THE CONFLICT BETWEEN FREE TRADE AND PUBLIC HEALTH MEASURES: THE ROLE OF SCIENCE

by

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STATEMENT

I declare that *The Conflict Between Free Trade and Public Health Measures: The Role of Science* is my own work and that all the sources I have used or quoted have been indicated and acknowledged by means of complete references.

Signed: Date: 1 December 1999

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The Conflict Between Free Trade and Public Health Measures: The Role of Science

Summary

The needs of the free trade regime and governments' legitimate regulatory aims in the area of public health protection conflict. Government health measures create barriers to free trade and are thus disciplined by the trade regime.

This conflict is addressed in the rules of the World Trade Organization, in the Agreement on the Application of Sanitary and Phytosanitary Measures. This Agreement uses science to mediate the conflict. The reason for the reliance on science is the view that it provides a neutral, universally-valid discipline and that thus the results of testing health measures for scientific validity would be acceptable to both parties in a dispute.

This uncritical approach towards science is called into question. An analysis of the relevant science-based disciplines of the SPS Agreement and their interpretation in WTO dispute settlement shows the flaws in this system. A re-evaluation of the WTO rules governing health regulation is called for.

Key Terms

International trade law; World Trade Organization; Public health measures; Science-based disciplines; Scientific uncertainty; Free trade; Agreement on Sanitary and Phytosanitary Measures; Risk assessment; Risk management; Standard of review; Burden of proof; Expert review group; Science policy.

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Part 1: Problem Definition

1.1 Introduction

The protection of public health is an important part of the duties of national government. It requires the creation of various regulations and other measures to deal with potential health risks. However, these measures often have a negative impact on international trade. As such, they have been subject to the scrutiny of the organs of the multilateral trade order, represented by the World Trade Organization,[1] under internationally-agreed-upon rules.[2] These rules are embodied in the various international free trade agreements that form part of what is now known as WTO law.

This paper aims to examine the way in which WTO law seeks to resolve the conflicting values of trade liberalisation and the protection of public health. It will focus specifically on the role given to science and scientific analysis in current WTO rules policing the use of health regulations by national governments. The appropriateness of such rules will be questioned in the light of the application thereof by the dispute settlement organs of the WTO.

The discussion will start by situating itself within the broader ambit of what is known as the trade linkage debate, in order to provide the context within which the more specific issue of the conflict between trade and public health can be understood. The trade linkage debate received much attention in the run up to the Millennium Round of trade negotiations held in Seattle under the auspices of the WTO.[3] It deals with the impact of continuing trade liberalisation on other important social values, such as the protection of public health, labour standards, environmental protection and cultural identity. It is only within the general

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1 The World Trade Organization [hereinafter referred to as the WTO] was established as a result of the Uruguay Round of trade negotiations, by the Marrakesh Agreement Establishing the World Trade Organization [hereinafter referred to as the Marrakesh Agreement], reprinted in *The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts* (1994) GATT Secretariat, Geneva at 6-18.

2 Other multilateral trade regimes exist on a smaller scale, such as, *inter alia,* the European Union [hereinafter referred to as the EU] and the North American Free Trade Agreement [hereinafter referred to as NAFTA]. However, this study will focus on the situation under WTO law as this organisation represents the most global example of a multilateral trade regime, having a current membership of 135 countries. Its rules, therefore, have the broadest impact on national health policies.

3 The Third WTO Ministerial Conference, held on 30 Nov.-3 Dec. 1999.[Hereinafter referred to as the Millennium Round] Masses of protestors, representing various social concerns such as labour and environment surrounding converged on the conference center. This is an indication of the importance of finding a resolution to the conflicts between trade liberalisation and societal values.

understanding of the interaction between free trade and national social policies, that the trade/public health linkage can be fully comprehended.

A specific discussion of the reasons for the conflict between free trade and the protection of public health will follow. This section will aim at providing an understanding of the relevance of the issue. Finally, this introductory section will conclude by elucidating the role of scientific analysis in the resolution of this conflict.

Part 2 of this paper will focus specifically on the provisions of the Agreement on the Application of Sanitary and Phytosanitary Measures,[4] and their interpretation by WTO dispute settlement organs. This section will aim to show the effects of the use of scientific analysis to evaluate national health regulations. The central theme in this discussion will be the need for recognition of the pervasiveness of scientific uncertainty in the rules governing health regulations.

In Part 3, procedural aspects of the role of science in the mediation of the trade/public health conflict will be examined. These relate to problems of adjudication of disputes under the SPS Agreement's science-based disciplines.

This paper will conclude with a recommendation for the re-evaluation of the current WTO rules governing the balancing of the needs of the global trading system with the legitimate regulatory aims of national governments in the area of health protection.

1.2 The Linkage between Free Trade and Other Societal Values

Free trade enables countries to specialise in producing the goods or services in which they have a comparative advantage, thus maximising global wealth.[5] It also has beneficial side effects, such as the promotion of co-operation between nations, thus improving the prospects for peace, and accelerating the spread of technological innovation throughout the world. Clearly then, free trade is an important societal goal. It is thus important to protect the advances that have been made in trade liberalisation from protectionist attempts by national

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[4] Agreement on the Application of Sanitary and Phytosanitary Measures, 1994 [hereinafter referred to as the SPS Agreement], in annex 1A to the Marrakesh Agreement, reprinted in *The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts* (1994) GATT Secretariat, Geneva at 69-84.

[5] The theory of comparative advantage was expounded by Adam Smith in his famous book *The Wealth of Nations*. This represented a break away from the mercantilism of the past, which saw protecting local industry from imports as the way to secure the welfare of the country. Protectionism has been blamed for the trade wars that escalated into actual wars, as well as the financial crisis of the 1930s.

governments. These positive aspects of trade liberalisation led to efforts on the international arena to secure the benefits of free trade in multilateral agreements, such as the General Agreement on Tariffs and Trade of 1947.[6] Various rounds of multilateral trade negotiations followed under the auspices of GATT, increasing the areas covered by free trade agreements. Finally, as a result of the conclusion of the Uruguay Round negotiations, the World Trade Organization came into existence on 1 January 1995.[7] The WTO has become the main forum for multilateral trade negotiations.

However, in recent times, the euphoria enveloping this new organisation and increasing trade liberalisation initiatives has dissipated. It has become increasingly apparent that free trade, and the economic growth that accompanies it, has its price in other societal values, such as labour standards, public health and environmental protection. The ability of governments to protect and promote societal aims through regulations is now limited by their obligations under WTO law. This is because domestic regulations often have a restrictive impact on imports. The response of the free trade regime to these types of regulations has been to label them "non-tariff barriers" to trade and thus subject them to WTO disciplines. It is currently being questioned whether these disciplines sufficiently take into account the importance of these other values for society, or whether they are skewed in favour of free trade.

There is currently growing public pressure for the inclusion of social policy considerations within the multilateral trade regime and increased recognition of the linkages between trade and societal values.[8]

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6 The General Agreement on Tariffs and Trade 1947 [hereinafter referred to as GATT 1947], adopted at the conclusion of the Second Session of the Preparatory Committee of the United Nations Conference on Trade and Environment, opened for signature on Oct. 30, 1947, 61 Stat. A3, 55 U.N.T.S. 188, reprinted in *The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts* (1994) GATT Secretariat, Geneva 486-558. This agreement was never ratified but came into force through the Protocol of Provisional Application. It did not itself create an international organisation, but one came into being *de facto* to coordinate the application of the GATT. This agreement was incorporated by reference into the General Agreement on Tariffs and Trade 1994 [hereinafter referred to as the GATT 1994] by art. 1(A) thereof and its provisions are thus still applicable today.

7 By the Marrakesh Agreement *supra* fn. 1.

8 Protestors gathered at the conference center in Seattle at the commencement of the Millennium Round of trade negotiations (*supra* fn. 3), calling for a halt to further trade liberalisation efforts until a resolution for the conflict between trade and other important societal values has been found.

1.3 The Conflict between Free Trade and Public Health Measures

One important societal value which is impacted by continuing trade liberalisation, is that of public health protection. Normally governments have regulations in place to deal with potential risks to human, animal or plant life or health within their boundaries. Such measures are seen by governments as an exercise of their sovereign authority to regulate domestic affairs. However, the increasingly free flow of agricultural goods and other products with possible health implications across national borders, means that these regulations are no longer enough. Governments now have to regulate imports to ensure that they meet their health standards. Different governments have different health priorities which are manifested in their health regulations.

Clearly, such health measures have a negative effect on international trade. Thus, free trade regimes[9] impose certain disciplines on the use of government regulations for the protection of health. The policing of national health measures by the multilateral trade regime, as embodied in WTO law, is based on the core question of when the needs of the system of free trade should override national choices in the field of protection of public health. This boils down to the basic issue of the appropriate level of decision-making in health matters, in cases where international trade is impacted. To what extent should the sovereign authority of national governments to act in the interests of their citizens on health matters be restricted by the multilateral trade regime? The search for balance between the objectives of the trade regime and the legitimate regulatory aims of WTO Members is reflected in the provisions of various WTO agreements.

This paper will focus on the use of scientific analysis to achieve this balance, as reflected in the SPS Agreement. Thus, before undertaking brief examination of the relevant provisions of the applicable agreements, it is necessary to provide a general introduction to the role of science in limiting the ability of national governments to enact public health measures.

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9 Such as the WTO, the EU and NAFTA.

1.4 Introduction to the Role of Science in Policing Health Measures

Science is playing an increasingly important role in the structure and functioning of international agreements limiting the capacity of governments to enact measures for the protection of public health.[10] It thus acts on the interface between the conflicting societal values of economic growth through trade liberalisation and the protection of public health.[11]

The reason for the appeal of science for international trade negotiators lies in its appearance of objectivity and universal validity. Science enjoys enormous prestige in our technological world. It seems to provide rational and testable results. If national measures can be tested against neutral rules, the results would be acceptable to both parties. The use of science as the standard against which to evaluate the validity of health regulations is aimed at reducing international disputes in this important area and providing clear guidelines for national decision-makers. It would seem to provide the perfect tool for balancing the needs of the trade regime with the protection of public health. If health measures cannot be scientifically justified it seems beyond dispute that they do not serve to protect public health, but are instead unjustified barriers to international trade.

This paper aims to examine the appropriateness of this emphasis on scientific justification in seeking the balance between free trade and public health goals. For this reason, it is necessary to first understand the role that science plays within the national regulatory process before examining its role in the multilateral trade order.

National health regulation is frequently based on scientific findings. Without such basis, regulatory measures would be subject to criticism on national level. Scientific assessments of risks to the public determine areas in which regulatory action is necessary, and science is

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[10] The field of health is currently unique in its use of scientific analysis for determining the validity of national regulations, despite the fact that other areas, such as that of environmental protection, also use scientific studies as a basis for regulatory action. See further on this issue, in particular as regards the emergence of science-based disciplines in NAFTA and WTO rules, David A. Wirth, "Symposium: The role of science in the Uruguay Round and NAFTA trade disciplines," *Cornell International Law Journal* 27 (1994): 817.

[11] The emergence of science as the principal touchstone for establishing the validity of national health regulation is not only reflected in the results of the Uruguay Round of multilateral trade negotiations (15 Dec. 1993, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations [hereinafter referred to as the Final Act], and the Marrakesh Agreement (*supra* fn. 1), substantially reprinted in *The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts* (1994) GATT Secretariat, Geneva at 1-482), but also in the North American Free Trade Agreement (17 Dec. 1992, Can.-Mex.-U.S., 32 I.L.M. 296 and 32 I.L.M. 605) [hereinafter referred to as NAFTA].

also used to evaluate the efficacy of the various possible measures in order to design an appropriate regulation.[12]

However, that is not the whole story. In practice, regulatory design is more than just a scientific discipline. Public health measures often also reflect social policy choices. One must bear in mind that regulations are drafted in a particular economic, social and political context. As a result, disparate regulatory measures result across national boundaries even where the scientific rationale for the measures is the same. Science does inform the process, but is not decisive in determining the outcome.

