Supra* note 2.

[45] Free-Trade Agreement, Dec. 22, 1987 Jan. 2, 1988, Can.-U.S., 27 I.L.M. 281 (1988) [hereinafter CUSFTA].

The operation of the Canada-U.S. agreement, however, has been suspended for so long as the NAFTA remains in effect.[46] Consequently, the earlier bilateral agreement may shed some light on regional practise in North America, but the NAFTA is the operative instrument currently governing trade among these three North American countries. The NAFTA, like the Uruguay Round, contains distinct provisions on sanitary and phytosanitary measures and technical barriers to trade. Although both these issues were considered in the Uruguay Round negotiations before the formal NAFTA negotiations began, the NAFTA was adopted first. Accordingly, prior developments in the Uruguay Round informed the NAFTA texts, which themselves then influenced the final form of the Uruguay Round agreements.

1. Sanitary and Phytosanitary Measures

Like the Uruguay Round text, chapter 7 of the NAFTA contains specific provisions governing sanitary and phytosanitary measures[47] as a specific category of standards. Similar to the

[46] *See* Statement of Administrative Action, North American Free Trade Agreement Implementation Act, at 8 (1993), *reprinted in* H.R. Doc. No. 159, 103d Cong., 1st Sess. 450, 457 (1993).

[47] The NAFTA defines "sanitary or phytosanitary measure" as follows:

a measure that a Party adopts, maintains or applies to:

(a) protect animal or plant life or health in its territory from risks arising from the introduction, establishment or spread of a pest or disease,

(b) protect human or animal life or health in its territory from risks arising from the presence of an additive, contaminant, toxin or disease-causing organism in a food, beverage or feedstuff,

(c) protect human life or health in its territory from risks arising from a disease causing organism or pest carried by an animal or plant, or a product thereof, or

(d) prevent or limit other damage in its territory arising from the introduction, establishment or spread of a pest,

including end product criteria; a product related processing or production method; a testing, inspection, certification or approval procedure; a relevant statistical method; a sampling procedure; a method of risk assessment; a

(contd.)

Uruguay Round SPS Agreement, the NAFTA encourages the use of internationally agreed standards and declares that those standards are presumptively valid.[48] By comparison with the Uruguay Round, the NAFTA is somewhat more explicit about a party's right to establish its own "appropriate levels of protection"[49] and to implement measures more stringent than international standards.[50] Those measures more stringent than international standards must be:

- "based on scientific principles . . . ;"
- "not maintained where there is no longer a scientific basis . . . ;" and
- "based on a risk assessment . . . ."[51]

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47 (contd.)

packaging and labelling requirement directly related to food safety; and a quarantine treatment, such as a relevant requirement associated with the transportation of animals or plants or with material necessary for their survival during transportation. . . .

NAFTA, *supra* note 2, art. 724.

[48] *Id.* art. 713, paras. 1 & 2.

[49] *Id.* art. 712, para. 2. Article 724 defines "appropriate level of protection" as "the level of protection of human, animal or plant life or health in the territory of a Party that the Party considers appropriate." *Id.* Like the Uruguay Round, the NAFTA requires that the level of protection "minimiz[e] negative trade effects." *Id.* art. 715, para. 3(a). Like the Uruguay Round SPS Agreement, the analogous NAFTA text requires parties to ensure that they "avoid arbitrary or unjustifiable distinctions in . . . levels [of protection] in different circumstances, where such distinctions result in arbitrary or unjustifiable discrimination against a good of another Party or constitute a disguised restriction on trade between the Parties." *Id.* para. 3(b).

[50] *Id.* art. 712, para. 1.

[51] *Id.* art. 712, para. 3. Article 724 defines "scientific basis" as "a reason based on data or information derived using scientific methods." The same article defines a "risk assessment" as

an evaluation of:

(a) the potential for the introduction, establishment or spread of a pest or disease and associated biological and economic consequences; or

(contd.)

Risk assessments supporting national sanitary and phytosanitary measures must take into account international risk assessment methodologies and "relevant scientific evidence."[52] As in the Uruguay Round SPS Agreement, NAFTA parties may provisionally adopt a sanitary or phytosanitary measure "on the basis of available relevant information" when "available relevant scientific evidence or other information is insufficient to complete the [risk] assessment."[53]

2. Technical Barriers to Trade: Standards-Related Measures

Chapter 9 of the NAFTA contains trade disciplines on regulatory standards[54] other than sanitary and phytosanitary measures that are analogous to those found in the Uruguay Round TBT Agreement and the Tokyo Round Standards Code. As in the case of the other standards related texts in the Uruguay Round and the NAFTA, this passage establishes the presumptive validity of internationally agreed standards when applied as national measures[55] and articulates a party's right to establish

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51. (contd.)

(b) the potential for adverse effects on human or animal life or health arising from the presence of an additive, contaminant, toxin or disease-causing organism in a food, beverage or feedstuff;

Id.

[52] *Id.* art. 715, para. 1 (a), (b). As in the case of the Uruguay Round SPS Agreement, the NAFTA text on sanitary and phytosanitary measures establishes additional disciplines not directly related to science. So, for instance, sanitary and phytosanitary measures must be non-discriminatory, *id.* art. 712, para. 4, may not operate as disguised restrictions on trade, *id.* art. 712, para. 6, must be "necessary for the protection of human, animal or plant life or health," *id.* art. 712, para. 1, and may be "applied only to the extent necessary to achieve [a party's] appropriate level of protection," *id.* art. 712, para. 5.

[53] *Id.* art. 715, para. 4.

[54] *Id.* art. 901. Like the Uruguay Round TBT Agreement, the NAFTA text on technical barriers applies to both mandatory and advisory requirements not only for products, but also for "related processes and production methods." *Id.* art. 915.

[55] *Id.* art. 905, para. 2.

its own more demanding level of protection in pursuing "legitimate objectives" such as protection of the environment, consumer safety, or public health.[56]

Unlike the Uruguay Round and NAFTA SPS texts, national regulations more stringent than international standards can be, but are not required to be, justified by means of scientific data and analysis. Consequently, a party "may . . . conduct an assessment of risk . . . tak[ing] into account . . . available scientific evidence or technical information."[57] In cases of incomplete or unavailable data, as in the case of the Uruguay Round SPS Agreement, a party may adopt a provisional regulation until the scientific uncertainty is reduced or eliminated.[58]

II. SCIENCE AND THE NATIONAL REGULATORY PROCESS

The Uruguay Round and the NAFTA texts on sanitary and phytosanitary measures purport to apply scientifically-based trade disciplines to the domestic process of adopting regulatory measures in the area of public health and food and drug safety. Because these new trade disciplines establish constraints on

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[56] *Id.* art. 904, para. 2. Article 915 specifies that legitimate objective includes an objective such as:

(a) safety,

(b) protection of human, animal or plant life or health, the environment or consumers, including matters relating to quality and identifiability of goods or services, and

(c) sustainable development,

considering, among other things, where appropriate, fundamental climatic or other geographical factors, technological or infrastructural factors, or scientific justification but does not include the protection of domestic production. . . .

Id.

[57] *Id.* art. 907, para. 1(a). Article 915 defines "assessment of risk" as an "evaluation of the potential for adverse effects." *Id.*

[58] *Id.* art. 907, para. 3. Like the Uruguay Round TBT Agreement, the analogous NAFTA text articulates a basic test of non-discrimination, *id.* art.

(contd.)

domestic regulatory processes designed to preclude protectionist abuse of national measures, the effects of those new requirements in turn depend on the role of science in regulatory processes in these areas.[59]

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58. (contd.)

904, para. 3, and retains the core test of an unnecessary obstacle to international trade. *Id.* art. 904, para. 4.

The Canada-U.S. bilateral agreement contains a passage addressing technical standards that specifies that

> [n]either Party shall maintain or introduce standards-related measures or procedures for product approval that would create unnecessary obstacles to trade between the territories of the Parties. Unnecessary obstacles to trade shall not be deemed to be created if:
>
> (a) the demonstrable purpose of such measure or procedure is to achieve a legitimate domestic objective; and
>
> (b) the measure or procedure does not operate to exclude goods of the other Party that meet that legitimate domestic objective.

CUSFTA, *supra* note 45, art. 603. "[L]egitimate domestic objective" is defined as "an objective whose purpose is to protect health, safety, essential security, the environment, or consumer interests." *Id.* art 609. While there is no panel jurisprudence on the meaning of "unnecessary obstacles to trade" under the bilateral agreement, Canada relied on this passage in challenging the United States asbestos ban in a domestic U.S. tribunal. *See* Corrosion Proof Fittings v. Environmental Protection Agency, 947 F.2d 1201 (5th Cir. 1991).

[59] Scientific analyses are obviously relevant not only to regulatory measures designed to public health, but also to national efforts to address environmental and ecological effects. However, as discussed above, the Uruguay Round scientifically-based trade disciplines are confined to the area of sanitary and phytosanitary measures, which are the only category of standards for which the NAFTA mandates risk assessments. For this reason, the remainder of this analysis addresses the role of science primarily in the context of regulation to protect public health and addresses regulation of environmental and ecological effects only to the extent the context indicates.

A. Risk Assessment, Risk Management, and Science Policy

One fundamental axiom admonishes that regulations to protect public health involve social policy choices.[60] Because theregulatory process is not wholly scientific, science does not have all the answers. There is no way to infer regulatory outcomes solely on the basis of scientific data, especially when regulations are implicitly or explicitly crafted to respond to a particular social, economic, and political context. While scientific analysis can provide assistance in attaining a given public health goal, the choice of that goal reflects societal values concerning which science may provide little, if any, guidance. In other words, science may inform the regulatory process but cannot, by itself, determine the result with particularity. For instance, a risk assessment may help in setting a standard designed to limit the probability that an individual will develop cancer after a lifetime of exposure to a particular chemical substance to no more than one chance in a million. By contrast, the choice of the one-in-a-million goal—as opposed to, say, zero or one-in-a-thousand—is one of public policy.

