



International Environmental Law Attempts to be “Mutually Supportive” with International Trade Law: A Compatibility Analysis of the Cartagena Protocol to the Convention on Biological Diversity with the World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures

CAMERON HUTCHISON*
University of Toronto

cameronhutchison@hotmail.com

1. Introduction

The adoption of the Cartagena Protocol (“the Protocol”) to the Convention on Biological Diversity last year represented a significant development in the field of international environmental law, and its sometimes tense relationship with international trade. As an environmental protection treaty, it is noteworthy as one of the first international agreements enjoying widespread support to operationalise the precautionary principle. In fact, the precautionary principle is a central precept to the Protocol’s regulation of the trans-boundary movement of genetically modified organisms (GMO) for intentional release into the environment, and as food and related products.

The threshold level for precautionary action is low in the Protocol, and will justify measures in cases where risks have been identified and evaluated on a preliminary and largely scientifically uncertain basis. At the same time, the Protocol accomplishes little in protecting against the more ominous scenarios sometimes attributed to the potential long term and presently unknowable risks posed by GMOs. This is a reflection of the central role of immediate science to the functioning of the Protocol, itself the result (at least in part) of an overarching concern that the Protocol be compatible with international trade regulations.

Viewed in the context of the long-running debate on the issue, the Protocol may be seen as a culmination of the position that international agreements on trade and the environment should be “mutually supportive” in achieving sustainable development [9, paragraph 167]; see also [13, Article 2.10(d)]. The influence of the *Agreement on the Application of Sanitary and Phytosanitary Measures* (“SPS Agreement” or “the Agreement”) on the content of

* This paper is the author’s LLM dissertation, University of Nottingham, Department of Law. The author is a Ph.D. candidate at the University of Toronto.

the Protocol is unmistakable, particularly in terms of the risk assessment-based approach to analysing risk and justifying measures. Clearly, however, the Protocol establishes a separate and distinct regulatory regime for sanitary and phytosanitary (SPS) risks posed by GMOs, most notably a system of advanced informed agreement with respect to living modified organisms intended for release into the environment.

The language of the SPS Agreement is (and its judicial interpretation by the Appellate Body of the World Trade Organisation (WTO) has been) sufficiently nebulous and permissive to accommodate the terms of the Protocol. But in at least one key respect, i.e., the reliance on international standards of bodies such as the Codex Alimentarius Commission (Codex), the two agreements may be fundamentally at odds, a conflict all the more critical in light of the limited science on GMO in a science-based discipline.

To the extent the two agreements supplement and complement each other, it will be argued that the Protocol's stated intention of mutual supportiveness with international trade is achievable. In effect, this will mean that Protocol decisions must abide by the dictates of the SPS Agreement's trade provisions. However, if and where the agreements conflict, it will be submitted that the law of treaties decrees the Protocol to be the applicable regime for GMO.

The scope of this paper is narrowed to consideration of import prohibition measures taken by states to protect against potential risks posed by GMO to the environment through the proliferation of pests or disease, or to human health through food consumption.

2. The nature of the GMO problem

The Cartagena Protocol defines a *living modified organism* (LMO) as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology."¹ In turn, *modern biotechnology* under Article 3(i) means the application of certain techniques², including recombinant DNA technology, "that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection." The ambit of the Protocol therefore extends to any organism, whether plant or animal, that is genetically modified through artificial means, though it excludes traditional breeding and selection methods and other techniques not specified in the definition of 'modern biotechnology.'

There exists an array of genetic engineering techniques though only a few are widely used [13, pp. 353, 356]. A common technique, which comes within the scope of the Protocol, is 'recombinant DNA technology' (rDNA). Premised on the removal of a desirable gene from species *X* to accomplish the same function in species *Y* [13, p. 359], rDNA is often associated with the creation of transgenic crops, e.g., genetic transfer to increase weed or insect resistance.

¹ Article 3(g). "Living organism" is also defined in Article 3(h).

² The specific techniques referred to are "a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells and organelles, or b) fusion of cells beyond the taxonomic family."

The core concern of many commentators is the *unpredictability* of GMO not just in terms of their own possible altered functioning, but also as they may interact within complex ecosystems [13].³ Indeed, scientific uncertainty about how ecosystems work compounds the state of scientific ignorance regarding GMO. The introduction of GMO into the environment has therefore raised fears of ecological disaster, on a more far-reaching scale than the more traditional problem of non-native species introduction [13, p. 360]. For example, crop seeds designed to resist herbicides, have bred resistance into weeds through cross-pollination thus creating ‘superpests’ [13]. Once released into the environment, GMO have the ability to travel considerable distances [32, pp. 110, 120] and unlike most forms of pollution, the damage cannot be contained [21, p. 5].

Uncertainty is exacerbated by the fact that the study of GMO-impacts on ecosystems demands long-term data collection that is not yet available [17, p. 10]. The risk is more pronounced in tropical regions and centres of origin since most field trials have taken place in temperate zones [17, p. 9].⁴ In turn, this has fuelled fears that GM crops introduced into vulnerable centres of origin may lead to a loss of genetic diversity, and thus threaten global food security.⁵ Proponents of modern biotechnology counter that GMO enhances global food security by increasing crop yields and will even help protect biological diversity by decreasing world demand for arable land.⁶

Polarised arguments are also put forward on the issue of whether GMO will aggravate, or diminish, more conventional forms of environmental damage. While some commentators fear that herbicide-resistant seeds may encourage farmers to use more pesticides on their crops [13, *supra* note 5, p. 360], proponents emphasise that less fertilisers and herbicides will be needed to increase crop yields [13, p. 358].

Supporters also point to the possibility of reduced food prices and the health benefits of genetically modified (GM) foods, e.g., through less use of pesticides on food [17, *supra* note 12, p. 8] and the engineering of higher nutritional value [1, *supra* note 15, p. 171]. However, disturbing cases have surfaced where engineered food has been contaminated with undesirable and potentially dangerous properties due to genetic transfer, the most

³ “The problem is that genes do not function like tiny machines. The expression of their outcome varies, depending upon their genetic and cellular environment. In other words, the actions of genes are unpredictable. Moreover, the fact (is) that genetic research takes place in a sterile laboratory environment where GMOs are intentionally kept from interacting with other organisms. . . (T)he effects of a newly created GMO observed in the lab will often dramatically differ once it is released into an environment in which it has freedom to interact with thousands of organisms. Finally, genes usually have multiple effects. Undesirable traits that are restrained in species X may begin to express themselves when transplanted in species Y.”

⁴ Centres of origin are places where particular crops originate from, and where large varieties still exist.

⁵ Wild plant relatives and local crop varieties, in particular, risk acquiring genetically engineered traits that could disrupt habitats. A potential loss of genetic diversity means that crops will have less ability to adapt to changing environmental conditions.

⁶ Genetic engineering could increase crop yields by enhancing resistance to frost, pests, soil toxicity and salinity, and drought and by reducing spoilage through delayed ripening. Modern biotechnology promises to do this faster and more inexpensively than current plant breeding methods. In turn, this offers a partial solution to problems of world hunger, while also helping to preserve natural habitats and biodiversity through reduced demand for farmland [1].

famous being the crossing of a Brazil nut allergen to an engineered soybean [32, *supra* note 10, p. 126].

Although no peer-reviewed scientific article has found adverse effects resulting from the general consumption of GM foods, there is uncertainty about the potential long-term effects of GM food on human health [17, *supra* note 12, p. 9]. Long-term human health concerns include possible increased allergenic tendencies and toxicity or altered nutritional value in food [36]⁷ and increased resistance to antibiotics [20, pp. 147, 177]. As with ecosystems, the interaction of GM foods within the human body can not be fully anticipated or tested before commercial approval [36, *supra* note 22].

What emerges from the above discussion of environmental and human health risk is an unsettling state of scientific uncertainty about the effects of GMO. The Protocol effectively addresses identified risks that may not be well understood, e.g., a discovery of a particular crop contamination or a novel allergen in food, but is weak in dealing with risks that have not, and can not, be identified unless and until long term monitoring and data collection is undertaken.

3. The Cartagena protocol on biosafety

As the parent agreement to the Cartagena Protocol, The Convention on Biological Diversity (CBD) failed to establish firm or specific commitments with respect to the regulation of risks posed by LMOs.⁸ In fact, the need for a Protocol on biosafety was specifically envisioned under Article 19 (3) of CBD. Concluding seven years of preparation and negotiations, the Cartagena Protocol was finally adopted by 130 states on January 29, 2000 [4, p. 46].⁹

It is significant in terms of the ambiguous content of key aspects of the final agreement to identify the main points of contention between a relatively small number of biotechnologically-developed states looking for secure markets, and a large bloc of developing states seeking protection through strong regulation.¹⁰ Four main issues delayed agreement: the scope of the Protocol beyond LMOs intended for intentional introduction into the environment; the treatment of LMOs for food, feed or processing; the adoption of the precautionary principle; and the relationship between the Protocol and existing trade agreements [4, *supra* note 26, pp. 46–47].

⁷ Also, for increased allergenic tendencies, see [32, *supra* note 10, p. 113].

⁸ In typically weak wording of the CBD, Article 8(g) requires parties to adopt domestic measures to, as far as possible and as appropriate, regulate, manage and control the risks associated with living modified organisms that are *likely* to have adverse impacts on biological diversity, taking into account the risks to human health. Interestingly, the main text of the Protocol refers only to adverse effects, and not *likely* adverse effects.

⁹ As of April 22, 2001, the Protocol has been signed by 90 state parties and ratified by 2 state parties, see [3].

¹⁰ The Miami Group of biotechnology states consisted of the US (not party to CBD), Canada, Australia, Argentina, Uruguay and Chile, whereas the Like-Minded Group was made up of many developing states, see [38, footnote 1].

3.1. *The objective*

The objective is stated in Article 1:

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that *may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health*, and specifically focusing on transboundary movements. (Italics added.)

