The International Regulation of Modern Biotechnology

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I. INTRODUCTION

Products derived from modern biotechnology are subject to a growing array of international institutional oversight, both technology-based and sector- or product-based. Over recent years, several new instruments have been elaborated that address biosafety, while existing institutions and regimes have also turned their attention to the development of specific standards on genetically modified organisms (GMOs) or the derivatives of such organisms. These developments present both a safeguard and a challenge for developing countries. On the one hand, internationally agreed rules and standards aim to ensure that developing countries do not become "testing" or "dumping" grounds for potentially harmful technologies and products. Negative experiences in relation to hazardous wastes and chemicals have given rise to a cautious attitude on the part of many developing countries when faced with new applications of biotechnology. On the other hand, the international instruments pose implementation and capacity challenges. In addition, the instruments themselves, being the subject of intense international debate and controversy, incorporate certain "negotiated ambiguities" that suggest that implementation will have to be mediated through further international negotiation. Given the range of applicable instruments, multiple fora exist within which these further negotiations may occur. Far from setting out a clear "rule-based" system, the current international institutional framework presents developing countries with a series of policy choices that need to be worked out in specific legal and political contexts, including food aid; debt; trade and investment; development assistance; multilateral environmental agreements (MEAs); and World Trade Organization (WTO) membership and the post-Doha negotiations.

In developed countries, GMOs have been the subject of intense policy debate, both within and between States. Significant claims have been made about the capacity of modern biotechnology to contribute to food security, in particular, by increasing agricultural production in developing countries and by enhancing the nutritional value of basic foods.[1] At the same time, serious concerns have been expressed about the potential impacts of GM crops on the environment and on human health as well as about their potential socio-economic impacts. With respect to the latter, there are concerns about the potential distributive impacts of GMOs, for instance, under what conditions would GM seeds be made available to farmers and to what restrictions would they be subject; what impact might GMOs have on traditional varieties of crops relied upon by farmers in developing countries and how would they affect centres of origin and centres of diversity of agricultural biodiversity; and what impact might the introduction of GMOs in

[1] For a discussion of these claims and counterclaims, see Scoones, (2002).

developed countries have on commodity exports from developing countries? While scientific opinion regarding the extent of any environmental and health risks remains divided, research has given rise to concerns about a number of potential risks associated with the release and use of GMOs. These risks tend to fall into a number of categories, including: (1) the potential impacts of GMOs on non-target species, such as beneficial insects or birds; (2) the potential for cross-pollination between GM and non-GM (and organic) crops or between GM crops and wild plants—"genetic drift" or "genetic pollution"; (3) the introduction of non-native or "exotic" species into the environment with the potential displacement of native species, for example, the spread of GMOs as weeds or "volunteers"; (4) the indirect effects on the environment, for example, through changed agricultural practices, particularly changes in herbicide and pesticide spraying; and (5) the potential effects on human health, for example, through the consumption of food produced using genetically modified crops and their derivatives. Two principal areas of concern relate to allergenicity of foodstuffs as a result of introduced proteins and the potential transfer of antibiotic resistance, as a result of the use of antibiotic resistance marker genes in the production of GMOs.

With regard to human health and environmental concerns, most developing countries have tended to emphasize their lack of capacity to assess and manage the risks associated with GMOs. These concerns were strongly expressed during the negotiation of the Cartagena Protocol on Biosafety (Biosafety Protocol).[2] Developing countries were, on the whole, strongly in favour of the adoption of the Protocol, and they supported a stringent safety assessment and advance informed agreement procedure, the incorporation of the precautionary principle, the possibility to take socio-economic considerations into account when deciding whether to allow imports of a specific GMO, and the primacy of the Protocol over relevant WTO obligations. While developing countries were attracted to the potential of modern biotechnology to contribute to food security needs, during the debate over the regulation of GMOs and particularly during the Biosafety Protocol negotiations, they tended to stress issues of uncertainty, capacity, social and economic concerns, and priorities relating to food security and the protection of human health and the environment. In discussions on the labelling of GM food, India, for example, has expressed support for the labelling of all foods derived from modern biotechnology, irrespective of differences with other foods, in order to ensure consumer information and allow consumer choice.[3] By contrast, in discussions in the WTO, developing countries have tended to express concerns about the effect of non-tariff barriers on market access for their goods. Thus, they have been concerned not to expand the discussion of trade and environment issues in the WTO in a manner that might increase the possibility of unilateral trade-related environmental measures by developed countries, and they have been supporters of the harmonization of international standards, coupled with enhanced participation of developing countries in international standard-setting bodies and capacity building for the implementation of international standards. Market access concerns have

[2] Cartagena Protocol on Biosafety, 29 January 2000, in force 11 September 2003, 39 ILM (2000) 1027, also available at <http://www.biodiv.org/biosafe/BIOSAFETY-PROTOCOL.htm>. [hereinafter Biosafety Protocol].

[3] *Report of the Thirtieth Session of the Codex Committee on Food Labelling*, 6-10 May 2002, Doc. ALINORM 03/22, at para. 43.

been at the heart of the positions put forward by many developing countries in discussions in the WTO on trade and environment, on technical barriers to trade and on sanitary and phytosanitary measures, and in the context of the Agreement on Agriculture.[4] These positions may seem difficult to reconcile. To some degree, they may simply be reflective of the different, and often inconsistent, approaches adopted by trade, environment, or agriculture ministries. However, they also represent a more complex reaction to the introduction of a relatively new technology, the benefits and risks of which remain uncertain, and about which gaps in knowledge still exist in relation to the long-term impacts on the environment and on human health and in relation to the potential socio-economic impacts.[5]

This paper suggests that the present (emerging) system of international governance for modern biotechnology does not adequately accommodate this range of concerns. It suggests that developing countries should be accorded secure policy space in which to consider, through public consultations as well as through technology, product, and environmental and social impact assessments, whether and how to integrate modern biotechnology into domestic agricultural systems. This accommodation is all the more necessary given the enormous capacity gap that presently exists. Mechanisms need to be developed (or applied to the extent that they already exist) to provide a higher degree of flexibility and autonomy to developing countries in this area. This may mean recognizing, through the judicial or political interpretation of existing agreements, or through new agreements, a wider range of justifications for trade measures in the face of scientific and socio-economic uncertainty—justifications that take into account the particular concerns and circumstances of developing countries in relation to food security.

International Law and Policy Framework

The main aim of this paper is to detail the international legal and institutional context within which developing countries operate as they elaborate and implement national biotechnology and biosafety policies and legal frameworks. The primary focus of the paper, as it is in the international agenda, is on agricultural biotechnology and related biosafety issues. The paper considers international rules and guidelines setting out the *rights or obligations to regulate* biotechnology/biosafety as well as the international legal obligations that *discipline* the rights of countries to apply food safety, health, and environmental regulations and to take food security considerations into account in making regulatory decisions on the import and use of GMOs. International instruments of relevance include the Biosafety Protocol, the International Plant Protection Convention

[4] Agreement on Agriculture, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement], Annex 1A, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement], Annex 1A, WTO, *The Results of the Uruguay Round Multilateral Trade Negotiations: The Legal Texts*, 33 also available at http://www.wto.org/english/docs_e/legal_e/14-ag.pdf

[5] See, for example, Zarilli, (2000)

(IPPC),[6] and the Codex Alimentarius.[7] Disciplines on domestic regulation are imposed principally by relevant WTO agreements, particularly the General Agreement on Tariffs and Trade (GATT),[8] the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement),[9] and the Agreement on Technical Barriers to Trade (TBT Agreement).[10] Given the debate over the role of socio-economic considerations in the Biosafety Protocol and over the appropriate shape and content of national biosafety frameworks, the focus of this article is on the extent to which domestic regulatory systems for GMOs, including national biosafety frameworks under development, can take into account environmental, health, agricultural, and broader food security considerations in decision-making.[11] It does not specifically address other policies and measures that countries may utilize to promote or protect particular forms of agriculture or particular social groups.

In addition to the instruments and institutions already mentioned, there are a wide range of other relevant, or potentially relevant, instruments and processes at the international level.(Mackenzie 2001) These include soft law and policy guidance processes, for example, Chapter 16 of Agenda 21;[12] the Plan of Implementation from the World Summit on Sustainable Development (WSSD);[13] the World Food Summit Declaration and Plan of Action and the Declaration of the World Food Summit: Five Years Later;[14] and the work of the Food and Agriculture Organization (FAO) Panel of Eminent Experts in Ethics on Food and Agriculture (FAO 2001) and of the UN special rapporteur on the right to food.[15]

Rules or standards promulgated in one forum can significantly affect the content of rules under development in another. As discussed further below, during the Biosafety Protocol

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[6] International Plant Protection Convention, available at http://www.ippc.int/IPP/En/default.htm [hereinafter IPPC 1997]. The IPPC was originally adopted in 1951, and revised in 1979, see <http://www.ippc.int>.

[7] Codex Alimentarius, see http://www.codexalimentarius.net.

[8] General Agreement on Tariffs and Trade, 30 October 1947, 61 Stat. A-11, TIAS 1700, 55 UNTS 194 [hereinafter GATT].

[9] Agreement on the Application of Sanitary and Phytosanitary Measures, 15 April 1994, WTO Agreement, Annex 1A, WTO, *The Results of the Uruguay Round Multilateral Trade Negotiations: The Legal Texts*, 59, also available at http://www.wto.org/english/docs_e/legal_e/15-sps.pdf [hereinafter SPS Agreement].

