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Europe's Evolving Regulatory Strategy for GMOs — The Issue of Consistency with WTO Law: of Kine and Brine

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Robert Howse and Petros C. Mavroidis

Abstract

This Essay deals with one question: If challenged, how would regulatory restrictions on genetically modified organisms ("GMOs") be judged by a World Trade Organization ("WTO") adjudicating body. Many of the controversies about the effect of WTO law on domestic regulation have been influenced by the view that the law as it stands may well impede the ability of governments to regulate new and uncertain risks to health and the environment. The result in the Beef Hormones case is often cited for this proposition. In this Essay we aim to show that, contrary to an increasingly widespread popular perception, if WTO law is properly interpreted, GMO-related measures, where non-discriminatory against other WTO Members, can pass the test of consistency with even the most stringent of relevant WTO rules.

EUROPE'S EVOLVING REGULATORY STRATEGY FOR GMOS—THE ISSUE OF CONSISTENCY WITH WTO LAW: OF KINE AND BRINE

Robert Howse
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INTRODUCTION

This Essay deals with one question: If challenged, how would regulatory restrictions on genetically modified organisms (“GMOs”) be judged by a World Trade Organization¹ (“WTO”) adjudicating body. Many of the controversies about the effect of WTO law on domestic regulation have been influenced by the view that the law as it stands may well impede the ability of governments to regulate new and uncertain risks to health and the environment. The result in the *Beef Hormones* case (“*Hormones* case”) is often cited for this proposition. In this Essay we aim to show that, contrary to an increasingly widespread popular perception, if WTO law is properly interpreted, GMO-related measures, where non-discriminatory against other WTO Members, can pass the test of consistency with even the most stringent of relevant WTO rules.

Since it is real world regulations that are actually subject to challenge in WTO dispute settlement, we have chosen the evolving approach in the EU to the regulation of GMOs in order to illustrate this proposition. It is EU regulation, and U.S. objections to it, that have made GMOs a high profile trade issue, in the first place. And European regulation is explicitly and self-consciously based on a precautionary or conservative approach to new or not well known risks. Finally, the EU has one of the few already highly developed regulatory regimes for GMOs.

In Part I, we provide a brief account of the potentially rele-

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1. Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 1, 33 I.L.M. 1125 (1994) [hereinafter WTO Agreement].

vant WTO Agreements that can be used as a benchmark in examining the consistency of GMO-related measures. We conclude, for reasons explained in the section, that the WTO Agreement on the Application of Sanitary and Phytosanitary Measures² (“SPS”) is the forum that will in all likelihood entertain challenges against measures prohibiting or limiting the use of GMOs. In Part II we provide an account of the WTO case-law on the SPS Agreement. In this section, we aim to clarify what the Appellate Body and Panels have stated so far when dealing with SPS-related issues. We apply the dicta in Part III to GMO-related measures and in the final section we conclude.

I. WTO PROVISIONS APPLICABLE TO GMOS

A. *In General: The Three Musketeers*

The WTO contract, with some notable exceptions like the Agreement on Trade Related Intellectual Property Rights³ (“TRIPS”), is not about regulatory harmonization. The traditional paradigm between the WTO and General Agreement on Tariffs and Trade (“GATT”) is essentially that WTO members are free to enact their domestic policies.⁴ Such policies, to the extent that they might affect trade flows (actually or potentially, as standing GATT-WTO case-law has made it clear), will be judged WTO-compatible if they respect the non-discrimination principle and are enacted and applied transparently and non-arbitrarily, so as to avoid hidden or embedded protectionism.

This point was made clear in the recent notorious *Shrimp-Turtle* litigation where the Appellate Body ruled that conditioning market access to prior adoption of domestic policies is not

2. Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, WTO Agreement, Annex 1A, at http://www.wto.org/english/docs_e/legal_e/final_e.htm [hereinafter SPS Agreement].

3. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, WTO Agreement, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 1197 (1994) [hereinafter TRIPS].

4. See Frieder Roessler, *Increasing Market Access Under Regulatory Heterogeneity*, in REGULATORY REFORM AND INTERNATIONAL MARKET OPENNESS: OECD PROCEEDINGS 117-30 (1996); see also David Leebron, *Lying Down with Procrustes: An Analysis of Harmonization Claims*, in FAIR TRADE AND HARMONIZATION: PREREQUISITES FOR FREE TRADE? 41, 65 (J. Bhagwati & R.E. Hudec eds., 1996); Michael J. Trebilcock & Robert Howse, *Trade Liberalization and Regulatory Diversity: Reconciling Competitive Markets with Competitive Politics*, 6 EUR. J.L. & ECON. 5, 21-22 (1998).

per se inconsistent with the WTO rules.⁵ However, some earlier GATT jurisprudence has suggested measures that are non-discriminatory with respect to the country of origin of products that may nevertheless violate Article XI of the GATT and/or the non-discrimination principle in Article III of the GATT, if they treat products differently on the basis of the manner in which they are produced.⁶ However, as the Appellate Body has stressed in another case, depending on the non-discrimination provision at issue and the regulatory context, a wide range of factors may be relevant to distinguish products as “unlike.”⁷ Let us take the example of a WTO Member that wishes to distinguish the treatment of maize from that afforded to GMO-maize for health reasons. A WTO Member adopting its health policy might be making distinctions between two otherwise “like or directly competitive products” and thus violate its obligations under GATT Article III (national treatment). In such a case, an appropriate reading of Article III(4) of the GATT would accept that

5. See *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, Report of the Appellate Body, WT/DS58/AB/R (Oct. 12, 1998). The point that WTO rules apply on a context of regulatory diversity has been subsequently confirmed. See *United States—Tax Treatment for Foreign Sales Corporations*, Report of the Appellate Body, WT/DS108/AB/R (Feb. 8, 2000). It should be noted that the outcome reached in the two cited reports is perfectly compatible with public international law, amounting to the proposition that no transfer of national sovereignty to the international plane should be presumed.

6. See, e.g., *United States—Restrictions on Imports of Tuna*, DS21/R (Sep. 3, 1991) (not adopted) and DS29/R (Jun. 16, 1994) (not adopted).

7. *Japan—Taxes on Alcoholic Beverages*, Report of the Appellate Body, WT/DS8/AB/R (Oct. 4 1996). See also *Chile—Taxes on Alcoholic Beverages*, Report of the Appellate Body, WT/DS110/AB/R (Dec. 13, 1999). However, a panel recently came to the conclusion that WTO Members could not, consistent with the National Treatment Obligation, distinguish between products based on their harmfulness to human health. *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products*, Report of the Panel, WT/DS135/R (Sept. 18, 2000). This finding has now been reversed by the Appellate Body, which has held that the health effects of products may be relevant to the analysis of whether they are “like,” both in terms of physical characteristics and consumer perceptions and behavior. Whatever the “physical” differences between GM and non GM food products, there is a great deal of evidence that many consumers perceive these as “unlike.” The Appellate Body also held that even where two products are considered “like,” they can still be distinguished in regulations, provided the distinction in question does not result in the protection of domestic production. *European Communities—Measures Affecting Asbestos and Asbestos-containing Products*, Report of the Appellate Body, AB-2000-11, (Mar. 12, 2001). On the flimsy legal basis for the product/process distinction in GATT law and jurisprudence and the implications of the *Japanese Alcohol* case for that distinction, see Robert Howse & Donald Regan, *The Product/Process Distinction—An Illusory Basis for Disciplining “Unilateralism” in Trade Policy*, 11 EUR. J. INT’L L. 249 (2000).

these products are “unlike,” if only because there are differences between them that will likely matter a great deal from the perspective of the consumer. Moreover, the products are being distinguished based on the operational requirements of a non-protectionist scheme for health regulation, and there is no element of discrimination between domestic products and imports built into the distinction in question—domestically-produced GMO-maize is treated no better nor worse than imported GMO-maize.⁸

Moreover, the WTO paradigm does not make even the non-discriminatory principle into an absolute. Thus, even where found to be discriminatory, in some cases, a Member’s policies could be justified under Article XX, for example as necessary for the protection of human or animal life or health XX(b). This is subject to the general proviso, the “chapeau” of Article XX, that such policies not be applied in such a manner as to constitute arbitrary or unjustified discrimination between countries where the same conditions prevail, or a disguised restriction on international trade. Article XX of GATT is one possible forum to entertain GMO-related issues; this could happen if elements of discrimination between imports and domestic products were found to be built into a Member’s approach to GMO regulation. As the Appellate Body emphasized in *Japanese Alcohol*, the factors that may distinguish like from unlike products are open-ended, and the analysis of likeness is fact-intensive and must be done on a case-by-case basis. Thus, it is far from unimaginable that the Appellate Body might find that some distinctions in a Member’s overall scheme for regulating GMOs result in less favourable treatment of “like products,” as opposed to differential treatment of products that are “unlike.” This would depend on a detailed examination of scientific and regulatory facts.

The Agreement on Technical Barriers to Trade⁹ (“TBT”) is another possible WTO forum for the examination of GMO-re-

8. In the real world, unlike this simplified example, it is not always easy to discern whether there might be protectionist or discriminatory elements built into an apparently neutral scheme and its application. This is a major rationale for the sanitary and phytosanitary (“SPS”) provisions that we will discuss in due course, which impose particular disciplines on the regulatory process, even where the overall scheme may well be non-discriminatory.

9. Agreement on Technical Barriers to Trade, Apr. 15, 1994, WTO Agreement, Annex 1A, at http://www.wto.org/english/docs_e/legal_e/final_e.htm [hereinafter TBT Agreement].

lated regulations: A WTO Member could very well, through enactment of a technical regulation in accordance with Article 2.2 of the TBT, provide for compulsory labelling of all GMO-treated goods. In such a case, if challenged, the WTO Member at hand will have to demonstrate (provided of course, that the complaining party has absolved its burden of proof) that it respected the TBT disciplines when enacting its labelling requirements.

Finally, to the extent that the WTO Member adopts a sanitary or phytosanitary measure (fearing for example, the spread of a disease through importation of GMO-treated goods) it might be called to justify its policies under the SPS Agreement.

If the test in all three Agreements (GATT, TBT, and SPS) was identical, the question of whether to subordinate GMO-related concerns would be immaterial. This is hardly the case though. Except for temporary or provisional measures, the SPS Agreement is the only one that requires that regulations be based on scientific evidence. Consequently, in what follows we examine the relationship between the three Agreements.

B. *TBT and SPS*

The relationship between the TBT and the SPS Agreements is at first glance quite clear: Article 1.5 of the TBT provides that the provisions of the TBT Agreement do *not* apply to measures defined as Sanitary and Phytosanitary Measures in Annex A of the SPS Agreement. The definition of Annex A is broad, and includes almost all relevant measures to protect human or animal health, life, or the environment, generally arising from importation of foods and agricultural products. Essentially all existing GMO-related regulation in developed countries is characterized in this fashion, and thus one can confidently say that SPS applies exclusively. However, ethical rationales have sometimes been stated for restrictions on genetic engineering, as well as rationales connected to the social economy required to preserve indigenous agriculture and traditional ways of life. Where regulations are explicitly addressed to these purposes, the application of SPS exclusively may need to be reconsidered.

C. *SPS and Article XX of GATT: An Issue*

The relationship between Article XX of GATT and the SPS Agreement has not been clarified in the WTO case-law as of yet.

This is due to a number of reasons. First, the General Interpretative Note, which regulates the relationship between GATT and its annexed Agreements (both the TBT and the SPS are annexed to GATT), has not been scrutinized with sufficient precision by WTO adjudicating bodies. The fact that the Panel Report *Indonesia—and Certain Measures Affecting the Automobile Industry*,¹⁰ which discussed *in extenso* the General Interpretative Note, ultimately, was not appealed has not been helpful.

Second, assuming *arguendo* that the General Interpretative Note is to be interpreted in light of the *lex specialis* rule, we note: The maxim of *lex specialis* is not a model of clarity. Bartels notes that the maxim dates, at the latest, from Grotius who believed that “special provisions are ordinarily more effective than those that are general.” The maxim, however, was never reflected in the Vienna Convention on the Law of Treaties, which codifies customary international law with respect to interpretation of treaties. This fact alone casts doubt as to the pertinence and the ambit of the principle.

Arguably, the principle can have value if viewed in the context of effective treaty interpretation. Viewed from this angle, the argument runs as follows: If the same factual situation can be submitted to two different treaty provisions that contain different tests, it is almost certain that plaintiffs will challenge measures under the relatively more stringent test for the defendant. Hence, in as much as the jurisprudence is clear on which standard gives the plaintiff an advantage, there are good chances that the relatively relaxed standard will fall in *desuetudo*. The interpreter can avoid such an outcome by carefully circumscribing the ambit of *lex specialis*, which is, in the Grotian sense, the more effective rule, and prescribing applicability of the more general rule to the extent that there is no overlap, or more generally, as evidence of the “spirit” of the special rule.