While the Protocol is concerned with safe transfer, handling and use, its central focus is on regulation of the transboundary movement of LMOs. The italicised words are repeated throughout the Protocol and in Annex III, and may suggest a primary purpose of protection of biological diversity while only ‘taking into account’ human health risks.¹¹ This appears to be supported by the fact that the terms of the Protocol afford importing States a greater measure of protection against threats posed to biological diversity than to human health. The term ‘biological diversity’ is not defined in the Protocol, though a broad definition appears in Article 2 of CBD and includes diversity *within* species. Together with the stated low threshold of damage (i.e., ‘may have adverse effects’), this definition seems to signal an objective committed to strong environmental protection.

A number of provisions in the Protocol demand adherence to the objective and/or the terms of the Protocol, thus implicitly attributing different meanings to these two concepts.¹² For example, both import decisions for GMO food and trade with non-parties are to be consistent with the objective. On the other hand, the domestic regulatory framework implemented by States for LMO import decisions must be consistent with the Protocol and, by implication, the advanced informed agreement mechanism. The objective offers less protection since it does not require advanced informed agreement procedures prior to importation. Furthermore, the threshold for precautionary action is somewhat higher than the operational definitions of the precautionary principle (see section 5.3). Where consistency with the objective is mandated, States will have discretion in implementing mechanisms that meet the baseline duty of ensuring an adequate level of protection against the possible risks associated with modern biotechnology.

¹¹ There are two kinds of threats posed to human health: consumption of GM foods, and exposure of workers and farmers to GMOs, see [32, *supra* note 10, p. 122]. It seems clear from the Protocol that both types of health risks are within the scope of the Protocol.

¹² Article 2(4) provides that States may take more protective action than the Protocol provided it is consistent with both the objective and the provisions of the Protocol. Bilateral and multilateral agreements may be made between States provided they are both consistent with the objective and do not result in a lower level of protection than that provided by the Protocol (Article 14(1)). The domestic regulatory framework for advanced informed agreement for LMO imports is to “consistent with this Protocol” (Article 9(3)). Article 11(4) provides that the domestic regulatory framework for LMO/FFP import decisions is to be “consistent with the objective of this Protocol.” Transboundary movements of LMO between parties and non-parties shall be “consistent with the objective of this Protocol” (Article 24(1)).

Different categories of GMOs are subject to different treatment under the Protocol. Separate regulatory procedures are in place for LMOs intended for food, feed and processing (hereinafter referred to as “LMOs/FFP”) and LMOs for intentional introduction into the environment (hereinafter referred to as “LMOs”). Special exceptions or rules exist for pharmaceuticals, LMOs in transit and LMOs for contained use (Articles 5 and 6), and these will not be addressed in this paper.

3.2. *The regulation of LMOs: Advanced Informed Agreement*

A rigorous procedure of *advanced informed agreement (AIA)* applies to the first intentional transboundary movement of LMOs for intentional introduction into the environment by the party of import. Under Article 8(1), a party of export is required to give the competent national authority of the party of import written notification in accordance with Annex I. At minimum, this information will include: details of the exporter and importer; dates and quantity of the planned transfer; scientific and genetic information about the LMO and its origins; its intended use; suggested methods for handling; the regulatory status of the LMO in the country of export; the results of any previous notice by the exporter to other states regarding the LMO; and a *previous and existing risk assessment consistent with Annex III*. In turn, this information is used to conduct a risk assessment, which is to be prepared by one of the parties as chosen by the party of import.

Within 90 days, the party of import is required to acknowledge receipt of notification indicating the adequacy of the information provided, and whether a decision will be made under its domestic regulatory framework (which must be consistent with the Protocol) or under the decision procedure in Article 10 (see Article 9(1)–(3)). A failure to acknowledge receipt does not imply consent of the party of import under Article 9(4).

After the initial acknowledgement period, the party of import thereafter has 270 days to notify the party of export and the Biosafety Clearing-House (see Article 20) of its import decision. This decision must be based on the risk assessment and may take into account a broad formulation of the precautionary principle under Article 10(6). The party of import may decide to: approve the import, with or without conditions, and indicate the effect of the decision on subsequent imports of the same LMO; prohibit the import; request additional information in accordance with Annex I or its domestic regulatory framework; or indicate that it is extending the notification period by a *defined* period of time (Article 10(3)). The established timeframes, and implied limitation on open-ended extensions, will therefore permit monitoring of LMO in the range of one year.

In all cases but unconditional consent, reasons are to be given by the party of import. As with the acknowledgement period, failure to reply within the 270-day notification period does not imply consent. The above outlines the strictest application of the Protocol, although less onerous procedures may be employed by the party of import.¹³

¹³ Article 10(2) allows for approval by the party of import within the 90-day acknowledgement period. Article 13 provides a simplified procedure which completely circumvents AIA.

3.3. *The regulation of LMO/FFP*

Commodities (LMO/FFP) comprise 90% of all GMO trade [38, *supra* note 27, p. 5]. The distinction between the two categories is not always clear as for example in the case of grain, which can be used both as seed (LMO) and for food processing (LMO/FFP) [12, p. 2]. The only guidance on this issue in the Protocol is the repeated reference to the intended use of the GMO, though the agreement fails to specify which party's intention is relevant.¹⁴ Notwithstanding the issue of intended use, Article 11(1) appears to mandate that dual purpose GMO will at least be subject to the regulatory provisions for LMO/FFP.¹⁵

Article 11 prescribes a much less stringent procedure for LMO/FFP, the main difference being that transboundary movement is *not* subject to AIA. Thus, no timelines or consent procedures are in place. Furthermore, there is no requirement to prepare a specific risk assessment prior to importation nor is there a duty that the receiving State must make an import decision. The exception is Article 11(6) which allows AIA procedures to be employed by developing countries and economies in transition that do not have domestic regulatory frameworks in place.¹⁶

Parties that make final decisions concerning domestic use (including placing on the market) of LMO/FFP that may be subject to transboundary movement are to inform other parties through the Biosafety Clearing-House.¹⁷ At minimum,¹⁸ the party is to post the information outlined in Annex II which, though less comprehensive than Annex I, includes: description of the LMO and the method of biotechnology employed; its approved uses; the centres of origin of the recipient organism and point of collection of the donor organism; suggested methods of safe handling, transport, storage and use; and a risk assessment consistent with Annex III.

Under Article 11(4), parties of import are not obligated to make import decisions but, if they do, such decisions are to be consistent with the objective of the Protocol.¹⁹ Import decisions are to be based on risk assessment and may take into account a permissive formulation of the precautionary principle under Article 11(8).

¹⁴ One would think that only the party of import can have an *intended* use in the territory of the importing state (see Article 7(1)). However, Annex I(i) requires that the party of export provide information on the intended use.

¹⁵ Regulatory procedures for GMOs under the Protocol are rooted in intended use. However, according to Article 11(1), a party that markets LMO/FFP will be subject to Article 11 procedures if the product "*may* be subject to transboundary movement for direct use as food, feed or for processing. . ."

¹⁶ The limited capabilities of developing countries is acknowledged in the 8th recital of the preamble. The Protocol weakly addresses capacity building in Article 20 and the financial mechanism is outlined in Article 28.

¹⁷ Or national focal points for parties that do not have access to the Biosafety Clearing-House.

¹⁸ Article 11(3) allows a party to request additional information from the party approving domestic use.

¹⁹ Article 11(4) provides: "A Party *may* take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol." Parties therefore are not obligated to make import decisions once Annex II information is posted by an exporting State but, if the Party does make an import decision, it must be consistent with the objective of the Protocol. Obviously, this imposes a weak duty on importing States since they are under no obligation to assess risk.

3.4. *Extra measures of precaution*

In making import decisions, an extra measure of precaution is afforded to developing countries which may take into account “socio-economic considerations” arising from the impact of LMO on biological diversity with particular regard to “the value of biological diversity to indigenous and local communities.”²⁰ In addition, Article 2(4) permits States to take more protective measures provided they are consistent with the objective and provisions of the Protocol. The caveat to the above provisions is that they must be accord with the Party’s international obligations. Import decisions may also be reviewed in light of new scientific evidence under Article 12.

3.5. *Dispute Settlement and the likely recourse to the WTO*

A dispute settlement mechanism has yet to be developed under the Protocol.²¹ It is likely that any dispute relating to the relationship of the Protocol with WTO Agreements will come before a dispute settlement panel of the WTO.²²

4. Which WTO Agreement applies?

The Protocol potentially impacts on a range of WTO Agreements. However, this paper is concerned exclusively with import prohibitions placed on GM products. Determining which Agreement applies depends on the *purpose* of the measures [31, pp. 373, 383]. For example, requirements to label all trade in GM products in an effort to facilitate consumer awareness would likely be considered a technical regulation or standard and thus would be reviewed under the *Agreement on Technical Barriers to Trade (TBT)* [7]. If that same measure is imposed with the objective of protecting human health, then it should be considered under the provisions of the SPS Agreement. Import prohibitions of GMO would likely be imposed for the purposes of either protecting human health or the environment and thus should fall under the SPS Agreement.

4.1. *The SPS Agreement*

The SPS Agreement came into force in 1995 and is a multilateral agreement binding on all members of the WTO. The Agreement attempts to fulfil four goals: to interpret Article XX(b) of GATT, 1994 specifically in relation to SPS measures; to minimise trade effects; to promote harmonised standards; and to ensure measures are based on sound science [16, pp. 89, 95]. The Agreement seeks to ensure that measures taken to protect human, animal and plant health have a scientific basis, and thus justification for trade restrictions may arguably be more demanding than under GATT, 1994 or the TBT Agreement.

²⁰ Article 26(1).

²¹ See Article 34. Compliance procedures are to be considered at the first meeting of the parties of the Protocol.

²² It is of course possible, that a dispute could be resolved before the International Court of Justice.

4.1.1. Relationship with GATT, 1994. The relationship of the SPS Agreement with Article XX(b) of GATT, 1994 is stated in two provisions of the former agreement. The last paragraph of the preamble indicates a desire to elaborate GATT, 1994 rules which relate to SPS measures and “in particular the provisions of Article XX(b).” Article 2 provides that SPS measures which conform to the SPS Agreement “shall be *presumed*” to be in accordance with GATT, 1994 provisions and in particular Article XX(b). Thus, compliance with the SPS Agreement creates a presumption of conformity with Article XX(b). This implies that complaining states which fail to establish a violation of the SPS Agreement may still have recourse to GATT, 1994. In fact, successive Panels have not pre-empted the application of GATT, 1994, in cases where compliance with the SPS Agreement is established [27,28]. It is, however, beyond the scope of this paper to consider the compatibility of the Protocol with GATT, 1994.