Although by no means universally accepted,[61] one approach

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[60] A former Administrator of the United States Environmental Protection Agency quotes Alvin Weinberg's influential and trenchant observation as follows:

> Attempts to deal with social problems through the procedures of science hang on the answers to questions that can be asked of science and yet which cannot be answered by science. I propose the term *trans-scientific* for these questions. . . . Scientists have no monopoly on wisdom where this kind of trans-science is involved: they shall have to accommodate the will of the public and its representatives.

William D. Ruckelshaus, *Risk, Science, and Democracy*, ISSUES SCI. & TECH., Spring 1985, at 19, 26 (emphasis in original) (quoting Alvin Weinberg, *Science and Trans-Science*, 10 MINERVA 209, 222 (1972)).

[61] For critical observations with respect to the risk assessment/risk management bifurcation, *see, e.g.*, ACCEPTABLE EVIDENCE: SCIENCE AND

(contd.)

that expressly acknowledges this dichotomy prescribes a bifurcation of the regulatory process into two phases: "risk assessment," which in principle establishes the strictly scientific basis for regulatory action, and "risk management," which is the multidisciplinary process of choosing regulatory measures:

> Risk assessment is an exercise that combines available data on a substance's potency in causing adverse health effects with information about likely human exposure, and through the use of plausible assumptions, it generates an estimate of human health risk. Risk management is the process by which a protective agency decides what action to take in the face of such estimates. Ideally the action is based on such factors as the goals of public health and environmental protection, relevant legislation, legal precedent, and application of social, economic, and political values.[62]

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61. (contd.)

VALUES IN RISK ASSESSMENT (Deborah G. Mayo & Rachelle D. Hollander eds., 1991); CARL F. CRANOR, REGULATING TOXIC SUBSTANCES: A PHILOSOPHY OF SCIENCE AND THE LAW (1993); Ellen Silbergeld, *The Uses and Abuses of Scientific Uncertainty in Risk Assessment*, NAT. RESOURCES & ENV'T, Fall 1986, at 17.

[62] Ruckelshaus, *supra* note 60, at 28. Another influential publication has described the distinction as follows:

> We use *risk assessment* to mean the characterization of the potential adverse health effects of human exposures to environmental hazards. Risk assessments include several elements: description of the potential adverse health effects based on an evaluation of results of epidemiologic, clinical, toxicologic, and environmental research; extrapolation from those results to predict the type and estimate the extent of health effects in humans under given conditions of exposure; judgements as to the number and characteristics of persons exposed at various intensities and durations; and summary judgements on the existence and overall magnitude of the public health problem. Risk assessment also includes characterization of the uncertainties inherent in the process of inferring risk.
>
> The term *risk assessment* is often given narrower and broader meanings than we have adopted here. For some observers, the term is
>
> *(contd.)*

In this two-stage methodology, scientific questions can supposedly be isolated and addressed in an objective matter through risk assessment methodologies at the beginning of the regulatory process. But the allegedly scientific process of risk assessment necessarily requires inferences, choices, and assumptions that themselves reflect policy preferences, an area sometimes known as "science policy."[63]

Pure policy choices are supposedly confined to the second place, risk management. At this stage, science may be relevant for such tasks as evaluating technical options. Risk management decisions, however, also engage other considerations, most notably social values.[64] Regulatory policy, then, is not exclusively the domain of scientists, but of public authorities

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62. (contd.)

synonymous with *quantitative risk assessment* and emphasizes reliance on numerical results. Our broader definition includes quantification, but also includes

qualitative expressions of risk. Quantitative estimates of risk are not always feasible, and they may be eschewed by agencies for policy reasons. Broader uses of the term than ours also embrace analysis of perceived risks, comparisons of risks associated with different regulatory strategies, and occasionally analysis of the economic and social implications of regulatory decisions—functions that we assign to risk management.

COMMITTEE ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUBLIC HEALTH, COMMISSION ON LIFE SCIENCES, NATIONAL RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 18 (1983) (emphasis in original) [hereinafter NATIONAL RESEARCH COUNCIL].

[63] *See, e.g.*, NATIONAL RESEARCH COUNCIL, *supra* note 62, at 28-37 (analysing scientific and policy judgements in risk assessment); CARNEGIE COMMISSION ON SCIENCE, TECHNOLOGY, AND GOVERNMENT, RISK AND THE ENVIRONMENT: IMPROVING REGULATORY DECISION MAKING 78 (1993)(noting that "[r]isk assessment can be most useful when those who rely on it to inform the risk management process understand its nature and its limitations, and use it accordingly"); John P. Dwyer, *Limits of Environmental Risk Assessment*, 116 J. ENERGY ENGINEERING 231 (1990) ("The enormous scientific uncertainties at each stage of risk assessment . . . make quantifying risks impossible without making value-laden, simplifying assumptions. As a result, environmental risk assessment often does not provide scientificguidance for regulatory decisions."); Thomas O. McGarity, *(contd.)*

who make judgements about how to achieve social goals that are informed by scientific data and scientific inferences.

Because the recently adopted texts on sanitary and phytosanitary measures and technical barriers to trade in the Uruguay Round and the NAFTA echo these themes, the risk assessment/risk management duality provides a useful vehicle for analysing the new trade disciplines. Thus, both the Uruguay Round and the NAFTA texts on sanitary and phytosanitary measures specify that domestic regulations must be based on a risk assessment.[65] Both these texts, as well as the NAFTA technical barriers text (under which, as discussed above, a risk assessment is optional rather than mandatory), then specify

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63. (contd.)

Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA, 67 GEO. L.J. 729 (1979). *See also* JOHN STOSEHOUSE, SCIENCE, RISK ANALYSIS AND ENVIRONMENTAL POLICY DECISIONS (United Nations Environment Programme Environment and Trade Series 1994) (observing that, because risk is a composite concept of objective probability and subjective evaluation, a distinction between the purely scientific task of risk assessment and the objective, but not scientific, process of "risk evaluation" can be made). While some of the choices in risk assessments involve trans-scientific decisions, the options are usually drawn from some scientific basis — *e.g.*, extrapolation from animal to human dosimetry. *See* NATIONAL RESEARCH COUNCIL, SCIENCE AND JUDGEMENT IN RISK ASSESSMENT (1994 forthcoming).

> [*R*]*isk management* . . . describes the process of evaluating alternative regulatory actions and selecting among them. Risk management, which is carried out by regulatory agencies under various legislative mandates, is an agency decision-making process that entails consideration of political, social, economic, and engineering information with risk-related information to develop, analyze, and compare regulatory options and to select the appropriate regulatory response to a potential chronic health hazard. The selection process necessarily requires the use of value judgements on such issues as the acceptability of risk and the reasonableness of the costs of control.

NATIONAL RESEARCH COUNCIL, *supra* note 62, at 18-19 (1983) (emphasis in original).

[65] *See supra* text accompanying notes 37 & 51.

certain elements that must characterise the risk assessment methodology employed.[66] The Uruguay Round SPS Agreement requires "sufficient" scientific evidence.[67] The texts require that regulators consider, respectively, "available"[68] or "relevant"[69] scientific evidence. Both the Uruguay Round and NAFTA texts on sanitary and phytosanitary measures state that national regulatory authorities must take into account international risk assessment methodologies. Neither the Uruguay Round nor the NAFTA text appears, at least as an explicit matter, to accommodate measures that are not adopted by technically expert regulatory authorities, but that instead are enacted directly by legislatures or as a result of popular referenda without a formal risk assessment.[70]

In the risk management phase, the texts expressly recognise the importance of social value choices. This is somewhat clearer in the two NAFTA passages, which expressly identify each party's right to establish its own levels of protection.[71] Similarly, the Uruguay Round SPS Agreement repeatedly acknowledges the significance of an appropriate level of sanitary or phytosanitary protection in excess of that implicit in international standards.[72] In contrast to the scientific process of risk

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[66] *See supra* text accompanying notes 38, 39 & 52.

[67] Uruguay Round SPS Agreement, *supra* note 19, para. 6.

[68] *Id.* para. 17.

[69] NAFTA, *supra* note 2, art. 715, para. 1(a).

[70] *See, e.g.*, Safe Drinking Water and Toxic Enforcement Act of 1986, CAL. HEALTH & SAFETY §§ 25249.5 .13 (West 1992) (citizen-sponsored initiative at subnational level in United States which requires manufacturers to warn consumers that a product contains a known carcinogen). Although this law was adopted by popular referendum, its implementation relies on scientific criteria for identifying potential reproductive and cancer hazards and for determining whether those hazards contribute to an identifiable excess risk.

[71] NAFTA, *supra* note 2, art. 712, para. 2 & art. 904, para. 2.

[72] Uruguay Round SPS Agreement, *supra* note 19, Preamble para. 6, paras. 11, 14, 18, 19, 20, 21, 29, 32, 41 & Annex B, para. 2.1(c).

assessment, which is subject to trade disciplines of varying degrees of rigour in the Uruguay Round and the NAFTA texts, those passages by and large leave the choice of a national level of protection---*i.e.*, the endpoint of the regulatory process reflecting social value choices—to each contracting party. But both texts specify that the choice of level of protection should be responsive to the objective of minimising negative trade effects.

As discussed above, scientific considerations play a relatively smaller role in risk management than in risk assessment.[73] Similarly, although both the new Uruguay Round and NAFTA texts on standards establish trade disciplines governing choice of regulatory measures, the requirements for that stage are not as a general matter based on scientific tests. For instance, the Uruguay Round SPS agreement specifies that sanitary and phytosanitary measures must be "necessary for the protection of human, animal, or plant life or health," must be "applied only to the extent necessary to protect human, animal or plant life or health," must not "arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail," must not "be applied in a manner which would constitute a disguised restriction on international trade," and may not be"more trade restrictive than required to achieve [a WTO member's] appropriate level of protection, taking into account technical and economic feasibility."[74] The application of these requirements does not address the scientific underpinnings for

[73] Some would say that this is necessarily so, because the boundary between risk assessment and risk management is not inherent, but socially "constructed." *See, e.g.*, SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS 12-13 (1990); Brian Wynne, *Establishing the Rules of Laws: Constructing Expert Authority*, *in* EXPERT EVIDENCE: INTERPRETING SCIENCE IN THE LAW 23 (Roger Smith & Brian Wynne eds., 1989).