[10] Agreement on Technical Barriers to Trade, 15 April 1994, WTO Agreement, WTO, *The Results of the Uruguay Round Multilateral Trade Negotiations: The Legal Texts*, 121, also available at http://www.wto.org/english/docs_e/legal_e/17-tbt.pdf [hereinafter TBT Agreement].

[11] While this article focuses on measures that regulate the import and use of GMOs, issues of access to, and the transfer of, biotechnology are addressed in more detail in another paper produced for the *Globalisation and the International Governance and Modern Biotechnology* project. See Yamin (2003)

[12] Agenda 21, Report of the United Nations Conference on Environment and Development, Rio de Janeiro, 3-14 June 1992, UN Doc A/CONF.151/26, Vol I-III, 12 August 1992, Annex II, available at http://www.un.org/esa/sustdev/documents/agenda21/english/agenda21doc.htm.

[13] See the World Summit on Sustainable Development [hereinafter WSSD], Plan of Implementation, available at <http://www.johannesburgsummit.org >, at para. 42(r) and (t).

[14] World Food Summit Declaration and Plan of Action, available at http://www.fao.org/wfs/index_en.htm ; Declaration of the World Food Summit: Five Years Later, 10-13 June 2002, Doc. WFS:fyl 2002/3, available at <http://www.fao.org/worldfoodsummit/english/index.html>, especially at para. 25.

[15] See *Reports of the Special Rapporteur to the Commission on Human Rights*, 7 February 2001, UN Doc. E/CN.4/2001/53 and 20 December 2001, UN Doc. E/CN.4/2002/57.

negotiations, there were frequent references to relevant WTO agreements and an attempt to adopt provisions that were *prima facie* compatible with WTO requirements. In negotiations in the Codex Alimentarius, similar references to the WTO requirements are found. Discussions on traceability and labelling of GMOs in the Codex[16] may well impact upon future negotiations on the identification and documentation requirements for agricultural commodities under Article 18 of the Biosafety Protocol, and each of these in turn may be subject to consideration within the WTO. And within the WTO itself, internal coherence poses a challenge as related issues are taken up in different committees and negotiating groups.[17] With relatively little capacity for preparation and participation in these processes, some developing countries can find their interests profoundly affected by rules adopted in processes in which they have played little role.

Food security has been a central feature of debates concerning the role of modern biotechnology in agriculture (Scoones 2002) yet it is not the primary objective of the regulatory instruments addressed in this article. Indeed, in most of these instruments, food security is not mentioned explicitly at all, yet all are relevant to broader food security concerns. Within the context of these instruments, there are three key sets of questions to be addressed:

(1) What rules apply and how do they relate to each other? Section II tracks drives to harmonize approaches to sanitary and phytosanitary regulation and risk assessment between countries in order to minimize trade barriers, while allowing countries to apply safety standards; and it seeks to identify the international obligations of developing countries with respect to biotechnology and biosafety. Section III considers the legal and political interactions between the relevant agreements and processes.
(2) How and to what extent do the relevant agreements provide "space" for food security considerations? Section IV explores the relevance of food security within the various agreements and the scope for developing countries to raise food security concerns, and Section V raises certain relevant domestic implementation issues.
(3) What opportunities do the various institutions provide for developing countries to promote food security and broader socio-economic considerations in policymaking? Section VI considers the formal and informal policy- and decision-making processes within the key institutions, and the extent to which developing countries participate in them.

II. APPLICABLE LAW AND INSTITUTIONS

[16] *Report of the Thirtieth Session of the Codex Committee on Food Labelling*, supra note 3.
[17] See, for example, Committee on Trade and Environment [hereinafter CTE], *Summary Report on the First Meeting of the Special Session held on 22 March 2002*, Note by the Secretariat, 22 March 2002, Doc. TN/TE/R/1, at para. 74, regarding the role of the CTE, the Council for Trade in Services Special Session, and the Negotiating Group on Market Access for Non-Agricultural Products in relation to environmental goods and services.

This section considers international rules and guidelines that require or authorize countries to take measures to *regulate* biotechnology/biosafety as well as international legal obligations that *discipline* the rights of countries to apply such measures. International institutions have been active in efforts to harmonize approaches to sanitary and phytosanitary regulation and risk assessment between countries in order to minimize trade barriers while allowing countries to apply safety standards. There has been growing activity in the area of international policymaking on modern biotechnology. New instruments have been developed, and existing instruments and organizations have turned their attention towards the development of sectoral rules and/or standards applicable to GMOs. The result is a complex framework of relevant international rules and standards, many of which are still under development. There processes are supplemented by numerous international workshops, symposia, and training courses, which are sponsored by governments, international organizations, the private sector, and non-governmental organizations (NGOs). Thus, one challenge for national policymakers lies simply in keeping up with the international policymaking processes, with all that this implies in terms of human and financial resources, information exchange, preparation for negotiations, and problems of national-level coordination of policy across the relevant fora, for example, among trade, environment, agriculture, and science and technology ministries.

The basic tension inherent in policymaking in biotechnology and biosafety is reflected in Chapter 16 of Agenda 21. Agenda 21 recognized the potential benefits of biotechnology in contributing to enhanced food security through sustainable agricultural processes. Among other things, it sought to promote activities to enhance biosafety regulation and international mechanisms for cooperation, as well as enabling mechanisms for the development and environmentally sound application of biotechnology. In particular, Agenda 21 called for the further development of internationally agreed principles on risk assessment and management of all aspects of biotechnology. It also called for the promotion of the development and application of biotechnologies, with special emphasis on developing countries. In this regard, it noted that

> [t]he accelerated development and application of biotechnologies, particularly in developing countries, will require a major effort to build up institutional capacities at the national and regional levels. In developing countries, enabling factors such as training capacity, know-how, research and development facilities and funds, industrial building capacity, capital (including venture capital), protection of intellectual property rights, and expertise in areas including marketing research, technology assessment, socio-economic assessment and safety assessment are frequently inadequate.[18]

Since Agenda 21, significant developments have occurred in relation to the development of internationally agreed principles on risk assessment and the management of biotechnology. In addition, other developments have occurred that impact on the regulation of biotechnology at the national level. These developments and principles are examined in this section. Section III then considers the interactions between these various applicable principles and institutions. The four instruments or sets of instruments

[18] Agenda 21, *supra* note 13, at chapter 16.37.

considered in this section are: (1) the 1992 Convention on Biological Diversity (CBD)[19] and the 2000 Biosafety Protocol; (2) the IPPC; (3) the Codex Alimenatarius; and (4) the WTO agreements.

While the primary focus and objective of each of the instruments differs, each represents an effort towards international harmonization of standards and procedures in relation to modern biotechnology.[20] Among these instruments, the Biosafety Protocol and the WTO agreements are presently of primary potential relevance for the movement of GMOs and agricultural biotechnology into developing countries for research and development, field trials, and/or commercial cultivation. The other instruments are considered briefly, given their ongoing work to generate international standards and guidelines of relevance to GMOs and the status of such standards within the WTO's SPS and TBT Agreements.

1. The Convention on Biological Diversity and the Biosafety Protocol

The CBD,[21] which was adopted in 1992, specifically addresses biosafety in two articles: Article 8 (on *in-situ* conservation) and Article 19 (on the handling of biotechnology and the distribution of its benefits). Article 8(g) requires Parties, as far as possible and as appropriate, to regulate, manage, or control risks associated with the use and release of living modified organisms resulting from biotechnology that are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health. Article 19(4) addresses the transboundary movement of GMOs[22] and requires a Party that provides GMOs to another party to provide any available information about the use and safety regulations applicable to those organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Party into which they are to be introduced. Article 8(g) and Article 19(4) are binding upon all states Parties to the CBD (187 in total, as of 14 May 2003) regardless of whether or not they become Parties to the Biosafety Protocol.

Article 19(3) provides a specific legal basis for the mandate to negotiate the Biosafety Protocol, requiring parties to the CBD to "consider the need for and modalities of a Protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation

[19] Convention on Biological Diversity, 5 June 1992, in force 29 May 1994, 31 ILM 818 (1992) or 1760 UNTS 79, available at http://www.biodiv.org/convention/articles.asp [hereinafter CBD].

[20] Such efforts have been ongoing for a number of years in other, limited membership, organizations, such as the Organization for Economic Co-operation and Development [hereinafter OECD]; and, internationally, in relation to the elaboration of voluntary guidelines such as those contained in the UN Environment Programme [hereinafter UNEP], International Technical Guidelines for Safety in Biotechnology (1995); and the UN Industrial Development Organization, Voluntary Code of Conduct for the Release of Organisms into the Environment (1992).

[21] CBD, *supra* note 22.