4.1.2. Application of the SPS Agreement to Import Prohibitions under the Protocol. The SPS Agreement applies to all SPS measures “which may, directly or indirectly, affect international trade” (Article 1.1). Thus, a two step inquiry must be made to determine: first, whether the measure is an SPS measure; and second, whether it has trade impacts. With respect to the second element, it is axiomatic to say that an import prohibition has trade effects.

The critical question is whether the import prohibition qualifies as a SPS measure, defined in Annex A.1 as any measure applied:

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

The definition goes on to provide a non-exhaustive list of SPS measures.

A textual approach to treaty interpretation requires that terms be accorded an ordinary meaning in their context.²³ Considering human health risks from food in subparagraph (b), ‘disease’ may be defined as “any condition that impairs the normal state of an organism, and usually alters the functioning of one or more of its organs or systems” [39, p. 185]. The ordinary meaning of “disease” or “disease-causing organism” would seem to extend

²³ Article 31 of the Vienna Convention on the Law of Treaties, 1969 states that “A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the Treaty in their context and in light of its object and purpose.” The primary approach suggested under the Convention is the textual approach, see [33, p. 130].

to GM foods that may impair human health, e.g., the creation or transfer of allergens. The point appears confirmed by the recent mandate of Codex, the standard-setting body for food safety under the SPS Agreement, to establish an Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology.²⁴ Furthermore, footnote 4 to Annex A.1 broadly states that “contaminants” include “extraneous matter.” The Appellate Body (AB) in *EC Measures Concerning Meat and Meat Products (Hormones)* case (hereinafter “Beef Hormones”) indicated a willingness to give a liberal interpretation of Annex A.1 when it found naturally-occurring hormones injected into beef to be a “contaminant” [16, *supra* note 50, p. 114].

Subparagraphs (a) and (d) pertain to risks posed to, inter alia, plant life and or health. The proliferation of an invasive species that threatens to damage crops or disrupt an ecosystem would likely be considered a “pest” under the ordinary, contextual meaning of the word. In fact, footnote 4 to Annex A.1 specifically states that “pests” include “weeds.” Furthermore, Article II.1 of the International Plant Protection Convention (IPPC), the standard-setting body for plant protection under the SPS Agreement, defines “pest” as “any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products.” The IPPC has unofficially suggested that the Convention “place no restrictions on the source or origin of the pest,” and that “living modified organisms may pose some phytosanitary risk and therefore are within the scope of the IPPC” [30].

5. The precautionary principle

The precautionary principle is at the core of the Protocol and thus requires elaboration in its own right. In turn, this begs discussion of how science and decision-makers deal with risk and uncertainty.

5.1. Risk assessment and scientific uncertainty

Risk assessment uses science in an attempt to make objective findings about the relationships between causes and effects. The European Community (EC) Commission identifies the scientific components of risk assessment as follows [11] (the list summarises the contents of Annex III):

- (i) *Hazard identification.* Identifying agents that may have adverse effects on health or the environment; for example, a new substance may reveal itself through its effects on the environment, and it may be possible to describe the actual or potential effects in the environment before the cause is identified beyond doubt.
- (ii) *Hazard characterisation.* Determining in quantitative or qualitative terms, the nature and severity of adverse effects associated with causal agents, i.e., the relationship between the amount of the hazardous substance and the effect; the relationship is

²⁴ The task force is charged with devising standards, guidelines and principles for GM foods, and is due to submit its report in 2003, see [8].

sometimes difficult or impossible to prove because, for example, a definite causal link has not been established.

- (iii) *Appraisal of exposure.* A qualitative or quantitative evaluation of probability of exposure to the agent; apart from information on the agents (i.e., source, distribution, concentrations, characteristics, etc. . .), data is also needed on the probability of contamination or exposure of (say) the environment to the hazard.
- (iv) *Risk characterisation.* Based on the above three steps and the “uncertainties, variations, working hypotheses and conjectures made at each stage,” a qualitative and/or quantitative estimation of probability, frequency and severity of known or potential adverse effects to health or the environment.

The repeated interchanging of quantitative and qualitative determinations reveals the difficulty of placing a *quantitative* numerical value on risk in environmental and health risk assessment. A lack of information and understanding about probability of effects and exposures and their dynamic behaviour will at best, often make only *qualitative* indications of risk possible, i.e., ‘high,’ ‘medium’ or ‘low’ characterisations of risk [5, pp. 1, 3].

Scientific uncertainty pervades the very *process* of risk assessment, requiring policy choices between available data, models and assumptions in estimating risk [41, pp. 251, 304]. For example, a common policy is to use animal models to determine potential health effects on humans. The science policies chosen to address uncertainties will reflect different levels of precaution employed by States. This suggests that a number of methods may be used in risk assessment, any of which may be acceptable provided it is “scientifically plausible.” Consider the following:

... a causal account can be said to be scientifically plausible whenever it is supported by empirical data (as opposed to mere speculation or personal intuition) and by a line of reasoning (often including a model and theory) which together provide a rational basis for drawing a conclusion. . . Thus, there can be several scientifically plausible conclusions or accounts, with wide disagreement among scientists as to which conclusions or accounts will ultimately prove correct [41, pp. 258–259].

Lack of scientific consensus, as manifested by competing albeit scientifically plausible accounts, may represent a form of scientific uncertainty.

5.2. *Scientific uncertainty as ignorance: threats posed by GMO*

Profound forms of scientific uncertainty may exist in respect to ascertaining adverse effects on human health or the environment. First, risk assessment may be confronted with a *lack of data*, which is usually the result of inadequate monitoring due to short assessment periods and a limited scope of inquiry [18, p. 9]. Scientific models tend to simplify complexities such as ecological interactions [18] and experiments are conducted in timeframes too short to be accurate. Second, there is scientific uncertainty as *ignorance*, meaning that many hypotheses used in risk assessment are not ‘modelable’ since they can not be generalised due to natural variability and chaotic fluctuations [19, p. 64]. Third, *indeterminacy*

recognises the enormous complexity and unpredictability of systems and interrelationships that can not be scientifically accounted for [18, *supra* note 62, p. 9].

It is likely that risk assessment of GMOs, whether in terms of human health or environmental impacts, will in many cases suffer from all of these forms of uncertainty. It is generally recognised for example, that a more accurate assessment of adverse effects to human health or the environment will require monitoring periods of several years.²⁵ However, GMOs are being approved after much shorter assessment periods. In respect to GM foods, there is the concern that animal models may not be adequate proxies for assessing possible human impacts, and that the variety of factors that may affect human health make determining the effects of GM foods difficult to isolate.²⁶ The challenges for assessing environmental effects are equally daunting:

... given the complexity of the environment and ecological processes, and our lack of knowledge of how they function, GMO may pose long-term hazards which have not been observed even in non-modified organisms, indeed, have not yet been imagined. It is not just the individual GMO being introduced that have to be considered but the extent to which they may be able to pass on their new genes to closely related organisms, and what kinds of unpredicted and unpredictable genetic combinations might result. If the nature of the hazard is hard to determine, it is even harder to determine the magnitude of the consequences of a hazard being realised. This uncertainty is also related to the complexity of the environment. . . Lastly, determining the probability of realisation of a hazard is effectively impossible. There are so many different variables in terms of the environmental factors that could make a difference that putting numbers to any one of them is a meaningless exercise [14, *supra* note 66, pp. 177–178].

As well, the more GMOs that are approved and released into the environment, the more complicated it will become to determine cause and effect linkages [14, p. 172]. It is now necessary to review the precautionary principle against the backdrop of scientific uncertainty.

5.3. *The precautionary principle in the Protocol*

The precautionary principle is considered a conservative [41, *supra* note 60, p. 268] strategy of risk management. Risk management refers to deciding which measures to take,

²⁵ [14, pp. 172, 180]: In the ecosystem, for descendants of GMOs to show “weedy characteristics” may take as long as 50 years; and at [14, p. 181]: The state of science’s understanding of ecological interactions is so poor however, that long periods of monitoring may still give us limited or no understanding of the impact of GMOs.

²⁶ [26, p. 5]: Foods are complex mixtures of compounds characterised by wide variation in composition and nutritional value. Therefore, finding adverse effects and relating it to individuals characteristics of food can be extremely difficult; and [26, p. 9]: The problem is compounded by variability of predisposition to adverse effects in human populations; and [26, p. 18]: Reliable animal models for allergenicity are not available.

if any, in dealing with risk with reference to: the results of risk assessment; an examination of the costs, benefits and consequences of options; and value judgements about societal goals and objectives [41, p. 267]. It therefore considers the science of risk assessment against mainly political and/or economic decisions about the desirability of benefits derived from the activity that gives rise to the risk, and the public's tolerance of the risk.

The precautionary approach, as defined in Principle 15 of the Rio Declaration on Environment and Development (hereinafter "Principle 15"), is explicitly referred to in the preamble and more importantly, the objective of the Protocol. Principle 15 states:

In order to protect the environment, the precautionary approach shall be widely applied by states according to their capabilities. Where there are threats of serious and irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

A second version of the precautionary principle (hereinafter referred to as the "operational definition") is spelled out in Articles 10(6) and 11(8) of the Protocol in respect of import decisions concerning the two categories of GMOs. For example, Article 10(6) dealing with LMOs, states:

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation of sustainable use of biological diversity in the Party of import, taking 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 organism in question as referred to in paragraph 3 above, in order to avoid or minimise such potential adverse risks.

While quite different, these two formulations do not necessarily conflict. Principle 15, the first sentence sets out a general *duty* to widely apply the precautionary principle according to a state's capability while the second sentence establishes a more specific duty in cases where there is a threat of serious or irreversible damage. The operational definition, on the other hand, creates an explicitly worded *right* of States to implement precautionary measures where there is scientific uncertainty about the extent of potential adverse effects. This right does not conflict with the duties established in Principle 15.