We should note, however, that an interpretation of the *lex specialis* maxim in the light of the principle of effective treaty interpretation has not been accepted (nor rejected) as yet in the context of WTO case-law. Hence, the question as to which of the SPS Agreement and Article XX of GATT prevails remains unanswered at the positive level. At the same time, *lex specialis*, cast in

10. *Indonesia—Certain Measures Affecting the Automobile Industry*, Panel Report, WT/DS54/AB/R (July 2, 1998).

terms of effective treaty interpretation, is closely related to judicial economy, a principle of adjudication endorsed by the Appellate Body.¹¹ The idea of *lex specialis* is also consistent with the Appellate Body's emphasis on the duty of a treaty interpreter to consider all the relevant words of the treaty. Where a general standard or norm is embodied in a more specific treaty text, a failure to consider the more specific terms would be a dereliction of this duty. On the other hand, to the extent that the more general standard or norm is adequately embodied in the more specific text, the principle of judicial economy, and more generally of effective treaty interpretation, would seem to militate against a further application of the general norm or standard itself, once the more specific text has been applied.

D. *SPS and Article XX of GATT: An Issue Yes, But Does It Matter?*

So far we established that there is no doubt that the SPS Agreement applies to the exclusion of the TBT Agreement and that it is not clear that the SPS Agreement prevails over GATT.¹² We submit next that the relationship between Articles III and XX of GATT and the SPS Agreement can in practice be a non-issue in order to justify our conclusion to examine the consistency of GMO-related issues within the SPS Agreement only.

As noted above, the SPS Agreement is the only WTO instrument that imposes on WTO Members the obligation to base their measures on scientific evidence, regardless of whether the measures are discriminatory or violations of other basic provisions of GATT. This extra obligation in fact imposes a higher justificatory burden on all WTO Members wishing to protect themselves from GMOs and at the same time makes it easier for potential complaining parties to challenge them. Hence, it should be expected that GMO-related measures will in all likelihood be challenged as being inconsistent with the SPS Agree-

11. See generally *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, Report of the Appellate Body, WT/DS58/AB/R (Oct. 12, 1998); *Japan—Taxes on Alcoholic Beverages*, Report of the Appellate Body, WT/DS8/AB/R (Oct. 4, 1996); David Palmetier & Petros Mavroidis, *The WTO Sources of Law*, 92 AM. J. INT'L L. 398-413 (1998).

12. In our discussion we assume of course that the complaining party has not decided to challenge a GMO-related measure only under one agreement. In such a case, all our discussion is irrelevant since the WTO adjudicating body will have to entertain a claim as presented to it. As we show, however, chances are that complaining parties will choose to invoke the SPS Agreement.

ment. Here, because the strictures appear to go significantly beyond the non-discrimination requirement at the core of what we have called the traditional GATT/WTO paradigm, the proposition to be challenged in this Essay takes on the greatest plausibility. At the same time, it must be understood that it is up to the complaining party to prove a violation of a WTO Agreement—thus the complainant would have to at least raise a presumption that the Member's GMO related regulations were *not* based on scientific evidence. In some cases, it could be easier for the complainant to raise a presumption that the non-discrimination principle in Article III(4) has been violated, and then force the defendant to justify its measures scientifically as "necessary" within the meaning of Article XX(b). Take for instance, a ban on GMOs originating from a defined list of countries that are deemed not to have adequate risk management strategies in place. Since, in such a case, a violation of Articles I and III of GATT is obvious, by going the GATT XX route, the complainant forces the defendant to bear the justificatory burden for its measures. Whereas if the SPS route were taken, the complainant in the first instance would have to show—or raise a presumption—that the defendant's measures were not scientifically justified. In an area such as GMOs, where the science is complex and there are many uncertainties, one could not entirely dismiss the attractiveness to a complainant of a litigation strategy that requires the exercise of justification by the defendant.

This being said, most of the trade controversy surrounding GMO regulations is not focussed on explicitly discriminatory regulations, but instead on general regulatory schemes, facially applicable on equal terms to both domestic products and imports regardless of country of origin. Thus, determining under Article III(4) whether the measures are discriminatory, will involve evaluating subtler claims concerning elements of discrimination against imports built into facially neutral regulation. Here, the real issue is the possibility of hidden or structurally embedded protection. The concepts of "like" products and "less favourable treatment" in Article III(4), even as clarified by the Appellate Body recently in the *EC-Asbestos* case, provide substantially less guidance for drawing the delicate line between innocent non-discriminatory regulation and facially neutral, but covertly and/or structurally discriminatory measures (which violate Article III(4)), than the detailed procedurally-oriented disci-

plines of SPS, which require that we be able to see into the regulatory process and ascertain its non-protectionist bona fides.¹³ In sum, if the adjudicator were to do a good job in dealing with these kinds of measures under Article III(4), she would need the kind of tools supplied in SPS. And in turn, once she has used these tools, the need for a separate analysis under III(4) and XX will be superfluous. Facially-neutral measures that pass muster under all the explicit disciplines of SPS could not plausibly be shown by a complainant on the balance of probabilities to be a violation of Article III(4). The complainant loses no legitimate litigation advantage by the adjudicator then on the basis of the effectiveness of treaty interpretation and judicial economy not proceeding to the GATT claim.

These various considerations follow from the basic choice in WTO for a complainant-driven dispute settlement process. The WTO Agreement does not describe an institution that resembles the *avis consultatifs* that a U.N. organ can request from the International Court of Justice. In such a case, there would be a shift in the initiative and hence one could well imagine that a WTO Member wishing to enact a GMO-restraining legislation could very well ask questions as to its compatibility with Article XX of the GATT.

WTO Members have of course the possibility to request a decision by a WTO Committee. However, as the recent WTO case-law however makes it clear,¹⁴ WTO adjudicating bodies are not bound by decisions of such bodies and will proceed to their own review independently of what has been decided in the context of such Committees. Hence, it will be of little (or no) legal significance to WTO Members to initiate a far-fetching discussion on GMOs in the context of such Committees.

The only option available left to WTO Members would be to request an authoritative interpretation of the Agreement or a formal amendment (in accordance with Articles IX and X respectively of the WTO Agreement) to the effect that GMO-re-

13. For an analogous discussion of the relationship between Articles III and XX and the TBT Agreement, see Robert Howse & E. Tuerk, *The Impact of the WTO on Internal Regulation in the EU*, in CONSTITUTIONAL CHANGE IN THE EU (forthcoming 2001).

14. See generally *India—Quantitative Restrictions on Imports of Agricultural, Textile and Industrial Products*, Report of the Appellate Body, WT/DS90/AB/R (Apr. 6, 1999); *Turkey—Restrictions on Imports of Textile and Clothing Products*, Panel Report, WT/DS34/R (May 31, 1999).

straining legislation be judged compatible with the WTO. Such action would pre-empt review by WTO adjudicating bodies since the latter (agents) would have to respect the will of the former (principals).

Such an initiative, however, has not taken place so far and hence the relevance of the following Sections is clear since we examine how GMO-related issues would be reviewed in the context of the SPS Agreement as interpreted so far. We should note that in what follows we do not deal with the issue *quid* in case an international agreement banning or restraining the use of GMOs is signed outside the WTO context and its relevance for WTO purposes is requested. So far, such a dispute (which would in fact ask whether the WTO contract should be interpreted as self-contained or not) has not been brought before the WTO. However, opinions on this issue have already been expressed in the literature.¹⁵

II. *THE SPS AGREEMENT IN LIGHT OF THE WTO JURISPRUDENCE*¹⁶

A. *In General*

The TBT Agreement itself acknowledges that when a disputed measure qualifies as an SPS-measure, the SPS Agreement takes precedence over the TBT. There is nothing like a comparable statement in the WTO Agreement with respect to the relationship between the SPS and Article XX of GATT (or XIV GATS). This is particularly troublesome, since, unlike SPS, Article XX(b) on its face does not require that health-based measures blocking trade must be based on scientific evidence. In practice, however, it would be difficult for the defendant to meet its burden of proof that otherwise illegal GATT measures are “necessary” for the protection of health without some resort to scientific evidence. The fundamental difference between justification under Article XX(b) and the scientific evidence requirement in the SPS Agreement is that under Article XX in general, the defendant bears, in the first instance, the burden of proof for justifying its measures, but (as discussed above) only those

15. See Joel P. Trachtman, *Decisions of the Appellate Body of the World Trade Organization*, 9 HARV. J. INT’L L. 551 (1999); Palmetier & Mavroidis, *supra* note 11.

16. This Section relies on HENRIK HORN & PETROS C. MAVROIDIS, *FLASH BACK: WHAT WERE YOU THINKING WHEN ENACTING HEALTH POLICIES* (2000).

measures that have already been shown to violate some provision of GATT.

B. *Health Measures and International Standards*

Article 3 of the SPS Agreement deals with the relationship between domestic SPS regulations and international standards. There is a general obligation to base domestic SPS measures on international standards. This is subject to a right to deviate from international standards where the result is a higher level of protection. This right to deviate is in turn conditioned on the requirements of scientific risk assessment in the regulatory process that are detailed in Article 5 of SPS. In addition to measures based on international standards and those that deviate from international standards in accordance with 3.3 in order to achieve a higher level of protection, a third category is measures that "conform to" international standards. In the case of the last category, there is a presumption that the measure at hand is compatible with the WTO, including that it could be justified under Article XX of GATT.¹⁷ As the Appellate Body noted in *Measures Concerning Meat and Meat Products*¹⁸ ("*Hormones*"), "conformity" suggests a closer fit than "based on," measures may take international standards as their point of departure, but reflect considerable variation at the level of detail, and this is consistent with their being "based on" international standards.

In sum, Article 3 of the SPS gives an incentive to states to comply with international standards but it should not be equated to an obligation to follow them.

The rest of the Essay deals with the case where a WTO Member has decided to seek a higher level of protection than that provided by existing international standards, thereby making it clear that the strictures of Article 5 of the SPS apply.

III. NATIONAL HEALTH STANDARDS

A domestic measure adopted under the SPS must be based on risk assessment, taking into account scientific evidence.

17. The text of Article 3.2 of the SPS does not make it clear whether the presumption established is an irrebutable one.

18. *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, Report of the Appellate Body, WT/DS26/AB/R (Jan. 16, 1998).

Moreover, it must be non-discriminatory,¹⁹ in the sense that it will be applicable in a neutral manner and must also be part of a coherent and consistent policy. Some of the key issues (risk, risk assessment, scientific evidence, non-discrimination, and coherence) have been already interpreted in the WTO case law. We take them in turn.

A. Must Be Based on a Risk Assessment (Article 5.1 of the SPS)

Logically, for the term “risk assessment” to be interpreted, one must first have a clear idea about what the term “risk” might mean. It is impossible to speak of a “risk-free” situation, for every factual situation might entail a certain level of risk. The example of incidence of lead in water (that is, how much lead in how much water is dangerous for a policy prohibiting lead in water to be addressing a risk) illustrates this point.

The *Hormones* Appellate Body report acknowledged this point (upholding a previous finding by a panel) when it stated that:

[T]he Panel opposes a requirement of an “identifiable risk” to the uncertainty that theoretically always remains since science can *never* provide *absolute* certainty that a given substance will not *ever* have adverse health effects. We agree with the Panel that this theoretical uncertainty is not the kind of risk which, under Article 5.1, is to be assessed.²⁰

However, the Appellate Body also opines that:

To the extent that the Panel purported to require a risk assessment to establish a minimum magnitude of risk, we must note that imposition of such quantitative requirement finds no basis in the SPS Agreement.²¹

We can conclude from the above that a “risk” in the sense of Article 5.1 of the SPS must be an ascertainable risk and not the mere hypothetical or abstract possibility of risk, which is inherent in everyday life precisely because of the limits of human

19. This question must be distinguished from the question whether a demonstration of discrimination is a necessary precondition for invoking the SPS Agreement. It is clear by now that such is not the case, that is, the SPS Agreement comes into play independently whether discrimination has previously been shown.

20. *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, Report of the Appellate Body, WT/DS26/AB/R (Jan. 16, 1998).