[22] GMOs are referred to as "living modified organisms" [hereinafter LMOs] in both the CBD and the Biosafety Protocol. For ease of reference, this article refers to GMOs throughout, except in relation to GM commodities ("living modified organisms intended for direct use as food or feed, or for processing" in the terminology of the protocol), which are referred to by the abbreviation "LMO-FFPs."

and sustainable use of biological diversity." In 2000, the Parties to the CBD adopted a more specific agreement on biosafety under the enabling provision in Article 19(3), the Biosafety Protocol.[23] The objective of the Biosafety Protocol is:

> In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development ... 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 also into account risks to human health, and specifically focusing on transboundary movements.[24]

An Intergovernmental Committee for the Cartagena Protocol (ICCP) was established to prepare for entry into force of the Protocol, and it adopted a series of recommendations for consideration of the first meeting of the Parties.[25]

The focus of the Protocol is on the transboundary movement of GMOs (referred to as "living modified organisms" (LMOs) in the Protocol). The central procedural mechanism set out in the Protocol to regulate the transboundary movement of living modified organisms is advance informed agreement (AIA). The AIA procedure essentially requires that before the first transboundary movement of a GMO subject to the AIA procedure, the party of import is notified of the proposed transboundary movement and is given an opportunity to decide, within 270 days, whether or not the import shall be allowed and upon what conditions. This decision must be based upon a risk assessment, carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Article 15 sets out the risk assessment requirements in more detail. Annex III of the Biosafety Protocol contains guidance on the objective of risk assessment, the general principles of risk assessment, the methodology to be applied, and several points to consider in risk assessment. The Protocol recognizes that risk assessment must be environment-specific, that is, it must consider the risks associated with the release and use of the GMO in the environmental conditions into which it is to be introduced. Where there is a lack of scientific certainty about the extent of the adverse effects of a LMO, a Party may take precautionary action to avoid or minimize the potential adverse effects.[26] The Party of import may also take into account certain socio-economic considerations, pursuant to Article 26 of the Protocol, in reaching a decision on the proposed import. However, any such consideration must also be consistent with that Party's other international obligations. In addition, the Biosafety Protocol contains certain obligations regarding public awareness and participation. The obligation to involve the public in decision-making on GMOs is qualified by a reference to national laws and regulations.[27] The Protocol also provides for the protection of confidential information.[28]

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[23] The Biosafety Protocol will enter into force on 11 September 2003. For a detailed analysis of the provisions of the Protocol, see Mackenzie *et al* (2003).
[24] Biosafety Protocol, *supra* note 2, at Article 1.
[25] The first meeting of the Parties to the Protocol is scheduled to take place in February 2004.
[26] Biosafety Protocol, *supra* note 2, at Articles 10(7) and 11(8).
[27] *Ibid.*, at Article 23.
[28] *Ibid.*, at Article 21.

The AIA procedure only applies to the first transboundary movement of a particular GMO into a country for *intentional introduction into the environment* (for example, for open field trials or for commercial growing). Central to the Biosafety Protocol negotiations were attempts by the biotechnology industry and by the Miami Group[29] to carve out an exemption from the procedural rules for agricultural commodities. (see Newell and Mackenzie 2000; Falkner 2000; Gupta 2000; Pythoud 2002) As a result, separate, and less onerous, provisions apply to the import of LMOs intended for direct use as food or feed or for processing (LMO-FFPs).[30] This procedure, which essentially comprises a multilateral information exchange mechanism, centres on the biosafety clearing-house (BCH), which was established under Article 20 of the Biosafety Protocol. On the one hand, Parties that authorize potential LMO-FFPs at the domestic level inform other parties through the BCH; while, on the other hand, Parties that require advance notification and approval before the import of an LMO-FFP into their territory alert other Parties and exporters to this fact through the BCH. The distinction between the treatment of LMOs and LMO-FFPs in the Protocol is curious, insofar as it was widely recognized during the negotiations that although LMO-FFPs were not *intended* to be introduced into the environment of the Party of import, they may in practice be released into the environment given the lack of adequate control on the ground—the introduction into the environment could happen accidentally, through spillage during transport, or intentionally, where grains are used as seeds in the receiving country.

The import and export provisions of the Biosafety Protocol are backed up by requirements, setting out what information must be provided in documentation accompanying transboundary movements of GMOs.[31] This information is intended to provide a means to identify and track transboundary movements of GMOs; provide information to the Party of import at the border; and offer a contact point for further information about the consignment in question. The specific requirements vary according to the intended use of the GMOs in question.

The Protocol does not prohibit trade in LMOs between Parties and non-Parties, but it requires that such transboundary movements be carried out in a manner "consistent with the objective" of the protocol.[32] This was the subject of significant debate during the Protocol negotiations since one of the major exporters of GMOs, the United States, is presently unable to become a party to the Biosafety Protocol as it has not yet ratified the CBD.[33]

Provisions on capacity building[34] and financial resources[35] are incorporated into the Biosafety Protocol and are subject to further elaboration. In relation to capacity building, it is notable that during the negotiations developed countries were concerned to limit any obligations in this regard to capacity building in biosafety rather than to biotechnology as

[29] Argentina, Australia, Canada, Chile, the United States of America, and Uruguay.
[30] Biosafety Protocol, supra note 2, at Article 11.
[31] *Ibid.*, at Article 18(2).
[32] *Ibid.*, at Article 24.
[33] CBD, *supra* note 22, at Article 32(1).
[34] Biosafety Protocol, supra note 2, at Article 22.
[35] *Ibid.*, at Article 28.

such. Developing countries, on the other hand, sought more extensive commitments extending to biotechnology *per se*.[36] A compromise was adopted referring to capacity building in "biosafety, including biotechnology to the extent that it is required for biosafety".[37]

The Biosafety Protocol does not contain specific provisions relating to the settlement of disputes arising under it. Instead, it relies on the relevant provisions of the CBD, which provide for optional judicial or arbitral settlement or compulsory (at the request of one party), but non-binding, conciliation.[38] In this respect, the Protocol is significantly weaker than the WTO agreements (see discussion later in this article). The Protocol also provides for the establishment of a non-compliance procedure.[39]

2. International Plant Protection Convention

The IPPC is aimed at achieving international cooperation in controlling pests of plants and plant products (including grains) and in preventing their international spread, particularly their introduction into endangered areas. The convention, which was originally adopted in 1951, was revised in 1979 and again in 1997.[40] The 1997 convention introduces significant changes, particularly with respect to the elaboration and adoption of international phytosanitary standards, and explicitly reflects WTO principles. Phytosanitary measures are to be technically justified on the basis of conclusions reached using an appropriate pest risk analysis or other comparable evaluation, and they are not to be applied in such a way as to constitute either a means of arbitrary or unjustified discrimination or a disguised restriction, particularly on international trade.[41] The 1997 version of the convention is not yet in effect, with the amendments that it introduces requiring ratification by two-thirds of the parties to the IPPC.[42]

The 1997 IPPC incorporates a process for the development of international standards for phytosanitary measures. Pending the entry into force of the 1997 IPPC, an Interim Commission on Phytosanitary Measures (ICPM) has been established. The ICPM has established a working group to develop a detailed standard specification on plant pest risks associated with LMOs/products of modern biotechnology.[43] Thus, there is some subject matter overlap between the development of a standard for plant pest risks under the IPPC and the procedures and guidelines established under the Biosafety Protocol, although the subject matter of the Protocol is broader. The ICCP has urged the ICPM to

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[36] *See, for example, Legal Text of Certain Elements of the Biosafety Protocol Being Developed under the Convention on Biological Diversity—India*, 1997, Doc. UNEP/CBD/BSWG/3/5, at para. 8.
[37] Biosafety Protocol, *supra* note 2, Article 22(1).
[38] CBD, *supra* note 22, at Article 27.
[39] Biosafety Protocol, *supra* note 2, at Article 34. This has been the subject of discussion in the Intergovernmental Committee for the Cartagena Protocol [hereinafter ICCP], see ICCP, Recommendation 3/2, Doc. UNEP/CBD/ICCP/3/10, 27 May 2002 at annex.
[40] IPPC 1997, *supra* note 6.
[41] IPPC 1997, *supra* note 6, at preamble, Article VI, and Article VII(2).
[42] By April 2003, forty-four parties had ratified the amendments.
[43] Third Interim Commission on Phytosanitary Measures [hereinafter ICPM], Rome 2-6 April 2001, Doc. ICPM 01/REPORT, para. 5 and Appendix II.

ensure that the standards to be developed are in harmony with the objective and all relevant requirements of the Biosafety Protocol.[44] International standards adopted under the IPPC are the standards, guidelines, and recommendations recognized as the basis for phytosanitary standards applied by WTO members under the SPS Agreement (see further discussion later in this article).

While the IPPC does not explicitly refer to food security, it seeks to control the introduction and spread of pests of plants and plant products that may threaten food crops. The changes introduced in the 1997 IPPC suggest that this control is increasingly to be achieved through international harmonization of phytosanitary standards, developed through the Committee on Phytosanitary Measures within the FAO. However, Contracting Parties retain the sovereign right to regulate the entry of plants and plant products into their territory, for example, through import controls, quarantine and inspection requirements, and movement restrictions, subject to the conditions laid down in the IPPC.[45] Article III of the 1997 IPPC states that nothing in the convention shall affect the rights and obligations of the contracting parties under relevant international agreements. It seems clear that rights established under the IPPC are to be exercised in accordance with obligations under the WTO. In some respects, this approach seems to suggest an inversion of the WTO/IPPC relationship. The IPPC contains a conciliation-based dispute settlement procedure, whereby a committee of experts can be established to look into technical aspects of a dispute between two Contracting Parties and make recommendations.[46] This procedure is stated to be complementary to, and not in derogation of, dispute settlement procedures provided for in other international agreements dealing with trade measures.[47] Materials produced by the IPPC Secretariat suggest that the committee of experts procedure in the IPPC may generate useful findings for WTO dispute settlement (see later discussion in this article) and that the IPPC Secretariat could provide technical background to the WTO's dispute settlement processes and nominate experts for WTO panels.[48] A subsidiary body on dispute settlement has been established by the ICPM.