5.4. *The Threshold of Action in the Protocol*

While the threshold of precautionary action in the objective is to ensure an adequate level of protection against risks that "may have adverse effects," the operational definition lowers the threshold to a lack of science regarding "the *extent of* potential adverse effects." Furthermore, the operational definition seems to specifically embrace the more profound forms of scientific uncertainty noted above. Indeed, the use of the words "due to insufficient relevant scientific information and knowledge" appears to be an explicit reference to

the problems of data gaps, ignorance and indeterminacy, all of which severely restrict the level of scientific certainty regarding the identification and evaluation of possible adverse effects.

At the same time, the operational definition connotes at least a minimum level of scientific justification for measures, while barring speculation or pure theory. This appears supported by their ordinary meaning, and is also consonant with the *travaux* [25]²⁷ and the risk assessment-based approach under the Protocol.

Therefore, a minimum basis for action under the Protocol may be established where a party can demonstrate a scientifically plausible explanation of cause and effect, and potential non-negligible²⁸ adverse effects. For example, in the absence of detailed scientific information and knowledge, identifying that a GM plant *may* have spread undesirable traits to non-modified plants giving rise to *possible* non-negligible adverse effects should suffice to justify precautionary measures under the Protocol.

While made in the context of the Treaty of Amsterdam, the EC Commission's comments on the precautionary principle are appropriate here:

its scope. . . covers those specific circumstances where scientific evidence is insufficient, inconclusive or uncertain and there are *indications through preliminary objective scientific evaluation that there are reasonable grounds for concern* that potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection [11, *supra* note 58, p. 10]. (Italics added.)

To the extent that the EC Communication refers to a preliminary scientific evaluation that gives rise to reasonable grounds for concern, these comments appear consistent with the threshold set under the Protocol. The Communication is also explicit in stating that an absence of scientific proof of a cause-effect relationship should not be used to justify inaction [11, p. 17].

While only minimal science may be needed in cases of suspected plant contamination, or for an allergen identified in GM food, the operational definition will not justify action to address possible or unforeseeable long-term effects that are not identified in risk assessment.

6. Agreement v. Protocol: similarities and incompatibilities

6.1. Risk assessment procedures

6.1.1. Generally. Neither the Agreement nor the Protocol requires states to adhere to specific procedural requirements. Nevertheless, binding general standards are set out in both agreements.

²⁷ The EC pushed for the operational definition and also advocated the need for a "basis of science-based risk assessment" with respect to current Article 10(6).

²⁸ See [6], where it is noted that all formulations of the precautionary principle require risk of non-negligible harm.

6.1.1.1. *The SPS Agreement.* Article 5.1 of the SPS Agreement provides:

Members shall ensure that their sanitary and phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organisations.

Articles 5.2 and 5.3 elaborate a list of considerations that shall be taken into account in assessing risk, including “available scientific evidence” and “cost-effectiveness of alternative approaches to limiting risk.” Article 2.2 requires that SPS measures be based on scientific principles.

6.1.1.2. *The Protocol.* For LMOs, Article 15 provides:

Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognised risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking into account risks to human health.

Annex III elaborates details with respect to the objective and use of the risk assessment, in addition to general principles, methodology, and points to consider in its preparation. The content of the latter three subheadings is expressed in non-binding language. The sharp contrast in wording between Article 15 (“shall . . . be in accordance with Annex III”) and the permissive wording of key elements of Annex III itself raises an interesting issue of interpretation that will be addressed *infra*. Annex III repeats most of the Article 15 requirements, although the obligation to base risk assessment on previous science is missing. LMO/FFP trade only requires that the party of export post a risk assessment that is *consistent* with Annex III²⁹, but not necessarily in accordance with Article 15, thus giving parties of export more procedural discretion in preparing risk assessments.

6.1.1.3. *Similarities and incompatibilities.* Both the SPS Agreement and the Protocol require that the risk assessment use scientific principles and, with the exception of LMO/FFP in the Protocol, give consideration to other available scientific information.

However, important differences are apparent. For LMOs, the Protocol compels that a specific risk assessment be undertaken by one of the parties, as chosen by the party of import. By contrast, the WTO Appellate Body in *Beef Hormones* clarified that under the SPS Agreement, States may in fact base their measures on risk assessments conducted by other Members or international organisations [24].

Furthermore, Annex III sets out in some detail the kinds of *scientific* factors that the risk assessment should consider. The Agreement on the other hand, mandates that the parties

²⁹ Annex II(j).

look at a different set of mostly *economic* and *technical* considerations under Articles 5.2 and 5.3. In part, the factors in the Agreement seemed designed to ensure due consideration of territorial and trade factors during risk assessment. The different considerations no doubt reflect the fact that one is a trade agreement while the other is concerned with environmental protection. Mutual supportiveness (discussed *infra*) will likely require that, insofar as they are complementary, both sets of considerations be taken into account in preparing risk assessment.

Most importantly, the Protocol states that the risk assessment shall “take into account” *recognised* risk assessment techniques, making reliance on international guidelines completely optional (Annex III, paragraph 3). Risk assessment techniques that need only be ‘recognised’ appears to embrace all scientifically plausible accounts of risk, as discussed *supra*. In tandem with the operational definitions of the precautionary principle, the Protocol affords maximum flexibility for the implementation of precautionary measures in accordance with the principles of sound science. By contrast, the Agreement requires that Members “take into account” risk assessment techniques developed by *relevant international organisations*.³⁰ Risk assessment parameters under the Agreement are therefore not as broad and the development of international standards has the potential to create a fundamental incompatibility between the two agreements.

6.2. *Scope of the risk assessment*

Annex A.4 of the SPS Agreement defines risk assessment and in so doing, establishes a separate scope of scientific inquiry in respect of threats posed by pests or disease, and (more leniently) risks presented by food, beverages or feedstuffs. The scope of assessment in the Protocol is ambiguous though the same standard is applied to all risks.

6.3. *Food*

6.3.1. *The SPS Agreement and the Beef Hormones Case.* The second sentence of Annex A.4 defines risk assessment as “the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.” The Panel in *Beef Hormones* suggested that this entailed a two-step process of identification of adverse effects and, second, evaluation of the potential or probability of the occurrence of these effects. The Appellate Body (AB) did not overturn the methodology,³¹ though it explicitly denounced the concept of quantifying risk. It stated that a quantitative minimum magnitude of risk finds no basis in the SPS Agreement and that measures need only be “sufficiently supported

³⁰ Annex A.3 of SPS defines international standards, guidelines and recommendations for food safety as those of the Codex Alimentarius Commission and for plant health, those developed under the auspices of the International Plant Protection Commission. Neither body has to date, developed GMO standards.

³¹ AB, *Beef Hormones*, *supra* note 77, at paragraph 184: it notes the methodology does not appear to be substantially wrong.

or reasonably warranted by the risk assessment.”³² It also stated that the ordinary meaning of ‘potential’ relates to ‘possibility’ as opposed to ‘probability.’

Most importantly, it suggested that the risk to be evaluated must be ‘ascertainable risk’ and that “theoretical uncertainty is not the kind of risk which under Article 5.1 is to be assessed.”³³ Furthermore, risk is to be ascertained not only in the science laboratory, “but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.”³⁴

The AB found that the scientific studies relied on by the EC did not rationally support the import prohibition of North American beef, since they were not specific to the cause and effect relationship under consideration in that case [34, pp. 471, 479–480]. Indeed, there was a paucity of evidence to support the EC position and, as one writer observed, it is unlikely that there will ever be a clearer case of a Member refusing to follow the advice of scientists [16, *supra* note 50, p. 118]. To comply with the SPS Agreement, risk assessments must examine the health risk in specific relation to the activity allegedly giving rise to the risk and from there, a rational relationship must exist between the risk assessment and the measure adopted.

6.3.2. Comparison with the Protocol. Risk assessment for LMO/FFP need not be *specifically* prepared prior to transboundary movement. However posted risk assessments must be consistent with the generally non-binding requirements of Annex III. The requirements for LMO/FFP risk assessment therefore seem vague and, as previously noted, more flexible than LMO.

A review of Annex III leaves an initial impression that its provisions at best only awkwardly apply to LMO/FFP. In large part this is due to the reference that potential adverse effects be evaluated “in the likely potential receiving environment.” However, the UNEP technical guidelines upon which Annex III is based, indicate that this includes the human body [40, paragraph 19].³⁵

Importantly, Annex III.3 states that risk assessments should be carried out in a scientifically sound manner and, “can take into account expert advice of, and guidelines developed by, relevant international organisations.” The controversial guidelines that are currently being negotiated within the Codex Alimentarius Commission will therefore not have to be adhered to under the Protocol, if and when they are developed.³⁶ As previously dis-

³² *Id.* at paragraph 186, see discussion *infra* with respect to risk management.

³³ *Id.* at paragraph 184, 186.

³⁴ *Id.* at paragraph 187.

³⁵ The UNEP guidelines were intended to provide a technical framework for risk analysis under the Protocol, and were generally viewed favourably by State Parties: see [37].

³⁶ Codex has established an Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology that is charged with devising standards, guidelines and principles for GM foods, and is due to submit its report in 2003. The task force was urged to produce a substantial interim report before this time at the G-8 summit in Japan in 2000. A number of commentators have noted that representation at Codex tilts the organisation toward an industry bias. See [21, *supra* note 11, p. 16; 20, *supra* note 23, p. 189].

cussed, the status accorded to international standards is a point of departure between the Agreement and the Protocol.

It will be argued *infra* that Annex III, paragraph 8 is a non-binding requirement and, that being the case, there is no incompatibility between the two agreements with respect to the scope of risk assessment for food risks.

6.4. *Pests and Diseases*

6.4.1. *The SPS Agreement and the Australia Salmon case.* Risk assessment is defined in Annex A.4 as “the evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of any importing state to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences.” As distinguished from food risks, the scope here is to examine the *likelihood* of risk *against possible SPS measures*, in addition to an evaluation of possible consequences. This is obviously a more focused and demanding standard of inquiry.

The AB in the *Australia-Import of Salmon* case (hereinafter “Australia Salmon”) established the following risk assessment requirements under Annex A.4:

1. Identification of diseases whose entry, establishment or spread a Member wants to prevent, as well as potential biological and economic consequences;
2. Evaluation of the *likelihood* of entry, establishment or spread of these diseases, as well as associated potential biological and economic consequences; and
3. Evaluation of the *likelihood* of entry, establishment or spread of these diseases *according to the SPS measures which might be applied* [22, paragraph 122]. (Italics added.)