21. *Id.*

knowledge. Risk cannot simply be asserted in this general way. There must be some empirical investigation of specific risks. This point has been re-emphasized by the Appellate Body in subsequent case law:

As stated in our Report in *European Communities—Hormones*, the risk evaluated in a risk assessment must be an ascertainable risk; theoretical uncertainty is “not the kind of risk which, under Article 5.1, is to be assessed.”²²

We can conclude from the above that a risk in accordance with Article 5.1 of the SPS must be an ascertainable risk. However, at the same time, once there is empirical evidence of risk, it is perfectly legitimate for a Member to seek to reduce the risk so ascertained to zero. Moreover, the notion of ascertainable risk does not establish some minimum threshold concerning the level of uncertainty or error that is tolerable in a finding of risk. It merely indicates that such a finding must be based on investigation consistent with scientific principles, rather than mere untested hypothesis.

Now that we have established what “risk” is, we turn to the notion of risk assessment. The *Hormones* Panel Report made a distinction between risk assessment and risk management. We should note first that the term “risk assessment” is already defined in the SPS Agreement. Annex A contains the following definition:

The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feed-stuffs.²³

The *Hormones* Panel Report understood this term as follows: “an assessment of risk is, at least for risks to human life or health,

22. *Australia—Measures Affecting Importation of Salmon*, Report of the Appellate Body, WT/DS18/AB/R (Oct. 20, 1998) (quoting from *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, Report of the Appellate Body, WT/DS26/AB/R (Jan. 16, 1998).

23. SPS Agreement, Annex A.

a *scientific* examination of data and factual studies; it is not a policy exercise involving social value judgments made by political bodies."²⁴

The panel distinguishes from "risk assessment," as defined above, "risk management," which is the second step in a decision by a WTO Member to enact an SPS measure. That is, after a risk assessment has been carried through, and logically provided that we are in presence of an ascertainable risk as defined above, WTO Members can choose their appropriate level of sanitary or phytosanitary protection.²⁵ As the panel implies, WTO Members—provided that they respect the disciplines laid out in Article 5.4-5.6 of the SPS—are free to choose the level of protection that seems appropriate to them. This finding is in line with the finding of the Appellate Body that WTO members can legitimately pursue a zero risk-policy. The notion of risk assessment was further clarified in the Appellate Body Report on *Measures Affecting Importation of Salmon*.²⁶ There, in an often quoted subsequent case-law passage, the Appellate Body report holds for the following proposition:

[W]e consider that . . . a risk assessment within the meaning of Article 5.1 must:

- (1) *identify* the diseases whose entry, establishment or spread a Member wants to prevent within its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these diseases;
- (2) *evaluate the likelihood of entry*, establishment or spread of these diseases, as well as the associated potential biological and economic consequences; and
- (3) evaluate the likelihood of entry, establishment or spread of these diseases *according to the SPS measures which might be applied*.²⁷

So, according to this definition, a WTO Member must pro-

24. *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, Complaint by the United States, Report of the Panel, WT/DS26/R/USA (Aug. 18, 1997).

25. Surprisingly, the Panel Report does not reflect that the term "appropriate level of sanitary or phytosanitary protection" has already been interpreted in Annex A in a way that essentially condones regulatory diversity.

26. See *Australia—Measures Affecting Importation of Salmon*, Report of the Appellate Body, WT/DS18/AB/R (Oct. 20, 1998).

27. *Id.* § 121 (emphasis added).

vide evidence probative of causal relationship between the SPS measure it is about to enact and the disease it wants to address, in the sense that its measure will be the antidote to the identified risks. Moreover, there must be a likelihood of entry of the identified disease, which in turn must be evaluated. The outcome of such evaluation amounts to risk assessment. Likelihood, as the Appellate Body notes, is more than a mere possibility. The *Hormones* Appellate Body Report notes in this respect: "The ordinary meaning of 'potential' relates to 'possibility' and is different from the ordinary meaning of 'probability.' 'Probability' implies a higher degree or a threshold of potentiality or possibility."²⁸

The *Salmon* Appellate Body report confirmed: "[I]t is not sufficient that a risk assessment conclude that there is a *possibility* of entry, establishment or spread of diseases and associated biological and economic consequences."²⁹

However, the Appellate Body did not endorse the Panel's misuse of the statistical concept of probability. It merely reverted to the notion, developed in *Hormones*, that a risk must be ascertained and defined, rather than being stated in vague terms as a simply possibility—something, that like all events in a underdetermined universe, *could* occur. Hence, we can conclude that, in the relevant Appellate Body case-law, a risk assessment is a process whereby the likelihood of entry of a disease will be ascertained.

Now, for an SPS measure to be WTO-compatible it must be based on a risk assessment. What exactly the words "based on" mean formed the partial subject-matter of the *Hormones* litigation. Two aspects of the term have been interpreted: the time dimension and the question of overlap between the SPS measure enacted and the risk assessment. We take each issue in turn.

The Panel Report in the *Hormones* litigation stands for the proposition that "the Member imposing a sanitary measure needs to submit evidence that at least it actually *took into account* a risk assessment when it enacted or maintained its sanitary measure in order for that measure to be considered as *based on* a risk assessment."³⁰

28. *Id.* § 184.

29. *Id.* § 123.

30. *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, Complaint by the United States, Report of the Panel, WT/DS26/R/USA (Aug. 18, 1997).

Hence, according to this view, scientific evidence that did not serve as the basis for the enactment of the measure can only be taken into account if it is shown that the WTO Member somehow considered it either when they first enacted the measure or when they re-examined it.³¹

The Appellate Body reversed the Panel's findings in this respect and ruled that scientific evidence can be submitted at a later stage as well. The operative consequence of this ruling is that a WTO Member can, for the first time, submit that it based a measure on a risk assessment when challenged before a WTO adjudicating body.³² Hence, according to the prevailing view, a WTO Member can lawfully enact a measure even when it cannot offer a basis of risk assessment at the moment of enactment of such measure, provided that a basis can be offered, if and when the measure is challenged before a WTO adjudicating body.

The *Hormones* Appellate Body Report, reversing the Panel Report in this respect, made it clear that "based on" should not be understood to mean that the SPS measure must conform absolutely to the risk assessment. A certain margin of discretion in favour of the WTO Member enacting legislation must be acknowledged. The relevant passage reads: "[a] measure, however, based on the same standard might not conform to that standard, as where only some, not all, of the elements of the standard are incorporated into the measure."³³

Both the Panel and the Appellate Body Report referred to the use of international standards. Hence, it is clear that national SPS measures based on international standards can pass the test of WTO legality, even if they reflect only elements of the international standard.

B. *A Risk Assessment Shall Take Into Account Scientific Evidence* (Article 5.2 of the SPS)

The SPS Agreement³⁴ imposes on all WTO Members con-

31. *Id.* § 8.115.

32. See *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, Report of the Appellate Body, WT/DS26/AB/R (Jan. 16, 1998).

33. *Id.* § 163.

34. See generally Joost Pauwelyn, *The WTO Agreement on Sanitary and Phytosanitary (SPS) as Applied in the First Three SPS Disputes*, 2 J. INT'L ECON. L. 641 (1999) (providing account of all SPS-related cases treated so far by WTO Appellate Body); Robert Howse,

cerned an obligation to base their measures on scientific evidence. In this respect, Article 2.2 of the SPS reads:

Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without scientific evidence, except as provided for in paragraph 7 of Article 5.

What exactly is scientific evidence?

The *Hormones* Panel Report did not discuss the issue in great detail. In § 8.130 of the Report though, we note that general information not relating specifically to the subject matter under discussion might be disregarded as impertinent. Hence, without explaining exactly which level of specificity is necessary for an opinion to qualify as scientific evidence, the panel report argues in favour of specificity-threshold.

The *Hormones* Appellate Body report in an often-cited passage tackles another angle with respect to what might constitute scientific evidence. It states:

Article 5.1 does not require that the risk assessment must necessarily embody only the view of a majority of the relevant scientific community. In some cases, the very existence of divergent views presented by qualified scientists who have investigated the particular issue at hand may indicate a state of scientific uncertainty. Sometimes a divergence may indicate a roughly equal balance of scientific opinion, which may itself be a form of scientific uncertainty. In most cases, responsible and representative governments tend to base their legislative and administrative measures on “mainstream” scientific opinion. In other cases, equally responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources.³⁵

Thus, minority scientific opinions by and large suffice for a WTO Member to have met its burden under the SPS.

Further light on the meaning of scientific evidence is provided, indirectly, by the Appellate Body, when examining an oral

Democracy, Science and Free Trade: Risk Regulation on Trial at the WTO, 98 U. MICH. L.R. 2329 (2000) (discussing all related cases).

35. *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, Report of the Appellate Body, WT/DS26/AB/R (Jan. 16, 1998).

statement by an expert (Dr. Lucier) invited to testify before it, the Appellate Body notes:

[T]his opinion by Dr. Lucier does not purport to be the result of scientific studies carried out by him or under his supervision focusing specifically on residues of hormones in meat from cattle fattened with such hormones. Accordingly, it appears that the single divergent opinion expressed by Dr. Lucier is not reasonably sufficient to overturn the contrary conclusions reached in the scientific studies referred to by the European Communities that relate specifically to residues of the hormones in meat from cattle to which hormones had been administered for growth promotion.³⁶

It is unclear why the Appellate Body dismissed the opinion of the expert. The term “accordingly” used by the Appellate Body seems to suggest that the decisive criterion for it to disregard the expressed opinion was the fact that Dr. Lucier merely offered an oral explanation without having previously conducted research on the issue. If this is the case, then the Appellate Body most likely rejected the opinion expressed because it did not meet its self-imposed (but not precise) scientific evidence-threshold. In such a case, the Appellate Body implicitly accepts that some “minimum methodological requirements” (albeit undefined so far) must be there for an opinion to have the status of scientific evidence. And on the other hand, that if this is the case, a minority opinion, provided that it meets standard mentioned above, suffices for a WTO Member to base on it its health policy. But these requirements, rather than residing in some conception of orthodox or mainstream contemporary natural science, denote the broader understanding of science as reasoned inquiry or investigation—a notion reflected in the broadness of meaning of the word for “science” in other European languages, for example *Wissenschaft* in German and *Nauke* in Russian. This is reflected in the following definition of the notion of science in the *Hormones* Appellate Body Report: a process characterized by systematic, disciplined and objective enquiry and analysis, that is, a mode of studying and sorting out facts and opinions.³⁷

36. *Id.* § 198.

37. *Id.* § 187.

C. *What Can be Taken Into Account Beyond Scientific Evidence*
(Article 5.2 of the SPS)

Article 5.2 of the SPS lists the factors to be taken into account when assessing risk. It mentions available scientific evidence; relevant processes and production methods; relevant inspection, sampling, and testing methods; prevalence of specific diseases and pests; existence of pest- or disease- free areas; relevant ecological and environmental conditions; and quarantine or other treatment.

In a notorious passage in its *Hormones* Report, the Appellate Body interpreted the objective function of the list:

[T]o the extent that the Panel purports to exclude from the scope of a risk assessment in the sense of Article 5.1, all matters not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences, we believe that the Panel is in error. Some of the kinds of factors listed in Article 5.2 such as “relevant processes and production methods” and “relevant inspection, sampling and testing methods” are not necessarily or wholly susceptible of investigation according to laboratory methods of, for example, biochemistry or pharmacology. Furthermore, there is nothing to indicate that the listing of factors that may be taken into account in a risk assessment of Article 5.2 was intended to be a closed list. It is essential to bear in mind that the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.³⁸

Hence, it seems that the Appellate Body in this passage, on the one hand, opts for a deferential posture to national regulators—by allowing WTO Members to view the factors mentioned in the list from the perspective of democratic regulation, not necessarily from that of laboratory science. On the other hand, the Appellate Body also adopts the position that the list of Article 5.2 of the SPS is not an exhaustive list and that other factors not mentioned in the list could eventually become integral parts

38. *Id.*

of the totality of factors that can be taken into account when a WTO Member assesses a risk.

At this stage, the Appellate Body has not yet elaborated on which other factors can be taken into account (beyond those mentioned in Article 5.2 of the SPS) or as to how the factors mentioned can, in practice, be evaluated from a non-scientific perspective. However, the Appellate Body may well have been wise not to prioritise the notion of “science” or the “scientific.” The kinds of factors that related to a “scientific” assessment of risk will evolve as science evolves and also cannot be considered in abstraction apart from the kind of risk at issue the kind of public policy decision to which the risk assessment is directed.

D. *Economic Factors Can be Taken Into Account When Assessing the Risk and Determining the Appropriate Level of Protection (Article 5.3 of the SPS)*

This Article has not been interpreted so far.