For this reason, a distinction has been drawn between two aspects of the regulatory process: risk assessment and risk management. Risk assessment is the scientific process of determining the potential risk in the light of the potential for harm in a substance and the predicted exposure to that substance.[13] Risk management is the process of evaluating the available regulatory options and choosing among them.[14] This is a policy decision-making process and involves not only a consideration of scientific evidence but also the making of value judgements based on political, social and economic considerations.[15]

The usefulness of this distinction for the role of science as part of the international discipline imposed on national health measures, lies in its recognition of the different nature of these two aspects of the regulatory process. Risk assessment is explicitly scientific and can thus be evaluated according to scientific criteria. On the other hand, the acknowledgement that risk management is a policy area allows the recognition of the sovereign right of national governments to make their own decisions in this area. Thus, this aspect of the regulatory process cannot be evaluated using science-based disciplines. The rules of the multilateral trade regime have consequently been fashioned in a way which takes this distinction into account when judging the validity of national health measures.

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12 Jeffery Atik, "Symposium - Institutions for international economic integration: Science and international regulatory convergence," *Journal of International Law and Business* 17 (1997): 736 at 736.

13 See Vern R. Walker, "Keeping the WTO from becoming the "World Trans-science Organization": scientific uncertainty, science policy, and factfinding in the growth hormones dispute," *Cornell International Law Journal* 31 (1998): 251 at 263-267 for an in-depth discussion of the main elements of a risk assessment.

14 See Walker, (*supra* fn. 13 at 267-277) for a description of the three functions that form part of risk management.

15 An example of this two-phase process would be the establishment, by scientific analysis of empirical data, of the existence of a 20% risk that persons consuming tinned fruit from a certain country where a particular preservative is used will contract a certain skin rash, followed by the decision by national regulatory authorities of one country to ban imports of tinned fruit from the exporting country in order to achieve a chosen zero-risk level of protection. Another importing country may have different priorities and be prepared to tolerate a higher level of risk, thus coming to the risk management decision of requiring only that the importer label the fruit in a way that warns consumers of the potential health risk.

However, even in the evaluation of the risk assessment part of the regulatory process, the use of science should be approached with caution. The traditionally uncritical view taken of science by the law is no longer acceptable. It is crucial to recognise that an element of scientific uncertainty is present in most risk assessments.[16] This is because science is not absolute, but is inherently historical and what is valid today may be totally disproved tomorrow. Further, there can be more than one scientifically valid conclusion drawn from the same data. This is known as the problem of duelling science. The state of scientific knowledge in a particular area is often limited and scientific analyses are thus made using certain assumptions, incorporating value judgements.[17] These value-based assumptions on what risks are acceptable, are referred to as "science policy" and pervade even risk assessments.[18] Thus science is not the objective, universally valid, neutral standard it appears to be. Any disciplines involving scientific justifications must thus take this important limitation into account. This is particularly so in the field of health, due to the complexity of the human body and the influence of psychological, environmental and social factors on human health.[19]

It now remains to examine the applicable provisions of WTO law to see the way in which science is used to find an acceptable balance between trade and health goals. A brief discussion of the rules under GATT and developments leading to the current situation will be followed by a more specific discussion of the way in which science has been used in the disciplines of the SPS Agreement.

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16 Walker, (*supra* fn. 13 at 258) identifies three main categories of uncertainty in risk assessment, namely measurement uncertainty, uncertainty associated with the use of scientific models and gaps in data.

17 The fact that science incorporates cultural and social biases is demonstrated by the disparate scientific consensuses that exist across countries. The example of Nazi racial studies and Lysenko's genetics in the USSR is raised by Atik (*supra* fn. 12 at fn. 11).

18 Walker, *supra* fn. 13, at 304.

19 Atik, (*supra* fn. 12, at 747-748) states: "In general, the science which underlies regulation, including SPS regulation, is science applied to immense complexity. The human body, the ecology of a particular locale and the interplay of social factors are all enormously complex systems, about which strong scientific assertion breaks down. Heuristics (rules-of-thumb) replace direct observation and synthesis in guiding the formation of scientific consensus and introduce the possibility of multiple outcomes."

Part 2: Substantive Legal Framework

2.1 Introduction

Before examining the actual WTO rules governing national regulatory measures in the area of public health, it is important to point out that these rules embody mainly negative obligations, that is, they limit the ability of governments to enact health measures.[20] A measure falling foul of the requirements set by the applicable provision is in violation of these obligations and must be removed or corrected. On the other hand, no positive obligations to achieve certain minimum standards in the area of health protection exist. This is due to the fact that the WTO has no supranational standard-setting authority.[21] It operates purely on the basis of intergovernmental agreements. As it would be very difficult to achieve consensus among all WTO Members regarding minimum applicable standards for health protection, it is unlikely that the responsibility for setting standards of health protection could be exercised at WTO level.[22] This makes even more important the achievement of an appropriate balance by WTO rules, leaving national governments sufficient freedom to enact efficient regulations for the protection of public health.

Before the conclusion of the Uruguay Round, Members could adopt and maintain measures for the protection of human, animal and plant life or health under a general exception for such measures from all GATT obligations. These obligations include particularly the prohibition on quantitative restrictions to trade[23] and the duty to provide non-discriminatory treatment[24] to imports from GATT Contracting Parties. The exception for health measures was contained in article XX(b) of GATT 1947, and was limited by the requirements that these measures not be applied in a manner that constitutes a means of arbitrary discrimination between countries where the same conditions exist, or a disguised restriction

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20 See further on this issue Wirth, *supra* fn. 10 at 818.

21 This is in marked contrast to the situation within the EU, where rules for the free movement of goods, services and persons fall under what is known as the First Pillar, where decisions are taken on supranational level by EU institutions. Thus negative integration (removal of barriers to the free trade) can proceed hand in hand with positive integration (creation of harmonised regulations on EU level to deal with the negative effects of liberalisation).

22 The question whether the WTO can or even should become a "global meta-regulator", with the authority to adopt health policies on acceptable risk levels has been raised. See Walker, *supra* fn. 13 at 255.

23 Article XI:1 of the GATT 1947.

24 This duty was set out in article I of GATT 1947 (*supra* fn. 6) , obliging each Contracting Party to extend any advantage it provides to any other country, to all GATT Contracting Parties (hereinafter referred to as the Most Favoured Nation Treatment obligation), and article III, establishing the duty to treat imports no less favorably than domestic products (hereinafter referred to as the National Treatment obligation).

on international trade,[25] and that the measure be necessary to protect human, animal or plant life or health.[26] The burden was on the respondent Member to prove that its measure fulfilled the requirements of the exception. The "necessary" requirement was interpreted to mean that the measure must be the least trade-restrictive or GATT-inconsistent measure possible.[27] No scientific justification requirement was read into this test. It is clear from these provisions that GATT 1947 provided a limited exception for health measures, but did not create specific disciplines regulating the use of these measures.[28]

The GATT rules were seen as ineffective in dealing with non-tariff barriers to trade, which included regulations. For this reason, in 1979, the Agreement on Technical Barriers to Trade[29] was adopted, regulating compulsory government specifications for industrial and agricultural products.[30] It aimed at reducing trade distortions caused by differences in national regulations. The criterion for validity of regulations under the Standards Code was whether the measure created an unnecessary obstacle to international trade. There was still no explicit reference to scientific justification, although the possibility of obtaining advice from technical expert groups was envisaged.[31] The Standards Code had limited effect in reducing the divergence in technical regulations.[32]

In the 1980s, a dispute arose between the US and the EU, concerning an EU ban on the use of hormones in livestock farming, except in limited circumstances, and an import prohibition on hormone-treated meat.[33] Despite attempts to address this dispute in informal

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25 These requirements were contained in the *chapeau* (headnote) of Article XX of GATT 1947 (*supra* fn. 6). They are now in the same article of GATT 1994.

26 This requirement was contained in article XX(b) of GATT 1947 (*supra* fn. 6). It is now in the same article of GATT 1994.

27 See Thailand - Restrictions on the Importation of and Internal Taxes on Cigarettes, GATT B.I.S.D., 37th Supp. 200, paras 74-81 (1991), 30 I.L.M. 1122 (1991) where it was held that the import restrictions on cigarettes were not justified by article XX(b) due to the availability of GATT-consistent or less GATT-inconsistent measures.

28 Dale E. McNiel, "The first case under the WTO's Sanitary and Phytosanitary Agreement: the European Union's hormone ban," *Virginia Journal of International Law* 39 (1998): 89 at 94.

29 Agreement on Technical Barriers to Trade, Apr. 12, 1979, 1186 U.N.T.S. 276, GATT, B.I.S.D., 26th Supp. 8 (1980), adopted as part of the Tokyo Round negotiations [hereinafter referred to as the Standards Code].

30 Wirth, *supra* fn. 10 at 822.

31 Standards Code, *supra* fn. 29 article 14.9-14.12, Annex 2.

32 This failure has been ascribed to the limited number of GATT contracting parties that subscribed to it as well as to the weakness of the dispute settlement mechanism under GATT 1947. See Atik, *supra* fn. 12 at 741.

33 Council Directive of 31 December 1985 Prohibiting the Use in Livestock Farming of Certain Substances having a Hormonal Action, 1985 O.J. (L.382) 228. See McNiel, (*supra* fn. 28 at 99-107) for details of the various EC Directives and proposals on this issue as well as this history of this dispute.

discussions and later in dispute settlement proceedings under the Tokyo Round Standards Code, the conflict remained unresolved.[34]

This inability of the existing agreements to deal effectively with this important dispute in the area of health protection was in the minds of the GATT Contracting Parties when they met in Punta Del Este, Uruguay to launch the Uruguay Round of trade negotiations. The agenda for the upcoming negotiations was set out in the Punta Del Este Declaration.[35] This included the goals of continuing the liberalisation of world trade and extending the application of GATT disciplines. Further, the Declaration called for bringing "...all measures affecting import access...under strengthened and more operationally active GATT rules and disciplines" by, inter alia, "minimising the adverse effects that sanitary and phytosanitary regulations and barriers can have on trade in agriculture, taking into account the relevant international agreements."[36] Clearly the position of sanitary and phytosanitary measures[37] was seen as meriting special attention, apart from the larger genus of technical standards.[38] This led to the drafting of two separate Agreements in the Uruguay Round. Firstly, the new Agreement on Technical Barriers to Trade[39] was established, applicable to technical regulations and standards other than sanitary or phytosanitary measures, which elaborated on the Tokyo Round Standards Code.[40] Secondly, the Agreement on the Application of Sanitary and Phytosanitary Measures was drawn up, in an attempt to provide an authoritative interpretation of article XX(b) that could set the limits of the use of health measures in ways that could affect international trade.

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34 After unsuccessful consultations on this dispute between the US and the EC, the US requested that the matter be referred to a technical expert group. The EC blocked the establishment of this expert group, so the dispute was not resolved.

35 Ministerial Declaration on the Uruguay Round: Declaration of 20 September 1986, (hereinafter referred to as the Punta Del Este Declaration) Sept. 20, 1986, GATT B.I.S.D. (33rd Supp.) at 19 (1987).

36 Punta Del Este Declaration, *supra* fn. 35 at 20. Quoted by McNiel *supra* fn. 28 at 95.

37 Hereinafter referred to as SPS measures.

38 Reasons that have been suggested for this view are the close link between agriculture and SPS standards, the importance of the beef hormone dispute and the fact that SPS measures were thought to raise problems different from those linked to other technical standards, for example the greater importance of scientific risk assessment, the greater divergence in national approaches to standard setting and the crucial role of national regulatory authorities in deciding on the need for regulation and the measures to be taken. See Wirth, *supra* fn. 10 at 824 and Eliza Patterson, "International efforts to minimize the adverse trade effects of national sanitary and phytosanitary regulations," *Journal of World Trade* 24 (1990): 91 at 95.

39 Agreement on Technical Barriers to Trade, Apr. 15, 1994, in annex 1A to the Marrakesh Agreement [hereinafter referred to as the TBT Agreement]. This Agreement replaces the Tokyo Round Standards Code of 1980 (*supra* fn. 29).

40 The TBT Agreement goes further than the Standards Code in that it applies to both mandatory standards and recommendations and extends not only to products but also related processes and production methods.