[74] *See supra* note 40.

a national regulatory requirement. Instead, these tests target the choice by national regulatory authorities among a variety of potential measures, as determined by such factors as the following: impacts on international trade, discriminatory effect, economic efficiency and technical feasibility, and the relationship between the regulatory goal and the measure chosen.

Overall, a number of generalisations can be made concerning the Uruguay Round and NAFTA TBT and SPS texts. First, the disciplines in the Uruguay Round TBT Agreement are not based on science. Second, while the analogous text in the NAFTA does allude to scientific principles concerning risk assessments, the performance of risk assessments is optional under that agreement. Of the two texts that require mandatory risk assessments grounded in science as an express condition of the validity of a national regulatory measure, the Uruguay Round and NAFTA SPS texts,

- both express a preference for internationally harmonised standards, which are presumptively valid if applied by a party to the agreement;

- both apply scientific tests to national measures more stringent than international standards; however, the NAFTA SPS passage is somewhat clearer on the absolute right of a party to adopt more stringent measures by reference to its chosen level of protection;

- both appear to segment the scientific underpinnings for a standard (risk assessment) from the choice of regulatory measure (risk management), with the NAFTA text being somewhat clearer in this regard by comparison with the Uruguay Round's juxtaposition of "scientific justification" and appropriate level of protection;

- both require consideration of applicable international risk assessment methodologies;

- only the Uruguay Round Agreement articulates a requirement that a national measure be based on "sufficient" scientific evidence;

- both define a level of protection reflecting social value judgements as a public policy choice made by each individual contracting party, with the NAFTA text somewhat more explicit that the choice of level is to be independent of scientific considerations;

- both require consideration of adverse trade effects in the national choice of level of sanitary and phytosanitary protection;

- neither, as a general matter, purports to subject the risk management phase of the regulatory process to science-based disciplines;

- the NAFTA text, by comparison with the Uruguay Round SPS Agreement's definition of "scientific justification," is somewhat more explicit in confining the scientific disciplines strictly to the risk assessment process and establishing that the choice of level of protection and selection of regulatory measures are independent of scientific considerations.

B. Scientific Uncertainty

The tasks of both risk assessment and risk management are complicated by uncertainty and lack of data that characterise much of the scientific basis for regulation. According to a former Administrator of the United States Environmental Protection Agency:

> From its earliest days, [the United States Environmental Protection Agency was often compelled to *act under conditions of substantial scientific uncertainty*.
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> . . . .
>
> [T]he problem of uncertainty was moved from the periphery to the center.
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> . . . .
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> For [some] substances—and these are the ones that naturally figure most prominently in public debate—the data remain ambiguous.[75]

Because science is incomplete, the scientific data set underlying any regulation is necessarily incomplete. That, however, does not diminish the scientific nature of the inquiry. Indeed, the appropriate handling of uncertainties is part of the scientific process of risk assessment.

In response to the challenge of prescribing regulatory requirements under conditions of uncertainty, a precautionary approach has begun to gain fairly wide acceptance on the supranational and international levels. The "precautionary principle" counsels governmental authorities to err on the side of environmental protection in formulating public policyin contexts characterised by conditions of scientific uncertainty.[76] Precautionary approaches can be interpreted as a

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[75] Ruckelshaus, *supra* note 60, at 19, 25-26 (emphasis in original).

[76] *See generally* Daniel Bodansky, *Scientific Uncertainty and the Precautionary Principle*, ENV'T, Sept. 1991, at 4; James Cameron & Juli Abouchar, *The Precautionary Principle: A Fundamental Principle of Law and Policy for the Protection of the Global Environment*, 14 B.C. INT'L & COMP. L. REV. 1 (1991); Lothar Gündling, *The Status in International Law of the Principle of Precautionary Action*, *in* THE NORTH SEA: PERSPECTIVES ON REGIONAL ENVIRONMENTAL COOPERATION 23 (David Freestone & Ton Ijlstra eds., 1990) (special issue of 5 INT'L J. ESTUARINE AND COASTAL LAW); Ellen Hey, *The Precautionary Concept in Environmental Policy and Law: Institutionalizing Caution*, 4 GEO. INT'L ENVTL. L. REV. 303 (1992); Bernard *(contd.)*

counterweight to, if not an outright rejection of, "wait and see" philosophies that emphasise a high degree of scientific certainty as a precondition to adopting policy responses.[77]

Various formulations of a precautionary approach can be found in such instruments as the Rio Declaration on Environment and Development,[78] the United Nations climate convention adopted in 1992,[79] and the Treaty of Rome[80] as amended by the Single European Act.[81] The principle has been elaborated withparticular detail in the Paris Commission[82] and the North

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76. (contd.)

A. Weintraub, Note, *Science, International Environmental Regulation, and the Precautionary Principle: Setting Standards and Defining Terms*, 1 N.Y.U. ENVTL. L.J. 173 (1992).

[77] *See, e.g.*, C. Boyden Gray & David B. Rivkin, Jr., *A "No Regrets" Environmental Policy*, FOREIGN POL'Y, Summer 1991, at 47 (article by Counsel to former U.S. President Bush and Associate General Counsel to U.S. Department of Energy emphasising scientific uncertainty in global warming debate).

[78] Rio Declaration on Environment and Development, June 14, 1992, Principle 15, U.N. Doc. A/CONF.151/5/Rev. 1 (1992), *reprinted in* 31 I.L.M. 876 (1992) ("In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.")

[79] United Nations Framework Convention on Climate Change, May 9, 1992, art. 3, para. 3, 31 I.L.M. 851 (1992) ("The Parties should take precautionary measures to anticipate, prevent or minimize the causes of climate change and mitigate its adverse effects. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures . . . ").

[80] Treaty Establishing the European Economic Community, Mar. 25, 1957, 298 U.N.T.S. 11 [hereinafter Treaty of Rome].

[81] Single European Act, Feb. 17 & 28, 1986, 19 BULL. EUR. COMM. Supp. (No. 2) at 5 (1986), 25 I.L.M. 506 (1986) (adding to the Treaty of Rome art. 130r, para. 2, specifying that "[a]ction . . . relating to the environment shall be based on the principle[] that preventive action should be taken.").

[82] *See* Convention for the Prevention of Marine Pollution from Land-Based Sources, Feb. 21, 1974, arts. 15-18, 13 I.L.M. 352, 361-64 (opened for signature at Paris, June 4, 1974) (creating Commission).

Sea Conferences.[83] There is, however, no universally agreed formulation for the precautionary principle.[84]

Through the central theme of sustainable development, the Uruguay Round may well have incorporated the precautionary principle into the international trade regime more generally. The Agreement Establishing the World Trade Organisation, one of the principal products of the Uruguay Round, refers to "optimal use of the world's resources in accordance with the objective of sustainable development."[85] Sustainable development was the principal theme of the United Nations Conference on Environment and Development—the "Earth Summit"—held in Rio de Janeiro, Brazil in June 1992. The Rio Declaration[86] suggests that the precautionary principle is a component of sustainable development.[87] Thus, one can interpret the Uruguay Round as endorsing the application of this principle as an element of the international trade regime. Indeed, one may even view the more specific Uruguay Round and NAFTA trade disciplines on standards, including sanitary and phytosanitary measures, as codifying a precautionary approach. Contrary to the treatment of many environmental issues in GATT 1947,[88] the new SPS texts explicitly acknowledge each state's right to establish its own level of protection.[89]

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[83] *See generally* THE NORTH SEA: BASIC LEGAL DOCUMENTS ON REGIONAL ENVIRONMENTAL CO-OPERATION (David Freestone & Ton Ijlstra eds., 1991).

[84] Indeed, in the United Kingdom, a distinction is made between the "precautionary principle," some formulations of which might be taken to reject the validity of scientific analyses, and a "precautionary approach," which is explicitly grounded in science and risk assessment.

[85] Agreement Establishing the World Trade Organization, *supra* note 22, pmbl. para. 1.

[86] *Supra* note 78.

[87] *Id.*

[88] *See supra* section I.A.

[89] *See supra* text accompanying notes 28 & 49.

There is no accepted quantitative methodology that prescribes those scientific inferences or regulatory outcomes that are appropriate under conditions of incomplete or unavailable information.[90] Indeed, it is very likely impossible to imagine a numerical calculus for anticipating the wholly unexpected or predicting the unpredictable. Instead, the realm of scientific uncertainty requires the exercise of judgement and discretion, both scientific and regulatory. Accordingly, the increasing acceptance of precautionary approaches as an international norm in international trade agreements and elsewhere strongly supports the validity of applying conservative assumptions in the absence of empirical data, as in estimating low dose cancer risks.

III. SCIENCE AND THE TRADE DISPUTE SETTLEMENT PROCESS

The quasi-adjudicatory GATT dispute settlement process, as modified and codified in the context of the newly established

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[90] Risk assessments consequently may be fraught with uncertainty:

> Virtually all elements of risk assessment are clouded with uncertainty, basically of two kinds. First, the various scientific disciplines involved in assessing risk are not sufficiently developed either to explain the mechanisms by which particular causes produce particular effects or to provide good quantitative estimates of cause-and-effect relationships. Second, the data needed to analyse particular risks are usually not available.

CONSERVATION FOUNDATION, RISK ASSESSMENT AND CONTROL 5 (1985). Uncertainties in a risk assessment, which may or may not be explicitly identified, can significantly affect risk management decisions:

> The current trend toward distinguishing risk assessment from risk management has concealed . . . problems [of scientific uncertainty] and exacerbated them. Yet, how they are resolved may influence policy choices for the risk manager. If the manager fails to understand how these issues [involving scientific uncertainty] were resolved in a specific risk assessment, it limits his understanding of his options. At present, . . . there is no definitive scientific resolution for [certain] issues. Their treatment is properly at the interface of risk assessment and risk management, an interface which the artificial segregation of these activities makes increasingly difficult to define and analyze.