The AB elaborated that “likelihood” has the same meaning as “probability” and that Article 5.1 will be violated if the risk assessment concludes that there is only a *possibility* of risk [22, paragraph 124], or if there is only *some* evaluation of likelihood of risk [22, paragraph 125]. The AB then indicated that likelihood may be expressed either quantitatively or qualitatively, and following *Beef Hormones*, noted that the risk assessment need not establish a certain magnitude or threshold of risk [22, paragraph 125]. The AB also reaffirmed the *Beef Hormone* requirement of “ascertainable risk” while barring theoretical uncertainty.

Applying this analysis to the case at hand, the AB noted that the risk assessment at issue stated a “mere possibility of adverse effects occurring, statements which constitute neither a quantitative or qualitative assessment of probability” [22, paragraph 130]. It went on to explain that the existence of unknown or uncertain elements does not justify departure from the explicit provisions of the SPS Agreement. The second requirement was therefore not satisfied. With respect to the third requirement, risk assessment must evaluate the likelihood of risk in relation to SPS measures that might be applied. Some evaluation of likelihood, as occurred in this case, will not fulfil this requirement [22, paragraph 135].

Considering the requirements laid out in *Australia Salmon*, it may be difficult in the face of scientific ignorance to establish a qualitative likelihood of risk that LMOs may harm the environment. As well, the requirement to relate the risk assessment to policy

options will likely restrict a Member's ability to impose an import prohibition, where a more proportionate response would demand a less trade-restrictive measure.

While a Member may set a high level of protection under the Agreement, what scope is there for doing so when the SPS Agreement effectively pre-empts measures that are not based on at least a qualitative likelihood of risk? In this sense, risk assessment for pests and diseases sets a much higher threshold of action than for food and related products.

6.4.2. Comparison with the Protocol. Risk assessment is not defined in the Protocol though its objective is set out in Annex III, paragraph 1:

The objective of the risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking into account risks to human health.

The objective of risk assessment compels identification and evaluation of possible (as opposed to likely) adverse effects, a concept consistent with Article 15. The scope of inquiry is however, narrowed by reference to "the likely potential environment." Given the chance of long range LMO contamination, it will be interesting to see to what degree remote areas away from the place of LMO introduction are permitted risk assessment by wary states should this become the standard.

Paragraphs 8(a)–(d) of Annex III elaborates the steps that should, "*as appropriate*," be taken to fulfil the objective of risk assessment:

- (a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;
- (b) An evaluation of the likelihood of these adverse effects being realised, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;
- (c) An evaluation of the consequences should these effects be realised;
- (d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realised;
- (e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage risks;
- (f) Where there is uncertainty regarding the level of risk, it may be addressed by requiring further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

The first two requirements of *Australia Salmon* are reflected in paragraphs (a)–(c) with some variation, including a failure to modify "consequences" in paragraph (c) with the word "potential." The third requirement of *Australia Salmon* is effectively absent, even

though paragraph (e) makes permissive reference to recommendations for risk management. Paragraphs (e) and (f) seem designed to encourage a proportionate risk management response to risk and uncertainty.

Paragraph 8(b) conforms to the SPS Agreement in that it is *likelihood* of risk which is to be evaluated. However, this rigorous requirement is not consistent with the strong precautionary approach and language of the Protocol, as discussed *supra*. The non-committal words of “as appropriate” at the beginning of paragraph 8 may be construed as indicating an intention that this be the *goal* of the risk assessment, where possible. This interpretation would recognise the current embryonic stage of LMO risk assessment techniques [32, *supra* note 10],³⁷ while acknowledging the potential for future advancement in this area of science.

6.5. Risk management: substantive requirements

Though risk management is not explicitly mentioned in the SPS Agreement, the concept finds expression through a Member’s right to set its own level of protection, and the implicit connection between level of protection and risk assessment. Indeed, the essence of risk management is the determination and application of an acceptable level of risk [41, *supra* note 60, p. 256]. The Protocol on the other hand, is not clear about an acceptable level of protection, though it explicitly addresses risk management.

6.5.1. Level of protection

6.5.1.1. SPS Agreement. A clear aim of the SPS Agreement is to harmonise SPS measures internationally, thus reducing the possibility of disguised protectionism.³⁸ Article 3.1 states that SPS measures shall be based on international standards,³⁹ where they exist. Article 3.3, on the other hand, allows Members to set a higher level of protection where there is scientific justification or in accordance with Article 5.⁴⁰

The AB in the *Beef Hormones* case clarified the relationship between Articles 3.1 and 3.3. It indicated that Article 3.1 established harmonisation as the goal, but that there was no intention based on a plain reading of the text to support a binding obligation that measures “conform to” international standards.⁴¹ The AB confirmed a Member’s autonomous right to determine its own level of protection which may be higher than that established by international standards.⁴² Indeed, this right is written into the SPS Agreement in Annex A, where “appropriate level of sanitary and phytosanitary protection” is defined as “the level

³⁷ Generally but in particular at p. 136.

³⁸ AB, *Beef Hormones*, *supra* note 77, paragraph 177.

³⁹ See *supra* note 78. Codex standards are not binding but recommendatory.

⁴⁰ The Appellate Body in *Beef Hormones* stated that these alternative bases may be more apparent than real, and a higher level of protection must in either event be based on compliance with Article 5.

⁴¹ AB, *Beef Hormones*, *supra* note 77, paragraph 165. Conformity with international standards creates a presumption of compliance with the SPS Agreement and GATT, 1994 (Article 3.2).

⁴² *Id.*, paragraph 172.

of protection *deemed appropriate by the Member.*” In *Australia Salmon*, the AB even went so far as to suggest that a Member may set a “zero risk” level of protection.⁴³

This right however is not absolute and a higher level of protection must be based on a risk assessment as established in Article 5.1.⁴⁴ Risk assessment under the SPS Agreement therefore, may be viewed as a countervailing factor against the sovereign right of Members to set their own level of protection.⁴⁵ It stands to reason that the same rule of scientific justification (in compliance with Article 5.1) applies where, as in the case of GMO, there are no international standards in place [34, *supra* note 83, p. 483]. But to escape international standards here is really not to escape them at all. It will be recalled that Article 5.1 mandates that Members take into account techniques for risk assessment developed by relevant international bodies, thus again exposing the tension between the two treaties on this issue.

The Agreement requires that trade-friendly considerations be moulded into the level of protection. Article 5.4 indicates that, when determining the level of protection, Members *should* take into account the goal of minimising negative trade effects. Members are also obliged to accept an exporting state’s measures as equivalent to their own where it “objectively demonstrates” to the importing state that the measures meet the latter’s level of protection (Article 4). Finally, there is an obligation under Article 6.1 to apply measures that suit the regional characteristics of a Member’s territory.

6.5.1.2. Comparison with the Protocol. No explicit mention is made in the Protocol of the right of States to set their own level of protection. The objective of the Protocol states an “adequate level of protection” though this phrase is not defined anywhere. A strong argument could be made to support a State’s right to set a high level of protection unencumbered by the standards of other states or international organisations, or by trade considerations. The Protocol does not require, even as a goal, that States base their decisions on international standards. It is also probative to note Annex III, paragraph 4, which indicates that scientific uncertainty should not necessarily be interpreted as indicating an acceptable level of risk. The only limitation is that risk management decisions, while based on the risk assessment, are to be imposed “to the extent necessary to prevent adverse effects” (Article 16(2)). Furthermore, the principle of mutual supportiveness (discussed *infra*), could be used to support a State’s right to set its own level of protection under the Protocol, via the SPS Agreement.

It is the position of the Organisation for Economic Co-operation and Development (OECD) that the benefits and risks of modern biotechnology must be viewed together, and that the trade off between the two will vary across different regions of the world, and between different economies [17, *supra* note 12, p. 9].⁴⁶ It is submitted that the Protocol is in fact designed to accommodate regional and national differences and ecological susceptibilities through a flexible and potentially high standard of “adequate level of protection.”

⁴³ AB, *Australia-Salmon*, *supra* note 88, paragraph 126. However, due to scientific uncertainty, many authorities believe that zero risk is not practically possible.

⁴⁴ *Id.*, paragraphs 173–177.

⁴⁵ *Id.*, paragraph 177.

⁴⁶ For human health risks, these may be more universal.

6.6. Risk management

6.6.1. The SPS Agreement

6.6.1.1. *Rational relationship: Articles 2.2 and 5.1.* Article 2.2 states that a Member may only apply an SPS measure to the extent necessary to protect human, animal or plant life or health, and provided it is based on scientific principles and not maintained without sufficient scientific evidence. Article 5.1 clarifies that such measures must be “based on” a risk assessment. The AB in *Beef Hormones* noted that Article 2.2 and 5.1 must be read together, as they impart meaning to each other. The AB stated that “based on” in Article 5.1 refers to “an objective situation that persists and is observable between the SPS measure and the risk assessment” (AB, *Beef Hormones*, *supra* note 76, paragraph 189). The AB then elaborated extensively on the relationship that must exist between the risk assessment and the measures taken to protect human health (*Id.*, paragraphs 193–194):

The requirement that an SPS measure must be ‘based on’ a risk assessment is a substantive requirement that there be a rational relationship between the measure and the risk assessment. We do not believe that a risk assessment has to come to a monolithic conclusion that coincides with the scientific conclusion or view implicit in the SPS measure. The risk assessment could set out both the prevailing view representing the ‘mainstream’ of scientific opinion, as well as the opinions of scientists taking a divergent view. 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, the 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. By itself, this does not necessarily signal the absence of a reasonable relationship between the SPS measure and the risk assessment, especially where the risk involved is life-threatening in character and is perceived to constitute a clear and imminent threat to public health and safety. Determination of the presence or absence of that relationship can only be done on a case-by-case basis, after account is taken of all considerations rationally bearing upon the issue of potential adverse health effects.