The SPS Agreement lays down specific rules and disciplines applicable to SPS measures, as defined in an annex thereto. Going further than a mere elaboration and clarification of article XX(b) of GATT 1994,[41] the SPS Agreement established a new, comprehensive set of norms for the adoption, maintenance and enforcement of SPS measures. Unlike the new TBT Agreement, the SPS Agreement emphasises the role of scientific justification for the validity of national health measures.

The SPS Agreement did not supplant the relevant provisions of the GATT 1947 (now incorporated by reference in the GATT 1994) applicable to health measures. Instead the two agreements now operate in complement to each other and to the TBT Agreement. Thus, the current position of measures for the protection of public health under WTO law, is determined by the relevant provisions of these three agreements and their interpretation by the GATT/WTO Panels and the Appellate Body.

This analysis will limit itself to an examination of the SPS Agreement. This seems logical as this Agreement is now the most important one in the area of public health in dispute settlement proceedings and thus has the greatest impact on national health measures. If, in a dispute settlement proceeding dealing with an SPS measure, the analysis started with the GATT, it would nevertheless be necessary to subsequently examine the SPS Agreement for the following reasons: if a violation of GATT (article III or XI) was found, it would be necessary to determine whether this violation could be justified under art XX(b), and an SPS measure can now only be justified under art XX(b) if it does not violate the SPS Agreement. If, on the contrary, it were found that the measure did not violate GATT, this would not imply consistency with the SPS Agreement, as it contains a wider range of obligations and encompasses non-discriminatory measures, so it would have been necessary to consider the latter in any case. On the other hand, SPS measures which are consistent with the SPS Agreement are presumed in conformity with the relevant GATT[42] and thus no further analysis would be necessary once consistency with the SPS Agreement was shown.[43] In cases where the contrary was found, the panel would still not have to proceed to an examination of GATT-conformity since the invalidity of the measure is already established.

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41 Previously article XX(b) of GATT 1947.

42 SPS Agreement, (*supra* fn. 4) art. 2.4 states, "Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of article XX(b)."

43 David R. Hurst, "*Hormones*: European Communities - Measures Affecting Meat and Meat Products," *European Journal of International Law* 9, no. 1 (1998): 1 at 3.

However, it must be borne in mind that the SPS Agreement does not apply to all measures for the protection of public health, but only those included in its definition of SPS measures. Other health measures must still be analysed in terms of the TBT Agreement and the relevant provisions of GATT 1994. The provisions of these agreements are thus still relevant. As they do not address scientific analysis, however, they are outside the scope of this investigation.

2.2 The SPS Agreement

As mentioned above, talks on SPS measures in the Uruguay Round negotiations began as an attempt to elucidate the health exception in article XX(b) of the GATT. By the time the SPS Agreement was completed, it had evolved into a complex range of disciplines including scientific justification, risk assessment, transparency and equivalency. It closed potential loopholes for protectionism while recognising the sovereign right of Member governments to make their own decisions regarding the levels of SPS protection in their countries. The SPS Agreement created the possibility for stricter scrutiny of domestic health regulations, tightening the existing exceptions in the GATT 1994, by linking the validity of heath measures to scientific principles.

2.2.1 Basic Rights and Duties

Article 2 sets out the basic rights and obligations under the SPS Agreement, which are then further elaborated in subsequent articles. This article articulates the purpose of balancing the legitimate right of sovereign governments to take health protection measures, with the need to promote free trade and prevent protectionism. The core of this article is the use of science-based disciplines.[44]

Firstly, article 2.1 recognises the right of Members to take SPS measures necessary for the protection of human, plant or animal life or health, provided they conform to the provisions

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[44] This article includes non-science disciplines as well. Article 2.3 lays down the requirements that SPS measures must not arbitrarily or unjustifiably discriminate between members where identical or similar conditions prevail, and that they must not be applied so as to constitute a disguised restriction on international trade. These requirements are drawn from the *chapeau* of article XX of GATT 1994 (*supra* fn. 6).

of the SPS Agreement. Art 2.2 lays down three requirements for SPS measures: they must be (1) applied only to the extent necessary to protect human, animal or plant life or health (2) based on scientific principles; and (3) not maintained without sufficient scientific evidence, except as provided for in article 5.7.

This core SPS provision establishes the role of science as a crucial part of the obligations undertaken by WTO Members in respect of SPS measures. Science is thus the touchstone against which measures are judged for validity. Once one recognises the fallacy inherent in a notion of universal science, it becomes necessary to ask: whose science must measures be tested against? Must the Panel defer to the choice of scientific approach made by the government imposing the measure, or can it substitute its own judgement for that of the government? In his statement when submitting the bill to implement the Uruguay Round Agreements, President Clinton claimed that the requirement of "sufficient scientific evidence" does not authorise a Panel to substitute its judgement for that of the government imposing the measure. He stated that by requiring only sufficient scientific evidence, rather than a weighing of the preponderance of the evidence, this provision recognises the existence of scientific uncertainty and the fact that decisions are based on choices between differing scientific views.[45] This approach would leave the evaluation and choice between the different scientific views in the hands of the government imposing the measure, and would require Panels and the Appellate Body to defer to these decisions. This interpretation of article 2.2 was made by the US administration and is thus not an authoritative statement of the way the article will be applied by Panels or the Appellate Body. In fact, as will be seen in the following discussion, the positions taken by Panels and the Appellate Body to scientific evidence do not indicate such deference. On the contrary, the Member imposing the SPS measure must be able to offer evidence that would be acceptable to prominent scientists.[46]

In *EC-Hormones*, however, the issue of competing scientific opinions did not arise as there was unusually broad consensus among scientists that the use of hormones for growth-promotion purposes, in accordance with good practice, is safe. A single scientist, Dr. Lucier, was of the opinion that using oestrogen for growth promotion could raise the risk of breast cancer by up to one in one million. His opinion was deemed, by the Panel and Appellate Body, to be of insufficient weight to overturn the contrary results of the studies referred to by the EC, as it was not the result of studies, carried out by him or under his supervision,

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[45] Statement of Administrative Action, H.R. Doc. 103-316, at 746 (quoted in McNiel, *supra* fn. 28 at 118) [hereinafter, the SAA].

[46] McNiel, *supra* fn. 28 at 118.

specifically focused on hormone residues in meat from cattle on which such hormones were used for growth promotion purposes. By implication therefore, if his opinion had been so based, it could have overturned the majority opinion.

Article 2.2 does, in any event, still raise the question of the meaning of "sufficient scientific evidence", both in terms of the quantity of evidence required and its quality or scientific validity[47]. In *EC-Hormones* the EC argued that the word "sufficient" refers to qualitative and not quantitative aspects of scientific evidence, just as the terms "risk" and "risk assessment" are defined in qualitative terms. Thus, as long as the scientific support for the measure is valid, it need not be of a certain weight or embody a majority view. Further, the EC argued that the requirement that measures be based on "scientific principles" reinforces the notion that neither article 2.2 nor the SPS Agreement in general require that measures be based on best science or a preponderance of scientific evidence. Instead they merely require the existence of a scientific basis for the measure. This issue was not addressed in *EC-Hormones* where the Panel found violations of articles 3 and 5 and thus did not consider it necessary to decide whether article 2 was violated also. The Appellate Body agreed with this application of judicial economy, but stated that it would have been more logical for the Panel to start by focusing on article 2 which sets out the basic rights and duties, before going on to article 5. It seems clear that if this issue had been decided, the Panel or Appellate Body would have found that there was not sufficient scientific evidence, since the EC measures at stake were adopted and maintained despite scientific proof that the use of the relevant hormones for growth promotion is safe when used in accordance with good practice. The use of judicial economy in this case to avoid deciding on this issue has been sharply criticised.[48] It is argued that now neither the fact that the evidence overwhelmingly supports the safety of the product for human consumption, nor the total lack of scientific proof of a health risk is sufficient to guarantee a finding that there is a lack of "sufficient scientific evidence" of a health risk or that the measure is not "necessary" to protect human health.[49]

In *Japan-Agricultural Products*[50] the Appellate Body addressed the meaning of "sufficient scientific evidence" in article 2.2. It held that sufficiency requires the existence of a sufficient or adequate relationship between two elements, here the SPS measure and the scientific

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47 McNiel, *supra.* fn. 28 at 117.

48 McNiel, *supra* fn. 28, at 134.

49 McNiel, *supra* fn. 28, at 134.

50 Japan-Measures Affecting Agricultural Products WT/DS76/AB/R, 22 Feb. 1999 [hereinafter referred to as *Japan-Agricultural Products*].

evidence.[51] It based its finding on an analysis of articles 5.1, 3.3 and 5.7, which it saw as making up the context of article 2.2. Firstly, the Appellate Body agreed with the Panel that its finding in *EC-Hormones* regarding article 5.1, provides guidance for the interpretation of art 2.2.[52] In the latter case it had held that the requirement in article 5.1 that a measure be "based on" a risk assessment, read together with art 2.2, means that there must be a rational relationship between the measure and the risk assessment. Secondly, the Appellate Body looked at article 3.3 which allows Members to introduce or maintain measures resulting in a higher level of protection than those based on the relevant international standard, *inter alia* if there is sufficient scientific justification. The Appellate Body held that there is sufficient scientific justification if there is a rational relationship between the measure and the available scientific information.[53] Thirdly, the Appellate Body turned to article 5.7, which allows Members to adopt provisional measures in case of insufficient scientific evidence. It held that this is a qualified exemption from article 2.2 and that a too-broad interpretation of article 2.2 would render it meaningless.[54]

The Appellate Body concluded, in the light of these considerations, that article 2.2 requires that there be a rational or objective relationship between the measure and the scientific evidence, which must be determined on a case by case basis and depends on the circumstances of the case, including the quantity and quality of scientific evidence.[55]

This "rational relationship-test" is far from laying down clear guidelines on what will be regarded as sufficient scientific evidence. By leaving a wide discretion to the Panel or Appellate Body to make *ad hoc* decisions based on their evaluation of the circumstances of the case, it explicitly leaves open the possibility that the Panel or Appellate Body could evaluate the quality or weight of the scientific evidence presented, a task for which these bodies which are primarily composed of trade experts, are not qualified.[56] From this decision it is thus not clear that the deference to national scientific judgements claimed by President Clinton in the SAA will actually be accorded by the Panel or Appellate Body.[57]

It is recommended that a Panel should limit its enquiry to the question whether there is scientific consensus or scientific uncertainty regarding the issue at hand. Scientific

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51 *Japan-Agricultural Products, supra* fn. 50 at para. 73.
52 *Japan-Agricultural Products, supra* fn. 50 at para. 76.
53 *Japan-Agricultural Products, supra* fn. 50 at para. 79.
54 *Japan-Agricultural Products, supra* fn. 50 at para. 80.
55 *Japan-Agricultural Products, supra* fn. 50 at para. 84.
56 The issue of the composition of the Panels is discussed further in Section 3.2 below.
57 See the discussion on the standard of review, in Section 3.5 below.

uncertainty is most often the case and is evinced by the presence of a good faith difference of opinion among scientists. In such cases, a Panel should determine which of the alternative accounts are found plausible by scientists and which are not. If there is any reputable scientific support for the Member's measure, it should be held to be based on "sufficient scientific evidence".[58]

Another important issue raised in this case was that of the applicability of what is known as the precautionary principle, under the SPS Agreement.[59] This principle has gained wide acceptance on international level,[60] in response to the increasing realisation of scientific uncertainty. According to the precautionary principle, in cases where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing measures to prevent such damage. [61] Japan's argument in this case that article 2.2 must be interpreted in the light of the precautionary principle, was rejected by the Appellate Body[62] which referred back to its decision on this point in *EC-Hormones*.[63] In the latter case, the Appellate Body felt unqualified to decide whether the precautionary principle now forms part of customary international law. However, it held that even if this were the case, the specific agreement on rules for cases of scientific uncertainty in article 5.7 of the SPS Agreement overrides any such general principle. Thus the precautionary principle cannot be used to justify an otherwise inconsistent measure except to the extent provided for in article 5.7.[64] The Appellate Body did, however, recognise that a Panel evaluating the question whether "sufficient scientific evidence" exists should bear in mind that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks are irreversible, e.g. life-terminating, damage to human health are concerned."[65] This does not sufficiently take into account the precautionary principle, however.[66]

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58 Walker, *supra* fn. 13 at 280.