Silbergeld, *supra* note 61, at 59.

World Trade Organisation, applies to standards directed atenvironment and public health, including those governed by the Uruguay Round SPS and TBT agreements. The NAFTA dispute settlement process, with certain embellishments set out in the following discussion, is patterned in its basic outlines on the GATT model.

Briefly, the GATT's dispute settlement mechanisms first encourage contracting parties to the agreement to settle differences through consultation and negotiation,[91] an approach that can be expected to result in successful resolution of a significant number of disagreements. If that mechanism proves fruitless, an aggrieved party may submit a complaint to the GATT Council, which can designate a panel of three independent experts appointed in their personal capacities to hear the dispute. In practise, panel members are often national officials responsible for international trade matters at GATT headquarters in Geneva. Panel members may not be representatives of any of the disputing parties. After receiving written submissions from both sides and from any other GATT member states whose interests are affected, the panel issues a report, which may find that actions of the respondent that are inconsistent with the agreement have "nullified or impaired" the aggrieved party's GATT rights.[92]

A. Adjudicating Scientific Controversies

Adjudication of scientific questions has been the subject of considerable controversy and disagreement. It is by no means apparent that, as a general matter, the direct application of scientific principles in the regulatory process is amenable to full, *de novo* review in an adversarial setting. To the contrary, experience strongly suggests that the adjudication by a third party

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[91] GATT 1947, *supra* note 1, art. XXII (consultation). *See generally* PIERRE PESCATORE ET AL., HANDBOOK OF GATT DISPUTE SETTLEMENT (1991).

[92] *See generally* Rosine Plank, *An Unofficial Description of How a GATT Panel Works and Does Not*, 4 J. INT'L ARB. Dec. 1987, at 53.

of scientific matters that arise in a regulatory setting, in which presumably expert technical authorities have already made scientific determinations, should be limited within clearly defined parameters that control and circumscribe the scope of that review.

First, scientists often disagree among themselves, especially on issues at the cutting edge of regulatory policy that may involve considerable scientific uncertainty.[93] Even in the supposedly strictly technical process of risk assessment, there may be considerable conflict among scientists.[94] Social value choices necessarily intrude into the analysis of physical phenomena by

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[93] As a former Administrator of the Environmental Protection Agency has noted:

> Science is only orderly after the fact; in process, and especially at the advancing edge of some field, it is chaotic and fiercely controversial. Thus, the expectation built into environmental law, that science can provide definitive answers to the kinds of questions that policymakers are obliged to ask under the terms of that law, will be disappointed to the degree that such answers derive from the forward edge of research.
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> . . . .
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> Nor can we order a consensus in the areas of greatest interest to environmental policy: pollutant exposure and effects. Policymakers, including me, have often deplored the tendency of scientific panels to engage in interminable debate rather than reach the agreement that was clearly indicated on the invitation. *Of course* scientists will disagree on issues involving the advancing edge of research; that is what they do for a living. And even if we could somehow get a group of scientists to endorse a consensus position, it would be, in the first place, only tentative and subject to revision with the arrival of new discoveries; and in the second place, it may be entirely wrong.
>
> In science, the majority does not rule, as the history of science amply demonstrates.

Ruckelshaus, *supra* note 60, at 24 (emphasis in original). Indeed, these propositions are regarded in some quarters as axiomatic or tautological. *See, e.g.*, DAVID COLLINGRIDGE & COLIN REEVE, SCIENCE SPEAKS TO POWER: THE ROLE OF EXPERTS IN POLICY MAKING (1986).

[94] [S]ome people in the regulated community believe that the structure of risk assessment inherently exaggerates risk, while many environmentalists believe that it will not capture all the risk that may actually exist. . . . [T]his disagreement is not resolvable in the short

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means of risk assessment methodologies through the selection of inferences and assumptions.[95] Consequently, there is unlikely to be a single, unique way to analyse *even the purely scientific significance* of much empirical data.[96] As a result, in a regulatory context science may be least helpful when there is a genuine scientific dispute.

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94. (contd.)

> run through recourse to science. Risk assessment is necessarily dependent on choices made among a host of assumptions, and these choices will inevitably be affected by the values of the choosers, whether they be scientists, civil servants, or politicians.

Id. at 28.

[95] *See supra* note 63 and accompanying text (discussing science policy).

[96] As an example, because the analysis of those data requires the application of certain scientific assumptions, hypotheses, and theories, the empirical data set underlying the establishment of a pesticide tolerance does not necessarily yield a single regulatory result in the form of a residue limitation on foodstuffs. For instance, the following observations have been made concerning the establishment of maximum residue limits (MRLs) and acceptable daily intakes (ADIs) for pesticides by the Codex Alimentarius Commission by comparison with the U.S. Environmental Protection Agency's (EPA's) approach:

> Even when the same data package is used, data may be interpreted differently, resulting in different scientific opinions on where to set MRLs or ADIs. Such differences may be legitimate, because data used to establish an ADI or MRL are often based on test results that provide estimates or ranges of effects. Different levels within a certain range may, in fact, be similar but they are translated into a proposed standard that is defined as a point estimate, the maximum in the case of an MRL.
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> . . .
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> Another difference in data interpretation is the consideration of outliers or extreme values from residue test data. Differences of opinion exist about whether or not outliers should be incorporated into the setting of MRLs or excluded because of the small likelihood they would occur as a result of pesticide uses. The EPA tends to include outliers to a greater extent than the [Codex].
>
> Also, there can be differences of opinion concerning the level of the safety factor to use in setting ADIs. Even when Codex and U.S. reviewers arrive at the same threshold value specifying the no observed effects level, a different ADI level can result because different safety factors are employed.

INTERNATIONAL FOOD SAFETY, *supra* note 27, at 23.

In this dynamic setting, the scientific peer review process operating in a regulatory context can reduce disagreement, identify gaps and holes, and articulate the need for further investigation. Scientific peer review is not fundamentally adjudicatory, but more "conciliatory," involving a sometimes protracted give and take among experts. Significantly, scientific peer review does not anticipate the sort of bipolar, "yes or no" result contemplated by an adjudicatory process. Instead, peer review is responsive to a characterisation of science as an ongoing search for knowledge against a constantly shifting and evolving background that by its very nature is always operating at new frontiers. On the other hand, peer review in a regulatory setting may also engage disputed, value-laden questions of science policy[97] and may be unresponsive to the development of new scientific methodologies that, while lacking general acceptance, may nonetheless be reliable.

An additional issue arises when decision makers in an adjudicatory setting, such as the members of GATT panels, are lay persons and not technical experts who are specially trainedin the scientific discipline relevant to a particular dispute. Although the text of the GATT does not require panels to giveparticular weight to conclusions of national authorities, a structure in which the members of reviewing panels are generalists may well suggest, or even require, an implicit principle of deference to governmental decision making processes. Presumably for precisely this reason, domestic courts in the GATT countries of France, Germany, the United Kingdom, and the United States, each of which has a relatively well-developed regulatory infrastructure in the areas of environment and public health, rarely, if ever, directly scrutinise the fundamental "correctness" of the conclusions drawn by technical experts from empirical

[97] *See, e.g.*, JASANOFF, *supra* note 73, at 61-83 (questioning validity of scientific peer review process).

measurements. Rather, those tribunals tend much more to supervise the processes or methodologies employed by regulatory authorities in reaching scientific conclusions from raw data.[98] Even then, there is a well-embedded notion in each of these legal systems calling for considerable deference to the informed judgement of technical experts to avoid a situation in which a tribunal of non-scientists might substitute its own judgement for that of scientific professionals. Similarly, municipal tribunals have been reluctant to second-guess regulatory authorities under conditions of scientific uncertainty.[99]

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[98] *See* RONALD BRICKMAN ET AL., CONTROLLING CHEMICALS: THE POLITICS OF REGULATION IN EUROPE AND THE UNITED STATES 112-15 (1985)(arguing that United States is much more aggressive in judicially reviewing regulators' methodology than any other country). *See, e.g.*, Baltimore Gas & Elec. Co. v. Natural Resources Defense Council, 462 U.S. 87, 103 ("a reviewing court must remember that the [expert administrative agency] is making predictions, within its area of expertise, at the frontiers of science. When examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential.") A recent case in the U.S. Supreme Court appears to urge greater judicial activism in reviewing the validity of scientific evidence, but nonetheless the Court emphasised that

> The inquiry envisioned [in determining the admissibility of expert scientific testimony] is, we emphasize, a flexible one. Its overarching subject is the scientific validity—and thus the evidentiary relevance and reliability—of the principles that underlie a proposed submission. The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S.Ct. 2786, 2797 (1993). That case, moreover, did not involve judicial review of a technically expert agency's regulatory decision. *See generally* JASANOFF, *supra* note 73, at 49-57 (analysing judicial review of science policy in United States and noting three key elements: (1) acceptance of decisions of technically expert regulatory authorities even on the basis of imperfect knowledge or under conditions of uncertainty; (2) acceptance of decisions of technically expert regulatory authorities as valid even if not universally accepted in the scientific community; and (3) acceptance of the resolution of scientific disagreements by technically expert regulatory authorities).

[99] In a seminal case, for example, a leading court in the United States opined as follows:

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Even when the "judges" are scientists, there are considerable impediments to the adjudication of scientific "facts". Significantly, about 25 years ago a recommendation surfaced in the United States calling for the creation of "science courts". The science court proposal anticipated an adversarial approach to resolving disputes concerning scientific questions in the policy making process. Accordingly, contested questions of "scientific fact" were to be isolated from the larger regulatory process, and particularly from social value choices. An adjudicatory tribunal composed of independent, objective scientists would resolve these questions.[100] That proposal is now generally regarded as impracticable precisely because many scientific issues are not inherently "justiciable" in such an adjudicatory, adversarial setting.[101]

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99. *(contd.)*

> Where a statute is precautionary in nature, the evidence difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge, the regulations designed to protect the public health, and the decision that of an expert administrator, we will not demand rigorous step-by-step proof of cause and effect. Such proof may be impossible to obtain if the precautionary purpose of the statute is to be served.