E. *When Stating Their Objective, WTO Members Must Seek to Minimize Negative Trade Effects (Article 5.4 of the SPS)*

None of the Appellate Body reports contain in their *ratio decidendi* reference to Article 5.4 of the SPS. However, an explicit reference to this Article is found in the *Hormones* Panel Report, which in pertinent part reads:

Guided by the wording of Article 5.4, in particular the words “should” (not “shall”) and “objective,” we consider that this provision of the SPS Agreement does not impose an obligation. However, this objective of minimizing trade effects has nonetheless to be taken into account in the interpretation of other provisions of the SPS Agreement.³⁹

F. *WTO Adjudicating Bodies Will Essentially Review the Means and Not the End (Article 5.6 SPS)*

Article 5.6 of the SPS is closely related to Article 5.4 of the SPS. The latter refers to the objective sought by WTO Members, whereas the former addresses the means applied in order to

39. *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, Complaint by the United States, Report of the Panel, WT/DS26/R/USA (Aug. 18, 1997).

reach the stated objective. As mentioned above, WTO adjudicating bodies will not question the level of the objective sought; all they can do is examine whether the means used are the least restrictive means that a WTO Member could use to reach its objective.

The logical link between means and ends prejudices the standard of review to be applied by WTO adjudicating bodies: If the goal is to reduce risk to zero, *any* precaution that makes some additional marginal contribution to bringing the risk closer to zero will, in principle, be necessary. Hence, adjudicating bodies will have less leeway to examine whether the means used are indeed the least restrictive option than in a case where the objective sought is not as inflexible as a zero risk-policy. All these issues have already been explored in WTO case-law.

With respect to the first, the *Salmon* Appellate Body decision holds that:

The determination of the appropriate level of protection, a notion defined in paragraph 5 of Annex A, as “the level of protection deemed appropriate by the Member establishing a sanitary . . . measure” is a *prerogative* of the Member and not of the panel or of the Appellate Body. . . . The “appropriate level of protection” established by a Member and the “SPS measure” have to be clearly distinguished. They are not one and the same thing. The first is an *objective*, the second is an *instrument* chosen to attain or implement that objective.⁴⁰

The closely related situation where a WTO member has enacted an SPS measure but has not clearly identified the appropriate level of protection sought, was addressed in the same report which relevantly reads:

[W]e believe that in cases where a Member does not determine its appropriate level of protection, or does so with insufficient precision, the appropriate level of protection may be established by panels on the basis of the level of protection reflected in the SPS measure actually applied. Otherwise, a Member’s failure to comply with the implicit obligation to determine its appropriate level of protection—with sufficient precision—would allow it to escape from its obligations under this Agreement and, in particular, its obligations under Arti-

40. *Australia—Measures Affecting Importation of Salmon*, Report of the Appellate Body, WT/DS18/AB/R (Oct. 20, 1998).

cles 5.5 and 5.6.⁴¹

Second, there is the issue of applying the appropriate test when reviewing the means used to reach the sought objective. Again, the *Salmon* Appellate Body report contains a relevant passage: "What is required under Article 5.6 is an examination of whether possible alternative SPS measures meet the appropriate level of protection *as determined by the Member concerned*."⁴²

And later, upholding the Panel's findings in this respect the Appellate Body provides the test to be used in order to examine whether a means is indeed the least restrictive means to reach the ends sought:

The three elements of this test under Article 5.6 are that there is an SPS measure which: (1) is reasonably available taking into account technical and economic feasibility; (2) achieves the Member's appropriate level of sanitary or phytosanitary protection; and (3) is significantly less restrictive to trade than the SPS measure contested. These three elements are cumulative in the sense that, to establish inconsistency with Article 5.6, all of them have to be met. If any of these elements are not proven, the measure in dispute would be consistent with Article 5.6. Thus, if there is no alternative measure available, taking into account technical and economic feasibility, *or* if the alternative measure does not achieve the Member's appropriate level of sanitary or phytosanitary protection, *or* if it is not significantly less trade-restrictive, the measure in dispute would be consistent with Article 5.6.⁴³

In subsequent case-law, the Appellate Body confirmed this finding.⁴⁴

During the Panel proceedings on *Measures Affecting Agricultural Products/Varietals* ("*Varietals* Panel Report"),⁴⁵ the United States advanced the argument that Japan could reach its stated objective by using another less restrictive means. The Panel examined and rejected the U.S. argument, and the Appellate Body

41. *Id.* § 207.

42. *Id.* § 204.

43. *Id.* § 194 (emphasis added).

44. See *Japan—Measures Affecting Agricultural Products*, Report of the Appellate Body, WT/DS76/AB/R (Feb. 22 1999).

45. See *Japan—Measures Affecting Agricultural Products*, Panel Report, WT/DS76/R (Oct. 27, 1998).

upheld the result.⁴⁶

It is clear that if presented with evidence by a party to the dispute that a means chosen by a WTO Member to reach a health objective is not the least restrictive one, WTO adjudicating bodies will have to entertain the argument and decide accordingly. But in case no argument is presented, or in case the presented argument is not convincing, can WTO adjudicating bodies still address questions to the parties in order to make up their mind on the degree of restrictiveness of a particular measure?

The WTO case-law provides some answers in this respect. We treat them though when we address the burden of proof issue.

G. *When Adopting National Standards, WTO Members Must be Consistent (Article 5.5 of the SPS)*

The *Hormones* Appellate Body acknowledges that “the objective of Article 5.5 is formulated as the ‘achieving [of] consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection.’”⁴⁷

This however should not be equated to a declaration in favour of always consistent SPS policies over time. The same report a few lines later explains:

[W]e agree with the Panel’s view that the statement of that goal does not establish a *legal obligation* of consistency of appropriate levels of protection. We think, too, that the goal set is not absolute or perfect consistency, since governments establish their appropriate levels of protection frequently on an *ad hoc* basis and over time, as different risks present themselves at different times. It is only arbitrary or unjustifiable inconsistencies that are to be avoided.⁴⁸

According to the same report, three elements must be cumulatively demonstrated for a violation of Article 5.5 SPS to exist:

The first element is that the Member imposing the measure

46. See *Japan—Measures Affecting Agricultural Products*, Report of the Appellate Body, WT/DS76/AB/R (Feb. 22, 1999).

47. *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, Report of the Appellate Body, WT/DS26/AB/R (Jan. 16, 1998).

48. *Id.*

complained of has adopted its own appropriate levels of sanitary protection against risks to human life or health in several different situations. The second element to be shown is that those *levels of protection* exhibit arbitrary or unjustifiable differences ('distinctions' in the language of Article 5.5) in their treatment of different situations. The last element requires that the arbitrary or unjustifiable differences result in discrimination or a disguised restriction of international trade. We understand the last element to be referring to the *measure* embodying or implementing a particular level of protection as resulting, in its application, in discrimination or in a disguised restriction on international trade . . . We consider the above three elements of Article 5.5 to be cumulative in nature; all of them must be demonstrated to be present if violation of Article 5.5 is to be found. In particular, both the second and third elements must be found.⁴⁹

According to the *Hormones* Appellate Body report, despite the fact that the European Community prohibited the use of some hormones in beef production, it authorised others for pig production. This was held compatible with Article 5.5 of the SPS, even though this difference of treatment was found to be arbitrary or unjustifiable. The fact of the matter was that, in the Appellate Body's view, the third element of its three-prong test was not met. The motivation of the Appellate Body is found in § 245 of the Report:

We do not attribute the same importance as the Panel to the supposed multiple objectives of the European Communities in enacting the EC Directives that set forth the EC measures at issue. The documentation that preceded or accompanied the enactment of the prohibition of the use of hormones for growth promotion and that formed part of the record of the Panel makes clear the depth and extent of the anxieties experiencing within the European Communities concerning the results of the general scientific studies (showing the carcinogenicity of hormones), the dangers of abuse (highlighted by scandals relating to black-marketing and smuggling of prohibited veterinary drugs in the European Communities) of hormones and other substances used for growth promotion and the intense concern of consumers within the European Communities over the quality and drug-free character of the

49. *Id.* §§ 214-15.

meat available in its internal market.⁵⁰

The *Salmon* Appellate Body Report applies the same three-prong test when it examines the compatibility of an Australian measure with Article 5.5 of the SPS.⁵¹ It further confirms the finding of the *Hormones* Appellate Body Report that differences in level of protection are a “warning signal” that the implementing measure in its application might be a discriminatory measure.⁵² It thus confirms that different levels of protection as such are not enough to satisfy the third element of the three-prong test. To this effect, they are a necessary, but not a sufficient, condition.

The *Salmon* Appellate Body then took note of the fact that the Panel had identified two more warning signals⁵³ and three additional factors.⁵⁴

The Appellate Body agreed with Australia that the first additional factor was a mere restatement of the first warning signal and hence should not be taken into account.⁵⁵ It accepts the remaining part of the Panel’s analysis and concludes as follows:

We have only reversed the Panel’s finding on the first “additional factor.” We consider, however, that this reversal does not affect the validity of the Panel’s conclusion in paragraph 8.159 of its Report, that the “warning signals” and “other factors,” considered cumulatively, lead to the conclusion that the distinctions in the level of protection imposed by Australia result in a disguised restriction on international trade.⁵⁶

At first glance, a discrepancy appears to exist between the two reports although the same standard was applied. There are two distinguishing factors between the two cases, however, that

50. *Id.* § 245.

51. *See Australia—Measures Affecting Importation of Salmon*, Report of the Appellate Body, WT/DS18/AB/R (Oct. 20, 1998).

52. *See European Communities—Measures Concerning Meat and Meat Products (Hormones)*, Report of the Appellate Body, WT/DS26/AB/R (Jan. 16, 1998).

53. *See Australia—Measures Affecting Importation of Salmon*, Report of the Appellate Body, WT/DS18/AB/R (Oct. 20, 1998) (citing substantial difference in levels of protection and inconsistency of SPS measure at hand with Article 5.1 SPS).

54. *Id.* §§ 167-74 (citing discrimination between salmon and herring used as bait, substantial but unexplained change in conclusion between two Reports recommending said SPS measures, and the absence of controls on internal movement of salmon products within Australia).

55. *Id.* § 169.

56. *Id.* § 177.

probably explain the difference in the outcome: First, § 8.32 of the *Salmon* Panel Report states that “the protection of human life or health is not at issue in this dispute.” Second, the anxieties of consumers mentioned in the *Hormones* Appellate Body report were reflected in the EC Directive (in its preamble) but not at all in Australian SPS. Indeed this could hardly be the case since, as Australia admitted, human life or health was not an issue. It appears hence, that the Appellate Body is leaning towards a more deferential standard when human life or health is at stake.⁵⁷

H. *National Standards Can be Adopted Even in Absence of Scientific Evidence (Article 5.7 of the SPS)*

Article 5.7 of the SPS reflects the “precautionary” principle, which allows WTO Members to take SPS measures even in absence of scientific evidence. Absence of scientific evidence is not tantamount to a statement that WTO Members are completely unconstrained when enacting SPS measures under Article 5.7 of the SPS. The *Varietals* Appellate Body Report explains that:

[A] Member may provisionally adopt an SPS measure if this measure is: (1) imposed in respect of a situation where “relevant scientific information is insufficient”; and (2) adopted “on the basis of available pertinent information.” Pursuant to the second sentence of Article 5.7, such a provisional measure may not be maintained unless the Member which adopted the measure: (1) “seek[s] to obtain the additional information necessary for a more objective assessment of risk” and (2) “review the . . . measure accordingly within a reasonable period of time.” These four requirements are clearly cumulative in nature and are equally important for the purpose of determining consistency with this provision. Whenever *one* of these four conditions is not met, the measure at issue is inconsistent with Article 5.7.⁵⁸

Since the Panel did not examine the two elements appearing in the first sentence of Article 5.7 of the SPS and based its conclusions only on the elements appearing in the second sen-

57. See generally Robert Howse, *Democracy, Science and Free Trade: Risk Regulation on Trial at the WTO*, 98 MICH. L. REV. 2329 (2000) (forthcoming).

58. *Japan—Measures Affecting Agricultural Products*, Report of the Appellate Body, WT/DS76/AB/R (Feb. 22, 1999).

tence, the Appellate Body did not have the opportunity to interpret the first sentence.

With respect to the elements appearing in the second sentence, the Appellate Body observed:

Article 5.7 states that the additional information is to be sought in order to allow the Member to conduct “a more objective assessment of risk.” Therefore, the information sought must be germane to conducting such a risk assessment, i.e., the evaluation of the likelihood of entry, establishment or spread of, *in casu*, a pest, according to the SPS measures which might be applied.”⁵⁹

And later:

[W]hat constitutes a “reasonable period of time” has to be established on a case-by-case basis and depends on the specific circumstances of each case, including the difficulty of obtaining the additional information necessary for the review *and* the characteristics of the provisional SPS measure. In the present case, the Panel found that collecting the necessary additional information would be relatively easy. Although the obligation “to review” the varietal testing requirement has only been in existence since 1 January 1995, we agree with the Panel that Japan has not reviewed its varietal testing requirement “within a reasonable period of time”.⁶⁰

What emerges from case-law, however, is that the additional information must be pertinent and that in case it is relatively easy for a WTO Member to collect the additional necessary information, such collection must have taken place within four years (since the Appellate Body Report was issued on February 22, 1999).