Permissive elements exist in the rational relationship approach. Measures do not have to strictly correspond to the conclusions or recommendations of the risk assessment. Further, where there is a lack of scientific consensus, measures may be based on a “divergent opinion coming from qualified and respected sources.” The AB appeared to accord particular lenience to imminent threats posed to human health. Rational relationship, however, must also be considered in conjunction with risk assessment procedures which, it will be recalled, requires ascertainable risk, and in the cases of pests and diseases, mandates exclusive consideration of the probability of risk.

A more restrictive approach is implied in *Japan-Measures Affecting Agricultural Products* (hereinafter, *Japan Varietals*) where it was stated that rational relationship will depend on the particular circumstances of the case “including the characteristics of the measure at issue and the quality and quantity of scientific evidence” [24, paragraph 85]. Seemingly at variance with *Beef Hormones*, the implication here seems to be that a more trade-restrictive measure will bear a greater quantitative burden of scientific evidence. If this becomes the new standard under the Agreement, it would lead to a fundamental incompatibility with the standard of scientific proof required under the Protocol.

While the Appellate Body in *Beef Hormones* did not specifically deal with the standard of “sufficient scientific evidence,” analysis of Article 2.2 in *Japan Varietals* merely echoed the rational relationship approach discussed above.

6.6.1.2. The precautionary principle and Article 5.1. In *Beef Hormones*, the EC argued that the precautionary principle is customary international law, or at least a general principle of law, and thus should be used to interpret Article 5.1. The AB held that the precautionary principle is reflected in Article 5.7, in addition to a Member’s right to set its own level of protection and the cautious approach that may be taken by governments under the rational relationship approach. However, it refused to go any further:

... the principle has not been written into the SPS Agreement as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in the particular provisions of that Agreement. . . (T)he precautionary principle does not, by itself, and without a clear textual directive to that effect, relieve a panel from the duty of applying the normal (i.e., customary international law) principles of treaty interpretation in reading the provisions of the SPS Agreement (AB, *Beef Hormones*, *supra* note 77, paragraph 124).

Interestingly, if *lex specialis* applies the Protocol to GMO risks via mutual supportiveness (discussed *infra*), then suddenly a “clear textual directive” is present and thus, the low threshold of scientific proof in the Protocol would indeed have to be interpreted alongside the provisions of the SPS Agreement.

6.6.1.3. Provisional measures and Article 5.7. The exception to Article 5.1 is found in Article 5.7, which states:

In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary and phytosanitary measures on the basis of available pertinent information, including that from the relevant international organisations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and the review the sanitary and phytosanitary measure accordingly within a reasonable time.

In *Japan Varietals* (AB, *Japan Varietals*, *supra* note 110, paragraph 90) the AB set out the following cumulative requirements of Article 5.7:

- Provisional measure may be *adopted* in situations where “relevant scientific information is insufficient” and “on the basis of available pertinent information;” and
- These measures may only be *maintained* where the Member “seeks to obtain additional information necessary for a more objective assessment of risk,” and the Member “reviews the measure accordingly within a reasonable period of time.”

To maintain measures, the AB held that the information sought must be germane to conducting a risk assessment, i.e., the evaluation of the likelihood of risk in relation to the SPS measures that may be applied (*Id.*, paragraph 93). As for the temporal requirement, a reasonable period of time must be established on a case-by-case basis with consideration given to the difficulty in obtaining additional information necessary for the review *and* the characteristics of the provisional SPS measure (*Id.*, paragraph 94).

The first part of the temporal requirement could be used, for example, to support longer field trials for LMOs. However, it is implicit in the second requirement that trade restrictive SPS measures will not be tolerated for lengthy periods of time. The EC Commission observes, however, that provisional measures under Article 5.7 do not impose a temporal limitation. Instead, provisional measures are bound only to the limits of scientific knowledge, the development of which demands further evaluation under the section [11, *supra* note 58, pp. 12, 20].

It remains unclear what meaning is to be accorded to key concepts such as ‘insufficient’ relevant scientific information, and ‘available pertinent information.’ In the absence of international standards or measures applied by other Members, the provision is open to a broad interpretation possibly justifying measures based on theoretical scientific speculation and a low public tolerance to risk. Indeed, if Article 5.1 sets a lenient threshold of ascertainable risk and (less so) rational relationship, then should not insufficient scientific evidence relax the threshold even further? This would indeed be a peculiar result since it could justify measures taken to protect against long-term theoretical risks posed by GMOs, thus exceeding the level of precaution permitted in the Protocol.

In keeping with the science-based spirit of the Agreement and its judicial interpretation to date, it is likely however that some concrete scientific basis for the measures would be needed. Still, Article 5.7 could be cited in adopting measures that fail to meet the strict procedural requirements of risk assessment under Article 5.1. In other words, Article 5.7 could save SPS measures that are not based on a risk assessment establishing a qualitative likelihood of risk of pestilence or disease. If this interpretation holds, Article 5.7 may serve as a bridge between the two agreements.

6.6.2. *The dilemma of international standards.* The eventual development of international standards by Codex or the IPPC may open a deep wedge between the two agreements. In the face of profound scientific uncertainty, a party to the Protocol may still find reasonable preliminary scientific grounds of concern for a particular GMO and legitimately restrict imports. If international standards develop on that same product which mandate less trade restrictive measures, then a party to the SPS Agreement must base its measures on this. To go beyond the international standards requires scientific justification based on an Article 5.1 risk assessment, which (assuming consistency between international standards) would likely be lacking.

Recourse may then be had to Article 5.7, as discussed above. However, the permissive scope of Article 5.7 may contract sharply where international standards and guidelines are in place. Indeed, while an inadequate risk assessment may in isolation qualify as “available pertinent information,” it may not measure up to “that from the relevant international organisations.” Furthermore, for less developed states without regulatory frameworks and that are unable to rely on science from other Members, it may be practically impossible to refute international standards.

With respect to food standards, commentators have noted that representation at Codex reflects an industry bias,⁴⁷ and thus the development of international rules may undermine the permissive elements of the Protocol vis-à-vis the SPS Agreement. The importance of such standards is not lost on the leaders of the developed world. At the 2000 G-8 summit in Japan, the Joint Communiqué urged the Codex Task Force to “produce a substantial interim report before completion of its mandate in 2003.”

6.6.3. Comparison with the Protocol. The risk management provisions in the Protocol appear to apply to both categories of GMOs. Article 16(1) calls on States to, *inter alia*, take “appropriate” measures “to regulate, manage and control risks identified in the risk assessment provisions of this Protocol. . .”. Further, Article 16(2) provides:

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

Three observations may be made here. First, a reading of Articles 10(1), 15(1), 16(1) and 16(2) together suggests a clear intention that measures are to be based on the risk assessment. Second, the inclusion of the words “to the extent necessary” may signal an implicit requirement that measures be as trade-friendly as possible, though this should not derogate from high level of protection that seems to be afforded to States. Third, risk management decisions may take into account the precautionary principle as it is articulated in Articles 10(6) and 11(8).

6.6.4. Article 16.4 and a more precautionary approach? The UNEP technical guidelines state that GMO risk analysis should be based on familiarity (i.e., scientific knowledge and experience) with the organism, the intended application and the potential receiving environment. Thus, “risk assessment may vary from a very short process to an extensive review, depending on the extent of familiarity” [40, *supra* note 86, paragraph 20]. No doubt, “extensive review” could potentially extend beyond the time frames set under the Protocol, and may even justify monitoring periods of several years.

Under mutual supportiveness (discussed *infra*), Article 5.7 could be invoked to argue that an inadequate monitoring period for an ‘unfamiliar’ GMO qualifies as ‘insufficient’

⁴⁷ Powell [21, *supra* note 11, p. 16] notes that industry is heavily represented at Codex while environmental and consumer groups have substantially less representation. Pardo-Quintillan [20, *supra* note 23, p. 189] notes that 81% of non-governmental participants or national delegations represented industry.

science and ‘available pertinent information’ justifying import prohibition pending proper scientific review. An even more effective argument could be made here by referring to the goal of sustainable development, as stated in the preamble of the Protocol. However, to stretch the meaning of the SPS Agreement and grasp at notions not expressed in the Protocol, and which run counter to its time frames, is not convincing. In addition, the trade provisions of the Agreement demand a proportionate risk management response, even in cases of scientific uncertainty.

One possible loophole to this regime is Article 16(4), which provides:

Without prejudice to paragraph 2 above, each party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.

While the words “shall endeavour” may impose some obligation⁴⁸ to follow to the terms of Article 16(4), the provision nonetheless fails to establish an absolute duty. In other words, a failure to monitor LMOs during its life-cycle or generation time will not prima facie result in a violation of Article 16(4). Limiting observation to the life-cycle of generation time may not, in any event, address the issue of long-term risk.

7. Trade provisions in the SPS Agreement

There is no reference to trade principles per se in the Protocol. Still, the SPS is replete with such provisions, including Articles 2.2, 2.3, 5.4, 5.5 and 5.6, and the Annexes to the Agreement.

7.1. Article 5.5

The first sentence of Article 5.5 has received the most judicial attention from the AB. It reads:

With the objective of achieving consistency in the application of the concept of appropriate level sanitary and phytosanitary protection against risks to human life or health, or to animal and plant life or health, *each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade.* (Italics added.)

In referring to the first clause of this sentence in *Beef Hormones*, the AB declared that there is no legal obligation for Members to establish consistent levels of protection,

⁴⁸ See, for example, [10, p. 37] where J. Mason held that the words “shall endeavour,” as contained in Article 5 of the Convention for the Protection of the World Cultural and Natural Heritage, does in fact create a legal obligation.

provided the inconsistencies are justifiable (AB, *Beef Hormones*, *supra* note 77, at paragraph 213). With respect to the balance of the first sentence, the AB outlined a three-step test that a complaining Member must prove cumulatively in order to show a violation of Article 5.5.

First, a Member must be shown to have adopted varied levels of protection in different and comparable situations (*Id.*, paragraph 217 (comparable), and paragraph 214 (different)). In *Beef Hormones*, it was found that in fact different levels of protection existed for the various hormones under consideration (*Id.*, paragraph 218). An expansive scope for comparable situations was established in *Australia Salmon*, wherein the AB held that risk of the same or similar disease, or risk of the same or similar associated biological and economic consequences, suffices to make situations comparable.⁴⁹ This finding is consistent with the higher standard of judicial scrutiny applied to pests/diseases than to food and related products.