Ethyl Corp. v. EPA, 541 F.2d 1, 28 (D.C. Cir. 1976) (en banc).

[100] *See, e.g.*, Task Force of the Presidential Advisory Group on Anticipated Advances in Science and Technology, *The Science Court Experiment: An Interim Report*, 193 SCI. 654 (1976), *reprinted in* 4 RISK: ISSUES IN HEALTH & SAFETY 179 (1993).

[101] For a sampling of the voluminous writing on science courts, much of it critical, *see* Jon R. Cavicchi, *The Science Court: A Bibliography*, 4 RISK: ISSUES IN HEALTH & SAFETY 171 (1993). Even in the context of carcinogenic risk assessment, where scientific methodologies are relatively highly developed, disagreements about such questions as fundamental as statistical significance of empirical data and sufficiency of the scientific evidence may mean that a particular dispute is not amenable to adjudication. *See* Carl F. Cranor, *Science Courts, Evidentiary Procedures and Mixed Science-Policy Decisions*, 4 RISK: ISSUES IN HEALTH & SAFETY 113 (1993). *Cf.* Uruguay Round SPS Agreement, *supra* note 19, para. 6 (specifying that sanitary and phytosanitary measures must "not [be] maintained without sufficient scientific evidence"). Similarly, a review of the activities of a science

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101. (contd.)

advisory panel on pesticides convened under the auspices of the United States Environmental Protection Agency concludes that "[t]he science court mode of operation, in short, has severe drawbacks. In practical terms there is little or no chance that a science court could definitively settle the issues in cases of intense controversy, and certainly not in a timely fashion." BRUCE L.R. SMITH, THE ADVISERS: SCIENTISTS IN THE POLICY PROCESS 72 (1992).

One of the members of the Presidential task force on the science court, *see supra* note 100, a self-described "agnostic about the value of an institutionalized court," concludes, based on empirical simulations, that science courts could be useful in segmenting scientific questions from policy preferences and in narrowing the range of scientific disagreement. Ultimately, however, the central impediment of scientific uncertainty would prevent the definitive resolution of most scientific questions of any interest to the regulatory process:

> [T]he few scientific claims upon which adversaries continued to disagree have always been unresolvable with the present state of knowledge, usually because suitable data were lacking. This has always become apparent to us during the process, and I assume that judges evaluating such cases would realize it too. But if science court judges would inevitably be confronted by questions that they cannot answer for lack of data, so that their reports would predictably read, "not answerable with the current state of knowledge," then what function is served by the judges? This reasoning leads me to a surprising conclusion: *There is no need for a panel of judges* to decide which adversary is correct because, most likely, neither adversary will be clearly correct. If I were reformulating the science court proposal today, I would leave out the judges, making it in effect a mediation process. This ought to satisfy critics who fear that the court would become authoritarian. It is enough for the adversaries, with the aid of a referee, to work out in clear language the relevant scientific points upon which they do and do not agree. That, I suggest, would be useful information for policy makers, journalists and the interested public.

Allan Mazur, *The Science Court: Reminiscence and Retrospective*, 4 RISK: ISSUES IN HEALTH & SAFETY 161, 165, 168 (1993) (emphasis in original). Significantly, this reformulated proposal bears much greater resemblance to the scientific peer review process as part of a continuous search for knowledge that is constantly changing than to an adjudicatory, adversarial process. *See also* Sheila Jasanoff, *Procedural Choices in Regulatory Science*, 4 RISK: ISSUES IN HEALTH & SAFETY 143 (1993) (arguing that approach similar to science court proposal would be less useful than procedures more sensitive to the distinctive characteristics of regulatory science).

In an environmental or public health context, the adjudication of "scientific facts" may be particularly difficult precisely because of the difficulty, if not impossibility, of demonstrating that an environmental contaminant or pollutant is safe or has no effect from a scientific point of view.[102] In such a situation, the allocation of burden of proof alone may be dispositive of the result. Another significant drawback to the science court approach in a regulatory setting is the possibility or, indeed, inevitability that resolution of scientific disputes with public policy implications will involve not only purely scientific questions, but also science policy judgements.[103]

B. Science in Trade Agreements Prior to the Uruguay Round and the NAFTA

Presumably because it contains no reference to science, GATT 1947 embodies no express requirement for deference to the determinations of scientific experts. One very important dispute which was the subject of a 1989 panel report[104] applying GATT principles under the.-Canadian bilateral free trade agreement,[105] suggests the extent to which panels may substitute their own judgement for that of scientific experts. This panel report is noteworthy for: its intrusive review of the exercise of expert scientific judgement by national regulatory authorities; its lack of deference to science-based decisions of technically-oriented policy makers; its willingness to substitute the panel's own judgement for the numerical determinations of governmental

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[102] *See* STONEHOUSE, *supra* note 63.

[103] *See supra* note 63 and accompanying text (discussing science policy).

[104] In the Matter of Canada's Landing Requirement for Pacific Coast Salmon and Herring, Panel No. CDA-89-1807-01 (Oct. 16, 1989) (LEXIS, Intlaw library, USCFTA file) [hereinafter CUSFTA Salmon and Herring Panel Report].

[105] *See supra* note 45 and accompanying text.

experts based on the panel's own reading of scientific texts; and its relatively limited appreciation of the significance of scientific uncertainty in the regulatory process, which leads to an adjudicatory review that is exactly contrary to that prescribed by precautionary approaches.

An earlier dispute settlement panel proceeding in the GATT had determined that Canada's requirement that all salmon and herring caught in Canadian waters be processed in Canada was inconsistent with the GATT.[106] The United States then challenged new Canadian regulations requiring that all commercial harvests of roe herring and five species of salmon caught commercially in Canadian waters, including that intended for export from Canada, be off-loaded or "landed" in Canadian territory. The panel concluded that the effect of the "landing" requirement constituted an impermissible export restriction contrary to article XI of GATT 1947.[107]

The panel then considered the availability of GATT 1947's exception in article XX(g) for measures "relating to the conservation of exhaustible natural resources," incorporated by reference into the bilateral instrument.[108] The binational panel,referring to GATT jurisprudence, concluded that a measuremust be primarily aimed at conservation to qualify for

[106] Canada – Measures Affecting Exports of Unprocessed Herring and Salmon, *supra* note 11. This report addressed a challenge by the United States to a previous ban on the export of herring and salmon from Canada. The GATT panel concluded that this "processing in Canada" requirement was an export restriction in contravention of article XI of GATT 1947, was not primarily aimed at conservation, and therefore was not justified by article XX(g). *See supra* text accompanying notes 8-12. After adoption by the GATT Council of this report, Canada removed the export ban and replaced it with the "landing" requirement, which was designed to achieve similar conservation and management goals and was subsequently challenged by the United States under the auspices of the bilateral agreement.

[107] CUSFTA Salmon and Herring Panel Report, *supra* note 104, para. 6.13. Article XI of GATT 1947 is incorporated by reference in CUSFTA art. 407.

[108] CUSFTA, *supra* note 45, art. 1201.

this exemption.[109] In applying this test, the panel suggested that relatively little deference should be given to national determinations regarding the desirability or utility of a particular measure. Instead, the panel stated that it

> must examine the objective factors that go into a decision to adopt such a measure, including the conservation benefits that the measure itself would produce and whether there is a genuine conservation reason for choosing the actual measure in question as opposed to others that might accomplish the same objective.[110]

Among other things, the United States challenged Canada's asserted need to "land" 100 percent of commercially-taken herring and salmon, including all catches intended for exportation from Canada, as a regulatory vehicle for assuring high-quality biological data concerning harvests and stocks of those species. The panel reviewed authorities on statistics and determined "on the basis of logical analysis"[111] and with the aid

[109] *See supra* note 11 and accompanying text.

[110] CUSFTA Salmon and Herring Panel Report, *supra* note 104, para. 7.08. Similarly, the panel inferred an unstated, implied test under article XX(g) that turns on the balance of costs and benefits of the challenged measure, taking into account the regulatory burdens to foreign commercial interests. The desirability or utility of a disputed national regulatory requirement, according to the report, is then subject to re-evaluation by panels based on this cost benefit criterion. Consequently, the panel must determine "whether the government would have been prepared to adopt that measure if its own nationals had to bear the actual costs of the measure." *Id.* paras. 7.09-.10. This aspect of the panel's decision has been criticised as an "idealistic but dubious proposition" and "a mode of analysis so inherently subjective" that it "leaves environmental regulations vulnerable to a broad array of challenges." Steve Charnovitz, *Exploring the Environmental Exceptions in GATT Article XX*, 25 J. WORLD TRADE 37, 50-51 (1991).

[111] CUSFTA Salmon and Herring Panel Report, *supra* note 104, para. 7.21.

of texts on the science of fisheries that "reliable sampling data can be obtained without requiring access to 100% of the catch."[112] Acknowledging that scientific uncertainty would increase as sample size decreased[113] and that "the choice of a particular percentage figure would be to a certain extent arbitrary,"[114] the panel nonetheless observed that "it is never easy to justify imposing tangible burdens for the purpose of avoiding uncertain risks."[115]

Consequently, the panel concluded that sampling of no more than 80 to 90 percent of the total catch would be necessary to achieve the conservation purposes of the landing requirement.[116] Therefore, "Canada's insistence on the necessity of access to 100% of the catch was not supportable."[117] Although the panel may have been correct that Canada's "landing" requirement was protectionist in both intent and effect, the report's stated reasoning places heavy emphasis on the panel's own

[112] *Id.* para. 7.29.

[113] *Id.* para. 7.22. According to the panel report

> Canada placed considerable emphasis on the need for stratification of sampling — the practice of sometimes dividing the populations to be sampled into smaller sub-populations according to characteristics such as the dates fished, the gear used, and the sub-area within which the fishery took place. With certain catch populations being divided into smaller sub-populations, there would be a greater chance that unlanded exports might be concentrated in a particular sub-population, with the result that the size of the export share could rise to a point where it was too large to omit from sampling altogether.