3. Codex Alimentarius

The Codex Alimentarius Commission is a FAO/World Health Organization (WHO) body that elaborates standards, general principles, guidelines, and recommended codes of practice in relation to food safety. The Codex has underway a number of relevant processes addressing principles of risk assessment for genetically modified foods and related labelling and other issues. A Task Force on Foods Derived from Biotechnology has elaborated a set of Draft Principles for the Risk Analysis of Foods derived from Modern Biotechnology for consideration by the Codex Alimentarius Commission in 2003.[49] The Codex Committee on General Principles has undertaken work on Draft

[44] ICCP Recommendation 2/12, 10 October 2001, Doc. UNEP/CBD/ICCP/2/15.
[45] IPPC, *supra* note 6, at Article VII.
[46] *Ibid.*, at Article XIII.
[47] *Ibid.*, at Article XIII(6).
[48] FAO, *Guide to the International Plant Protection Convention* 18 (undated brochure, on file with author).
[49] The Task Force, which commenced its work in 2000 has also elaborated a Draft Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants and a Draft

Working Principles for Risk Analysis to guide work within the framework of the Codex itself.[50] This addresses, *inter alia*, issues of scientific uncertainty and incomplete scientific data in the standard-setting process. The same Committee has also commenced work on draft principles of risk analysis for food safety, which are intended to provide guidance to governments.[51] It has held discussions on traceability or product tracing, and is to develop a definition of this concept for Codex purposes.[52] The Committee on General Principles is also considering a Draft Revised Code of Ethics for International Trade in Foods, which may provide further scope for the consideration of food security issues within the Codex.[53] The Committee on Food Labelling is drawing up proposed draft guidelines for the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.[54] Other work of potential relevance to modern biotechnology is taking place in the Committees on Food Import and Export Inspection and Certification Systems and on Methods of Analysis and Sampling.

As with the IPPC standards, national sanitary and phytosanitary measures that conform to the Codex standards, recommendations, or guidelines are deemed necessary and presumed to be consistent with the WTO SPS Agreement.[55] Stakes within the Codex are higher since the adoption of the WTO agreements, as governments seek to have their own national approaches reflected in international standards that will benefit from a presumption of WTO consistency (Victor 2000; Kennedy 2000) The proper relationship between work in the Codex and relevant WTO rights and obligations is now a prominent feature of Codex debates.[56] The plethora of Codex committees and other bodies, as well as the working practices of the Codex Alimentarius have tended to limit meaningful participation by developing countries in its work. Efforts have begun to enhance developing country participation in the standard setting process (see Section VI below).

4. WTO Agreements[57]

Guideline for the Conduct of Food Safety Assessment of Foods Produced using Recombinant-DNA Micro-organisms. The outputs of the Task Force were scheduled to be considered by the 26th session of the Codex Alimentarius Commission in Rome 30 June - 7 July 2003.

[50] *Report of the Eighteenth Session of the Codex Committee on General Principles*, Paris 7-11 April 2003, Doc. ALINORM 03/33A, at paras. 10-31 and Appendix IV.

[51] *Ibid*, at paras.32-42

[52] *Ibid*., at paras.85-98. The issue of traceability/product tracing is also under discussion in the Codex Committee on Food Import and Export Inspection and Certification Systems and has been the subject of discussion in the Task Force and in the Codex Committee on Food Labelling.

[53] *Ibid.*, at paras. 43-73.

[54] *Report of the Thirty-First Session of the Codex Committee on Food Labelling*, Ottawa 28 April-2 May 2003, Doc. ALINORM 03/22A, paras. 69-74.

[55] SPS Agreement, *supra* note 9, at Article 3.2.

[56] See for example Codex discussions on the Draft Working Principles for Risk Analysis for Food Safety, *Report of the Eighteenth Session of the Codex Committee on General Principles*, *supra* note 54, paras. 34-35; and discussions on the Proposed Draft Revised Code of Ethics for International Trade in Foods, *ibid*., paras.57-73.

[57] The sections on the GATT and the TBT and SPS Agreements later in this article and the applicability of these agreements draw extensively on the appendix to Mackenzie *et al.*, (2003). The lead author of the appendix was Jacob Werksman.

The three main WTO agreements of relevance to the domestic regulation of biotechnology and biosafety are the 1994 GATT, the TBT Agreement, and the SPS Agreement. These agreements share the common purpose of ensuring that measures that affect the trade in products do not discriminate on the basis of a product's country of origin and that these measures are no more trade restrictive than is necessary to achieve the purpose for which they were designed. Each agreement has detailed rules and a growing body of practice that develops these disciplines further. The basic content of these agreements and other relevant WTO provisions are outlined in this section. The way in which some of the relevant provisions have been interpreted in dispute settlement proceedings in the WTO is considered briefly in Section III.

A. GATT

GATT disciplines govern all products traded between WTO members, including GMOs. The central disciplines in the GATT are contained in Articles I, III, and XI. Under GATT Article I (most favoured nation), any advantage, favour, privilege, or immunity offered by any member to any product originating in, or destined for, any other country shall be accorded immediately and unconditionally to the like product originating in, or destined for, the territories of all other members. Article III (national treatment) prohibits measures that directly or indirectly discriminate between like products on the basis of their country of origin. Article XI (quantitative restrictions) forbids WTO members from instituting or maintaining prohibitions or quantitative restrictions on the importation of products from another WTO member (through quotas, import licences, or other measures). Measures that are found to violate Article I, III.4, or XI may qualify for an exception under GATT Article XX. The member defending the measure bears the burden of provisionally justifying it under one of the policy objectives enumerated in the subparagraphs of Article XX. These subparagraphs include measures that are necessary for the protection of "human, animal or plant life or health" (Article XX(b)) or, under certain conditions, are related to the conservation of natural resources (Article XX(g)) or are necessary to protect public morals (Article XX(a)). Under the "chapeau" of Article XX, the member must then also demonstrate that the measure is not being applied in an arbitrary or unjustifiable manner or as a disguised restriction on trade.[58]

B. TBT Agreement

The TBT Agreement covers all products traded between WTO members, including GMOs. However, it applies only to particular kinds of trade-related measures. TBT-covered measures include technical regulations, voluntary standards, and conformity assessment procedures, which are based upon product characteristics. TBT measures include "marking or labelling requirements as they apply to a product, process or

[58] On the application of Article XX, see generally *United States – Standards for Reformulated and Conventional Gasoline*, Report of the Panel and the Appellate Body, 29 April 1996, WTO Doc. WT/DS2/AB/R, and Report of the Appellate Body, 20 May 1996, WTO Doc. WT/DS2/AB/R [hereinafter *US – Gasoline*]; and *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, Report of the Appellate Body, 12 October 1998, WTO Doc. WT/DS58/AB/R [hereinafter *US – Shrimp-Turtle*].

production method" compliance with which is mandatory.[59] They can, however, also include import prohibitions or exceptions to these prohibitions when these measures are based on product characteristics.[60]

WTO members must ensure that technical regulations are not more trade restrictive than necessary to fulfil a *legitimate objective*, including (but not limited to) protection of human health or safety, animal or plant life or health, or the environment.[61] WTO members should use relevant international standards, where they exist, as a basis for their technical regulations unless these standards are inappropriate to fulfil the legitimate objectives pursued, for example, because of fundamental climatic or geographical factors or fundamental technological problems.[62] Conformity with international standards creates a rebuttable presumption that the technical regulation does not create an unnecessary obstacle to international trade.[63] Given the important role of international standards in the TBT Agreement, it promotes participation in the work of international standardizing bodies.[64] Relevant international bodies are not specifically identified in the agreement but are defined as bodies or systems whose membership is open to the relevant bodies of at least all WTO members.[65]

Transparency provisions in the agreement require WTO members to notify other members of proposed technical regulations that may have a significant effect on international trade either when there are no relevant international standards or when the proposed regulation is not in accordance with existing relevant international standards.[66] A number of measures related to GMOs have been notified to the TBT Committee under this provision.

C. SPS Agreement

The SPS Agreement elaborates rules for the application of the provisions of GATT 1994, which relate to the use of sanitary or phytosanitary measures, in particular, the provisions of Article XX(b).[67] Any measure found consistent with the SPS Agreement will be presumed to conform to the GATT.[68] The SPS Agreement was developed during the Uruguay Round negotiations in the context of negotiations on agriculture. Its origin was a proposal by the United States in 1989 to amend Article XX(b) of the GATT to require measures to protect human, animal, or plant life or health to be consistent with sound scientific evidence and to recognize the principle of equivalency. (Stewart 1993) The

[59] TBT Agreement, *supra* note 10, at Annex 1, para. 1.
[60] *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, Report of the Appellate Body, 12 March 2001, WTO Doc. WT/DS135/AB/R, at para. 66, et seq [hereinafter *EC – Asbestos*].
[61] TBT Agreement, *supra* note 10, at Article 2.2.
[62] *Ibid.*, at Article 2.4.
[63] *Ibid.*, at Article 2.5.
[64] *Ibid.*, at Article 2.6.
[65] *Ibid.*, at Annex 1, para. 4.
[66] *Ibid.*, at Article 2.9.
[67] SPS Agreement, *supra* note 9, at preamble, 8th recital. A footnote to the preamble indicates that this reference to Article XX(b) is intended to include the "chapeau" of Article XX.
[68] *Ibid.*, at Article 2.4.