Second, the levels of protection must exhibit arbitrary or unjustifiable differences in their treatment of different situations (AB, *Beef Hormones*, *supra* note 77, paragraph 214). Here, the AB found a fundamental distinction to be made between naturally-occurring hormones and added hormones (whether natural or synthetic) used for cattle (*Id.*, paragraph 221) and thus the different levels were not unjustifiable. One wonders if a Panel would extend a similarly generous interpretation to different levels of protection as between potential threats posed by natural versus GM foods. However, an unjustifiable difference was found by the AB with respect to a pig feed additive used in the EC and known to be a carcinogen, and growth hormones (an alleged carcinogen) in cattle (*Id.*, paragraph 235). Thus, it may be that the specific health risk, and less its source, will demand consistent levels.

Third, it must be shown that arbitrary and unjustifiable differences demonstrably (*Id.*, paragraph 215) result in discrimination or a disguised restriction on trade. Here, the AB applied a lenient analysis to the EC's position on the issue. It found that the impetus for the import ban came from the EC's desire to protect its population from a cancer risk and not to shield domestic beef producers against imports (*Id.*, paragraph 246). It therefore found that the differences in the levels of protection between growth hormones and the carcinogenic pig feed additive, while unjustifiable, did not result in discrimination or a disguised restriction on trade, and thus did not violate Article 5.5.

Beef Hormones therefore suggests that measures taken with a bona fide purpose of allaying consumer concern will not, even in the absence of scientific support, be viewed as disguised protectionism. A more rigorous analysis⁵⁰ of the third requirement was applied in *Australia Salmon*, suggesting either stricter treatment for either pests/diseases or more generally, cases where public concern is less of a factor in risk management decisions.

⁴⁹ AB, *Australia Salmon*, *supra* note 88, paragraph 147; also at paragraph 153, the AB indicated that it is not necessary that they share risk of all diseases of concern, but risk of only one disease of concern is sufficient.

⁵⁰ AB, *Australia Salmon*, *supra* note 88, paragraphs 160–179.

7.2. Article 5.6

Article 5.6 reads:

Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical or economic feasibility.⁵¹

The AB in *Australia Salmon* noted that the following requirements must be cumulatively met before a violation of Article 5.6 will be found: there must be an SPS measure that first, is reasonably available taking into account technical and economic feasibility; second, achieves the Member's appropriate level of SPS protection; and third, is significantly less restrictive to trade than the SPS measure contested (AB, *Australia Salmon*, *supra* note 88, paragraph 195).

On the facts of that case, it was held that the risk assessment at issue had set out five options that "merit consideration" (*Id.*, paragraph 184). The AB accepted the Panel's finding that this implied that the alternatives provided were technically and economically feasible options, and thus the first element was satisfied. It is interesting to note that the first requirement here corresponds with the third step of risk assessment for pests and diseases, i.e., determining the likelihood of risk in relation to SPS options. Importantly, however, no similar requirement is mandated for food risks.

With respect to the second element, the AB confirmed that "level of protection is an element in the decision-making process which logically precedes and is separate from the establishment . . . of the SPS measure" (*Id.*, paragraph 204). While the Member is not obliged to express the appropriate level of protection in quantitative terms, it must not determine the level of protection with "such vagueness and equivocation" that the application of the SPS Agreement is defeated (*Id.*, paragraph 207). In cases where a Member does not state the appropriate level with sufficient precision, the Panel may establish this by referring to the SPS measure actually applied (*Id.*, paragraph 208). Due to the shortcomings of the risk assessment in *Australia Salmon*, the second and third elements could not be analysed.

7.3. Article 2.3

The first sentence of Article 2.3 denotes similar obligations as those found in the most favoured nation and national treatment rules, and incorporates part of the Article XX chapeau (*Id.*, paragraph 252):

⁵¹ The footnote to the provision provides that "a measure is more trade restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of [SPS] protection and is significantly less trade restrictive."

Members shall ensure that their [SPS] measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. . .

The AB in *Australia Salmon* stated that a violation of the third requirement of Article 5.5 would necessarily imply a violation of Article 2.3 (*Id.*, paragraph 253). However, it maintained that other routes may lead to a violation of Article 2.3. Insufficient factual evidence prevented an examination of the issue in the case. Still, the AB noted that an Article 2.3 inquiry would bring into question risks of disease as it applies to the various regions of a Member's territory (*Id.*, paragraph 256).⁵²

7.4. Summary of trade provisions

The SPS Agreement, as interpreted in *Beef Hormones*, is lenient in allowing Members to establish different levels of protection against SPS risks, where there is a strong public health concern. However, this leniency was tightened up in *Australia Salmon*, and thus one wonders whether Members must now establish greater coherence as between risks where public concern is not an overriding factor in risk management.

It is also clear that various SPS options outlined in risk assessments will be subjected to a close analysis vis-à-vis the level of protection chosen, thus restricting the ability of states to decree import bans. Furthermore, it seems Members may not impose blanket measures but must tailor them to specific regions where there is a risk. The trade provisions will ensure that measures are proportionate to the risk and the level of protection chosen.

8. Trade with Non-Parties

Article 24(1) states:

Transboundary movements of living modified organisms between parties and non-parties shall be consistent with the objective of the Protocol. The parties may enter into bilateral, regional and multilateral agreements and arrangements with non-parties regarding such transboundary movements.⁵³

If we assume that the objective of the Protocol asserts new rights and obligations that conflict with the SPS Agreement, then Article 24 may lead to both a contravention of the latter agreement and a violation of the principle of consent under the law of treaties (Article 34). For example, State A, which is a party to both agreements, may invoke measures under the Protocol to restrict trade in LMOs from State B, which is party to only the SPS Agreement, notwithstanding that trade would otherwise be permitted under the latter agreement. To resolve this dilemma, Article 30(4) of the Vienna Convention on

⁵² This observation is consistent with Article 6 of the SPS Agreement.

⁵³ Article 24(2) further requires Parties to encourage non-parties to adhere to the Protocol, and to contribute information the Biosafety Clearinghouse.

the Law of Treaties (hereinafter “Vienna Convention”) is clear in stipulating that it is the treaty which both states are party to, i.e., the SPS Agreement, which prevails in this type of situation. Still, in this scenario, Article 24 puts contracting States in the awkward position of violating their obligations under one of the treaties vis-à-vis non-parties.⁵⁴

9. Relationship with existing international agreements

Together with the precautionary principle, agreement on the declared relationship between biosafety regulation and trade was achieved only at the last minute. Reflecting compromise, the relationship is set out in the ninth, tenth and eleventh recitals of the preamble to the Protocol:

- *Recognising* that trade and environment agreements should be mutually supportive with a view to achieving sustainable development;
- *Emphasising* that this Protocol shall not be interpreted as implying a change in rights and obligations of a Party under any existing international agreements;
- *Understanding* that the above recital is not intended to subordinate this Protocol to other international agreements.

Sinclair observes that the rules in Article 30 of the Vienna Convention dealing with successive treaties are residuary rules that will operate in the absence of express treaty provisions regarding priority [33, *supra* note 53, p. 97]. Indeed, the solution is to be found in the intention of the parties [29], which as expressed in the terms of the Protocol, should be “mutually supportive with a view to achieving sustainable development.” This is reinforced by the fact that the last two recitals would be exposed to contradiction if there is any irreconcilable discrepancy between the two agreements. The implication here is that, while the two agreements may supplement and complement each other, they may not conflict. It is therefore necessary to find a reasonable way to construe the term “mutually supportive” in this context.

This paper has highlighted a number of procedural and substantive differences between the two agreements. In the key areas of potential conflict however, one of the agreements has been drafted or interpreted in sufficiently vague terms to conceivably derive complementary meaning from the other. A crucial example is Article 5.7 of the Agreement which may be interpreted to accommodate the low threshold of action mandated under the Protocol; while at the same time, the Protocol’s science-based approach limits its potentially open-ended meaning. Another example is the vague level of protection afforded to States under the Protocol, which may derive meaning from the more exact and possibly higher standard under the Agreement. In this way, it can be seen that, while the agreements may not coincide in absolute terms, they may inform each other on GMO SPS measures, and thus be compatible in a relative sense. Relative mutual supportiveness may also extend to

⁵⁴ Denunciation of the SPS Agreement or invalidity of the Protocol would not likely be alleged since provision is made in the preamble for the relationship between trade agreements and the Protocol, suggesting the continued applicability of both; see, for example, [15, p. 1215] where it is stated that the intention to create an interdependent treaty regime is valid.

supplemental features of the two agreements. In other words, the trade provisions in the Agreement would be applicable to measures taken under the Protocol.

However, the agreements may be in direct conflict on the issue of international standards and guidelines. If mutual supportiveness is not achievable or is not strictly binding in the sense that its expression is found in the preamble and not the main text of the Protocol, resort may be had to Article 30 of the Vienna Convention to resolve conflicting treaty provisions relating to the same subject matter. Whether both treaties pertain to the same subject matter is not entirely clear. While both are concerned with the regulation of transboundary movement of food or organisms that may pose a threat to human, animal and plant life or health, they do so from entirely separate perspectives of trade and environmental protection. More importantly, the Protocol addresses a particular type of threat while the SPS Agreement is of more general application.

Assuming the subject matter is the same, Article 30(2) stipulates that “when a treaty specifies that it is subject to, or that it is not to be considered as incompatible with, an earlier or later treaty, the provisions of that other treaty prevail.” A strict application of this rule favours the SPS Agreement since this is the ‘other treaty’ which the Protocol is not to be incompatible with under the 10th recital of the preamble.

The weight of legal principle under the law of treaties however, supports the opposite conclusion. Article 30(3) provides that as between two treaties whose subject matter is the same, and the earlier treaty is neither suspended nor terminated, “the earlier treaty applies only to the extent that its provisions are compatible with those of the later treaty.” With respect to trade principles that prohibit disguised protectionism or discrimination, for example, these are not addressed or refuted in the Protocol and thus they would apply to trade in GMOs under the Protocol. Where the two agreements conflict however, the later treaty (being the Protocol) will prevail.