59 For further discussion of the role of the precautionary principle in the SPS Agreement, see Wirth, (*supra* fn. 10) at 838-40.

60 The precautionary principle is recognised in the following international instruments amongst others: the Treaty of Rome, as amended by the Single European Act (1987 O.J. L169 in art. 12), the Framework Convention on Climate Change (1992 31 I.L.M. 849 in art. 3.3), and the Rio Declaration on Environment and Development (1992 31 I.L.M. 876 in Principle 15).

61 This definition was adapted from the one appearing in the Rio Declaration (*supra* fn. 60) at 879.

62 *Japan-Agricultural Products, supra* fn. 50 at para. 81.

63 Appellate Body Report: European Communities- Measures Concerning Meat and Meat Products (Hormones) WT/DS26/AB/R, 16 Jan. 1998, [hereinafter referred to as *EC-Hormones*] at para. 125.

64 The question whether article 5.7 deals adequately with the issue of lack of certainty in science will be discussed in Section 2.2.4 hereunder.

65 *EC-Hormones, supra* fn. 63 para. 124.

66 Under the points for negotiation raised in the Millennium Round trade negotiations (*supra* fn. 3) is the need to strengthen the precautionary principle in the SPS Agreement, as art. 5.7 does not go far enough in recognising this principle.

This decision applies not only to the interpretation of article 2.2, but to all the science-based rules in the SPS Agreement. When one bears in mind the pervasiveness of uncertainty in scientific analysis and the influence of this factor on most risk assessments and other scientific aspects of the regulatory process, it seems at odds with reality to confine its recognition to a single article providing for temporary measures.[67]

2.2.2 Harmonisation around International Standards

In the preamble of the SPS Agreement, one of the aims expressed is the promotion of the use of harmonised SPS measures by Members, based on international standards developed by the relevant international organisations,[68] without requiring Members to change their appropriate level of protection.

The SPS Agreement thus attempts to balance the aim of increasing free trade through harmonising SPS measures and thus reducing the trade barriers caused by differing standards, with respect for the right of Members to choose their own level of protection. Thus harmonisation around international standards is encouraged by means of a presumption of consistency with GATT 1994 and the SPS Agreement, but it is not actually mandated even where global standards would be most trade efficient. This is in tune with the fact that the choice of a level of protection is viewed as a sovereign decision and accorded substantial deference in the SPS Agreement. Thus a government is not obliged to accept an international standard that leads to a level of health protection lower than that which it has established to be appropriate. This strategy is embodied in Article 3 of the SPS Agreement.

As the WTO is not a regulatory body with norm-setting capacity, it does not set the standards itself, but relies on those set by the international organisations listed in Annex A, paragraph 3, namely Codex Alimentarius, the International Office of Epizootics, the Secretariat of the International Plant Protection Convention and other international organisations open for membership to all WTO Members as identified by the Committee on

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67 Article 5.7 of the SPS Agreement will be discussed in Section 2.2.4.

68 The SPS Agreement lists several relevant international organizations in article 3.4. The most important of these in the area of health is the Codex Alimentarius Commission, which was established in 1962. This Commission has as its aim the protection of consumer health as well as ensuring fair practices in the food trade. (See the Statutes of the Codex Alimentarius Commission, article 1.a). The Commission has the mandate to adopt voluntary multilateral good practice standards on issues such as labelling, food processing techniques, the composition of food products, food additives and inspection procedures.

SPS Measures. Members are obliged under article 3.4 to participate in the work of these organisations, to the extent that their resources permit, and to promote development and periodic review of SPS standards.

The specific provisions of article 3 and their interpretation by the Appellate Body deserve particular attention here, as they provide a good illustration of the use of science in the policing of national regulation. Article 3.1 expresses the aim of harmonising SPS measures on as wide a basis as possible, and states the obligation of Members to "base" their SPS measures on international standards, guidelines or recommendations, where they exist, except as provided for in article 3.3. Art 3.2 creates a presumption of consistency with GATT 1994 and the SPS Agreement for measures which "conform to" international standards. These measures are also deemed to meet the requirement of being necessary for the protection of human, animal of plant life or health. Article 3.3 recognises the right of Members to use SPS measures which result in a higher level of protection than would be achieved by measures "based on" the relevant international standards and sets certain requirements for this. The various options open for Members under these provisions were identified by the Appellate Body in *EC-Hormones*. It rejected the Panel's approach of seeing articles 3.1 and 3.2 as the general rule and article 3.3 as the exception. [69] Instead it identified three options available to Members under these provisions.

Firstly, Members may choose under article 3.1 to base their SPS measures on international standards. In *EC-Hormones* the meaning of "based on" in article 3.1 was addressed. The Panel had held that article 3.1 does not define "based on" but that article 3.2 equates measures "based on" international standards with those which "conform to" these standards. It had also held that to be "based on" an international standard, the measure must achieve the same level of sanitary protection as that standard, a conclusion implied by article 3.3. The Appellate Body rejected this reasoning, finding that the plain meaning of the terms "based on" and "conform to" differ.[70] Whereas a thing is based on another if it is founded or built upon it, it only conforms to the latter if it corresponds with it in form or manner. Therefore a measure "based on" an international standard might incorporate some but not all elements of the international standard and thus not "conform to" that standard. The Appellate Body also pointed out that the Panel's interpretation was contrary to the object of article 3, which sets the harmonisation around international standards as a goal to be achieved in the future, not as a current obligation on Members. However, the Appellate

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69 *EC-Hormones, supra* fn. 63, para. 168.

70 *EC-Hormones, supra* fn. 63, para. 163-166.

Body did not proceed to examine whether, in this case, the measure adopted any elements of the existing international standard set by Codex Alimentarius. It appears to have assumed that this was not the case, as it continued by analysing the measure under the requirements of article 3.3 for measures which are not based on international standards.[71]

The Appellate Body also refrained from deciding on the correctness of the rest of the Panel's analysis on this point. It would appear that the Panel was correct in informing the term "based on" in article 3.1 with reference to the use of the same term in article 3.3. Thus in order to be regarded as "based on" an international standard, the SPS measure must result in the same level of protection, besides adopting at least some of the elements of the international standard.[72] If it is not "based on" the international standard, it must then meet the requirements of article 3.3.

The question arises whether article 3 obliges Members to maintain at least the minimum level of health protection that is reflected in relevant international standards, while allowing higher, but not lower, levels of protection. This would seem to be the case from an examination of the words of the relevant provisions, since a Member is obliged to adopt measures which are "based on" international standards, that is, achieving the same level of protection, unless the provisions of article 3.3 are complied with. The latter article allows SPS measures resulting in a *higher* level of protection in certain conditions. Nowhere are measures aimed at a lower level of protection mentioned. It has been argued that a measure should not be analysed under article 3.3 simply because the Member imposing it claims that the measure achieves a higher level of protection than the international standard.[73] In *EC-Hormones* the EC did not actually prove that its challenged measure resulted in a higher level of protection.[74] Still, the Appellate Body went on to examine its measure under article 3.3. It seems unlikely that a positive obligation of a certain minimum level of health protection was intended or would be accepted by WTO Members. Further, it is hard to imagine one Member challenging another for having a too low level of health protection for its own citizens.

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71 *EC-Hormones, supra* fn. 63, para. 176-177.

72 *EC-Hormones, supra* fn. 63, para. 171.

73 McNiel, *supra* fn. 28 at 126.

74 This is so because the scientific evidence did not establish that the hormones at issue posed any health risk at all, so the EC's measure cannot be said to achieve a higher level of protection. The Panel simply assumed, for the purpose of analysis, that the EC's chosen level of protection would be higher than the level achieved by the relevant Codex standards, and the Appellate Body stated that it agreed with the Panel's finding that this was so. However, it is clear that the Panel did not make such a finding. See McNiel, *supra* fn. 28 at 126.

A further question which arises regards the consequences of choosing the option under article 3.1. Clearly the Member which merely bases its SPS measures on international standards, without conforming to them, does not enjoy a presumption of compliance of its measures with the SPS Agreement and GATT 1994. Still, it seems logical that there should be an advantage over the situation under article 3.3. It has been argued[75] that as a measure based on an international standard is automatically based on a risk assessment (that conducted by the relevant international organisation), the measure need not comply with article 5.1-5.3.

The second option a Member has is to choose to establish an SPS measure which conforms to the relevant international standard. The measure must then completely embody the international standard. The SPS Agreement promotes such measures by granting them a presumption of consistency with the SPS Agreement and GATT 1994. However, this presumption was held to be rebuttable in *EC-Hormones*.[76] One could question the real benefit of such a presumption for the defending Member since, in any case, the burden of proving a violation of GATT or the SPS Agreement would rest on the challenging Member, even in the absence of this presumption. A Member is always presumed to be in compliance with its obligations until a prima facie case to the contrary is shown by the complaining Member. The efficacy of this provision in promoting adherence to international standards is thus doubtful.

It has been argued that the fact that a measure that is in accordance with international standards enjoys a presumption of validity, increases the importance of standard setting on international level. This is relevant as the distribution of power here is different than on national level as certain interests, like consumer or environmental groups, are underrepresented while others, such as producers, have a lot of influence[77]. Once it is recognised that the scientific process, on which the standard-setting activities of international organisations are based, rests on assumptions which fill gaps in scientific knowledge, it is easy to see that the bias in these assumptions will result in standards that favour producers rather than consumers.

The third option open to Members is to promulgate SPS measures providing a higher level of protection than would measures "based on" the relevant standards. This provision recognises the rights of Members to choose their own level of protection, an important

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75 Hurst, *supra* fn. 43, at 8.
76 *EC-Hormones*, *supra* fn. 63 at para. 170.
77 Atik, *supra* fn. 12 at 744.

principle in the SPS Agreement. The Appellate Body held in *EC-Hormones* that this is an autonomous right and not an exception to article 3.1. Thus the burden of proof regarding compliance with article 3.3 does not shift to the defendant Member and there is no "punishment" for Members choosing to follow this option.

However, this is not an unqualified right and two science-related conditions are set in the alternative. Either there must be a scientific justification for the measures, or they must be the result of the higher level of protection chosen by the Member in accordance with article 5.1-5.8. In both cases the measures must be consistent with all other provisions of the SPS Agreement.

The distinction made in article 3.3 between these two possible situations creates problems of interpretation. In *EC-Hormones* the EC argued that there was a "scientific justification" for its measure, so it need not be in accordance with article 5.1-5.8, which requirement is set for the second situation only. It thus claimed that no risk assessment was required as a basis for its ban on hormone-treated beef. The Appellate Body held that the distinction between the two situations identified in article 3.3, is more apparent than real.[78] In fact both situations require a risk assessment in accordance with article 5. The Appellate Body based its finding on two facts. Firstly, the last sentence of article 3.3 requires that in both situations, measures be consistent with all the provisions of the SPS Agreement, thus including article 5. Secondly, the footnote to art 3.3,[79] attached to the end of the first sentence, defines scientific justification as an "examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement...".[80] This appears to be of the nature of a risk assessment as required in art 5.1 and defined in Annex A, paragraph 4. Thus this ruling should be taken as requiring that a Member claiming scientific justification for its deviation from international standards, must base such a claim on a valid risk assessment.[81] The Appellate Body went on to point out that the article 5 was meant as a counterbalance to the Members' right to choose their own level of protection.[82]

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78 *EC-Hormones, supra* fn. 63 at para. 175.

79 Note 2 to SPS Agreement article 3.3 reads: "For the purposes of paragraph 3 of Article 3, there is sufficient 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 are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection."

80 This definition was inserted after the controversy surrounding the use of the term "scientific justification" in the Dunkel Draft (an interim negotiating text of the Uruguay Round, 20 Dec., 1991, GATT Doc. MTN.TNC/W/FA) due to fears that this term could be interpreted to require a strict cause-and-effect link between the SPS measure adopted and empirical scientific data.

81 McNiel, *supra* fn. 28 at 126.

82 *EC-Hormones, supra* fn. 63 at para. 177.