We are still in the dark, however, as to the interpretation of the term “available pertinent information” as it appears in the first sentence of Article 5.7 of the SPS. This term is perhaps the cornerstone of the whole Article: Since it is by definition less authoritative than scientific evidence, we need to know how much less is necessary for the “precautionary” principle to be invoked in the first place.

59. *Id.* § 92.

60. *Id.* § 93 (emphasis added).

I. *To Prove SPS Consistency: Allocation of Burden of Proof to the Parties and the Extent of Control by WTO Adjudicating Bodies*

The WTO (like most public international law bodies) contains a de-centralized system of enforcement. This means, among other things, that, in principle, parties to a dispute will carry the burden of proof for their arguments. On the other hand, WTO adjudicating bodies administer the process and are obliged, under Article 11 of the DSU, to conduct an objective assessment of the dispute before them. An issue intimately connected with the allocation of burden of proof is the question whether WTO adjudicating bodies can move away from claims presented to them by the parties to a dispute in order to honour their commitment to provide an objective assessment. In other words the question arises as to whether WTO adjudicating bodies have to provide an objective assessment within what has been submitted by the parties to the dispute or, conversely, whether in order to provide an objective assessment they can move to arguments and claims not submitted by the parties?

The role of panels in seeking expert evidence is laid out in a rudimentary form in Article 13 of the DSU and Article 11.2 of the SPS, which essentially enable WTO adjudicating bodies to look for outside expertise in order to decide SPS-related cases. However, none of the texts mentioned makes it clear whether such expertise should be confined to the claims and arguments as presented by parties to the dispute or whether it can extend to issues not covered by the parties.

Hence, there is an intimate relationship between allocation of the burden of proof and the extent of control by WTO adjudicating bodies. We take each issue in turn.

The *Hormones* Appellate Body report establishes the rule to be followed when allocating the burden of proof:

The initial burden lies on the complaining party, which must establish a *prima facie* case of inconsistency with a particular provision of the *SPS Agreement* on the part of the defending party, or more precisely, of its SPS measure or measure complained about. When the *prima facie* case is made, the burden of proof moves to the defending party, which must in turn

counter or refute the claimed inconsistency.⁶¹

Hence, it is clear that there is nothing like an *ex ante* control of consistency of SPS measures. Such measures are presumed to be consistent with the WTO unless challenged (and proven to be inconsistent) before a WTO adjudicating body.

The issue presented itself once again in the context of the *Varietals* litigation. This time, however, with a slight “twist” that actually bridges the gap between burden of proof and extent of control by WTO adjudicating bodies, the United States claimed that Japan did not use the least restrictive option to reach its objective.⁶² According to the U.S. argument, Japan should have conducted a “testing by product” in order to ensure that its regulatory objective be met. The Panel sought advice from experts to see if Japan indeed had not chosen the least restrictive option. It did so, however, not with respect to “testing by product,” as the United States had argued, but with respect to “sorption levels”—another method used to reach Japan’s revealed preference, which had not been argued by the United States. Hence, the question arose whether the Panel had exceeded the limits of its power by seeking expertise to establish that another (potentially) less restrictive method, not argued by the complaining party, could have helped Japan reach its objective. The Appellate Body dealt with the issue in the following manner: “[w]e note that the Panel explicitly stated that the United States, as complaining party, did *not specifically argue* that the ‘determination of sorption levels’ met any of the three elements under Article 5.6.”⁶³ And later:

Article 13 of the DSU allows a panel to seek *information* from any relevant source and to consult individual experts or expert bodies to obtain their *opinion* on certain aspects of the matter before it. In our Report . . . we noted the “comprehensive nature” of this authority . . . to enable a panel to discharge its duty imposed by Article 11 of the DSU. . . .⁶⁴

And then:

61. *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, Report of the Appellate Body, WT/DS26/AB/R (Jan. 16, 1998).

62. *See Japan—Measures Affecting Agricultural Products*, Panel Report, WT/DS76/R (Oct. 27, 1998).

63. *Japan—Measures Affecting Agricultural Products*, Report of the Appellate Body, WT/DS76/AB/R (Feb. 22, 1999)

64. *Id.* § 127.

[W]e note that the present dispute is a dispute under the *SPS Agreement*. Article 11.2 of the *SPS Agreement* explicitly instructs panels in disputes under this Agreement involving scientific and technical issues to “seek advice from experts.”⁶⁵

And finally:

Article 13 of the DSU and Article 11.2 of the *SPS Agreement* suggest that panels have a significant investigative authority. However, this authority cannot be used by a panel to rule in favour of a complaining party which has not established a *prima facie* case of inconsistency based on specific legal claims asserted by it. A panel is entitled to seek information and advice from experts and from any other relevant source it chooses, pursuant to Article 13 of the DSU and, in an SPS case, Article 11.2 of the *SPS Agreement*, to help it to understand and evaluate the evidence submitted and the arguments made by the parties, but not to make the case for the complaining party.⁶⁶

In a nutshell: The Panel at hand could have sought expertise to ensure that the U.S. argument with respect to “testing by product” was indeed correct but could not have done so with respect to “sorption levels” since the complaining party—the United States—did not make a specific argument to this effect. This means that panels have unlimited discretion to seek outside expertise in order to determine whether a *prima facie* case has been made. This point was further underlined in the *India—Quantitative Restrictions* case where the Appellate Body dealt with the question whether the Panel erred in seeking IMF (International Monetary Fund) expertise when examining whether the complaining party had indeed made a *prima facie* case. There, the Appellate Body held:

We do not interpret the above statement as requiring the panel to conclude that a *prima facie* case is made before it considers the views of the IMF or any other experts that it consults. Such consideration may be useful in order to determine whether a *prima facie* has been made.⁶⁷

Thus, a party challenging an SPS measure carries the burden of proof to show that the measure at hand is inconsistent

65. *Id.* § 128.

66. *Id.* § 129.

67. See *India—Quantitative Restrictions on Imports of Agricultural, Textile and Industrial Products*, Report of the Appellate Body, WT/DS90/AB/R (Apr. 6, 1999).

with the treaty. WTO adjudicating bodies can seek expertise to persuade themselves about the well-foundedness of the arguments presented by the parties to the dispute but cannot move to arguments not presented by the parties. That is, to use the cited *Varietals* litigation as example, WTO adjudicating bodies can seek expertise to examine the well-foundedness of the U.S. argument with respect to "testing by product." If they conclude that the U.S. argument is not correct, they cannot move on to examine whether another method (the 'sorption levels') is indeed less restrictive than the one chosen by Japan, even if they know that this is the case.

J. *The Role of the Expert Witness in the Quest for the Truth*

Article 13 of the DSU and Article 11.2 of the SPS allow WTO adjudicating bodies to select experts in consultation with the parties to the dispute. In the context of SPS, seeking outside expertise is a routine experience. This is so because of the issues involved: panelists are rarely accustomed to addressing scientific issues.

In the *Hormones* litigation, the panel first asked parties to the dispute to name one expert each. It then named two experts (from a list prepared by the Codex Commission and the International Agency for Research on Cancer) and one additional expert in the area of carcinogenic effects of hormones.⁶⁸ The European Community appealed the fact that one of the experts was national of a party or third party and had links with the pharmaceutical industry. The Appellate Body, distinguishing the selection of expert witnesses in the context of SPS from expert review groups (Appendix 4 of the DSU), dismissed the EC argument and held that: "[o]nce the panel has decided to request the opinion of individual scientific experts, there is no legal obstacle to the panel drawing up, in consultation with the parties to the dispute, *ad hoc* rules for those particular proceedings."⁶⁹

In the *Salmon* case, the Panel chose four experts after con-

68. See *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, Complaint by the United States, Report of the Panel, WT/DS26/R/USA (Aug. 18, 1997).

69. *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, Report of the Appellate Body, WT/DS26/AB/R (Jan. 16, 1998).

sultations with the Office International des Epizooties (“OIE”).⁷⁰ Finally, in the *Varietals* dispute, the Panel chose three experts after soliciting suggestions from the Secretariat of the International Plant Protection Convention (“IPCC”).⁷¹

Panels, it appears, will—in consultation with the parties to the dispute—seek expertise from outside sources following suggestions by the organizations mentioned in the SPS Agreement (i.e., OIE, IPCC, Codex). In the *Hormones* litigation, the parties to the dispute were given the opportunity to name one expert each.

In these cases the panels have exhibited some confusion about the appropriate role of scientific expertise. For example, in the *Salmon* case they asked laboratory natural scientists questions that related to the costs and benefits of regulatory alternatives, which bears on matters of politics and economics. It should not be presumed that the relevant expertise in SPS cases will always be that of natural scientists—following on the remarks of the Appellate Body in *Hormones* case about the real world in which people live and die, expertise concerning the effectiveness and consequences—social and economic, or even cultural—of particular forms of risk management and regulatory intervention may be appropriate.

K. *A Partial Conclusion*

The case law so far on SPS can be reduced to the following set of propositions:

- WTO Members can enact definitive SPS measures provided that a risk assessment has taken place.
- WTO Members can also enact provisional SPS measures in the absence of a risk assessment in the light of available pertinent information.
- When WTO Members enact definitive SPS measures, their risk assessment must be based on scientific evidence.
- For evidence to be considered scientific, some minimum requirements of procedural or methodological rigour must be met.
- SPS measures can be enacted following a risk assessment

70. See *Australia—Measures Affecting Importation of Salmon*, Report of the Appellate Body, WT/DS18/AB/R (Oct. 20, 1998).

71. *Id.*

based on minority scientific opinions, including views from “non-mainstream” science.

- The scientific evidence does not have to be provided at the moment an SPS measure is enacted; however, it must be provided when an SPS measure is challenged before a WTO panel.
- The scientific evidence supplied must support the view that there is more than a mere abstract or hypothetical possibility of the risk materializing unless the SPS measure at hand is enacted; there must be some actual empirical investigation or inquiry into risk.
- WTO Members are free to set the level of risk they are willing to undertake at any level they deem appropriate. When setting their objective, WTO Members can take into account economic factors as well.
- WTO adjudicating bodies can only examine to what extent the means chosen to achieve the level sought are the least restrictive of trade, and a Member’s duty to ensure that its *regulatory process* generates least trade-restrictive regulatory alternatives may be less onerous in cases of obvious serious threats to human health than in other kinds of situations.
- In order to examine whether an SPS measure is in accordance with the SPS Agreement, WTO adjudicating bodies can have recourse to expert witnesses. WTO adjudicating bodies select expert witnesses from the organizations mentioned in the SPS Agreement in consultation with the parties to the dispute. They might as well allow the possibility to parties to the dispute to name their own experts in addition to those named by the panel. WTO adjudicating bodies can decide to take into account unsolicited expertise.
- WTO Members challenging an SPS measure carry the original burden of proof to show that the relevant provisions of the SPS Agreement have not been complied with (inconsistency of an SPS measure with any of the above points mentioned above).
- WTO adjudicating bodies can seek outside expertise to inform themselves about the well-founded of a party’s argument but they have to use such expertise only to inform themselves about the value of arguments as presented by the parties and not in order to evaluate arguments that have not been presented by a party.
- When a WTO Member invokes the right to take provisional measures prior to a scientific risk assessment, under Article

5.7 it must show a rational relationship between the measure it enacts and the risk it wants to avoid.

- When a WTO Member invokes Article 5.7, it must seek to collect any additional information within a reasonable period of time, which in one case was deemed to be four years.
- In case an SPS measure has found to be inconsistent with the WTO, it must not be revoked *ab initio*. Remedies in the SPS context have an *ex nunc* (prospective) function.

IV. *SANITARY AND PHYTOSANITARY RISKS POSED BY RELEASE OF GENETICALLY MODIFIED ORGANISMS*

The *Manual for Assessing Ecological and Human Health Effects of Genetically Engineered Organisms* (“*Manual*”) summarizes the nature and rationale of genetic modification as follows:

Modern molecular methods increasingly are used to produce organisms that express novel traits. Such methods commonly are referred to as “genetic engineering” (that is, the isolation of nucleic acid molecules from one organism and their subsequent introduction into another organism in such a way that makes them part of the permanent genetic make-up of the recipient and allows them to be inherited by offspring). Genetic engineering techniques currently are used for such diverse purposes as improvement of agricultural crops and crop yields, enhancement of farmed fish and shellfish broodstocks and their associated yields, production of microbes for bioremediation and other specific tasks, and changes in disease-transmission rates by insect vectors.⁷²

The *Manual* identifies four broad types of environmental or human health risk that can arise from the new organisms that are the result of genetic modification (the *process* of genetic modification is not intrinsically hazardous—the risks arise from the characteristics of specific organisms produced from the process).