United States had also proposed the establishment of a special working group on sanitary and phytosanitary measures within the Negotiating Group on Agriculture.[69] Kennedy notes that the agreement was designed to ensure that the dismantling of barriers to agricultural trade, through the Agreement on Agriculture, was not undermined by the imposition of new protectionist SPS measures.(Kennedy 2000)

The SPS Agreement applies to the development and application of all sanitary and phytosanitary measures that may, directly or indirectly, affect international trade. SPS measures are defined in the agreement in such a way that not all measures relating to the regulation of GMOs would necessarily be covered. An SPS measure is any measure applied:

- to protect animal or plant life or health within the territory of the member from risks arising from the entry, establishment, or spread of pests, diseases, disease-carrying organisms, or disease-causing organisms;[70]
- to protect human, animal, or plant life or health within the territory of the member from risks arising from additives, contaminants, toxins, or disease-causing organisms in food, beverages, or foodstuffs;
- to protect human life or health within the territory of the member from risks arising from diseases carried by animals, plants, or products thereof or from the entry, establishment, or spread of pests; or
- to prevent or limit other damage within the territory of the member from the entry, establishment, or spread of pests.[71]

WTO members have the right to take SPS measures that are necessary for the protection of human, animal, or plant life or health, provided that such measures are not inconsistent with the provisions of the SPS Agreement. The agreement recognizes the right of members to establish their own "acceptable level of protection," but it requires that the application of measures to achieve this level of protection must otherwise be consistent with the agreement.[72] In addition, a member must avoid arbitrary or unjustifiable distinctions in the levels of protection it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members are to ensure that any measure taken is:

- applied only to the extent *necessary* to protect human, animal, or plant life or health;
- based on scientific principles; and
- not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.

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[69] *Ibid*., at 176.

[70] A footnote provides that, for the purposes of this definition "animal" includes fish and wild fauna; "plant" includes forests and wild flora; "pests" includes weeds; and "contaminants" include pesticide and veterinary drug residues and extraneous matter.

[71] SPS Agreement, *supra* note 9, at Annex A, para. 1.

[72] *Ibid.*, at Articles 2.1 and 3.3; Annex A, para. 5

SPS measures must not arbitrarily or unjustifiably discriminate between members where identical or similar conditions prevail, and they must not apply such measures in a manner that would constitute a disguised restriction on international trade. In order to satisfy this requirement, the SPS Agreement requires members to base their SPS measures on international standards, guidelines, or recommendations where they exist. Where such standards, guidelines, or recommendation do exist, measures that *conform* to those standards shall be deemed to be necessary to protect human, animal, or plant life or health, and rebuttably presumed to be consistent with the relevant provisions of the agreement and of the GATT.[73] The standards, guidelines, and recommendations of the Codex Alimentarius (food safety), the IPPC (plant health), and the International Office of Epizootics (animal health and zoonoses) are explicitly mentioned in this regard.[74]

However, the existence of international standards, guidelines, or recommendations does *not* prevent a member from introducing or maintaining measures resulting in a higher level of protection if there is scientific justification. A footnote to Article 3.3 in the SPS Agreement indicates that, for the purposes of that article, there is scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of the agreement, a member determines that the relevant international standards, guidelines, or recommendations are not sufficient to achieve its appropriate level of SPS protection. In order to establish the scientific basis for any SPS measure, a member is required to carry out a risk assessment that takes into account "available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment."[75]

The SPS Agreement recognizes that governments will sometimes have to apply measures in situations where full scientific certainty is not available. In this regard, Article 5.7 provides that

> [i]n 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 and 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 review the sanitary and phytosanitary measure accordingly within a reasonable period of time.

The SPS Agreement also provides some scope for considering economic factors in applying SPS measures. Under Article 5.3, in assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, members shall take into account as relevant economic factors: "the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or

[73] *Ibid.*, at Article 3.2.
[74] *Ibid.*, at Annex A, para. 3.
[75] *Ibid.*, at Article 5.2.

eradication in the territory of the importing member; and the relative cost-effectiveness of alternative approaches to limiting risks."

As in the TBT Agreement, transparency provisions require members to notify changes in their SPS measures.[76] A number of measures related to GMOs have been notified. A Committee on Sanitary and Phytosanitary Measures has been established under the agreement as a regular forum for consultations.[77]

D. Agreement on Agriculture

The Agreement on Agriculture, which was negotiated during the Uruguay Round, marked a more concerted attempt than in the past to apply GATT disciplines to agricultural products.(see Trebilcock and Howse 1999) Moreover, it provides one of the few spaces within the WTO where issues of food security and other non-trade concerns are explicitly debated and thereby integrated, to a limited extent at least, into the objectives and provisions of the agreement.

The Agreement on Agriculture focuses upon commitments of members to reduce support and protection in the areas of market access (through tariffication[78]), domestic support, and export subsidies. While the agreement makes provision for the special and differentiated treatment of developing countries and contains special provision for least developed and net food-importing countries, it has been the subject of significant criticism by developing countries. The bargain struck on the Agreement on Agriculture during the Uruguay Round essentially addressed concerns of the United States and the European Community (EC), as well as other large agricultural exporting countries. The agreement is presently under review,[79] and developing countries have been active in submitting proposals for its revision. The agreement recognizes certain non-trade concerns, including food security and the need to protect the environment.[80] Developing countries have put forward proposals related to food security in the present review. These have included the creation of a food security or development "box,"[81] which is designed to address food security as the "paramount non-trade concern."[82] One question that perhaps arises is whether and how the concerns being raised in the Agreement on Agriculture negotiations can be more effectively integrated into other areas of the WTO.

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[76] *Ibid.*, at Article 7; Annex B.
[77] *Ibid.*, at Article 12(1).
[78] Under Article 4 of the Agreement on Agriculture, *supra* note 4, Members are not to maintain, resort to, or revert to any measures of the kind which have been required to be converted into customs duties, except as otherwise provided for in the Agreement.
[79] Agreement on Agriculture, *supra* note 4, at Article 20; see also *Ministerial Declaration Adopted on 14 November 2001*, 20 November 2001, Doc. WT/MIN(01)/DEC/1, paras. 13-14.
[80] Agreement on Agriculture, *supra* note 4, at sixth preambular paragraph.
[81] See, for example, *Proposals by India*, 15 January 2001, Doc. G/AG/NG/W/102, for a series of measures constituting a "food security box" for developing countries; and the *Proposal by Kenya and Ten Other Developing Countries*, 22 June 2000, Doc. G/AG/NG/W/13.
[82] *Proposal by Kenya*, 12 March 2001, Doc. G/AG/NG/W/136, 3.

During the review of the Agreement on Agriculture, some WTO members have also sought to introduce additional issues into the negotiations of relevance to the regulation of modern biotechnology.[83] In particular, the EC proposed within the Agreement on Agriculture negotiations to clarify the application of the precautionary principle in relation to food safety, labelling with respect to production and processing of agricultural products, and environmental protection measures.[84] Some advocates of addressing food safety within the agriculture negotiations have argued that members should not rely on dispute settlement rulings but should use the negotiations to clarify such issues, taking existing dispute settlement reports into account.[85] Other members have expressed the view that these issues fall under the SPS Agreement, which is not subject to specific negotiations in the present round, or that they are within the purview of the Committee on Trade and Environment (CTE).[86]

E. Special and Differential Treatment

The WTO agreements incorporate provisions on the special and differential treatment (S&DT) of developing and least developed countries. These generally take the form of:

- time limited derogations, that is, longer transition periods, more favourable thresholds for undertaking certain commitments, and greater flexibility with respect to certain obligations; and/or
- clauses providing for specific, though undefined, action by developed countries under certain agreements, in their relations with developing countries.[87]

In relation to the SPS and TBT Agreements, S&DT provisions include the possibility for the SPS and TBT Committees, respectively, to grant specified time-limited exceptions to developing countries from obligations under the agreements, taking into account their financial, trade, and development needs.[88] Where possible, longer time frames for compliance with new SPS measures should be accorded on products of interest to developing country members so as to maintain opportunities for their exports,[89] and members should take account of the special development, financial, and trade needs of developing country members with a view to ensuring that technical regulations and standards do not create unnecessary obstacles to exports from developing country members.[90] The TBT Agreement recognizes that developing country members should not be expected to use international standards that are not appropriate to their development,

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[83] WTO Secretariat, *WTO Agriculture Negotiations: The Issues, and Where We Are Now*, updated 21 October 2002, available at <http://www.wto.org> at 30.
[84] *EC Comprehensive Negotiating Proposal*, 14 December 2000, Doc. G/AG/NG/W/90.
[85] WTO Secretariat, *supra* note 91, at 42.
[86] See, for example, *Statement by India at the Fifth Special Session of the Committee on Agriculture*, 15 February 2001, Doc. G/AG/NG/W/114, at 1-2.
[87] *Concerns Regarding Implementation of Provisions Relating to Differential and More Favourable Treatment of Developing and Least-Developed Countries in Various WTO Agreements*, Communication from India, 13 November 1998, Doc. WT/GC/W/108, at 2.
[88] SPS Agreement, *supra* note 9, at Article 10(3); TBT Agreement, *supra* note 10, at Article 12.8.
[89] SPS Agreement, *supra* note 9, at Article 10(2).
[90] TBT Agreement, *supra* note 10, at Article 12.3.

financial, and trade needs and that such members may adopt technical regulations or standards aimed at preserving indigenous technology and production methods and processes compatible with their development needs.[91] Both agreements promote the participation of developing countries in international standard-setting processes.[92]

Developing countries, in particular India, have raised serious concerns about the extent to which developed countries are implementing their S&DT obligations. Negotiations on S&DT are taking place in the Committee on Trade and Development under the Doha Ministerial Declaration mandate. The ministerial declaration that was adopted at Doha reaffirms that S&DT provisions are an integral part of the WTO agreements. Negotiations are reviewing all S&DT provisions with a view to strengthening them and making them more precise, effective, and operational.[93] While concerns expressed by developing countries have largely concerned market access for their exports,[94] the S&DT provisions might also provide some scope for justifying differential national measures imposed by developing countries to regulate imports.