Thus the requirements of a risk assessment in article 5.1 and of sufficient scientific evidence in article 2.3 are crucial in maintaining the balance between the competing interests of trade liberalisation and the protection of health. The role of science as the scale on which these interests are balanced is striking in this interpretation of this provision.

It has been argued that the reason behind distinguishing between the two different situations is to emphasise the difference in the scope of review in each case.[83] The first situation deals with the Member's judgement, on the basis of scientific information, regarding the adequacy of international standards to meet its level of protection. This could, for example, be the case where, due to local peculiarities, the international standard is ineffective in securing the level of health protection it was aimed at.[84] The second situation deals with the choice of a different level of protection by a Member, which is a policy choice. One could thus speak of a scientific justification and a policy justification.[85] Scientific justifications could be more rigorously reviewed than policy ones and thus harmonisation of the former more vigorously promoted than of the latter.[86]

What is clear from an examination of this harmonisation provision in the SPS Agreement, is the role of science, in the form of scientific justification or risk assessment, in providing norms or rules. Free trade necessitates harmonised health standards in order to do away with the barriers created by disparate requirements in various countries. However, the lack of a rule-making body in the WTO to take on the task of providing generally applicable health standards[87] creates an institutional gap. Article 3 attempts to fill this gap by making use of another, universally accepted and thus authoritative provider of uniform standards, namely science. Where a large degree of scientific consensus exists, as embodied in standards set by international organisations,[88] Members are encouraged to use these

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83 Walker, *supra* fn. 13 at 275-6.

84 See Panel Report: European Communities-Measures Concerning Meat and Meat Products (Hormones) - Complaint by Canada, WT/DS26/R/CAN, 18 Aug. 1997 [hereinafter referred to as *EC-Hormones* Panel Report] at para. 8.84. Here the Panel stated that both Canada and the EC interpreted the first situation as existing where the relevant international standard is outdated, inadequate, faulty or obsolete from a scientific perspective, for example where it in fact does not provide the level of protection it was intended to provide.

85 On the contrary, see Wirth (*supra* fn. 10, at 827), where he argues that the footnote explaining the meaning of "scientific justification" might be taken to mean that there are scientific constraints on the choice of the appropriate level of protection. However, it seems rather that the scientific analysis mandated by that footnote is directed at the question of whether the international standards are effective in achieving the Member's chosen level of protection, rather than at the choice of appropriate level itself.

86 Walker, *supra* fn. 13 at 275-6.

87 Unlike the situation which exists in the EU, where negative integration (lowering of trade barriers) is accompanied by positive integration (setting of general norms or rules). This is possible due to the norm-setting capacity of the EU institutions, which can operate on a supranational level, a characteristic which is absent in the WTO.

88 The Secretariat of the Codex Alimentarius Commission released a paper on the role of science in the Codex decision-making process. See Codex Alimentarius Doc. CX/GP 94/4.

standards. In the alternative, where no such standards exist or where Members wish to deviate from these standards, scientific justifications operate to generate norms and rules.[89] The reason for this approach is the fact that science is seen to be a universal body of knowledge, based on physical experience and neutral and thus valid for all. Therefore, the results of testing national regulations against the dictates of science, would hopefully result in greater uniformity of health measures by promoting gradual regulatory convergence across national borders.

While this would be the case if science were really universal and absolute, the fact of the matter is that the lack of consensus that exists among scientists as to the true state of scientific knowledge makes it not only an unreliable tool to use in judging the validity of national regulations, but also one unlikely to lead to greater uniformity in national health measures.

2.2.3 Risk Assessment and the Determination of an Appropriate Level of Protection

Article 5 deals mainly with two issues of particular importance to the role of scientific analysis in policing national health regulations, namely the distinction between risk assessment and risk management: paragraphs 1-3 deal with risk assessment and paragraphs 4-6 with the determination of an appropriate level of SPS protection, which is a risk management decision. Further paragraph 7 provides for the provisional adoption of SPS measures, where there is insufficient scientific evidence.

2.2.3.1 *Risk Assessment*

(i) Definition

Paragraph 4 of Annex A to the SPS Agreement defines two types of risk assessment. The first type is the evaluation of the likelihood of entry, establishment or spread of a pest or disease in the territory of the importing Member, according to the SPS measures that could be applied, and of the associated potential biological and economic consequences, and the second one is the evaluation of the potential for adverse effects on human or animal health

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89 Atik, *supra* fn. 12 at 739.

due to the presence of additives, contaminants, toxins or disease causing organisms in food, beverages or feedstuffs.

The Appellate Body examined these definitions in two cases. In *EC-Hormones*,[90] the second type of risk assessment was at issue. The Panel had held that there were two steps to this kind of risk assessment, namely the identification of the adverse effects of the hormones and, if such effects exist, the evaluation of the potential or probability of their occurrence.[91] The Appellate Body did not take issue with the two step test, but regarded the Panel's use of probability as an alternative for potential as cause for concern as the word implies a higher degree of potentiality and seems to introduce a quantitative element.[92] The Appellate Body also looked at the Panel's use of the terms "identifiable risk" and "scientifically identified risk". To the extent that the phrases were used in the sense that theoretical uncertainty is not the kind of risk to be assessed under article 5.1, the Appellate Body agreed with the Panel.[93] Thus there must be proof of an actual risk, not just uncertainty about whether there is a risk or not. However, where the Panel used the terms to imply that article 5.1 requires a certain magnitude of risk, the Appellate Body noted that this quantitative requirement has no basis in the SPS Agreement. A Panel must only determine whether the measure is sufficiently supported or reasonably warranted by the risk assessment.[94] Further, the Appellate Body stated that the risk assessment may go beyond the controlled conditions in a scientific laboratory, and take account of the actual potential for adverse effects in the real world.[95]

In *Australia-Salmon*,[96] the first type of risk assessment was relevant. The Appellate Body held that this type of risk assessment must fulfil three requirements.[97] First, it must identify the diseases whose entry, establishment or spread the member wishes to prevent, as well as the potential biological and economic consequences associated therewith. Second, it must evaluate the likelihood of entry, establishment or spread of these diseases and their consequences. Third, this likelihood must be evaluated according to the SPS measures that might be applied. In *Japan-Agricultural Products* the Appellate Body once again affirmed these requirements and found that a risk assessment, which Japan argued it had based its

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90 *EC-Hormones, supra* fn. 63.

91 *EC-Hormones*, Panel Report, *supra* fn. 84 at para. 8.98.

92 *EC-Hormones, supra* fn. 63 at para. 184-186.

93 *EC-Hormones, supra* fn. 63 at para. 186.

94 *EC-Hormones, supra* fn. 63 at para. 186.

95 *EC-Hormones, supra* fn. 63 para. 187.

96 Australia- Measures Affecting the Importation of Salmon WT/DS18/AB/B, 20 Oct. 1998 [hereinafter referred to as *Australia-Salmon*].

97 *Australia-Salmon, supra* fn. 96, at para. 121.

measure on, did not refer to any SPS measure which could be taken to reduce the risk, and thus did not comply with the third requirement.[98]

In *Australia-Salmon,*[99] the Appellate Body also pointed to the different language used in the first and second definitions of risk assessment. While the second calls for an evaluation of the "potential" for adverse effects, the first requires the evaluation of the "likelihood" of entry, establishment or spread of pests or diseases. The Appellate Body held that likelihood means the same as probability, thus more is needed than to show a possibility or "some likelihood" of entry, establishment or spread.[100] It thus seems that what the probability actually is must be established. Australia's evaluation of the probability as "low" or "small" was not deemed sufficient. Further, the Appellate Body found that the existence of unknown or uncertain elements does not justify a departure from the requirements of article 5.1-5.3.[101] The usefulness of the determination of probability is doubtful, since no matter what the probability of the risk occurring is, the state is free to set its own level of protection. One could also question what the purpose of this distinction between the two definitions is and whether it was intended by the drafters of the Agreement, since both types of risk assessment are aimed at determining the existence of equally important threats to health.

While in *EC-Hormones* the Appellate Body had expressed concern that the term "probability" might introduce a quantitative element into the second definition, in *Australia-Salmon*[102] it found that likelihood or probability in the first definition could be expressed quantitatively or qualitatively and confirmed the finding in *EC-Hormones* that the risk assessment need not establish a certain magnitude or threshold level of risk. However, this does not go far enough in recognising the nature of risk. By insisting on proof of probability, the Appellate Body ignores the fact that risk is not only found in actual knowledge of a certain likelihood of harm, but also in the lack of knowledge about a possible hazard.[103]

The Appellate Body in this case[104] distinguished between the evaluation of risk, which must show an ascertainable risk, not just a theoretical uncertainty, and the determination of an

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98 *Japan-Agricultural Products, supra* fn. 50, at para. 113.

99 *Australia-Salmon, supra* fn. 96, at para 123 and fn. 69.

100 *Australia-Salmon, supra* fn. 96, at para 124.

101 *Australia-Salmon, supra* fn. 96, at para 130.

102 *Australia-Salmon, supra* fn. 96, at para 124.

103 Walker, *supra* fn. 13, at 305. He states that: "On the continuum between a merely speculative risk and a conclusively demonstrated one lies a vast stretch of undemonstrated, unquantified, but scientifically plausible risks. Within that zone, the risk of harm is real so long as safety is unproven."

104 *Australia-Salmon, supra* fn. 96, at para 125.

appropriate level of protection, which may be premised on a zero risk level. It is thus possible for a Member, once an actual risk, however small, has been proven to have a certain probability, to choose a zero risk level of protection and institute SPS measures to achieve this level. As mentioned previously, this distinction is often referred to as the difference between risk assessment (the science-based process of determining the existence of a risk and the likelihood of it occurring according to the SPS measures which could be applied), and risk management (a policy-based choice of the level of protection deemed appropriate by a state, taking into account various social value judgements such as the citizens' tolerance of risk, economic considerations, *etcetera*).[105] While a Member's risk assessment must thus be founded on scientific analysis, more scope is left for risk management decisions in the setting of an appropriate level of protection. This distinction was recognised by the Panel in *EC-Hormones*.[106] It used this distinction to exclude from the scope of a risk assessment certain non-scientific reports and opinions of the European Parliament and the Economic and Social Committee, which evaluated reports submitted to them, as well as the question of risks associated with the problem of control of the use of hormones. It viewed these issues as having to do with social value judgements and thus as not scientifically based. The Appellate Body rejected the Panel's distinction, stating that the SPS Agreement nowhere refers to the term "risk management" but only to "risk assessment".[107] Thus the Panel's use of the distinction to limit the scope of what falls under risk assessment, was held to have no basis in the text.

While it is true that the term "risk management" is not explicitly mentioned in the SPS Agreement, this document clearly deals in different ways with the Members' obligation to base their SPS measures on a risk assessment and their right to establish their own level of protection. The former is subject to strict scientific criteria, whereas the latter choice is not reviewable, provided it takes into account the aim of reducing negative trade effects when determining the appropriate level of protection[108] and avoids arbitrary or unjustifiable distinctions in the levels of protection it sets in different situations.[109] The criteria for validity of the choice of level of protection do not have a scientific basis. This recognises the sovereign right of Members to make their own policy choices in the area of public health, taking into account various non-scientific considerations. The choice is ultimately one based on societal value judgements. The latter area of decision-making is commonly known as risk management.

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105 For a more detailed analysis of this distinction, see Walker, *supra* fn. 13.
106 *EC-Hormones* Panel Report, *supra* fn. 84 at para. 8.98.
107 *EC-Hormones, supra* fn. 63, para. 181.
108 SPS Agreement, *supra* fn. 4, art. 5.4.
109 SPS Agreement, *supra* fn. 4, art. 5.5.