The first kind of risk is that which arises from characteristics that produce “changes in ecological roles and functions.”⁷³ The *Manual* gives the example of “increased weediness among herbi-

72. Scientists’ Working Group on Biosafety, *Manual for Assessing Ecological and Human Health Effects of Genetically Engineered Organisms* (1998), at <http://www.edmonds-institute.org/manual.html> [hereinafter Scientists’ Working Group].

73. *Id.*

cide-tolerant crops. Increased weediness could have potential negative impacts on surrounding agricultural fields or on wild vegetation in nearby plant communities."⁷⁴ The second kind of risk is "changes in genetic relationships."⁷⁵ This occurs when genetically modified organisms are released into a setting where they cross-breed with other non-modified organisms. While cross-breeding of this kind is not intrinsically hazardous, it can in some cases produce contamination of economically important crops or even extinction of some species. The third kind of risk is characterized as "indirect effects."⁷⁶ This kind of risk occurs simply through the interaction over time of novel organisms to a particular ecosystem, that has not evolved their present characteristics in natural relationship with that ecosystem. The risks here include "changes in population mating structure, alteration of competitive hierarchies, disruption of trophic cascades, and modification of physical and chemical environments on which native species depend."⁷⁷

The fourth kind of risk, which is the one that has most captured the public imagination, is "changes in allergenicity, toxicity, or nutritional composition of foods."⁷⁸ I may know that I am not allergic to non-modified tomatoes, but how do I know that genetically modified versions do not have characteristics that release allergins to which I risk a severe reaction?

Because genetic modification is relatively new as a commercial technology, large scale empirical studies of these various effects are lacking. For obvious safety reasons, field trials have generally been small and undertaken with every effort to contain any large-scale risk from the trial.⁷⁹ One problem, identified by independent scientists, is that much of the relevant information and technical expertise resides with the industrial interests that have a stake in marketing GMOs, or with scientists and researchers with strong industry affiliations. Independent regulatory authorities evaluating risks from GMOs, therefore, face important information asymmetries. Nevertheless, there is an increasing

74. *Id.*

75. *Id.*

76. *Id.*

77. *Id.*

78. *Id.*

79. See ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, SAFETY CONSIDERATIONS FOR BIOTECHNOLOGY: SCALE-UP OF CROP PLANTS (1993).

body of research that is independent of industry,⁸⁰ although the results and methodology are often ferociously contested by the industry and its experts.

V. *PITH AND SUBSTANCE OF EUROPEAN UNION
REGULATION OF DELIBERATE RELEASE OF
GENETICALLY MODIFIED ORGANISMS*

The original centerpiece of EU regulation of GMOs is Directive 90/219/EEC. This Directive was amended in 1997, primarily with a view to introducing compulsory labelling of products containing GMOs. There are related, detailed regulations with respect to use of GMOs in pharmaceuticals, novel foods, feeds, and seeds; but, generally speaking these suppose and supplement the general regulatory approach contained in directive 90/219/EEC as amended.⁸¹ The approach in the Directive is to base approval of the deliberate release of GMOs or their marketing in products in the EU, on prior case-by-case assessment of risk to human health and the environment. GMOs and GMO products are only to be approved if they are determined to be "safe" for the environment and human health, on the basis of scientific risk assessment. The first step in this process is for the importer or manufacturer to notify the relevant authority of an EU member state, requesting permission for release or placing on the market. The notifying entity is required to supply a range of information in its possession that is needed to allow for an assessment of risk to human health and to the environment. If the member state authority approves the request, the Commission and other member states are to be given an opportunity to file objections. A decision is then taken at the Community level by weighted majority voting in the Council. The process of the decision making at the community level, provision is made for consultation with the scientific committees of the Commission. Since the entry into force of the original Directive, eighteen requests have been approved.⁸² However, since 1998, in response

80. See, e.g., Dr. Charles Benbrook, Who Control and Who Will Benefit from Plant Genomics?, Presented before The 2000 Genome Seminar: Genomic Revolution in the Fields: Facing the Needs of the New Millennium, AAAS Annual Meeting, Washington, D.C. (Feb. 19, 2000), at <http://www.biotechinfo.net/AAASgen.html>.

81. European Commission, *Facts on GMOs in EU*, MEMO/00/43 (July 13, 2000) (outlining roadmap of these regulatory schemes).

82. *Id.*

to increased public concern about GMOs many member states have instituted a de facto moratorium on approvals. In some cases, products authorized for placing on the market have been banned, based on Article XVI of the original Directive, which allows member states to take such action "provisionally," where they have "justified reasons" on human health or environmental grounds.

It is against this backdrop that the Directive has recently been revised, the outcome of a reconciliation exercise between the Commission and Council and the Parliament. The Joint Text approved by the Conciliation Committee⁸³ was adopted by the European Parliament in a legislative resolution of February 14, 2001.⁸⁴

A. *International Standards, SPS, and European Regulation of GMOs*

Is evolving EU regulation, especially as reflected in amended directive 90/220, "based on" international standards, guidelines, and recommendations, within the meaning of Article 3.1 of the SPS? Moreover, does it "conform to" international standards, within the meaning of 3.2? In the case of food safety, which is only one of the regulatory concerns in the case of GMOs, the relevant international standards are, according to Annex A of the SPS, those of the Codex Alimentarius Commission, and joint endeavor of the Food and Agriculture Organization ("FAO") and the World Health Organization ("WHO").

The Codex has established an Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology, which is charged with the task of developing standards for assessment of the safety of foods derived from biotechnology by the year 2004.⁸⁵ In addition, certain issues related to the regulation of GMOs are under consideration at the Codex Committee on General Principles (including issues related to the precautionary principle and labelling).

From the SPS perspective the issue is how Articles 3.1 and 3.2 should be applied when the Codex is explicitly in the process

83. CSL 3664/2000, hereinafter, "Joint Text."

84. PE R5 0075/2001.

85. See WORLD HEALTH ORGANIZATION, REPORT OF THE FIRST SESSION OF THE CODEX AD HOC INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY (Mar. 14, 2000).

of developing international standards, but these have not yet been promulgated. Pursuant to SPS Annex A.3(d), where food safety matters are “not covered” by Codex, reference is to be had to appropriate standards, guidelines, and recommendations of other relevant international organizations. Does “not covered” include a situation where the Codex is seized of the matter but has not yet promulgated standards? We submit that such a situation should indeed come under the meaning of “not covered,” for the alternative would be to ignore other relevant international standards until Codex has acted, which would be contrary to some of the general objectives of the SPS Agreement, including the encouragement of the use of harmonized international standards where they exist.⁸⁶

There are a range of non-Codex standards, guidelines, and recommendations concerning the regulation of risks from the release of GMOs, which deal *both* with food safety- *and* non-food safety related risks of GMOs. Of high relevance is the Statement of the FAO, one of the Codex partners, on biotechnology. According to the Statement:

[The] FAO supports a science-based evaluation system that would objectively determine the benefits and risks of each GMO. This calls for a cautious case-by-case approach to address legitimate concerns for the biosafety of each product or process prior to its release. The possible effects on biodiversity, the environment and food safety need to be evaluated, and the extent to which the benefits of the product or process outweigh its risks assessed. The evaluation process should also take into consideration experience gained by national regulatory authorities in clearing such products. Careful monitoring of the post-release effects of these products and processes is also essential to ensure their continued safety to human beings, animals and the environment.⁸⁷

While these suggestions are perhaps too general to be considered as standards, they are certainly at a minimum, recommendations or guidelines.

The *Cartagena Protocol on Biosafety*, concluded at Montreal last year—to which the European Union member states are sig-

86. See SPS Agreement.

87. Food and Agriculture Organization of the United Nations, FAO Statement on Biotechnology (2000), at <http://www.fao.org/biotech/state.htm> [hereinafter *FAO Statement*].

natories—facilitates the approach, recommended by the FAO, of case-by-case analysis prior to release, by imposing rights and obligations with respect to advance notice of proposed cross-boundary movement of GMOs and related material.⁸⁸ The *Protocol* also requires scientifically sound assessment of risk (Article 15), and in an Annex promulgates general principles and guidelines with respect to the methodology and factors to be taken into account in risk assessment. Further, the *Protocol* states that:

Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on conservation and sustainable use of biological diversity, taking also into account risk to human health, within the territory, of the Party of import.⁸⁹

Within 270 days of notification, a country of import must provide its decision to the notifier as to whether the import is permitted, and if so, under what conditions (Article 10).⁹⁰ To date sixty-eight states have signed the *Protocol*; because it is open to signature by any WTO Member (in fact by any State), the *Protocol* qualifies as the standards, guidelines, or recommendations of a relevant international organization, within the meaning of SPS Annex A.

By contrast, although the OECD has promulgated various guidelines with respect to biotechnology, as an organization whose membership is not open to all WTO Members, these pronouncements do not qualify as international standards within the meaning of the SPS.⁹¹

The main features of EU regulation, as reflected in the revised directive, and the novel foods regulation, are based on the approach now formally reflected in the international standards, namely case-by-case risk assessment prior to release of each individual GMO.⁹² Like both the FAO Statement and the *Cartagena Protocol on Biosafety*, EU regulation requires such risk assessment.

88. See Cartagena Protocol on Biosafety (Feb. 23, 2000, at http://www.jiwl.com/contents/Cartagena_Protocol.htm [hereinafter *Cartagena Protocol on Biosafety*]).

89. *Id.* art. 16.2.

90. *Id.* art. 10.

91. However, to the extent that the parties to an SPS dispute are also OECD members, OECD guidelines would still be relevant as sources of treaty interpretation under the Vienna Convention on the Law of Treaties, May 23, 1969, 115 U.N.T.S. 331 (entered into force Jan. 27, 1980) [hereinafter Vienna Convention].

92. Art 4.2, 4.3.

The amended Directive requires an environmental risk assessment (“ERA”) to be undertaken by the notifier, which provides the basis for an assessment report by competent member state authorities. While not identical, the kinds of risks and factors to be taken into account in ERA and in the Assessment Report are quite similar to those set out in the *Cartagena Protocol on Biosafety*. In several respects, the EU regulation is more favorable to imports than the *Cartagena Protocol on Biosafety*—it specifies a shorter time period for an initial decision of national authorities on whether release is to be permitted (ninety days). The amended EU directive specifically bans restrictions or prohibitions by member states on the placing on the market of GMOs that comply with the requirements of the directive (Article 22); in effect then restrictions on market access are as a matter of law limited to those based on health and environmental risks.

Does the EU regulation “conform to” international standards within the meaning of 3.2 of the SPS Agreement? The meaning of “conform to” is, according to the Appellate Body (as noted in the first part of this Essay), stricter than “based on.” Article 3.2 must be read in conjunction with Article 3.3—thus the real issue is whether in all relevant respects the EU regulation does not attempt to achieve a *higher* level of protection than that which would be achieved by international standards.

There are several relevant respects in which EU regulation could be considered to aim at a higher level of protection. While the FAO Statement appears to impose upon risk assessment a kind of cost benefit analysis, where if the prospective benefits of a GMO outweigh the risks identified in risk assessment the GMO might well be released, the approach of the EU directive is apparently more cautious. The the amended directive provides that “Member States shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or placing on the market of GMOs.”⁹³ The principles for Environmental Risk Assessment in Annex II and the Guidelines for Assessment Reports of member state authorities in Annex VI focus exclusively on risks. Potential benefits of release or placing on the market appear to play no part in the approval process. However, the FAO Statement does not suggest that in all cases

93. Art. 4.1.

release is appropriate if benefits outweigh costs.⁹⁴ It does, nevertheless, call for an assessment of benefits in relation to costs.

The *Cartagena Protocol on Biosafety* calls for the taking of measures that are “necessary” to protect biodiversity and human health as well. Does the use of the expression “appropriate” in the EU Directive indicate a higher standard of protection than the necessity test in the *Cartagena Protocol on Biosafety*? The answer is not ascertainable in the abstract, but depends upon the actual practice of EU member states in implementing the Directive, which so far, under the 1990 Directive, including as amended in 1997, has varied considerably.⁹⁵ However, the Guidelines for Assessment Reports define the relevant risks to human health and the environment from GMOs as “any new risks that may arise from the release of GMOs as *compared to* the release of the corresponding non-modified organism(s).”⁹⁶ Thus, while the amended directive requires that all appropriate measures be taken to ensure “safety,” the standard for safety is a relative one—relative to the existing levels of safety with respect to corresponding non-modified organisms. By contrast, the standard in the *Cartagena Protocol on Biosafety* is an absolute one, requiring that all necessary measures be taken to prevent harm to the environment from GMOs, apparently regardless of whether a signatory is taking comparable precautions against environmental harm or human health impacts from non-GMO products and materials.⁹⁷ In this sense, the level of protection in the *Cartagena Protocol on Biosafety* may actually be *higher*, rather than lower, than that provided for in the amended Directive. However, it is to be noted that Article 32 of the amended directive envisages that the Cartagena Protocol shall be fully implemented in EU law, and that where necessary there be further amendments to the directive in order to accomplish this.