F. Dispute Settlement

The WTO agreements are subject to mandatory and binding dispute settlement under the dispute settlement understanding (DSU).[95] The dispute settlement system is designed to be a central element in providing security and predictability to the multilateral trading system,[96] by providing a mechanism for the prompt settlement of situations in which a member considers that any benefits accruing to it directly or indirectly under the covered agreements are being impaired by measures taken by another member. In such circumstances, a member may request another member to enter into consultations and notify the dispute settlement body (DSB) of this request. If consultations fail to settle the matter, the complaining member may request the establishment of a panel to examine the matter. A panel must be established, unless the DSB decides otherwise by consensus.[97] The DSU also provides for a system of appellate review, by a standing Appellate Body. Rulings of the Appellate Body (and unappealed panel decisions) are automatically adopted by the DSB, unless there is consensus against adoption.

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[91] *Ibid.*, at Article 12.4.
[92] SPS Agreement, *supra* note 9, at Article 10(4); TBT Agreement, *supra* note 10, at Article 12.5.
[93] WTO Doha Ministerial Declaration, *supra* note 87, at para. 44; *Decision on Implementation-Related Issues and Concerns*, 20 November 2001, Doc. WT/MIN/(01)/17.
[94] *See, for example, Implementation of the Provisions for Special and Differential Treatment*, Statement by India at the Meeting of 21-2 June 2000, 21 July 2000, Doc. G/SPS/GEN/197; and *Special and Differential Treatment and Technical Assistance*, Submission made by India at the Meeting of 10-11 June 1998, 23 July 1998, Doc. G/SPS/GEN/85.
[95] Understanding on Rules and Procedures Governing the Settlement of Disputes, 1994, Annex 2 to the WTO Agreement, WTO, *The Results of the Uruguay Round Multilateral Trade Negotiations: The Legal* Texts 354 [hereinafter DSU]. See Sands, Mackenzie and Shany, (1999). The DSU is also under review with a view to agreeing to improvements and clarifications, see Doha Ministerial Declaration, *supra* note 87, at para. 30, and Special Session of the Dispute Settlement Body, Report by the Chairman, Ambassador Peter Balas, to the Trade Negotiations Committee, Doc. TN/DS/9, 6 June 2003..
[96] DSU, *supra* note 103, at Article 3.2.
[97] *Ibid.*, at Article 6.1. In effect then, panel establishment is automatic.

The DSU provides for the surveillance of implementation of rulings and recommendations. In the event that a ruling or recommendation is not implemented within a reasonable period of time, the DSB may authorize the complaining member to suspend the application to the other member concerned of concessions or other obligations under the covered WTO agreements. This suspension may extend not only to concessions in the sector and under the agreement that is the subject of the dispute, but also, in certain circumstances, to "cross-retaliation"—that is, the suspension of concessions in other sectors and under other covered agreements. While compensation is also mentioned as a potential remedy in the DSU, the most effective mechanism, namely the suspension of concessions, would, of course, be particularly persuasive where the complaining member is an economically powerful state.

The DSU contains its own "special and differential treatment" provisions. In particular, members are to exercise restraint in raising matters under the DSU that involve a least-developed country member[98] and in requesting compensation or seeking authorization to suspend concessions.[99] Particular consideration must be given to the special situation of least-developed countries in all stages of the determination of the causes of a dispute and of dispute settlement procedures involving a least-developed country member. And special efforts to resolve a matter must be attempted before the establishment of a panel is sought. In addition, the WTO Secretariat must make available a qualified legal expert from the WTO technical cooperation services to any developing country member that so requests. However, this assistance must be provided in a manner that ensures the continued impartiality of the Secretariat.[100] In recognition of the limitation of this provision, a Law Advisory Centre has been recently established to provide legal assistance to developing countries engaged in WTO disputes.

The WTO dispute settlement system contrasts starkly with the dispute settlement procedures available under the Biosafety Protocol, which, as described earlier, are largely non-mandatory and non-binding, as well as with the IPPC procedure, which can address technical aspects of disputes in a non-binding manner. In effect then, a dispute between two parties to the Biosafety Protocol, or perhaps more significantly between a party and a non-party, over a trade measure relating to a GMO, could well end up being determined by a WTO panel and/or the Appellate Body.[101] This possibility caused serious concern during the Protocol negotiations, as States sought to agree on language to address the

[98] The WTO recognizes as least-developed countries [hereinafter LDCs] those countries that have been designated as such by the United Nations. There are currently forty-nine LDCs on the UN list, thirty of which to date have become WTO members.
[99] DSU, *supra* note 103, at Article 24.
[100] *Ibid.*, at Article 27.
[101] In May 2003, the United States, Canada and Argentina requested consultations with the EC under the DSU in relation to measures taken by the EC and its Member States affecting products of biotechnology. See *European Communities – Measures Affecting the Approval and Marketing of Biotech Products, Request for Consultations by the United States*, Doc. WT/DS291/1, 20 May 2003; *European Communities – Measures Affecting the Approval and Marketing of Biotech Products, Request for Consultations by Canada*, Doc. WT/DS292/1, 20 May 2003; *European Communities – Measures Affecting the Approval and Marketing of Biotech Products, Request for Consultations by Argentina*, Doc. WT/DS293/1, 21 May 2003.

relationship between the Biosafety Protocol and the WTO. It is especially significant since the largest exporter of GMOs, the United States, is likely to remain a non-party to the Protocol for some time to come, but is, at the same time, an active user of the WTO's dispute settlement system. In common with other judicial bodies, the significance of the WTO dispute settlement system lies not only in its resolution of specific disputes between members but also in its interpretation of WTO rules, giving rise to the *de facto* evolution of WTO disciplines.[102]

III. LEGAL AND POLITICAL INTERACTIONS

The agreements and instruments described in the earlier sections interact in a number of different ways. Legal interactions arise as the scope and applicability of each instrument may overlap to some degree and issues of legal compatibility arise, as well as issues of "institutional economy" in terms of avoidance of duplication. Political interactions arise as links are built between the political and administrative institutions of the various bodies in an effort to mediate the substantive overlaps.

This section considers these interactions, and it also considers briefly what guidance might be gleaned from existing WTO case law on the potential impact of WTO rules on domestic biosafety measures. Section IV then considers more specifically how far these agreements and instruments, and other relevant instruments, provide scope for countries to take socio-economic considerations into account when regulating the import and use of GMOs.

1. WTO and MEAs

The relationship between the Biosafety Protocol and the WTO is part of a more wide-ranging discussion on the relationship between the WTO agreements and MEAs, which focuses on how MEAs that require or authorize trade measures relate to the relevant WTO rules. While no dispute has yet been brought to the WTO in relation to such measures, it is clear that such concerns now influence the negotiation of MEAs, as the Biosafety Protocol negotiations themselves illustrate.

The broader WTO/MEA relationship is currently being addressed within the WTO's CTE. While this issue has been on the CTE's agenda for several years, discussions so far have been general and inconclusive. At the fourth ministerial meeting in Doha, the CTE received a specific and renewed mandate to address the MEA question. Paragraph 31 of the Doha Ministerial Declaration provides:

> With a view to enhancing the mutual supportiveness of trade and environment, we agree to negotiations, without prejudging their outcome, on:

[102] Chaytor, (1998); Oxfam, (2000). However, the recommendations and rulings of the dispute settlement body cannot add to, or diminish, the rights and obligations provided in the WTO agreements, DSU, *supra* note 103, at Article 3.2. The ministerial conference and the General Council are the organs that have exclusive authority to adopt interpretations of the WTO agreement and the other multilateral trade agreements that form part of the single undertaking. *See* WTO Agreement, WTO, *The Results of the Uruguay Round Multilateral Trade Negotiations: The Legal Texts*, 3, at Article IX.2.

i. the relationship between existing WTO rules and specific trade obligations set out in multilateral environmental agreements (MEAs). The negotiations shall be limited in scope to the applicability of such existing WTO rules as among Parties to the MEA in question. The negotiations shall not prejudice the WTO rights of any Member that is not a party to the MEA in question;
ii. procedures for regular information exchange between MEA Secretariats and the relevant WTO committees, and criteria for the granting of observer status;
iii. the reduction or, as appropriate, elimination of tariff and non-tariff barriers to environmental goods and services.

This text in itself hints at some of the controversies that have dogged the WTO/MEA relationship. The reference to "mutual supportiveness" is now familiar, having been used in the text of the Protocol itself as well as in other MEAs[103] and recently in the WSSD Plan of Implementation.[104] Yet the practical implications of the term remain unclear. Paragraph 31(i) makes clear that any WTO outcome on the MEA relationship will preserve the position of non-parties to an MEA (for example, for the foreseeable future, the position of the United States in respect of the Biosafety Protocol). And subparagraph (ii) reflects the difficulties that have arisen for MEA secretariats in securing observer status in relevant WTO bodies. For example, the CBD Secretariat has been mandated by its Conference of the Parties (COP) to seek observer status in the Council to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement),[105] the Committee on Agriculture,[106] and, in relation to the protocol, the SPS and TBT Committees.[107] WTO members have engaged in a prolonged debate over the applicable criteria for observer status, which is linked to broader considerations of external transparency, and influenced by the strong "member-driven" nature of the WTO. In relation to the post-Doha negotiations on the WTO/MEA relationship, MEA secretariats were only in early 2003 granted ad hoc observer status in the special negotiating sessions of the CTE, although without prejudice to the broader question of observership in the Doha negotiations for intergovernmental organizations, including MEAs, which remains under discussion in the WTO General Council and the Trade Negotiations Committee.[108]

2. Negotiation and Evolution of the Biosafety Protocol

In the context of the broader WTO/MEA debate, and given the significance of international trade in GMOs and GM commodities, the negotiations of the Biosafety

[103] For example, the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, adopted 10 September 1998, Doc. UNEP/FAO/PIC/CONF/5, 38 ILM (1999) 1, available at http://www.pic.int.
[104] WSSD Plan of Implementation, *supra* note 14, at para. 92.
[105] CBD Conference of the Parties [hereinafter COP], Decision V/26, at para. 4; Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, Annex 1C to the WTO Agreement, WTO, *The Results of the Uruguay Round Multilateral Trade Negotiations: The Legal Texts*, 321.
[106] CBD COP, Decision IV/6, para. 9; CBD COP Decision V/5, para. 14; and CBD COP Decision VI/5, para. 7.
[107] *Ibid.*, at Decision VI/20, para. 29.
[108] 6(35) *Bridges Weekly Trade News Digest* (17 October 2002); 3(3) *Bridges Trade BioRes* (21 February 2003).