It would perhaps have made more sense for the Appellate Body to take issue with the Panel's classification of the risks of control as non-scientific and thus as not forming part of a risk assessment, rather than denying the *de facto* different treatment of risk assessment and risk management in the SPS Agreement. The Appellate Body partially recognised this when it overruled the Panel's decision that risks from failure to observe good veterinary practice and problems relating to detection and control of such failure must be rejected *a priori* because they are unscientific and thus do not fall within article 5.2. The Appellate Body found that the Panel had misinterpreted the scope of article 5.2 and that these considerations did, in fact, belong thereunder.[110]

It would appear that the Appellate Body's approach that the risks assessed under both definitions need not be identifiable or quantifiable, and the risks may be other than those that can be scientifically determined in a laboratory, together with its denial of the role of risk management under the SPS Agreement, may open the door for the inclusion of non-scientific factors within risk assessment and thus recognise the role of science policy. Thus, considerations normally forming part of risk management decisions could now be included under risk assessment.[111] It has been argued that this development should be approached with caution, as it would be disastrous to allow risk assessments to be based on pure emotion, such as the risk of public hysteria, fears of genetically modified foods *etcetera*.[112] However, it seems unlikely that such factors could be incorporated into the strict definition of risk assessment. Instead, it seems that the Appellate Body's holdings are an attempt to take into account factors that are not capable of strict quantifiable analysis, but nonetheless present a real risk for health. This should be seen as a positive development, although it stops short of explicitly recognising the role of science policy in risk assessment, as distinct from risk management decisions.

(ii) Requirement that measures be "based on" the risk assessment

Art 5.1 sets the requirement that SPS measures be "based on" an assessment of the risks to human, animal or plant life or health. The meaning of "based on" was discussed in *EC-Hormones*.[113] In this case the Panel had read a procedural requirement into the term,

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110 *EC-Hormones, supra* fn. 63, para. 187.

111 Walker, *supra* fn. 13, at 304.

112 Warren H. Maruyama, "A new pillar of the WTO: Sound science," *The International Lawyer* 32 (1998): 651 at 672.

113 *EC-Hormones, supra* fn. 63, para. 188-209.

obliging Members to actually take a risk assessment into account when enacting or maintaining SPS measures. It looked to preambles of EC Directives for evidence that this was in fact done.[114] The Appellate Body rejected this subjective requirement as having no basis in the text. Instead it held that the term "based on" refers to an objective relationship between the measure and the risk assessment. The Appellate Body noted that article 5.1 does not require a Member to conduct its own risk assessment. Instead Members may base their measures on other relevant assessments.[115] The Panel's interpretation could lead to the disregard of existing scientific evidence that supports the measure.[116] The Appellate Body also rejected the use of preambles as evidence as they are not required by the SPS Agreement and are not normally used to show that a Member has complied with its international obligations.

The Panel had also found that article 5.1 contained a substantive requirement, namely that the scientific conclusions reached in the risk assessment and those implicit in the SPS measure should conform.[117] The Appellate Body agreed with the relevance of the relationship between the two sets of conclusions, but emphasised that this is only one of the relevant factors. It held that " based on" sets the substantive requirement that there must be a rational relationship between the measure and the risk assessment. In other words, the measure must be sufficiently supported or reasonably warranted by the risk assessment.[118] This does not mean that the risk assessment must come to a single conclusion, reflected in the measures adopted. It may embody divergent opinions. The Appellate Body recognised that responsible governments may in good faith adopt measures based on divergent opinions from qualified and respected sources, without this negating the existence of a rational relationship. It proposed an *ad hoc* approach to the determination of the existence of a rational relationship.[119] This conclusion has been criticised for leaving intact the issue of duelling science and opening the door for the use of "hired scientists" in future dispute settlement cases.[120] However, it should be recognised that this is the only realistic approach which could be taken in the light of the lack of consensus that exists within the scientific community.

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114 *EC-Hormones* Panel Report, *supra* fn. 84, para. 8.116-8.119.

115 *EC-Hormones, supra* fn. 63, para 190. However, the Appellate Body did require that proof that a risk assessment supporting the measure does exist, be produced at dispute-settlement proceedings.

116 *EC-Hormones, supra* fn. 63, para. 189-190.

117 *EC-Hormones* Panel Report, *supra* fn. 84, para 8.120.

118 *EC-Hormones, supra* fn. 63, para. 193.

119 *EC-Hormones, supra* fn. 63, para. 194.

120 McNiel, *supra* fn. 28, at 134.

This still leaves considerable scope for interpretation as to what kind of relationship would be considered rational. Would a measure based on a single divergent scientific opinion be considered rationally related to the risk assessment? What is clear from this case is that for a risk assessment to be considered to rationally support a measure, it must be sufficiently specific.[121] The EC had conducted studies showing that the use of the relevant hormones (except MGA for which no studies were available) for growth-promotion purposes was safe. It had also submitted studies showing a general risk of cancer from hormones but not focusing specifically on the carcinogenic potential of residues of the relevant hormones in beef when used for growth-promotion purposes These reports were found to be insufficiently specific to form a rational basis for the measures. It would thus seem that it would be sufficient if the EC in the *EC-Hormones* dispute were to have found a single scientist willing to report that human consumption of beef treated with hormones for growth-promotion purposes poses a real risk of cancer. Thus would seem to frustrate the SPS Agreement's goal of using science to create clear rules and disciplines.[122] On the other hand, to do otherwise would be to deny the reality of diverging scientific opinions. The creation of clear rules would not truly serve the end of achieving economic efficiency unless the rules were a scientifically accurate reflection of the risks, costs and benefits involved. While there is still no definite scientific answer to these questions, Members should be free to choose among plausible alternatives, rather than have the WTO impose the views of a single group of scientists on all its Members.[123] Thus, it is better for WTO panels to limit their enquiries to the question of the reasonableness or plausibility of Members' risk assessment decisions.

(iii) Relevant Factors

Although the SPS Agreement does not specify a methodology to be used in making a risk assessment, it does list the scientific and economic factors which Members must take into account, in article 5.2 and 5.3.

Firstly, article 5.2 provides that Members must take certain scientific factors into account when assessing risks. These are: available scientific evidence, relevant processes and production methods, relevant inspection sampling and testing methods, prevalence of specific diseases or pests, existence of pest- or disease-free areas, relevant ecological and

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121 *EC-Hormones, supra* fn. 63, para. 198-200.

122 McNiel, supra fn. 28 at 93.

123 Walker, *supra* fn. 13, at 281. Walker also lists other reasons why the WTO should refrain from interfering in Members' science-policy choices.

environmental conditions, and quarantine or other treatment. As stated above, the Panel in *EC-Hormones* had held that the risks relating to detection and control of failure to observe good veterinary practice should be excluded from risk assessment *a priori* because they are non-scientific and thus do not fall within the scope of article 5.2's provision on "relevant inspection sampling and testing methods", but rather are taken into account in risk management. The Appellate Body rejected this finding, holding that the scope of article 5.2 allowed the taking into account of these risks. It held that the SPS Agreement requires an assessment of the potential for adverse effects on human health from contaminants or toxins in food and that the object and purpose of the Agreement justify the assessment of such risks, regardless of their origin. Whether such a risk must be examined should be determined on a case-by-case basis, and it should not be excluded *a priori*. The Appellate Body further rejected the risk assessment/risk management distinction made by the Panel, holding that it has no basis in the text of the SPS Agreement. As discussed above, it is debatable whether the denial of this distinction is correct, provided that certain risks are not artificially excluded for the scope of risk assessment.

Article 5.3 sets out certain economic factors to be taken into account in assessing risks to animal or plant (not human) life or health and in determining which SPS measure should be applied[124]. This implies a recognition of the fact that risk assessments are not purely science-based but involve economic considerations as well.

2.2.3.2 *Appropriate Level of Protection*

Once it is established that there is scientific evidence of risk, Members are free to choose their own appropriate level of protection. The choice of a particular level of protection is what is typically called a risk management decision. Such decisions are taken by national administrations on the basis of societal value judgements, not purely on the basis of scientific analysis. In other words, once it has scientifically been established that a health risk exists and what the magnitude of that risk is, by means of a risk assessment, other policy issues come into play. SPS measures seldom have the protection of health as their sole objective. Instead several other significant factors are incorporated into the decision. One such factor may be the tolerance of consumers in that country for a particular type of risk. Another might be economic efficiency. The decision is at core a political one, reflecting

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[124] These are " the potential damage in terms of loss of production or sales in the event of entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks" SPS Agreement *supra* fn. 4, art. 5.3.

societal value choices. The SPS Agreement recognises this, by placing no requirement of establishing a scientific basis on the choice of the appropriate level of protection. Thus particularised national health measures result even where the scientific basis for the measures is same everywhere.[125]

However, the choice of an appropriate level of protection is subject to some limitations. With regard to the determination of an appropriate level of sanitary or phytosanitary protection, article 5.4 provides that Members should have regard for the objective of minimising negative trade effects. The use of the word "should" rather than "shall" , as was used in the previous paragraph, seems to indicate that this is not a mandatory provision but rather a recommendation. Article 5.5 on the other hand, obliges Members to avoid arbitrary and unjustifiable distinctions in the levels of protection they consider appropriate in different situations, if this results in discrimination or a disguised restriction on trade. Members are further obliged to co-operate in the SPS Committee to develop guidelines for the practical implementation of this provision.

The Panel and Appellate Body in *EC-Hormones* found that this provision must be read together with the basic obligation of Members to avoid discrimination and disguised restrictions on trade in article 2.3.[126] This provision reiterates the obligation set out in the *chapeau* to article XX of GATT 1994.[127] In this case, the Appellate Body found that the goal of "achieving consistency in the application of the concept of appropriate level of sanitary and phytosanitary protection" is merely one to be achieved in the future and imposes no obligation of consistency in levels of protection.

The Appellate Body also set out the elements required for a violation of this article to be shown. These are that: (1) the Member has set its own level of protection in different situations; (2) the levels of protection show arbitrary or unjustifiable differences in their treatment of different situations; and (3) these arbitrary or unjustifiable differences lead to discrimination or a disguised restriction on trade (referring to the effect of the measure used to reflect the particular level of protection).[128] These elements were found to be cumulative, thus proof of different treatment of different situations is not sufficient, though it might serve

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125 Atik, *supra* fn. 12, at 737.

126 *EC-Hormones supra* fn. 63, para. 212.

127 For the interpretation of this provision, see *United States-Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, Apr. 29, 1996, [hereinafter referred to as *US-Gasoline*] at 22, discussed hereunder. However, the Appellate Body rejected the Panel's use of this GATT case as a precedent for the interpretation of the relevant provisions of the SPS Agreement.

128 These elements were reiterated in *Australia-Salmon, supra* fn. 96, para. 140.

as a warning signal that the measure might be discriminatory or a disguised restriction on trade.

It is obvious that not all health risks can or should be treated the same. Thus, with regard to the first element, the Appellate Body in *EC-Hormones* found that to compare the different levels of protection deemed appropriate by a Member the situations dealt with must be comparable, that is, have some common element or elements.[129]

Regarding the second element, the Appellate Body took into account the fact that governments determine levels of protection *ad hoc* as various health risks arise and held that the goal is thus not perfect consistency, but only the avoidance of arbitrary or unjustifiable inconsistencies. This approach is in line with the wording of the article, which only obliges Members to avoid *arbitrary or unjustifiable* distinctions, not all distinctions. This is sensible in the light of to the exigencies of health protection decision-making. The difficulty in evaluating the justifiability of distinctions lies in the problem of explaining why a society takes some risks rather than others or values some goals more than others. It is therefore suggested that national choice of levels of protection should be respected except in "the most blatant or unexplainable cases".[130]

On the third requirement of article 5.5, the Appellate Body in *EC-Hormones* disagreed with the Panel's finding that the decisions in *US-Gasoline*[131] with respect to article XX and that in *Japan-Alcoholic Beverages*[132] regarding article III:2 of GATT 1994 can be used as precedents for the interpretation of article 5.5.[133]

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129 The Panel had proposed that situations involving the same substance or the same adverse health effect could be compared (*EC-Hormones* Panel Report, *supra* fn. 63, para. 8.176). In *Australia-Salmon* (*supra* fn. 96 at para. 146) the Appellate Body held that it is not necessary that both the disease and the associated biological and economic consequences be the same or similar. The fact that the risk to be assessed is the risk of both the entry, establishment or spread of a disease and the associated consequences was held not to be relevant to the question of whether different situations are comparable, thus both those risks need not be similar. Further, the Appellate Body found that it is not even necessary that the risk of entry, establishment or spread of a disease be examined to determine the comparability of situations, it is also possible to look at the risk of introduction of a disease, even if this is taken to mean something other than a shorthand term for entry, establishment and spread. Lastly, the Appellate Body stated that comparability does not require that the situations have in common the risk of entry, establishment or spread of all the diseases of concern – one common disease is sufficient.