Secondly, while the amended directive contains even more complex and precise provisions on labelling and traceability than did the 1997 amendment to the 1990 GMOs directive, neither the FAO Statement nor the *Cartagena Protocol on Biosafety*

94. See *FAO Statement*, *supra* note 87.

95. See René von Schomberg, *An Appraisal of the Working in Practice of Directive 90/220/EEC on the Deliberate Release of Genetically Modified Organisms*, Jan. 2, 1998, at http://www.europarl.eu.int/stoa/publi/pdf/gmostudy_en.pdf.

96. Annex VI(4) (emphasis added).

97. See *Cartagena Protocol on Biosafety*, *supra* note 88.

explicitly requires labelling. However, the FAO Statement declares that “[c]areful monitoring of the post release effects of these products and processes is also essential to ensure their continued safety human beings, animals and the environment.”⁹⁸ Without the ability to identify and trace the presence of GMOs in particular products or processes, monitoring their effects once released would be highly impracticable, if possible at all. Hence, labelling and traceability requirements are, in the context of GMOs, a necessary implication of the notion of “careful monitoring of post release effects,” and in this sense conform to the standards, guidelines, and recommendations in the FAO Statement. Moreover, as is recognized in the provisions in the *Cartagena Protocol on Biosafety* on transboundary shipment of GMOs, identification may be crucial to risk management and control, preventing inadvertent release of GMOs in contexts or ecosystems where they can cause damage. In the case of foods and food products as well, labelling may be a “necessary” measure for the protection of human health within the meaning of Article 16 of the *Cartagena Protocol on Biosafety*, alerting persons with allergies, or hyper-sensitivity to certain foods that the properties in a food containing GMOs may be different from those in the non-modified version, which are known to such individuals as safe for them.⁹⁹ This is discussed further below.

Finally, the amended directive, in the guidelines for Assessment Reports by member state authorities, provides for “assessment of whether the genetic modification has been characterized sufficiently for the purpose of evaluating any risks to human health and the environment.”¹⁰⁰ This raises the possibility that an assessment report could come to the conclusion that a GMO not be released on precautionary grounds, i.e., because of not being able to characterize the modification sufficiently in order to evaluate risks to human health and the environment. This is reinforced by references to the Precautionary Principle in a number of places in the amended directive, and especially in Article 4.1, which states that all appropriate measures are to be taken to avoid adverse effects “in accordance with the precautionary principle.” However, this conforms with the articulation

98. *FAO Statement*, *supra* note 87.

99. See Gillian Hadfield & David Thomson, *An Information-Based Approach to Labelling Biotechnology Consumer Products*, 21 J. CONSUMER POL'Y 193 (1998).

100. Annex VI, para. 3.

of the Precautionary Principle in the *Cartagena Protocol on Biosafety*, Article 11.8 of which provides:

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate with regard to the import of that living modified organisms intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.¹⁰¹

In sum, it is our view that evolving EU regulation as reflected in the amended directive, and in the novel foods regulation, conforms to such international standards, recommendations, and guidelines as now exist, within the meaning of the SPS Agreement. At the same time, since, as noted, international standards are evolving, particularly in Codex Alimentarius, it is far from an academic exercise to consider, *arguendo*, if EU regulation, as it is evolving, could be sustained under the SPS if it did not “conform to” international standards, but sought to achieve a higher level of protection.

B. Articles 2.2 and 5.1-5.3 of the SPS

To the extent that there are elements of EU regulation that seek to establish a higher level protection, they do not enjoy the presumption that they are maintained on the basis of sufficient scientific evidence¹⁰² and they must be maintained consistently with the various provisions of Article 5.¹⁰³ As recalled, in the *Varietals* case, the Appellate Body, elaborating on its decision in the *Hormones* case, stated that the sufficient evidence standard in Article 2.2 is met where there is a rational connection between scientific evidence on the record and the measures taken.¹⁰⁴ However, the Appellate Body also indicated that a case-by-case

101. *Cartagena Protocol on Biosafety*, *supra* note 88, at art. 11.8.

102. See SPS Agreement art. 2.2.

103. See *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, Report of the Appellate Body, WT/DS26/AB/R (Jan. 16, 1998) (stating interpretation by Appellate Body of art. 3.3 of SPS Agreement).

104. See *Japan—Measures Affecting Agricultural Products*, Report of the Appellate Body, WT/DS76/AB/R (Feb. 22 1999).

contextual judgement is needed about what kind of underlying scientific evidence satisfies the requirement of rational connection. In some cases, this would have to include evidence probative of causal relationships.

To recall, Article 5.1 of the SPS requires that measures be based on an assessment of risk "appropriate in the circumstances." Articles 5.2 and 5.3 list a variety of factors to be taken into account in such risk assessments.

The amended directive requires that a member state determination of whether release and marketing of GMOs or GMO products is permitted be based on an Environmental Risk Assessment. This ERA is to be conducted by the firm requesting the permission. On the basis of this ERA, the member state authorities must prepare an Assessment Report. As already noted, the Report must include, *inter alia*, "[and] assessment of whether the genetic modification has been characterized sufficiently for purpose of evaluating any risks to human health and environment,"¹⁰⁵ and "[i]dentification of any new risk to human health and the environment that may arise from the release of the GMOs in question as compared to the release of the corresponding non-modified organisms, based on the environmental risk assessment."¹⁰⁶ Where it is concluded that a GMO should not be placed on the market, reasons must be given in the assessment report. While these provisions do not adopt the exact language of SPS Article 2.2, it is fairly obvious that the amended directive requires that the decision to prohibit release or marketing of GMOs be based on reasons grounded in scientific evidence of risks to human health and the environment. The only apparent exception is where the competent authority determines that there is insufficient scientific evidence to evaluate risk, in which case the overall approach of the amended directive would appear to permit a decision against release or marketing on precautionary grounds. In such a case, there would be a violation of SPS Article 2.2 unless the decision could be justified under SPS Article 5.7, to which we shall turn later in this article.

With respect to the labelling and traceability requirements as they exist in the amended directive,¹⁰⁷ an issue might seem to

105. Annex VI.3.

106. *Id.*

107. *See* Art. 19.3(e), Art. 21, Annex IV.

arise under Article 2.2, since the labelling and traceability requirements apply generally, regardless of the results of case-by-case risk assessment. However, these requirements must be understood in light of the inherent limitations of existing techniques of risk assessment to achieve high levels of certainty about the health and environmental effects of GMOs.¹⁰⁸ The quality and precision of risk assessment may depend upon increasing information about the effects of release of GMOs in the real world. Regardless of whether a new GMO has passed a risk assessment, there is likely to be continuing uncertainty as to its actual health and ecological effects. Without labelling and traceability, identifying genetic modification as a possible cause of real world health and ecological effects would be rendered much more difficult and costly. It would be contrary to the principle of effective treaty interpretation to read Article 2.2 of the SPS as raising a bar to measures that are themselves conditions precedent to fully adequate scientific assessment of risk, or to providing Members with a more adequate scientific foundation for their measures in the future. Moreover, as the Appellate Body emphasized in *Hormones*, risk assessment—in which it is determined whether scientific evidence is sufficient—includes consideration of the requirements of controlling risk in the real world, not just the laboratory. Thus, even if the labeling requirement is not the outcome of the case-by-case risk assessment required to determine whether more restrictive measures are appropriate, it can nevertheless be justified, in terms of a cost-effective response with respect to foods at least. But for labelling, the real and largely uncontroversial risk that genetically modified foods may contain allergens and toxins not contained in the non-genetically modified versions would be indistinguishable to the “thin-skull” or particularly susceptible consumer.

The substantive threshold of “sufficient” scientific evidence in SPS Article 2.2 is closely related to the procedural requirements of risk assessment as set out in SPS Articles 5.1-5.3. These latter provisions require that SPS measures be based on a scientific assessment or risk and specify some of the factors that must be taken into account. As discussed in depth in the first part of this Essay, in the *Salmon* case, the Appellate Body held that

108. See Von Schomberg, *supra* note 95; see also Scientists' Working Group, *supra* note 72.

under Article 5, a risk assessment must establish not simply the mere possibility of a risk event occurring but rather the likelihood or probability of such an event.¹⁰⁹ At the same time, in not requiring that such assessment of likelihood or probability be quantitative, the AB apparently embraced the view that the SPS Agreement does not establish or impose thresholds for scientific certainty, determinacy, or margins of error, below which SPS measures are not considered to be “based on” scientific risk assessment, other than the threshold of “sufficient scientific evidence” in Article 2.2. It is in this sense that the precautionary principle is built into Article 5 *as a whole*—it does not prevent regulators from acting in response to possible serious harm even where there are significant elements of uncertainty or indeterminacy in the risk assessment.

In the case of GMOs, these elements of uncertainty or indeterminacy are of several different kinds. One kind of uncertainty relates to the extent one can extrapolate results of small field trials to larger regions, populations, or ecosystems. Investigators have been understandably reluctant to expose larger populations of humans or other species to such trials, precisely because the extent of adverse effects is not well known yet.¹¹⁰ One response might be to conduct computer simulations based upon existing knowledge of the properties of larger ecosystems. But here too there are inevitable elements of uncertainty or imprecision in predicting effects in actual ecosystems. Another kind of uncertainty relates however to the simple failure to design and conduct a particular experiment: “[F]or example, we may not know how bio-tech crops will affect soil micro-organisms simply because experiments have not been designed to detect such effects.” It is doubtful whether this kind of uncertainty in risk assessment could be acceptable under the SPS, since it results from a failure to undertake possible further investigations. However, in the case of prevention of life threatening risks where those further investigations are unwarranted from the perspective of costs or would result in delays of a kind that could result in irreparable harm, it might be possible to mount a justification for regulations on the basis of more uncertain results.

109. See *Australia—Measures Affecting Importation of Salmon*, Report of the Appellate Body, WT/DS18/AB/R (Oct. 20, 1998).

110. See generally, Von Schomberg, *supra* note 95.

The Principles for Environmental Risk Assessment in Annex II of the amended directive address themselves to the range of factors stated in SPS Articles 5.1-3.¹¹¹ Potential adverse effects of the GMO are to be identified, as well as the magnitude of such effects, and the likelihood of their occurrence. This is to be the basis for an estimate of risk to health and the environment, to the extent that the state of the art permits such an estimate to be made. The ERA is to be carried out in a scientifically sound and transparent manner. They are moreover broadly consistent as already noted with the risk assessment guidelines present in the *Cartagena Protocol on Biosafety* and they are reflective as well of best scientific practice, as codified for instance in the Scientists' Work Group on *Manual*.¹¹²

With respect to the requirement stated in the definition of risk assessment in Annex A, paragraph 4 of the SPS, that a risk assessment evaluate the "likelihood" of adverse effects materializing the Principles in Annex II of the amended directive would appear to satisfy the concern of the Appellate Body in *Salmon* that evaluation of "likelihood" not merely be a matter of stating a vague or abstract possibility, but consist in an effort to state with some precision or specificity the incidence of risk.¹¹³ Thus, evaluation of the "likelihood of the occurrence of each identified potential adverse effect" is required, taking into account the real-world conditions of the environment into which the release is going to take place.¹¹⁴ Similar precision is required with respect to estimation of the magnitude of the harmful consequences. Moreover, with respect to effects, these must be clearly classified in terms of direct or indirect, and immediate or delayed.

Of particular importance, given the apparent availability of more precise and adequate techniques of risk assessment in cases like *Salmon* and *Varietals*,¹¹⁵ is the stipulation in the Principles that "estimation" of risk be made as far as possible, "given

111. See Annexes II, VI.

112. See generally, Scientists' Working Group, *supra* note 72.

113. See *Australia—Measures Affecting Importation of Salmon*, Report of the Appellate Body, WT/DS18/AB/R (Oct. 20, 1998).

114. *Common Position* Annex II, Part C, para. B.