Protocol were permeated by concern and debate about the potential relationship between the Protocol and the relevant WTO agreements.(Newell and Mackenzie 2000; Chayton Palmer and Werksman 2003) The two sets of agreements both potentially address the same subject matter, namely the transboundary movements of GMOs, but in the context of different objectives. Concerns therefore arose as to whether the agreements might impose conflicting obligations upon countries that were both WTO members and parties to the Biosafety Protocol. This concern was acute because of the trade measures inherent in the AIA procedure in the Protocol as well as in other aspects of the Protocol, such as identification requirements. In the event that such a conflict between treaty provisions arose, there would also be a question as to which agreement would prevail between countries that are parties to both. Under international treaty law, the general position is that, as between countries that are both parties to agreements on the same subject matter (such as Parties to the Biosafety Protocol and members of the WTO), the treaty that is later in time would prevail.[109] In addition, it is generally accepted that under customary international law, the more specific treaty will prevail. Other concerns relate to the fact that not all countries trading in GMOs are likely to become parties to the Biosafety Protocol, raising potential issues of uneven international commitments.

During the Protocol negotiations, discussion focused on whether to include specific language addressing the relationship between the Protocol and the WTO. Proposals from most developing countries favoured explicitly giving primacy to the Biosafety Protocol. The Miami Group of countries[110] favoured a "savings clause," which would have specifically preserved rights and obligations under existing international agreements. Others favoured silence on this issue, allowing for the operation of general rules of international treaty law.

At the same time as these discussions were happening, the operative provisions of the Biosafety Protocol, and specifically its AIA procedure, were also being crafted, and these appear to have been developed in such a way as to minimize any *prima facie* conflict with the provisions of the WTO agreements. In this respect, the influence of WTO rules in the Protocol negotiations was significant. An analysis of the main provisions of the AIA procedure seems to reveal a basic compatibility with WTO requirements for decision-making based on risk assessment. As noted earlier, additional rights set out in the Protocol, such as the right to take into account certain socio-economic considerations[111] and the right to apply a higher level of protection than is provided for in the Protocol,[112] are subject to a requirement of consistency with other international obligations. And the Biosafety Protocol does not prohibit trade with non-parties, provided it is carried out in a manner consistent with the objective of the Protocol.[113]

The Protocol addresses its relationship with other international agreements, and specifically the WTO agreements, in three preambular paragraphs:

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[109] Vienna Convention on the Law of Treaties, 23 May 1969, 8 ILM 679, at Article 30.
[110] See *supra* note 32.
[111] Biosafety Protocol, supra note 2, at Article 26.
[112] *Ibid.*, at Article 2(4).
[113] *Ibid.*, at Article 24.

> *Recognizing* that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,
> *Emphasizing* that this Protocol shall not be interpreted as implying a change in the 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.

Taken together, these three paragraphs fail, in the view of many commentators, to establish a clear hierarchy or relationship.(Mackenzie *et al* 2003; Eggers and Mackenzie 2000; French 2001; Stoll 2000)[114] There is now much academic analysis of the relationship between the Protocol and the WTO agreements. Many commentators have taken the view that there is little by way of clear conflict between the two—in the sense that it is difficult to identify provisions of the Protocol that would *require* a Party to act inconsistently with its WTO obligations. In that sense, it should be possible for a Party to the Biosafety Protocol to act consistently with its commitments under both sets of instruments. Among the specific differences, but not necessarily conflicts, that exist are the potential in the Protocol for a Party of import to require a notifier to pay for a risk assessment and the lack of a specific obligation in the Protocol to seek information to review precautionary measures adopted under Article 10(6) or 11(8) within a reasonable period of time.[115]

Nonetheless, while the Biosafety Protocol elaborates a procedure and risk assessment guidelines for transboundary movements of certain GMOs and, in this sense can represent a useful supplement to WTO rules, it does not dictate, or even predict, the outcomes of these procedures at the domestic level. While the Protocol does not require parties to implement their obligations under the Protocol in a manner that is inconsistent with WTO rules, it does authorize certain trade measures. In this respect, one might well anticipate disputes arising regarding measures applied by Parties of import that are authorized under the Protocol (for example, import bans or restrictions), which may be subject to challenge under the disciplines of the WTO. It is conceivable that a country could implement measures that are required or authorized under the Protocol in a manner that other States consider to be WTO-inconsistent.

3. WTO and International Standards

As noted in section II above, certain WTO agreements require or promote the use of international standards, as a means to avoiding unjustified or discriminatory trade barriers. Under the SPS Agreement, if domestic SPS measures conform with standards or guidelines promulgated under the Codex Alimentarius, the IPPC, or the International Office of Epizootics, they are deemed to be necessary to protect human, animal, or plant life or health and (rebuttably) presumed to be consistent with the relevant provisions of the SPS Agreement and the GATT 1994. In any event, members are required to base their

[114] However, others argue that the relatively unambiguous language of the second paragraph is effective as a savings clause (with respect to WTO rights and obligations), notwithstanding its location in the preamble of the Protocol and the other two recitals, Safrin, (2002).
[115] In contrast to Article 5.7 of the SPS Agreement, which is discussed in Section II earlier in this paper and in the following pages.

SPS measures on such standards where they exist, unless they can provide scientific justification for a higher level of protection. The SPS Agreement may identify other relevant international organizations that are open to the membership of all members—the standards, guidelines, or recommendations of which will be presumed to be consistent with the SPS Agreement and the GATT.[116] So far, no additional organizations have been so identified.

In contrast to the SPS Agreement, the TBT Agreement does not identify specific international standard-setting organizations in this regard, but rather defines an "international body or system" as "a body or system whose membership is open to the relevant bodies of at least all Members."[117] Thus, in principle, the Biosafety Protocol could potentially be considered to be the source of international standards for the purposes of the TBT Agreement—for example, in relation to the identification requirements for shipments of GMOs.(see Howse and Meltzer)

For the present, the status of the Protocol under the SPS Agreement can be contrasted with that of the Codex and the IPPC. For the time being at least, the Biosafety Protocol's relationship with the WTO can be characterized primarily as part of the broader trade and environment relationship rather than as an aspect of the relationship between the WTO and the constellation of international standard-setting bodies. This relationship has practical implications, for example, with respect to observer status. At the same time, the role of the Codex and, to a lesser extent, the IPPC, is considered by some to have changed the nature of these bodies, resulting in the politicization of what were previously narrower technical fora. As the significance of the role of the Codex standards in the WTO has been more fully understood, demands have grown for greater participation in the Codex by governments and civil society (see Section VI below) and for greater transparency in its work. Given the privileged status that the Codex standards have under the SPS Agreement, some commentators have cast them as now being, in practice, "binding," (Victor 2000) although this view does not seem to be supported by the WTO Appellate Body.[118] Some concerns have been voiced that, given this status, developing countries participating in the Codex may seek to lower Codex standards in light of concerns about market access for their goods.[119]

The SPS Committee has adopted procedures to monitor the use of international standards. The TBT Committee has adopted a decision on the Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2.5 and Annex 3 of the TBT.[120] This decision sets out certain additional criteria to determine

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[116] SPS Agreement, *supra* note 9, at Article 3; Annex A, para. 3

[117] TBT Agreement, *supra* note 10, at Annex 1, para. 4.

[118] *EC Measures Concerning Meat and Meat Products (Hormones)*, Report of the Appellate Body, 16 January 1998, Doc. WT/DS26/AB/R and Doc. WT/DS48/AB/R, at para. 165 [hereinafter *EC – Meat Hormones*].

[119] See, for example, Silverglade, (2000) who notes that, without adequate technical assistance, developing countries may be forced to argue for downward harmonization of standards in the Codex on the grounds that they will be unable to meet high international standards.

[120] *Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2.5 and Annex 3 of the TBT*, 13 November 2000, Doc. G/TBT/9, at paras. 17-25 and Annex 4.

whether or not an international standard can be used as a basis for TBT compliance, including transparency, openness, impartiality and consensus, effectiveness and relevance, coherence, and the development dimension. Concerns have been expressed that the TBT Committee may have in effect trespassed into the areas of competence of other international bodies.(see TMC 2002) Other analysts have suggested, however, that "[t]he purpose of the decision was not to dictate to other international organizations how they should proceed but rather to encourage the participation of members in the law making (standard setting) bodies to which the TBT seems to have lent certain quasi-legislative authority."(Marceau and Trachtman 2002)

4. Political and Administrative Interaction

While the instruments and agreements discussed earlier are all relevant to GMO regulation, they each have different mandates and objectives. In the interests of coordination, a range of political and administrative interactions between the various instruments has developed. This interaction ranges from cross-representation as observers in negotiating fora, through administrative interactions and cooperation between secretariats, including information exchange, to the possibility of input into dispute settlement processes.