130 Walker, *supra* fn. 13, at 270.

131 *US-Gasoline, supra* fn. 127, at para. 22.

132 Japan-Taxes on Alcoholic Beverages, WT/DS8/AB/R, Oct. 4, 1996 [hereinafter referred to as *Japan-Alcoholic Beverages*]

133 In *US-Gasoline* (*supra* fn. 127 at para. 22), the Appellate Body had found that that "arbitrary discrimination", "unjustifiable discrimination" and "disguised restriction on international trade" in art XX impart meaning to each other and that the fundamental theme is the purpose and object of avoiding abuse or illegitimate use of the exceptions in article XX. Thus the same considerations used to determine if a measure amounts to arbitrary or unjustifiable discrimination can be used to decide if the measure is a disguised

To support its finding that the difference in levels of protection for hormones and the antimicrobial agents, Carbadox and Olaquindox, were discriminatory or a disguised restriction on trade, the Panel pointed, among other factors, to the fact that the preambles of the relevant directives, the reports of the European Parliament and the opinions of the Social and Economic Committee of the EC indicated that the measure was aimed at harmonisation of laws within the EC, the removal of distortions of competition and barriers to intra-Community trade, the increase of beef consumption and the reduction of internal surpluses. The Appellate Body rejected this conclusion, stating that it did not attach the same importance as the Panel to the multiple objectives of the measure. It pointed to the demonstrated concerns within the EC regarding the studies showing the carcinogenicity of hormones, consumer concerns and the problems of abuse. It stated that the harmonisation of regulations was a result of the EC's mandate to establish a Common Market and that the reduction of beef surpluses not only benefited the EC but also other non-hormone beef producers. It thus concluded that it did not share the Panel's inference that the import ban was aimed at restricting beef imports from Canada and the US rather than protecting the EC's population from the risk of cancer.[134] The Panel's finding that there was a violation of art 5.5 was thus reversed.[135] The Appellate Body's decision makes it clear that the mere incorporation of various non-scientific considerations in the decision to impose a certain health measure is not sufficient to invalidate the measure. This decision implies a positive recognition by the Appellate Body of the important role of societal value judgements in the making of risk management decisions.

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restriction on international trade. The Appellate Body in *EC-Hormones* found that the structural differences between the *chapeau* of article XX of GATT 1994 and article 5.5 of the SPS Agreement are too great for this analogous interpretation to be made (in its argument, the EC pointed out that the three elements of the chapeau of art. XX of GATT 1994 are in the alternative, whereas those in art. 5.5 of the SPS Agreement are cumulative. See *EC-Hormones supra* fn. 63, para. 239). In *Japan-Alcoholic Beverages* (*supra* fn. 132), it was held that a large difference in the taxation applied to imports and that applied to domestic products could be sufficient to prove that it was applied so as to afford protection to domestic products, contrary to art. III of GATT 1994. The Appellate Body in *EC-Hormones* (*supra* fn. 63, para. 239) distinguished the reasoning in *Japan-Alcoholic Beverages* regarding tax differentials from the different question in this case regarding different levels of health protection. As tax is always expressed quantitatively and affects the competitiveness of imports, a tax differential necessarily protects domestic products. There is no such link between differences in levels of health protection and the issue of discrimination or a disguised restriction on international trade. The extent of the difference is only one factor among others to be taken into account in determining whether there is discrimination or a disguised restriction on trade (*EC-Hormones supra* fn. 63 at fn. 251). Regard must be had to the circumstances of each case.

134 See *EC-Hormones supra* fn. 63, para. 245.

135 See *EC-Hormones supra* fn. 63, para. 246.

2.2.4.3 *Not More Trade Restrictive than Required*

Art 5.6 obliges Members to ensure that their SPS measures are not more trade restrictive than required to achieve their appropriate level of protection, taking into account technical and economic feasibility. This amounts to a discipline on the choice of measure rather than on the selection of an appropriate level of protection. In a footnote, what is meant by "a measure not more trade restrictive than required" is defined. In *Australia-Salmon*[136] the Panel set out the three elements of this definition, which it held to be cumulative, namely that a measure is more trade restrictive than required only if there is another SPS measure which: (a) is reasonably available taking into account technical and economic feasibility; (b) achieves the Member's appropriate level of sanitary protection; and (c) is significantly less trade restrictive than the contested measure.

Regarding the second element, the Panel in *Australia-Salmon*[137] had found that the level of protection deemed appropriate by a Member could be implied from the level reflected in the SPS measure it adopts. Thus it must be determined whether the alternative measures meet the level of protection achieved by the measure actually imposed. The Appellate Body disagreed, holding that neither article 11 of the DSU, nor any other provision of the DSU or the SPS Agreement permits a Panel or the Appellate Body to substitute its own reasoning about the implied level of protection, for that consistently expressed by the Member.[138] The determination of an appropriate level of protection was held to be the prerogative of the Member. It distinguished the appropriate level of protection, which is an objective, and the measure used to achieve that level, which is an instrument to attain this objective. The relationship between the two is clarified by articles 3.3, 5.3, 5.4 and most importantly 5.6. Thus the appropriate level of protection determines what SPS measure will be used, not *vice versa*.[139] The Appellate Body found that to imply the appropriate level of protection from the measure would be to assume that the measure is always successful in achieving the required level of protection, which is clearly not so.

However, the Appellate Body held that although there is no explicit obligation on Members to determine their appropriate level of protection, this obligation is implicit in paragraph 3 of Annex B, and articles 4.1, 5.4 and 5.6. Otherwise certain provisions of the SPS Agreement

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136 Panel Report: Australia-Measures Affecting the Importation of Salmon WT/DS18/R, 12 June, 1992 [referred to hereinafter as *Australia-Salmon* Panel Report], para. 95.

137 *Australia-Salmon* Panel Report, *supra* fn. 136 at para. 8.173.

138 *Australia-Salmon, supra* fn. 96, at para. 199.

139 *Australia-Salmon, supra* fn. 96, at para. 203.

would be impossible to apply and Members would thus be able to evade their obligations.[140] If a Member does not determine its appropriate level of protection, or does so with insufficient clarity, Panels may determine the appropriate level based on the level reflected in the measure actually applied.

This judgement is important in that prevents the discipline in article 5.6 from limiting the ability of governments to adopt measures that achieve the level of protection they have chosen. It recognises that the choice of level of protection is the sole prerogative of national decision-makers. Only in cases where a government does not adequately determine its level of protection, may a panel infer it from the measure applied in order to prevent the avoidance of disciplines under the SPS Agreement.

2.2.4 Provisional Measures

Article 5.7 provides for cases of scientific uncertainty. This allows for provisional measures based on available information, provided Members seek additional information for an objective risk assessment and review the measure within a reasonable time. The requirements of this provision were set out in *Japan-Agricultural Products*. The Appellate Body held that Article 5.7 lays down four requirements for provisional measures. Under the first sentence, the measure may be imposed if it is: (1) imposed in respect of a situation where "relevant scientific information is insufficient" and (2) adopted "on the basis of available pertinent information". Under the second sentence, the measure may not be maintained unless the Member (1) seeks to "obtain the additional information necessary for a more objective assessment of risk" and (2) reviews the measure accordingly "within a reasonable period of time". These requirements were held to be cumulative. The Appellate Body rejected Japan's claim that the words "except as provided for in article 5.7" in article 2.2 refer only to the first sentence of article 5.7, holding that the text of article 2.2 does not support this proposition as it refers to article 5.7 as a whole.

Japan argued that the requirement to seek additional information was met by gathering information through the experience of the successful importation of varieties. It claimed that Members are obliged to seek information but no actual results are required. The Appellate Body recognised that no explicit requirements were set in the SPS Agreement regarding the information to be collected or the collection procedure and that the results to be achieved

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140 *Australia-Salmon, supra* fn. 96, at para 206.

are not specified. However, as the information must be sought to enable a Member to make "a more objective assessment of the risk", the information sought must be conducive to making such a risk assessment, that is to evaluate the likelihood of entry, establishment or spread of the relevant pest according to the SPS measures that might be used.

The Appellate Body also held that what is a reasonable period of time within which to review the measure must be decided on a case-by-case basis and depends on the circumstances of each case. These were held to include the difficulty of obtaining evidence and the characteristics of the measure.

As mentioned above, the Appellate Body in *EC-Hormones* held that article 5.7 incorporates and gives meaning to the precautionary principle.[141] Thus the applicability of this principle under the SPS Agreement is limited to the situation covered by this article. This seems to imply that scientific uncertainty exists only in limited cases which can be dealt with be means of temporary solutions until certainty is achieved. The true state of affairs is, however, that uncertainty is a more common situation than certainty in scientific affairs. It is incorporated in assumptions used in risk assessments. In this way, the biases underlying these assumptions remain hidden. It is argued that it would be better to deal openly with the uncertainties inherent in scientific analysis. By recognising the pervasiveness of uncertainty and gaps in information in scientific analysis and allowing Members to explicitly take account of these problems by adopting a conservative or prudent approach to health regulation in terms of the precautionary principle, the SPS Agreement could contribute to greater transparency in regulation.

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141 See discussion in Section 2.2.4.

Part 3: Procedural aspects

There are also several procedural issues relevant to the policing of public health measures under the world trading system which are affected by the emphasis on scientific justification. These pertain to the adjudication of disputes under the SPS Agreement.

3.1 Rules Applicable to Dispute Settlement

In terms of article 11.1 of the SPS Agreement, articles XXII and XXIII of GATT 1994, as elaborated by the Dispute Settlement Understanding[142] apply to consultations and settlement of disputes under the SPS Agreement, unless otherwise provided therein. However, article 11.3 preserves the rights of Members under other international agreements, including the right to avail themselves of the good offices or dispute settlement mechanisms of other international organisations or created by any international agreement.

3.2 Composition of Panels

Under the DSU,[143] if attempts to solve a dispute by means of consultations between the parties fail, a complaining party may request the establishment of a Panel. Thus Panels are created *ad hoc* for each dispute and there is no permanent Panel. Panels are composed of well-qualified governmental or non-governmental individuals with expertise (practical or academic) in the area of trade law or policy.[144] A list is kept by the Secretariat, with the names of persons suggested by Member governments who meet the requirements of article 8.1. Members may suggest new persons for inclusion on this list, providing information on their expertise in the area of international trade and the subject matter of the covered agreements. It is thus clear that Panellists are primarily trade experts. Although it is possible that persons with additional knowledge in the area of SPS protection may be included among them, there is no requirement that panels hearing cases on health measures include such persons.

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142 Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 to the Marrakesh Agreement of 1994 (*supra* fn. 1) [hereinafter referred to as the DSU].

143 DSU *supra* fn. 142, art. 6.

144 DSU *supra* fn. 142, art. 8.1.

There have been calls for reform in this area. Bearing in mind the often complex scientific issues that are involved in health regulation, it seems unlikely that persons without scientific expertise in this area would be in a position to make judgements thereon. This is particularly the case when one has regard to the broad ambit of the Panel's powers of review of the regulatory determinations of Member governments, as discussed below.[145] It has been argued that the primary focus on the trade expertise of Panellists leads to a definite slant towards free trade goals in Panel decisions, which results in inadequate attention being paid to the equally important aim of the protection of public health. What is suggested is a more balanced composition of Panels, including experts in both trade and public health.[146]

In principle, this would apply to many of the various sectors of the covered agreements where expertise in trade matters alone is insufficient to lead to a balanced decision, reflecting the conflicting interests involved. Admittedly, it would be problematic to find so many qualified individuals willing and able to serve on Panels on an *ad hoc* basis. One has to bear in mind that these persons are often government officials or persons in the private sector who have to take time out from their busy schedules to attend the Panel proceedings. Thus another suggestion has been made, namely that there should be a professionalisation of Panels. In other words, permanent Panels should be created, composed of individuals with expertise in the relevant areas of the covered agreements. These panellists would thus be salaried employees of the WTO, and would be able to develop a strong expertise in the agreements they would deal with.