115. The defendants in both of these cases did not give adequate explanations of their failure to employ.

the state of the art.”¹¹⁶

C. *Articles 5.4 and 5.6 of the SPS: Least-Restrictiveness of Trade*

Article 5.4 of the SPS states that Members should take into account the “objective of minimizing negative trade effects” when determining the appropriate level of protection. In turn, Article 5.6 requires that Members ensure that measures adopted are the least trade restrictive necessary to achieve the appropriate level of protection, “taking into account technical and economic feasibility.”

As the Appellate Body has emphasized particularly in the *Salmon* case, the application of Article 5.6 requires a characterization of a Member’s appropriate level of protection. As we have already suggested, the level of protection implicit in the amended directive is that of “safety,” *relative* to the corresponding non-genetically modified product or process and as determined by case-by-case risk assessment. In other words, the EU judges unacceptable *any* margin of risk beyond that posed by non-genetically modified equivalents. To what extent does this level of protection reflect the obligation to “take into account” the objective of minimizing negative trade effects in SPS Article 5.4? In this regard it should be noted that, in selecting as an effective baseline the degree of safety *already* required of non-modified organisms, the EU has chosen a level of protection consistent with the established expectations of its trading partners as to the conditions of market access for their products and processes to the common market, insofar as human health and environmental safety are concerned.

With respect to the least trade restrictive requirement in SPS Article 5.6, there are a number of features in amended directive that have the effect of limiting the potential trade restrictiveness of member states’ measures on GMOs. First, as noted above, 22 provides that once a GMO or GMO-containing product has been approved as safe on the basis of risk assessment, no further restrictions or prohibitions on market access shall be imposed by member states’ authorities (except where there is new information suggesting imminent threat to the environment or human health). Secondly, to the extent that the EU’s appropriate level of protection can be satisfied by less onerous or more

116. Annex II, C.2.4. para. 5.

expeditious approval procedures, provision for these is made in the amended directive.¹¹⁷ Thirdly, the amended directive contemplates the possibility of conditional consent to placing of GMOs on the market, i.e., that through appropriate methods of risk containment or risk management, the appropriate level of safety can be maintained without the obviously more trade-restrictive response of a denial of permission to market the GMO product or process.¹¹⁸ Finally, in order that labelling requirements not become an unnecessary impediment to market access, in cases where ascertaining whether there are “adventitious” traces of authorized GMOs in a particular product is technically unfeasible, the amended directive allows member states to establish a minimum threshold, below which labelling is not required.¹¹⁹ Moreover, the time frames provided in the amended directive for decisions on individual GMOs appear close to the minimum that could reasonably be required to undertake the necessary scientific verification and for regulatory decision-making consistent with meaningful consultation of scientific experts and the public.

The amended directive also reflects the recognition that scientific knowledge of GMOs is in a state of transition, as is the industry itself, and thus provides for review of experience with the directive in 2003. This review is to consider, *inter alia*, whether sufficient experience has occurred with “differentiated” i.e., streamlined procedures, to expand the scope for permitting the release or placing on the market of GMOS without prior individualized risk assessment.¹²⁰ Thus, at a point at which scientific knowledge and regulatory experience is such that a less restrictive approach is appropriate, it is foreseen that such an approach may be adopted.

D. SPS Article 5.5: “Arbitrary or Unjustifiable Distinctions”

Article 5.5 of the SPS requires that WTO Members avoid arbitrary or unjustifiable distinctions in the levels of protection they consider appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on inter-

117. *See id.* art. 7.

118. *See id.* art. 18, 3.c.

119. *See id.* art. 21.2.

120. *See id.* art. 31.7.c.

national trade. As already noted, the *Common Position* is based on a level of protection that can be characterized as no less safety than that attributable to corresponding non-modified organisms. However, it might be argued that, if one reads the EU's level of protection back from the kind of measures it is proposing, which could be the approach of the Appellate Body given that the level of protection is not explicitly stated as such in any provision of the amended directive, in fact the level is considerably higher than that for non-modified organisms. In general, with respect to the latter, no prior case-by-case risk assessment is required before the product is put on the market. Among the arguments of industry interests that proclaim GMOs to be "safe" is that genetic engineering merely imitates—and directs to human needs—genetic modification and adaptation of the kind that occurs in nature itself, and thus does not impose risks that are different in kind from those posed by cross-breeding and genetic modification of organisms in nature.

In fact, there are very important distinctive characteristics of GMOS that make the analogy to natural processes very misleading when seen from the perspective of risk assessment and management. These are summarized by Regal:

[R]DNA differs in at least four fundamental ways from both ordinary sexual reproduction and conventional breeding: 1) Adaptive traits can be leap-frogged over vast phylogenetic distances to form radically new combinations of competitive features; 2) sexual reproduction and traditional breeding are largely limited to exchanges of alleles (which are variants of genes, and exchanges typically demand substitutions and adaptive trade offs and compromises, but with rDNA this class of exchange-based trade-offs can be circumvented. 3) Sexual reproduction and traditional breeding cannot normally reprogram the large fraction of genomes that are functionally homozygous. But rDNA holds the potential to reprogram fundamentally important genetic programs that are normally protected against change. 4) Transgenes often have unusual genetic side effects, apparently when a host organism's editing and buffering systems do not recognize them and cannot correct or control them properly.¹²¹

What do these differences mean in terms of the challenges

121. Philip Regal, *A Brief History of Biotechnology Risk Debates and Policies in the United States* (1999), at <http://www.edmonds-institute.org/regal.html>.

for risk regulation? Simply put, genetic engineering removes or alters many restraints or controls that limit variation in nature, resulting in a vast potential expansion of variants and the speed at which they occur. Reliance on long-acquired general knowledge of the properties of non-genetically modified foods might be reasonable given the EU's level of protection, whereas a requirement that specific investigation be undertaken with respect to GMOs may also be reasonable, given the same level of protection, in light of the greater degree of uncertainty and relative speed at which new organisms with unknown risk properties relative to specific ecosystems can be created. Finally, we note that, in the *Hormones* case, the Appellate Body held that there might be a range of acceptable reasons why regulation of risks inherent in nature in the absence of any human intervention might reflect a lower level of protection than that of risks produced or exacerbated by human artifice.¹²²

VI. SPS AND THE PRECAUTIONARY PRINCIPLE

This brings us to Article 5.7 of SPS and its relationship to the precautionary principle or approach. Article 5.7 allows for provisional adoption of sanitary and phytosanitary measures where "scientific evidence is insufficient," provided the Member seeks more adequate information and reviews the measures accordingly within a reasonable period of time. One obvious meaning of Article 5.7 is that it allows for provisional measures where the state of scientific knowledge is such that the kind of risk assessment set out in the preceding paragraphs of Article 5 is not possible. While the overall EU scheme for regulation of GMOs in the amended directive is based on the precautionary principle, in the sense that it requires prior approval on a case-by-case basis, rather than assuming the safety of GMOs until proven otherwise, it is *not* precautionary in the sense evoked by Article 5.7.¹²³ As we have already noted, the amended directive

122. See *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, Report of the Appellate Body, WT/DS26/AB/R (Jan. 16, 1998).

123. We suppose that some might argue that the requirement of case-by-case risk assessment is itself an SPS measure that must be maintained on the basis of sufficient scientific evidence, or based on a scientific assessment of risk within the meaning of Articles 5.1-5.3. But such an interpretation is *in fine casuistical*. It would put, at least in the GMO context, the EU and other Members in a "Catch-22" situation. In order to meet the requirements of the SPS they must do risk assessment, but they cannot impose

specifies the elements of a risk assessment based upon scientific methodology. And in this it is consistent with the *Cartagena Protocol on Biosafety* as well as the particulars of SPS Articles 5.2-5.3. Yet, as the Appellate Body suggested in *Hormones*, Article 5.7 does not exhaust the relevance of the precautionary principle or the precautionary approach to the interpretation of the SPS Agreement. Caution or pre-caution is relevant to the way that politicians and regulators respond to elements of uncertainty, indeterminacy, and margins of error in risk assessment, especially where if harms do materialize the consequences will be grave or catastrophic.¹²⁴

As already noted, the Guidelines for Assessment Reports in the amended directive require that the member state authority include in its report an assessment of “whether the genetic modification has been characterized sufficiently for the purpose of evaluating any risks to human health and the environment.”¹²⁵ While the amended directive does not specify what decision concerning permission to place on the market is appropriate, where it is determined that the genetic modification has *not* been characterized sufficiently, clearly the *possibility* in such a situation that permission would be denied is contemplated. This would precisely be the kind of case where the EU would be required to invoke Article 5.7 to justify a denial of permission to place GMOs on the market.

With respect to the conditions in Article 5.7, the amended directive does not contain any provision for reconsideration of a decision to deny permission based on new information. This contrasts with the situation where permission has been granted, in which case there is a formal process provided for reconsideration of the permission in light of new information about risks.¹²⁶ This being said one must interpret the requirements of SPS Article 5.7 “to seek to obtain additional information” and to review

risk assessment itself as a precondition for a decision about their measures, unless they already have a scientific basis for doing so. However, once the properties of a standard set of GMOs are better known, as discussed above, imposing this kind of requirement could be more trade restrictive than necessary to achieve the EU’s appropriate level of protection; but the common position provides for consideration of streamlined procedures as better information about GMOs evolves.

124. See Katherine Barrett, *Applying the Precautionary Principle to Agricultural Biotechnology*, in SCIENCE AND ENVIRONMENTAL HEALTH NETWORK (2000).

125. Annex VI.3.

126. See *id.* art. 20.

the measure within a reasonable period of time, in light of the overall structure of the amended directive. Since information about the characteristics of GMOs is in the first instance in the hands of those who produce them, the amended directive clearly places the onus providing adequate information for an *assessment* based upon scientific evaluation of risks upon the party seeking permission. If, in a particular case the information is inadequate, the precautionary action by a member state authority may be taken. Nothing in the amended directive prevents a notifier who has been denied permission, from reapplying for permission, while providing more adequate information for purposes of evaluating risk. By not limiting in any way, or prejudicing such re-applications, the EU is in effect inviting, or “seeking” additional information. With respect to the SPS requirement of review of measures taken under Article 5.7, there is nothing in the structure and language of 5.7 that suggests that a WTO Member must undertake a review, in the absence of interest on the part of the market actor with an interest in the measure being reconsidered. In effect—as already suggested—a notifier can trigger review of a decision, not to permit release or placing on the market of GMOs, simply by submitting a new notification at any time, which the competent member state authority is required to respond to, based on the information provided in the notification, within the same time limitations as applied in the first instance.

To interpret the requirement Article 5.7 as imposing an obligation to review SPS measures on one’s own motion, as it were, would be administratively inefficient. Such review could be moot for any number of reasons. The GMO in question may have proven to lack the economic benefits predicted for it, and thus may no longer be a competitive product; another company may have succeeded in obtaining permission for a competing product that is more effective in achieving the same and similar results, and so on. In any case, for a review to be effective, the notifier will itself have to act to provide further information, as discussed above. In sum, in the GMOs context, a scheme that permits reapplication for permission at any time, and effectively invites submission of new information with any such reapplication, represents an efficient means of ensuring that precautionary measures are not maintained longer than is justified by lack of adequate scientific evidence

CONCLUSIONS

Although public controversy about GMOs remains intense within the Union, and there are broader ethical concerns raised by this kind of manipulation of nature, the thrust of EU-level regulation as it is evolving from the original 1990 Directive through the amended directive is to base decisions about the placing on the market of GMO products within the Union on a case-by-case scientific assessment of risk to human health and the environment. This is subject to the possibility of precautionary action, where there is not sufficient scientific knowledge available to evaluate risk in the case of some particular GMO. This approach is consonant with evolving international standards, as reflecting in the FAO Statement on Biotechnology and the *Cartagena Protocol on Biosafety*. The basic structure of EU regulation as reflected in the amended directive raises few serious risks of violating the SPS Agreement.

However, where individual member states choose to act on the basis, in whole or in part, of ethical concerns or considerations (which the amended directive allows them to “take into account”), and where the measure could not also be wholly justified based on a scientific assessment of risk, a situation could arise where the appropriate WTO framework would be Article III of GATT and, depending upon whether ethical concerns would be found on a basis for distinguishing modified and unmodified products as “unlike” products, Article XX(a) of GATT, the “public morals” provision might also be justified.

However, one of the most promising features of the *amended directive* is the emphasis on public consultation, and publicity and transparency of reasons for decisions with respect to GMOs. Public dissemination of risk assessments and assessment reports, and consultation procedures prior to each decision, as well as in the course of EU-level review of such decisions, may well lead to a more focused and informed public discourse about what is at stake in the GMOs debate. At the same time, such transparency and publicity provides trading partners with additional assurances against the possibility that hidden protection is embedded in case-by-case regulatory decisionmaking.