The Protocol would also be paramount under the customary principle of *lex specialis*, i.e., the more specific treaty takes precedence over the more general treaty. The edge may also be given to the Protocol because mutual supportiveness is modified by the consideration that it achieve “sustainable development.” Indeed, the more permissive elements of either agreement could be advanced in view of this consideration. Finally, given that it was adopted by 130 State Parties, sound policy dictates that the Protocol should be the governing instrument with regard to GMOs.

10. Conclusion

From the perspective of environmental protection, the Cartagena Protocol achieves mixed results. On the positive side, it implements a liberal formulation of the precautionary principle in the context of a trade agreement that is unclear in asserting an exact threshold of regulatory action for risks posed by GMOs. Furthermore, it does so through a system of advanced informed agreement (AIA), giving states an opportunity to make considered import decisions for LMO release into their environments.

The parameters of risk assessment are broad in the Protocol and, together with Articles 10(6) and 11(8), this assures maximum flexibility for the implementation of precaution-

ary measures in accordance with the principles of sound science. In failing to mandate advanced informed agreement for LMO/FFP, however, the Protocol offers weak regulatory protection for countries wary of imported food and related products that may contain GMOs.

The Cartagena Protocol is a treaty that may be too self-conscious of its relationship with international trade law. A more radical precautionary approach that is perhaps appropriate in cases of scientific uncertainty coupled with grave potential risk, would be to reverse the burden of proof on modern biotechnology requiring that GMO safety be proven prior to commercial release. By necessity, this would require longer-term data collection and monitoring than is provided under the advanced informed agreement framework, or (implicitly) the proportionality provisions of the SPS Agreement.

The general approach of both the Protocol and the SPS Agreement is that science can provide immediate answers to the questions of GMO safety, and where it is unable to do so, uncertainty should not interfere indefinitely with the free movement of goods. Thus, while the Protocol may be “mutually supportive” to international trade, such an approach may not be conducive to achieving the goal of sustainable development.

Incompatibility between the two agreements will most likely surface on the issue of international standards and guidelines for GMO products and risk assessment. In light of the industry bias in Codex, it is very possible that the development of international rules for GM foods may undermine the more permissive provisions of the Protocol with respect to risk assessment techniques and implementation of the precautionary principle.

References

- [1] Adler, J. “More Sorry than Safe. Assessing the Precautionary Principle and the Proposed Biosafety Protocol.” *Tx. Int’l L. J.* 35 (2000).
- [2] Agenda 21, Article 2.10(d). Available at <http://un.org/esa/sustdev/agenda21chapter2.htm>, visited on April 20, 2001.
- [3] Available at <http://www.biodiv.org/biosafety/signinglist.asp>.
- [4] Burhenne-Guilmin, F. “The Biosafety Protocol is Adopted in Montreal.” *Envtl. Pol’y & L.* 30 (2000).
- [5] Callow, P. “Environmental Risk Assessment and Management: the Whats, Whys and Hows.” In P. Callow (ed.), *Handbook of Environmental Risk Assessment and Management* (1998).
- [6] Cameron, J., and J. Aboucher. “Addressing Uncertainty: Law, Policy and the Development of the Precautionary Principle.” Working Paper, The Centre for Social and Economic Research on Global Environment (CSERGE).
- [7] Centre for International Environmental Law (CIEL). “Should the WTO Negotiate New Trade Rules on Genetically Modified Organisms.” Available at <http://www.consumerscouncil.org>, visited on April 22, 2001.
- [8] Codex Task Force Meets on Biotech Foods (March 21, 2000). Available at [http://www.newsbulletin.org/bulletins/getbulletin.CFM?SID=#Codex Task Force Meets On Biotech Foods](http://www.newsbulletin.org/bulletins/getbulletin.CFM?SID=#Codex+Task+Force+Meets+On+Biotech+Foods), visited on April 22, 2001.
- [9] Committee on Trade and the Environment. Report WT/CTE.1, paragraph 167 (1996). Available at <http://docsonline.wto.org/GEN>.
- [10] Commonwealth of Australia v. The State of Tasmania 158 CLR 1, Supreme Court of Australia, 1983.
- [11] European Community Commission. Communication from the EC on the Precautionary Principle. COM (2000). Available at http://europa.eu.int/eur-lex/en/com/enc/2000/com2000_0001en01.pdf, visited on April 22, 2001.
- [12] Greenpeace International. Summary of the Cartagena Protocol on Biosafety (February 2, 2000). Available at <http://www.greenpeace.org/~geneng/>, visited on April 22, 2001.

- [13] Hall, S. "The Genie in the Bottle: The International Regulation of Genetically Modified Organisms." *J. Int'l Wildlife L. & Pol'y* 1 (1998).
- [14] Hill, J. "The Precautionary Principle and the Release of Genetically Modified Organisms (GMOS) to the Environment." In O'Riordan and Cameron (eds.), *Interpreting the Precautionary Principle* (1994).
- [15] Jennings, R., and A. Watts. (1) *Oppenheim's International Law*, 9th edn. (1992). Peace Parts 2-4.
- [16] MacNeil D. "The First Case Under the WTO's Sanitary and Phytosanitary Agreement: The European Union's Hormone Ban." *Va. J. Int'l L.* 39 (1998).
- [17] Organisation for Economic Co-operation and Development (OECD). GM Food Safety: Facts, Uncertainties and Assessment, The OECD Edinburgh Conference on the Scientific and Health Aspects of Genetically Modified Organisms, Rapporteur's Summary (2000) p. 10. Available at <http://www.oecd.org/subject/biotech/Rapporteureng.pdf>, visited on April 22, 2001.
- [18] O'Riordan, T., and A. Jordan. "The Precautionary Principle: Science, Ethics and Politics." The Centre for Social and Economic Research on the Global Environment.
- [19] O'Riordan, T., and J. Cameron (eds.). *Interpreting the Precautionary Principle* (1994).
- [20] Pardo-Quintillan, S. "Free Trade, Public Health Protection and Consumer Information in the European and WTO Context." *J. World Trade* 33.
- [21] Powell, M.R. "Science in Sanitary and Phytosanitary Dispute Resolution 5" (September 1997). Available at http://www.rff.org/disc_papers/1997.htm, visited on April 22, 2001.
- [22] Report of the Appellate Body, Australia-Measures Affecting the Importation of Salmon WT/DS18/AB/R (October 28, 1998). Available at http://www.wto.org/english/tratop_e/dispu_e/hormab.pdf, visited on April 22, 2001.
- [23] Report of the Appellate Body, EC Measures Concerning Meat and Meat Products (Hormones). WT/DS26/AB/R, WT/DS48/AB/R (January 16, 1998) paragraph 190. Available at http://www.wto.org/english/tratop_e/dispu_e/hormab.pdf, visited on April 22, 2001.
- [24] Report of the Appellate Body, Japan-Measures Affecting Agricultural Products WT/DS76/AB/R (February 22, 1999). Available at http://www.wto.org/english/tratop_e/dispu_e/distab_e.htm, visited on April 22, 2001.
- [25] Report of the Extraordinary Meeting of the Conference of the Parties for the Adoption of the Protocol on Biosafety to the Convention on Biological Diversity (24-29 January 2000) paragraph 67. Resumed Session in Montreal. Available at <http://www.biodiv.org/biosafety/bswg-mtgs.asp>.
- [26] Report of the Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, Safety Aspects of Genetically Modified Foods of Plant Origin (2000). Available at <http://www.fao.org/es/esn/gm/gmreport.pdf>, visited on April 22, 2001.
- [27] Report of the Panel WT/DS18/R. Australia-Measures Affecting the Importation of Salmon (June 12, 1998) paragraph 8.185. Available at http://www.wto.org/english/tratop_e/dispu_e/distab_e.htm, visited on April 22, 2001.
- [28] Report of the Panel WT/DS26/R. "EC Measures Concerning Meat and Meat Products (USA)" (August 18, 1997) paragraph 8.42. Available at http://www.wto.org/english/tratop_e/dispu_e/distab_e.htm, visited on April 22, 2001.
- [29] Reuter, P. *Introduction to the Law of Treaties* 132, 2nd edn. (1995).
- [30] Roberts B. "Genetically Modified Organisms, Living Modified Organisms and Invasive Species." Unofficial discussion paper prepared for the IPPC Working Group. Available at <http://www.fao.org/apps/>, visited on April 22, 2001.
- [31] Roberts, D. "Preliminary Assessment of the Effects of the WTO Agreements on Sanitary and Phytosanitary Measures." *J. Int'l Econ. L.* 1 (1998).
- [32] Seidler R., L. Watrud and E. Georg. "Assessing Risks to Ecosystems and Human Health from Genetically Modified Organisms." In P. Callow (ed.), *Handbook on Environmental Risk Assessment and Management* (1998).
- [33] Sinclair, I. *The Vienna Convention on the Law of Treaties*, 2nd edn. (1984).
- [34] Slotbloom, M.M. The Hormones Case: An Increased Risk of Illegality of Sanitary and Phytosanitary Measures. *Common Market L. Rev.* 36 (1999).
- [35] SPS Agreement and GATT (1994).

- [36] Stilwell, M. and B. Van Dyke. "An Activists Handbook on Genetically Modified Organisms and the WTO" (July 1999). Available at <http://www.consumerscouncil.org>, visited on April 22, 2001.
- [37] Summary of the 1st Meeting of the Open Ended Ad Hoc Working Group on Biosafety (July 1996). Available at <http://www.biodiv.org/biosafety/bswg-mtgs.asp>, visited on April 22, 2001.
- [38] Swenarchuk, M. "The Cartagena Protocol: Opportunities and Limitations." Available at <http://www.cela.ca/Trad&Env/biosafe.htm>, visited on April 22, 2001.
- [39] *The Hutchinson Dictionary of Science* (1993).
- [40] United Nations Environment Program (UNEP). International Technical Guidelines for Safety in Biotechnology. Available at <http://www.unep.org/unep/program/natres/biodiv/irb/unepgds.htm>, visited on April 22, 2001.
- [41] Walker, V.R. "Keeping the WTO from Becoming the World Trans-science Organisation: Scientific Uncertainty, Science Policy and Factfinding in the Growth Hormones Dispute." *Cornell Int'l L. J.* 13 (1998).