Id.

[114] *Id.* para. 7.34.

[115] *Id.* para. 7.37.

[116] *Id.* paras. 7.34 & 7.40. Moreover, averred the panel, a consideration of the costs and benefits to both Canadian and U.S. nationals demonstrated that "the conservation benefits and other advantages that would have been derived from a landing requirement applicable to 100% of the salmon and herring catch would not have justified its adoption as a conservation measure." *Id.* para. 7.38. *See supra* note 110.

[117] *Id.* para. 7.21.

second-guessing of the "correctness" of the judgement of expert Canadian regulatory authorities — an approach that may have unfortunate implications in future disputes concerning the scientific validity of national regulatory measures when challenged by reference to the newly-established trade disciplines in the Uruguay Round and NAFTA SPS texts.

Other trade dispute settlement panels have been less intrusive and more deferential to national scientific determinations. In another recent decision,[118] also under the auspices of the Canada-U.S. bilateral agreement, Canada challenged a prohibition by the Commonwealth of Puerto Rico, a sub-national entity in the United States, on importation of ultra-high temperature (UHT) milk from the Canadian province of Québec. UHT milk is produced by treating fluid milk to a high temperature for a specified period of time, such as 138° C for at least two seconds. After cooling to room temperature and aseptic packaging in hermetically sealed containers, the shelf life of properly processed and handled UHT milk is between six and twelve months at room temperature.[119]

This dispute centered on the question of whether Québec's technical standards for processing UHT milk were equivalent to those of Puerto Rico. The panel emphasised that

> [s]tandard-setting is a significant prerogative of States. The issues posed by standards are all the more important as the public becomes aware of the need to protect public health through wise standards, governing products and production processes. It is also clear to the Panel that standards have an effect upon imported goods which cannot be ignored. In a

[118] In the Matter of Puerto Rico Regulations on the Import, Distribution and Sale of U.H.T. Milk from Québec, Panel No. USA-93-1807-01 (June 3, 1993) (on file with author).

[119] *Id.* para. 3.1.

> global economy and *a fortiori* in the special context of the Canada-U.S. Free Trade Agreement, cooperation and mutual consideration must be present if the imperatives of free trade are to be reconciled with the imperatives of public health.[120]

The panel characterised the U.S. standards governing the processing of UHT milk to assure the safety of that product as a domestic measure and not a quantitative restriction.[121] Abstaining from any determination with respect to national treatment, the panel noted that

> the starting point of any analysis must be the principles of non-protection and sovereignty which lie at the heart of Article III [of GATT 1947, incorporated by reference into the CUSFTA]. In the view of the Panel, Article III affords broad discretion in the setting of health standards applicable to imported products. The only qualification on the sovereign right of States to impose such standards upon imported products is that these standards must apply equally to domestic and to imported products and, secondly, that they should not be applied in a manner calculated to afford protection to domestic production.[122]

Based on this high degree of deference to national regulatory choices, the panel declined to conclude that the United States regulation violated the bilateral agreement.[123] At issue in this

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[120] *Id.* para. 5.2.

[121] *Id.* paras. 5.7-.8.

[122] *Id.* para. 5.14.

[123] The panel did, however, find a "non-violation" nullification of Canada's reasonable expectation that UHT milk, which had previously been imported from Canada, would not be excluded from the U.S. market pending the outcome of ongoing bilateral discussions concerning the extent to which Canadian UHT milk met the Puerto Rican standard. *Id.* paras. 5.52-.63.

case, however, was an equivalence determination, not the validity of Puerto Rico's underlying regulatory requirements. Consequently, this precedent may be of limited applicability in a case involving a direct challenge to the scientific legitimacy of a national standard.

Other disputes that raise scientific questions have been resolved on non-scientific grounds. Under the auspices of GATT, the United States challenged a ban by Thailand on the importation of foreign cigarettes which, unlike the Canadian landing requirement, was discriminatory not just in effect, but also on its face. The disputing parties agreed that cigarette smoking constitutes a serious risk to human health. Thailand, however, argued that the distinction between foreign and domestic cigarettes was justified by article XX(b) of GATT 1947, in part by the disparate health impact of imported and domestically manufactured products. The GATT panel rejected this argument, reasoning that all cigarettes, whatever their origin, presented a serious health risk and that Thailand's public health goals could consequently be accomplished in non-discriminatory fashion. Consequently, the panel did not directly adjudicate the scientific question whether American cigarettes did or did not present a greater risk to smokers than those manufactured in Thailand.[124]

This case is of interest as apparently the only GATT dispute settlement panel proceeding in which the opinion of a neutral outside expert was sought. Thailand requested the panel to consult with competent international organisations on technical aspects of the case, a request in which the complainant, the United States, acquiesced.[125] The panel then requested the World

[124] Thailand—Restrictions on Importation of and Internal Taxes on Cigarettes, *supra* note 10.

[125] *Id.* para. 3.

Health Organisation (WHO) to present an expert report on those issues. The report prepared by the WHO addressed health effects from smoking, the increase in smoking in developing countries, the differences between American and Thai cigarettes and their patterns of consumption in Thailand, the effects of opening closed cigarette markets in other countries in Latin America and Asia, and public policy strategies to reduce or deter smoking.[126] Although the United States disagreed with some of the conclusions of the WHO report, neither party appears to have challenged the expertise or objectivity of its preparers. The panel noted that "smoking constitute[s] a serious risk to human health" and therefore falls within the scope of article XX(b).[127] Although the panel's decision did not ultimately turn on the technical questions presented in the WHO's report, that information shaped the panel's analysis of how Thailand might control the demand and supply of cigarettes in a manner consistent with its obligations under the GATT.[128]

The case law in the European Union is noteworthy precisely because it does not address the role of scientific evidence, but instead concentrates on a hierarchy of policy priorities and the validity of the motivation behind the environmental measures through such doctrines as "proportionality". In a case challenging Denmark's mandatory recycling programme for beer and soft drink containers, the Court of Justice of the European Communities concluded without elaboration that the Danish scheme was "an essential element of a system aiming to secure the re-use of containers and therefore appears to be necessary to attain the [environmental] objectives of the disputed regulations."[129]

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[126] *Id.* paras. 51-57.

[127] *Id.* para. 73.

[128] *Id.* paras. 78-80.

[129] EEC Commission v. Denmark, 1988 E. Comm. Ct. J. Rep. 4607, 1 Comm. Mkt. L.R. 619, 631, 2 Common Mkt. Rep. (CCH) 1671 (1989).

To facilitate the recycling programme, the Danish government required that beer and soft drinks be marketed in one of not more than thirty containers approved by Danish authorities. To accommodate foreign manufacturers, the Danish scheme also permitted the sale of beer and soft drinks in recyclable but unapproved containers. Because unapprovedcontainers added to the complexity of the government established programme, producers utilising unapproved containers were required to set up their own recycling system and the total amount of beverages that could be marketed in unapproved containers was subject to a limitation of 3,000 hectolitres per year. In considering a challenge to this numerical restriction the Court of Justice then held, similarly without embellishment, that this limit was disproportionate with the environmental objective and therefore inconsistent with the Treaty of Rome.[130]

A recent case raised the question whether a local municipality within Belgium, another member state of the European Union, could restrict the disposal of waste originating from other regions of Belgium or from other EU member states.[131] The Court of Justice concluded that waste was an article in commerce governed by the Treaty of Rome. Without examining the Belgian assertion of "a genuine threat to the environment" in detail, the Court found that the relationship between the challenged requirements and "the protection of the environment must be regarded as well-founded." Moreover, the measures in question were held not to be discriminatory because

> [t]he principle that environmental damage should as a priority be rectified at source—a principle laid down by

[130] *Id.*, 1 Comm. Mkt. L.R. at 632 (1989).

[131] EC Commission v. Belgium (Case C-2/90), 1 Comm. Mkt. L.R. 265 (1993).

> Article 130r(2) [of the Treaty of Rome] for action by the Community relating to the environment—means that it is for each region, commune or other local entity to take appropriate measures to receive, process and dispose of its own waste. Consequently, waste should be disposed of as close as possible to the place where it is produced in order to keep the transport of waste to the minimum practicable.[132]

While it is difficult to draw any definitive conclusions from this small number of cases, it is nonetheless possible to make several admittedly speculative observations. Disputes that involve scientific questions, including all those discussed above, are also likely to raise non-scientific trade policy questions. In some instances, like the Danish bottles and Belgian waste cases in the European Court of Justice and the Thai cigarette dispute in the GATT, depending on the rule of decision employed, the resolution of scientific questions may not be necessary because the case is controlled by other principles, such as proportionality, non-discrimination, or the precedence given to the powers of subnational governmental units.

Other cases, such as Canada's "landing" requirement for unprocessed salmon and herring, may invite or require resolution of scientific controversies by a third party, such as a trade agreement dispute settlement panel. With the emphasis on explicit science-based trade disciplines in the Uruguay Round and NAFTA SPS texts, the number of disputes that fall in this category can be expected to increase. Neither these passages nor the text of GATT 1947 explicitly address the question of "scope of review," or the appropriate level of deference to

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[132] *Id. Contra* Fort Gratiot Sanitary Landfill, Inc. v. Michigan Department of Natural Resources, 112 S. Ct. 2019 (1992); Chemical Waste Management, Inc. v. Hunt, 112 S. Ct. 2009 (1992); Philadelphia v. New Jersey, 437 U.S. 617 (1978).

scientific determinations by national authorities. Moreover, those panel reports that implicitly address this question, principally those for the "landing" and UHT milk disputes decided under the Canada-U.S. bilateral agreement, tend to suggest conflicting answers. Taken together, these two cases may suggest a predisposition to greater deference in the context of regulations designed to protect public health, such as those at issue in the UHT milk dispute, than in situations involving preservation of the environment or natural resources, as in the case concerning unprocessed salmon and herring. Because of the lack of existing authority and the detailed new disciplines set out in the recently adopted texts, an analysis of both national practise with respect to science in the regulatory process and the context in which the new science-based tests were adopted is helpful and perhaps, indeed, necessary.