3.5.3 Establishment of Expert Review Groups or use of Scientific Experts

An attempt to deal with the lack of scientific expertise of Panellists is reflected generally in article 13 of the DSU and for health matters more specifically in article 11.2 of the SPS Agreement. Article 13.1 of the DSU authorises Panels to seek information and technical advice from any individual or body. Article 13.2 allows Panels to seek information from any source and to consult experts or request advisory reports from expert review.[147] Article 11.2 of the SPS Agreement states that in disputes under that Agreement, involving scientific or

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145 See Section 3.5 below.

146 A precedent for this might be the provision in art. 8.10 of the DSU (*supra* fn. 142) allowing developing country Members involved in disputes to insist that at least one panellist come from a developing country. This does not envisage that this panellist will favour developing countries, but that he or she will have a better understanding of the situation under dispute. The same rationale would apply to the inclusion of experts in SPS matters. See Steve Charnovitz, "Environment and health under WTO dispute settlement," *The International Lawyer* 32 (1998): 901 at 918.

147 These groups are set up in terms of Appendix 4 of the DSU (*supra* fn. 142).

technical issues, a Panel should consult experts chosen by it in consultation with the parties. For this purpose, the Panel may set up advisory technical experts groups or consult relevant international organisations.

In *EC-Hormones*[148] the Appellate Body affirmed the Panel's right to receive opinions from experts in their individual capacity rather than set up expert review groups. Article 11.2 of the SPS Agreement and article 13.2 of the DSU together with Appendix 4, do not limit this right. These provisions leave it to the discretion of the Panel to determine whether an expert review group should be established. Both provisions require the Panel to consult the parties to the dispute in the selection of experts. Since experts were chosen in terms of procedures agreed upon by the parties in this case, the Appellate Body found that the Panel had acted consistently with the article 13.2 and Appendix 4 of the DSU and article 11.2 of the SPS Agreement.

In this regard it should be noted that scientists consulted individually are unlikely to provide a clear picture of the state of scientific knowledge on an issue. Scientists' views reflect the scientific tradition of which they are part.[149] An expert review group is more conducive to understanding the range of possible interpretations of scientific data.

3.4 Burden of Proof

The question of which party bears the evidentiary burden is of particular importance in the case of disputes on health measures due to the degree of scientific uncertainty that exists in this area.

The Appellate Body first set out the burden of proof rules in *US-Shirts and Blouses*.[150] There it recognised that various international tribunals and most national jurisdictions apply the rule that the party who asserts a fact, whether plaintiff or respondent, must prove it. Once a party has adduced sufficient evidence to create a presumption that what is claimed is true, in other words established a *prima facie* case, the evidentiary burden shifts to the other party who must rebut the presumption or lose the case. In *EC-Hormones* the

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148 *EC-Hormones, supra* fn. 63, para. 147.

149 According to Atik (*supra* fn. 12 at 757), scientists are more likely to recognise a scientific justification for a measure where the scientific assertion is accepted in the scientific community to which they belong.

150 United States - Measures Affecting Imports of Woven Wool Shirts and Blouses from India, WT/DS33/AB/R, 23 May, 1997 at 14-16.

Appellate Body held that this rule applies equally to disputes under the SPS Agreement. It rejected the Panel's finding that the SPS Agreement allocates the burden of proof to the Member imposing the SPS measure.[151]

In *Japan-Agricultural Products*[152] the interaction between the obligation of a party to prove a *prima facie* case of inconsistency and the investigative authority of a panel was examined by the Appellate Body. In this case, the US had argued that Japan's varietal testing requirement was more trade restrictive than required to meet Japan's appropriate level of protection, contrary to article 5.6. It claimed that testing by product was an alternative measure, meeting the article 5.6 requirements. The Panel found that this measure would not meet Japan's appropriate level of protection. However, it went on to deduce another alternative measure, neither claimed nor argued by the US, from the opinions given by its expert advisors.[153] Although the Panel acknowledged that the US had not argued that this measure, the determination of sorption levels, met any of the three requirements of article 5.6, it held that it could be presumed that the requirements were met and that the US had offered views consistent with this.

The Appellate Body found that the US was obliged to establish a *prima facie* case that an alternative measure exists meeting all three requirements of article 5.6. As it had not even claimed that determination of sorption levels was such a measure, it did not meet its obligation. It recognised that the Panel is entitled under article 13 of the DSU to seek information from any relevant source and to consult experts, and that it is instructed under article 11.2 of the SPS Agreement to seek expert advice in technical and scientific matters. However, it held that this authority cannot be used to rule in favour of a party that has not established a prima facie case of inconsistency on grounds of the specific claims it asserted. The expert advice sought by the Panel is intended to help it understand and evaluate the evidence submitted and arguments made by the parties, not to make the complainant party's case for it. This finding is important in clarifying the respective roles of the Panel and the parties before it in the proceedings. It establishes that the panel

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151 The Appellate Body (*supra* fn. 63 at para. 102-105) dealt with the three grounds for the Panel's finding in turn. Firstly, it rejected the Panel's conclusion that the fact that many SPS provisions are worded "Members shall ensure that..." has any logical connection to the allocation of the evidentiary burden. Secondly, it held that article 5.8, under which Members may ask for an explanation of the reasons for an SPS measure from another Member and the latter is obliged to comply with the request, does not purport to address burden of proof issues, contrary to the Panel's finding. Instead this article is most likely to be used in pre-dispute situations in order to enable a Member to acquire information which it could later use to meet its burden of proof in dispute settlement proceedings.

152 *Japan-Agricultural Products, supra* fn. 50, para. 120-131.

153 Japan-Measures Affecting Agricultural Products, WT/DS76/R, 27 Oct. 1998 [hereinafter referred to as *Japan-Agricultural Product* Panel Report], para. 8.74.

procedure is adversarial, with the Panel acting as an impartial arbiter, rather than inquisitorial, where the Panel would have a more active role in the investigation of the facts and establishment of a case. The Panel's investigative authority is meant only to help its own understanding and evaluation of the cases presented by the parties before it.

3.5 Standard of Review

The issue of the appropriate standard of review is an important one, as it raises the question of whether Panels are entitled to interfere in Members' regulatory determinations, or whether they must defer to such decisions and confine themselves to the question of whether the procedural rules in making these decisions have been followed. This is crucial to the question of the limits to the policing of national regulatory choices in favour of free trade.

In *EC-Hormones*[154] the question of the appropriate standard of review was first dealt with. The EC argued that the Panel had failed to apply the appropriate standard of review, which it asserted to be a "deferential reasonableness standard", as exists for the Anti-Dumping Agreement.[155] Under such a standard, the Panel should not interfere in the investigation conducted on national level which led to the establishment of the measure. It should limit itself to determining whether the procedure set by WTO rules has been followed. Thus, if the Member has properly established the facts and conducted an objective, unbiased examination thereof, its conclusions should be deferred to by the Panel, even if it would have come to a different conclusion on the facts. Instead, the EC argued that the Panel had undertaken a *de novo* standard of review, under which it has complete freedom to examine the factual and procedural validity of the decision and to come to a different conclusion.

The Appellate Body rejected the extension of the standard of review set in the Anti-Dumping Agreement to the SPS Agreement, holding that this standard is textually specific to the former agreement and there is no evidence of an intention to adopt it in the latter agreement. Instead, it focused on the need for the standard of review applied to the SPS Agreement to reflect the balance created in that agreement between the jurisdictional

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154 *EC-Hormones, supra* fn. 63, para. 133.

155 Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994, (reprinted in *The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts* (1994) GATT Secretariat, Geneva at 168-196) [hereinafter referred to as the Anti-Dumping Agreement] at article 17.6 (i).

competences transferred by Members to the WTO and those retained by them. Neither the Panel nor the Appellate Body is authorised to change this balance. However, it could be argued that where this balance lies is not made explicit in the SPS Agreement and there is thus room for interpretation.

The Appellate Body found that although the SPS Agreement is silent on the issue of the standard of review, the DSU articulates this standard both for the determination of the facts and the legal characterisation of these facts, in article 11. The standard of review established by this article is neither deference nor *de novo* review, but rather the objective assessment of the facts (with respect to fact-finding) and an objective assessment of the matter, including the applicability of and conformity with the relevant covered agreements (with respect to legal issues). Thus whether the Panel's analysis is purely procedural or also substantive depends on the specific provision at issue.[156] Where the provision in question contains substantive elements, the Panel is at liberty to conduct a substantive analysis. There is thus no room for deference to the Member's regulatory determinations. The question arises whether this general rule is appropriate to the special circumstances of the SPS Agreement. This can be better decided in the light of the application thereof by the Appellate Body.

The issue of whether the appropriate standard of review was used thus depends, according to the Appellate Body, on the question whether there was an objective assessment of the matter, including an objective assessment of the facts. It held that failure to conduct such an objective assessment requires proof that there has been deliberate disregard of or refusal to consider submitted evidence or wilful distortion or misrepresentation of the evidence. These do not indicate a mere error of judgement but imply an egregious error, which calls into question the good faith of the Panel. It is apparent that the Appellate Body will not lightly find that this element of bad faith is present, as can be seen from its finding in this case that although the Panel had misquoted and misinterpreted the evidence, its actions had not been deliberate and there had thus been no failure to make an objective assessment of the facts.[157] It thus seems that the only limitation on the powers of review of the Panel, is its obligation to act in good faith. For the rest, it seems the Panel is free to substitute its own judgement for that of the Member government without any real limits.

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156 Hurst, *supra* fn. 43, at 27.

157 This trend continued in both *Australia-Salmon* (*supra*, fn. 96, para. 266) and *Japan-Agricultural Products* (*supra*, fn. 50, para. 142), where errors of the Panel in the appreciation of evidence were not characterised as failures to make an objective assessment of the facts, due to lack of an egregious nature.

Due to the limited interpretation given by the Appellate Body to the requirement to conduct an objective assessment, it is clear that the parties are to a large degree at the mercy of the Panel when it comes to its review of the evidence before it. This is problematic when one bears in mind the composition of Panels and their lack of expertise in scientific matters. Despite a lack of bad faith on the part of the Panel, it could still completely misunderstand or mischaracterise evidence before it. The lack of certainty that often exists in the scientific arena means that the Panel's possibility to consult experts does not constitute a real safeguard. The Panel is free to ascribe more weight to the opinions of its experts than those advising Member governments. This is a dangerous situation.

Part 4: Conclusion

The analysis of the use of science-based disciplines in the SPS Agreement, and their application and interpretation by WTO dispute settlement organs, brings to light certain important issues. These relate to the appropriateness of elevating science to the role of mediator in the conflict between free trade goals and the protection of public health.

What is immediately apparent is the need to take a realistic view of science itself and its limitations. While it would be very convenient to have a totally objective and universally valid standard against which to evaluate government health regulations, providing unassailable legitimacy to WTO disciplines, it is time to acknowledge that things are more complex than that. Science is imperfect, value-ridden and subject to differing interpretations. It can thus not provide the standard required.

While the SPS Agreement, and the interpretation thereof by WTO Panels and the Appellate Body, to some extent take account of this reality by making small concessions for scientific uncertainty and diversity of scientific opinion, this does not go far enough. The all-pervasiveness of scientific uncertainty and the social policy considerations that form an integral part of health regulation need to be explicitly recognised. These considerations make it obvious that science is not a useful tool for the determination of the validity of regulations aimed at protecting public health. Attempts to use this unrealistic standard can only lead to increasing the threat to human health inherent in trade liberalisation efforts. When one bears in mind the very high value that society attaches to human life and health, it is clear that this result is unacceptable.

It is particularly important to recognise this reality now, when the Millennium Round trade negotiations are in progress. There is urgent need for the reform of WTO rules relating to health measures. Such reform would go a long way to allaying the fears in society that have led to the massive protests against the continuation of trade liberalisation in the Millennium Round. This recognition would also prevent the extension of science-based disciplines to other areas, such as environmental regulation.

It is submitted that the use of an unrealistic and impracticable standard for policing government regulations, however prestigious and seemingly neutral it may be, ultimately does not serve the ends of the multilateral trade regime.

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