Deference to national regulatory judgements might under some circumstances be a "two-edged" sword, in that the decisions of national technical authorities might be insufficiently precautionary as well as excessively stringent.[133] However, given the "negative" structure of the current GATT trade disciplines, at least in the area of environment and public health, the trade agreement dispute settlement process can address only the latter and not the former. Because trade agreements as currently structured contain no minimum standards, panels may conclude that an excessively strict national standard violates international obligations, but they have no power to compel a government to strengthen measures that are unduly lax.[134]

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[133] *Cf.* Chevron, U.S.A. v. Natural Resources Defense Council, 467 U.S. 837 (1984) (U.S. Supreme Court opinion requiring courts to defer to administrative agency's reasonable interpretation of statutory standard).

[134] *But cf.* Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Uruguay Round Final Act, *supra* note 1, at II-A1C, arts. 12 & 33, *reprinted in* 33 I.L.M. 33 (1994) (requiring minimum 50-year copyright protection and minimum 20-year patent protection, respectively).

C. Dispute Settlement in the Uruguay Round and the NAFTA

The emphasis on the integrity of the strictly scientific components of the regulatory process in the Uruguay Round and the NAFTA trade disciplines governing public health standards means that dispute settlement panels established under either agreement may be called upon to evaluate the validity of scientific analyses underlying national measures to protect public health. Collecting relevant factual and scientific information may be difficult for trade agreement dispute settlement panels, which have limited fact finding capability and no subpoena power.[135]

Presumably for this reason, revised dispute settlement procedures adopted as part of the establishment of the new World Trade Organisation specify that "[w]ith respect to a factual issue concerning a scientific or other technical matter raised by a party to a dispute, a panel may request an advisory report in writing from an expert review group."[136] An "expert review group" is established by the panel, presumably on an *ad hoc* basis, and reports to the panel. Members of the expert review group are independent personalities appointed in their individual capacities and may not include either government officials of the parties to the dispute or nationals of the disputing states, except with the concurrence of the parties. Expert review groups may seek advice from "any source they deem appropriate". An expert review group prepares a draft report, which is to be made available to the parties to the dispute for comment, and a final version, which is transmitted to the panel and "shall be advisory only". The relevant text does not specify the number of members that may comprise expert review groups, which apparently may

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[135] *See generally* Plank, *supra* note 92.

[136] Understanding on Rules and Procedures Governing the Settlement of Disputes, para. 13.2 (1993), 33 I.L.M 114 (1994).

vary in size as appropriate for particular disputes.[137]

The Uruguay Round TBT Agreement establishes a very similar process, presumably an embellishment of a precursor in the earlier Tokyo Round Standards Code,[138] in which the analogous institution is known as a "technical expert group."[139] However, these technical expert groups may be established not only on the initiative of the panel itself, but also at the request of any party to a dispute, an option which is not expressly stated for expert review groups under other portions of the Uruguay Round.[140] The NAFTA contains a comparable provision under which dispute settlement panels can request a written report from a "scientific review board" established either by the dispute settlement panel itself or at the urging of a disputing party.[141]

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[137] *Id.* App. 4.

[138] *See supra* note 17 (technical expert groups in Standards Code). No technical expert group has ever been established pursuant to the Tokyo Round Standards Code. Although the United States requested the establishment of a technical expert group in connection with the beef hormone dispute with the European Union, such a group was never convened. *See* Froman, *supra* note 23, at 550; Halpern, *supra* note 23, at 142-43.

[139] Uruguay Round TBT Agreement, *supra* note 20, art. 14 & Annex 2 (establishing technical expert groups).

[140] *But cf.* text accompanying *supra* note 125 (parties to dispute concerning restrictions on importation of and internal taxes on cigarettes agreed to expert submission by World Health Organisation).

[141] The NAFTA provides in article 2015 as follows:

> Scientific Review Boards
>
> 1. On request of a disputing Party or, unless the disputing Parties disapprove, on its own initiative, the panel may request a written report of a scientific review board on any factual issue concerning environmental, health, safety or other scientific matters raised by a disputing Party in a proceeding, subject to such terms and conditions as such Parties may agree.
>
> 2. The board shall be selected by the panel from among highly qualified, independent experts in scientific matters, after consultations with the disputing Parties and the scientific bodies set out in the Model Rules of Procedure established pursuant to Article 2012(1).

(contd.)

A number of singular issues arise from the likelihood, given the structure of the new trade disciplines in the Uruguay Round and the NAFTA texts on standards, that the quasi-adjudicatory dispute settlement panels will be obliged to review the scientific foundation for national regulatory measures. The four texts expressly address none of the following three central questions:

- To what extent, if at all, must panels defer to expert scientific judgement underlying a national standard, especially if that judgement reflects minority or controversial views within the scientific community?[142]
- To what extent, if at all, must panels defer to expert scientific judgement underlying a national standard when that judgement is exercised under conditions of scientific uncertainty?[143]

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141. (contd.)

3. The participating Parties shall be provided:

(a) advance notice of, and an opportunity to provide comments to the panel on, the proposed factual issues to be referred to the board; and

(b) a copy of the board's report and an opportunity to provide comments on the report to the panel.

4. The panel shall take the board's report and any comments by the Parties on the report into account in the preparation of its report.

NAFTA, *supra* note 2, art. 2015

[142] *See, e.g.*, John H. Jackson, *World Trade Rules and Environmental Policies: Congruence or Conflict?*, *in* TRADE AND THE ENVIRONMENT: LAW, ECONOMICS, AND POLICY 219, 234 (Durwood Zaelke et al. eds., 1993) ("the 'scope of review' of international GATT/[World Trade Organisation] panels over national government regulatory decisions concerning environment needs to be better defined"). *See supra* text accompanying note 35 & note 51 (definitions of "scientific justification" in Uruguay Round SPS Agreement and "scientific basis" in NAFTA SPS text).

[143] *Cf. supra* text accompanying notes 40 & 53 (Uruguay Round and NAFTA provisions stating that sanitary and phytosanitary measures may be adopted on provisional basis under conditions of uncertainty).

- How should dispute settlement panels treat and structure requests for expert scientific advice in addressing issues raised by the previous two questions?

D. Interpreting Science-Based Trade Disciplines in the Dispute Settlement Process

Like the original GATT, the Uruguay Round and the NAFTA texts on standards contain no express instruction that dispute settlement panels must accord scientific determination by national regulatory authorities some measure of deference. Such a conclusion, however, is virtually inescapable. First, as discussed in section III.A above, allowing panels composed of lay persons to substitute their judgement for that of technical experts would tend to contradict policy and practise by municipal tribunals at the national level, where courts have been hesitant to second-guess the resolution of questions of scientific "fact" by technically expert regulatory authorities.

Second, to the extent that there is any evidence, the negotiating and drafting histories of the Uruguay Round and the NAFTA demonstrate a progressive relaxation in the rigour of the scientific tests. With respect to the Uruguay Round SPS Agreement, the interim 1991 Dunkel Draft acknowledged that measures more stringent than international standards were permissible, but subjected them to what might have been interpreted as a rigid cause-and-effect relationship of "scientific justification."[144] Although that term is retained in the final text, a clarifying footnote establishes that it is for individual governments to make a determination of scientific justification on the basis of an examination and evaluation of available scientific information.[145]

There is reason to believe that changes in the NAFTA text on sanitary and phytosanitary measures during the negotiation

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[144] *See supra* note 34 and accompanying text.

[145] *See supra* text accompanying note 35.

process were even more significant. A document dated February 20, 1992, which purports to be an interim negotiating draft of the NAFTA, was leaked to the press at the end of March of that year. The authenticity of this document has not been confirmed.[146] In any event, the leaked draft sets out a test of "scientific justification" similar to that in the December 1991 Dunkel Draft for those sanitary and phytosanitary measures which are more stringent than international standards. This requirement has been eliminated altogether in the final version of the NAFTA text. By comparison with the unofficial, leaked interim text, the final text much more explicitly confirms each party's right to establish its appropriate level of protection without regard to scientific constraints. Similarly, the final text on technical barriers was apparently modified by deleting a requirement that standards-related measures be the least restrictive to trade or no more trade restrictive than necessary.

The United States has given the following official interpretation of the role of science in the NAFTA SPS disciplines:

> under the NAFTA, the requirement that measures be based on "scientific principles" and not be maintained "where there is no longer a scientific basis" do *not* involve a situation where a dispute settlement panel may substitute its scientific judgement for that of the government maintaining the sanitary or phytosanitary measure. The question under the NAFTA in this regard is whether the government maintaining the sanitary or phytosanitarymeasure has "a scientific basis" for the

[146] *See Citizen Groups Say Leaked NAFTA Draft Would Undermine U.S. Standards*, Int'l Trade Daily (BNA), Mar. 26, 1992 (quoting United States Government official as saying she "had no way of saying whether the draft document is authentic").

measure. "Scientific basis" is defined as "*a* reason based on data or information derived using scientific methods."

> The question is also *not* whether the measure was based on the "best" science or the "preponderance" of science or whether there was conflicting science. The question is only whether the government maintaining the measure has *a* scientific basis for it. This is because [the NAFTA sanitary and phytosanitary text] is based on a recognition that there is seldom, if ever, scientific certainty and consequently any scientific determination may require a judgement among differing scientific opinions. The NAFTA preserves the ability of *governments* to continue to make those judgements.[147]

Although this is a unilateral interpretation subsequent to the conclusion of the NAFTA negotiations, it does stand for the very general proposition that the NAFTA, and by implication the analogous passages in the Uruguay Round, contain an implicit notion of deference to national scientific determinations.

If some deference is necessary to national scientific determinations, what can be said about the minimum level of scientific rationality that will suffice to support a national measure? The best conclusion is that these tests are the scientific analogue of a procedural, not a substantive, test.[148] Although

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[147] Statement of Administrative Action, North American Free Trade Agreement Implementation Act, *supra* note 46, ch. 7, § B(A)(8)(c), at 542 (emphasis in original). *See also* Letter from Michael Kantor, United States Trade Representative, to John Adams, Executive Director, Natural Resources Defence Council (Sept. 13, 1993), *reprinted in* INSIDE U.S. TRADE, Sept. 17, 1993, at 5-6 (same). *See also* OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, REPORT ON U.S. FOOD SAFETY AND THE URUGUAY ROUND: PROTECTING CONSUMERS AND PROMOTING U.S. EXPORTS (June 1994) (analysing Uruguay Round SPS Agreement disciplines).

there may be weaknesses in peer review as a vehicle for validating the "correctness" of a scientific determination,[149] that process should be adequate for assessing whether the inquiry that preceded a particular conclusion has been minimally "scientific". Accordingly, any domestic scientific determination that has withstood scientific peer review should categorically be presumed to satisfy the science-based disciplines in either the Uruguay Round or the NAFTA.

The absence of approval through a peer review process, however, ought not to be dispositive. As discussed above, regulatory authorities must often operate at the frontiers of scientific knowledge in advance of general acceptance and in the face of disputes over science policy choices. For those regulatory measures whose scientific support does not satisfy a peer review test, a panel might consider the following questions in determining whether a challenged measure qualifies as minimally "scientific":

- Was the adoption of the measure preceded by an attempt to gather empirical data?
- Are the data characterised by any indicia of reliability — *e.g.*, reproducibility?
- Do the principles underlying the attempts to gather empirical data, as through toxicological tests, enjoy any following in the scientific community?
- Are numerical conclusions, such as risk probabilities, based on calculations from empirical data?
- Are the assumptions made in performing the risk assessment disclosed?

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[148] *See, e.g.*, Daubert, *supra* note 98, 113 S. Ct. at 2797.

[149] *See supra* text accompanying note 97.

- To assure consistency, is there evidence of the application of objective principles that might govern a class of similar cases? For example, was the risk assessment performed using assumptions or inference guidelines that have been published or that have been utilised in other cases?
- Are the scientific conclusions as to effects sufficiently specific to permit the adoption of a minimally coherent regulatory standard? For example, if the concern is for birth defects, is there a finding of teratogenicity?

In distinguishing investigations of physical or natural phenomena characteristic of the scientific method from other modes of analysis, it is not necessary that each of these tests be satisfied. Rather, using guidelines such as these, a panel should make a determination based on the specific context of a particular challenged measure and the totality of the circumstances as to whether the measure is accompanied by an analysis that can be objectively identified by the attribute "scientific".

The Uruguay Round and the NAFTA texts on sanitary and phytosanitary measures both require that a national measure be "based on a risk assessment". As discussed in section II.A above, establishing regulatory requirements after completion of a risk assessment is characteristic of risk management. Although the risk management function can be and is subject to additional trade disciplines, those criteria are not grounded in science.[150] Accordingly, this requirement ought to be satisfied if the respondent government can point to a risk assessment—which, under both agreements, apparently need not be a quantitative risk assessment—that meets the tests set out above and that was prepared before, or contemporaneously with, the adoption of the measure.

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[150] *See supra* text accompanying note 73.

The Uruguay Round SPS Agreement's requirement that a measure not be "maintained without sufficient scientific evidence"[151] is somewhat troubling. The use of the word "sufficient," which does not appear in the corresponding passage in the NAFTA, might be taken to authorise panels to review the adequacy of the scientific data underlying a measure in a manner that is inconsistent with basic principles of adjudicatory review of science in the regulatory process. In keeping with the above principles, the best interpretation of this passage is probably that there is a need for a minimal level of scientific evidence. With this perspective, panels would not have the wholesale power to substitute their judgement for that of national authorities with respect to the adequacy of the scientific evidence. Rather, panels could only ask whether the empirical data are minimally adequate to support the national government's scientific conclusions.

An additional concern is the potential for dispute panels to second-guess the relationship between the scientific support and the regulatory measure chosen by national governmental authorities by demanding an excessively high correlation between the two. Neither the Uruguay Round nor the NAFTA SPS texts speak to whether empirical data must correlate with regulated exposures, to whether uses from which data are obtained must be identified with a high degree of particularity, or to the specificity with which uses or exposures might be regulated based on particular effects. For example, would data based on exposure to a substance by inhalation support the regulation of that substance through ingestion? Would data obtained from certain uses justify controls or bans on others? This difficulty is particularly apparent in the case of the Uruguay Round SPS Agreement, in which the scope of applicability of

[151] *See supra* text accompanying note 26.

the scientifically-based trade disciplines to the choice of regulatory measure is not entirely clear.

Presumably the texts constraining national regulatory powers over sanitary and phytosanitary measures are not intended to disrupt numerous regulatory schemes in place in many countries for such substances as drugs, food additives, and pesticides,[152] in which prior governmental authorisation is required before a substance may be manufactured, can enter commerce, or may be employed for a particular use. Typically, such frameworks require a private party applicant, such as a manufacturer, to demonstrate that the substance meets a test of safety or the absence of adverse effects. One way of looking at these requirements of prior approval is as a particularised expression of a precautionary approach.[153] As suggested above,[154] such requirements can be quite rigorous from a scientific point of view.

A refusal by regulatory authorities to approve a particular substance or use of that substance will very likely be based on the *absence* of sufficient scientific support, due to the applicant's failure to meet the burden of satisfying the statutory standard.

In such a situation, the effect of the regulatory decision — the rejection of the application — may be a prohibition or ban on the substance or use. Under such circumstances, however, it would plainly be absurd to consider that prohibition to be a "measure" within the meaning of the Uruguay Round and the NAFTA texts on sanitary and phytosanitary standards.[155]

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[152] *See, e.g.*, PESTICIDES: A COMPARATIVE STUDY OF INDUSTRIALIZED NATIONS' REGULATORY SYSTEMS, *supra* note 38.

[153] *See supra* section II.B.

[154] *See supra* text accompanying note 102.

[155] *See supra* notes 21 & 47 (definitions of sanitary and phytosanitary measures in Uruguay Round and NAFTA texts).

Otherwise, a successful challenge to such a prohibition could be based upon the rejection of an application for which no supporting data at all were supplied. This interpretation would then produce the unlikely, if not absurd, result that the less extensive the applicant's scientific support, the greater the likelihood of a successful challenge.

Lastly, the prerogative created by the Uruguay Round and the NAFTA for the establishment of expert review groups and scientific review boards, respectively, to provide the lay panel members with technical, scientific advice should be exercised with great care. Absent, greater precision in the delineation of the composition, structure, powers, and procedures for these entities, these innovations may very well do more harm than good.[156] For instance, it is unclear whether and to what extent a dispute settlement panel could request an expert review group or scientific review board to review the assumptions, hypotheses, and theories – – "science policy" choices – – on which a risk assessment is based. Although the reference to a neutral expert in the Thai cigarette dispute[157] appears to have been successful, that model may have limited applicability in cases that involve much more intense controversy about purely scientific questions at the frontiers of human knowledge.

The notion of deference by one scientist to another's defensible, but arguably incorrect, scientific determination is not necessarily well internalised among the scientific community. The composition of these expert groups is obviouslycrucial, but there is no requirement that the members

[156] By contrast, the availability of environmental and public health policy expertise through the choice of panelists with experience in that area – as distinct from members of expert review groups and scientific review boards – may broaden the perspective of individual panels in exercising their law-making functions and enhance panels' sensitivity to policy concerns other than international trade.

[157] *See supra* text accompanying notes 125–28.

be broadly representative of the range of scientific thought on the questions posed. Nor is it apparent that such a requirement would have any meaning in hotly contested disputes or with regard to issues at the edges of scientific thought.

The potential for aberrant results is particularly high in the case of the Uruguay Round SPS Agreement, in which the scope of scientific inquiry established by the text, as discussed above, is less than clear. For example, that new agreement appears to invite an inquiry into the sufficiency of the scientific evidence supporting a national regulatory measure. Instead of encouraging an appropriate level of deference to science-based determinations of national regulatory authorities, the availability of these groups may incorrectly suggest that scientific questions are justiciable in an adjudicatory and adversarial context.

CONCLUSION

The emphasis on science-based trade disciplines in the standards provisions of the Uruguay Round and the NAFTA raises new challenges both for national regulatory authorities in the public health area and for the international trade regime, and especially for the trade agreement dispute settlement process. The structure of these texts, the best thinking on the role of science in the national regulatory process, considerations of scientific uncertainty, and the negotiating histories of these agreements all suggest that dispute settlement panels should be highly deferential to the scientific determinations of national authorities that underlie regulatory measures to protect the environment and public health. This question of deference might well benefit from explicit clarification by the relevant bodies under the World Trade Organisation — the newly established Committee on Trade and Environment or the relevant bodies under the SPS

and TBT Agreements [158] — and the analogous institutions under the NAFTA,[159] including the new North American Commission for Environmental Cooperation.[160]

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[158] *See* Uruguay Round SPS Agreement, *supra* note 19, para. 38 (establishing Committee on Sanitary and Phytosanitary Measures "to provide a regular forum for consultations"); Uruguay Round TBT Agreement, *supra* note 20, art. 13, para. 13.1 (establishing Committee on Technical Barriers to Trade "for the purpose of affording Members the opportunity of consulting on any matters relating to the operation of this Agreement").

[159] *See* NAFTA, *supra* note 2, art. 722 (establishing Committee on Sanitary and Phytosanitary Measures to "facilitate . . . consultations on specific matters relating to sanitary or phytosanitary measures"); *id.* art. 913 (establishing Committee on Standards-Related Measures to "provid[e] a forum for the Parties to consult on issues relating to standards-related measures").

[160] North American Agreement on Environmental Cooperation, Sept. 13, 1993, Can.-Mex.-U.S., art. 8, 32 I.L.M. 1482, 1485 (1993) (establishing Commission for Environmental Cooperation).

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