There was a degree of political interaction between the WTO and the Biosafety Protocol during the Protocol negotiations. At this time, the CBD Secretariat was invited to brief an informal meeting of the SPS Committee on developments in relation to the Protocol,[121] even though the CBD Secretariat did not have observer status in the Committee. The WTO Secretariat was present as an observer at the later sessions of the Open-Ended Ad Hoc Working Group on Biosafety (BSWG) as well as at the sessions of the Extraordinary Meeting of the Conference of the Parties (ExCOP), which negotiated the Biosafety Protocol.[122] However, it has been noted that although a representative of the WTO addressed the Protocol negotiators, and informal consultations were established between the convention Secretariat and the WTO, this interaction had little impact on the negotiations, and the WTO departments dealing with issues specific to the Protocol were absent.(Chaytor Palmer and Werksman 2003)

The Protocol negotiations may also, paradoxically, have received a fillip from the failure of the WTO Ministerial Conference, which was held in Seattle in December 1999, shortly before the final negotiating session for the Protocol was scheduled to resume. The Seattle meeting had before it two proposals to establish a working group on biotechnology within the WTO,[123] and it was widely considered that if these proposals had been taken up, the Biosafety Protocol negotiations, which had been suspended in February 1999, would have been sidelined. The failure of the Seattle ministerial meeting is generally

[121] See Committee on Sanitary and Phytosanitary Measures, *Summary of Meeting Held on 15-16 September 1998*, 29 October 1998, Doc. G/SPS/R/12, at paras. 78-80.

[122] Doc. UNEP/CBD/BSWG/5/Inf.4; Doc. UNEP/CBD/BSWG/6/INF.10; and Doc. UNEP/CBD/ExCop/1/Inf.4.

[123] *Proposal for the Establishment of a Working Party on Biotechnology in the WTO* (Canada), 12 October 1999, Doc. WT/GC/W/359; *Proposal of Japan on Genetically Modified Organisms*, 12 October 1999, Doc. WT/GC/W/365.

credited with giving fresh impetus to the Protocol negotiations, in part by emphasizing the urgent need to address biosafety issues through an environmental agreement lest the issue be subsumed in the trade negotiations agenda, and in part by making negotiators keen to avoid successive failures in multilateral negotiations.

The CBD Secretariat has been requested by the Parties to the CBD to seek observer status in various WTO committees, including the CTE, the SPS Committee, the Committee on Agriculture, and the TRIPs Committees. While observership for MEAs in the CTE has been granted, even this status has proved to be contentious with respect to the negotiating sessions of the CTE in relation to the post-Doha negotiations on the WTO and MEAs, on the grounds that negotiations should not be open to observers. Until the decision in early 2003 to admit MEA observers on an ad hoc, meeting-by-meeting basis, interactions on the post-Doha negotiations had taken place in information exchange sessions [124] and in regular meetings of the CTE. [125] Observer status in relation to other relevant committees has proven to be even more difficult to achieve. By contrast, given their special status under the SPS Agreement, the Codex Alimentarius, the IPPC, and the International Office of Epizootics are granted observer status in the SPS Committee. The observer status controversy in the WTO stands in contrast to the relatively open admission of observers in most MEAs. [126]

There exist possibilities for involvement of other organizations and conventions in the WTO dispute settlement should a dispute on GMOs arise. Article 11(2) of the SPS Agreement refers to the possibility of seeking advice or establishing advisory technical experts groups in disputes involving scientific or technical issues. In fact, panels in the early SPS cases have sought advice, where relevant international bodies, such as the Codex, have been asked for input regarding appropriate experts. [127] Article 11(3) of the SPS Agreement also preserves the right to use the dispute resolution procedures of other organizations or agreements (including the CBD). There also exists a more general right of panels to seek information in Article 13 of the DSU, which could be utilized to obtain input from other international organizations and agreements addressing GMOs in the event of a dispute on this issue.(Chinkin and Mackenzie 2002)

Administrative interactions between the various bodies have also been established. For example, the IPPC and the CBD Secretariat have agreed a memorandum of understanding to facilitate cooperation regarding the work being carried out under the Biosafety Protocol and the ICPM's work on plant pest risks of GMOs. This device has been used frequently by the CBD to promote cooperation with conventions and organizations dealing with related subject matter. Many of the international bodies relevant to the GMO regulations also participate in the Inter-Agency Network on Safety in Biotechnology. This network was initially composed of a number of intergovernmental

[124] *See, for example, Report by the Chairperson of the Special Session of the Committee on Trade and Environment to the Trade Negotiations Committee*, 2 December 2002, Doc. TN/TE/4

[125] On forms of cooperation, see *Existing Forms of Cooperation and Information Exchange between UNEP/MEAs and the WTO*, Note by the Secretariat, 10 June 2002, Doc. TN/TE/S/2.

[126] *See, for example,* CBD, *supra* note 22, at Article 23(5); and Biosafety Protocol, *supra* note 2, at Article 29(8).

[127] For example, by the panel in the *EC – Meat Hormones, supra* note 129. See Christoforou, (2000).

agencies working in the field: the Consultative Group on International Agricultural Research (CGIAR), the CBD, the FAO, the International Centre for Genetic Engineering and Biotechnology (ICGEB), the International Office of Epizootics, the Organization for Economic Co-operation and Development, the UNCTAD BioTrade Initiative, the UN Development Programme, the UN Industrial Development Organization, the FAO/WHO Codex Alimentarius Commission, and the WTO. The purpose of the network is to exchange information and facilitate cooperation. It issues a newsletter describing the various activities of the organizations and is meant to hold regular meetings. However, it is already notable that at the first meeting at least not all relevant intergovernmental organizations were involved. For example, the UN Environment Programme (UNEP) and the Global Environment Facility (GEF) were not represented, despite an ongoing capacity-building program on biosafety. Moreover, in keeping with other UN attempts at synergy and promoting interlinkages between intergovernmental organizations, there is no sign as yet that the Inter-Agency Network on Safety in Biotechnology is intended to go beyond information exchange and general coordination by seeking a rationalisation of goals and activities.

5. WTO and Domestic Biosafety Measures

This paper has surveyed the general WTO disciplines of potential relevance to national biosafety measures. The relative lack of experience with GMOs worldwide, and the fact that countries are at very different stages in terms of their research and development into, and acceptance and use of, GMOs, suggests that countries regulating GMOs may well reach different conclusions about the appropriate level of protection to be achieved for the environment or for human health; about the acceptable levels and types of risk; about the interpretations of what constitutes risk and of the available scientific evidence; about the workability and effectiveness of risk management measures; and about the significance of socio-economic factors in reaching decisions on the import and use of GMOs. Discussions between WTO members on GMO regulation have taken place in the SPS and TBT Committees under the transparency provisions of these agreements. However, at the time of writing, no disputes involving GMOs have been decided by a panel or the Appellate Body. Before May 2003, only one request for consultations had been made in relation to trade restrictions on GMOs,[128] and it resulted in resolution without recourse to a panel. However, as noted earlier, in May 2003, requests for consultations were submitted by the United States, Canada and Argentina in respect of approval processes for GMOs applied by the European Communities. Several other WTO members sought to join these consultations.[129] Existing GATT/WTO case law on the relevant agreements may provide some guidance as to how a panel or the Appellate Body may assess domestic biosafety measures that are justified on environmental or health grounds.(Mackenzie *et al* 2003) This section briefly surveys some germane aspects of existing WTO case law, particularly with respect to the SPS Agreement's risk assessment requirements and with respect to the "environmental" exceptions in the GATT.

[128] *Egypt—Import Prohibition on Canned Tuna with Soybean Oil, Request for Consultations by Thailand*, 27 September 2000, Doc. WT/DS205/1.
[129] See *supra* note 109.

Measures taken in relation to imports of GMOs or their products could potentially fall under the GATT, the TBT Agreement, or the SPS Agreement, and any challenge of such a measure would likely raise alternative arguments under each agreement.[130] Although the relationship between the GATT, the SPS Agreement, and the TBT Agreement has yet to be fully explored by the WTO dispute settlement system, it appears that the three agreements were designed to work in a hierarchy that allows the most specific agreement to have priority. (Marceau and Trachtman 2002) The main distinction between each agreement is the extent to which it either identifies specific policy objectives behind the measures that it regulates or singles out the specific category of measures that it regulates. The TBT and the SPS Agreements were adopted to "further the objectives"[131] and to "elaborate rules for the application of the provisions"[132] of the GATT. As *lex specialis*, these more specific agreements could arguably be applied in the place of the GATT to any measures that fell within their defined scope.[133] The TBT Agreement specifically provides that it will not apply to sanitary and phytosanitary measures as defined in the SPS Agreement, while the SPS Agreement clarifies that it will not affect the rights of members under the TBT Agreement with respect to non-SPS measures.[134] For example, it would appear that a mandatory GMO labelling scheme, because it is a technical regulation, would be analyzed under the TBT Agreement. However, if the scheme were being applied for one or more of the health and food safety-related objectives set out in the SPS Agreement, it would then fall exclusively within the scope of that agreement.

Which WTO agreement will apply to a measure will therefore depend, in part, on the objectives invoked to justify it. In this sense alone, it may be difficult to predict with certainty the outcome of a particular dispute on GMOs. An analysis of the relationship between the WTO agreements and any trade-related measure taken in accordance with the Biosafety Protocol must, therefore, begin with an understanding of the policy

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[130] In their requests for consultations in May 2003 in respect of EC measures affecting the approval and marketing of biotech products, the United States, Canada and Argentina also invoked Article 4 of the Agreement on Agriculture, *supra* note 109.

[131] TBT Agreement, *supra* note 10, at preamble, 2nd recital.

[132] SPS Agreement, *supra* note 9, at preamble 8th recital.

[133] The relationship between the GATT and the SPS Agreement was raised in EC – Meat Hormones, *supra* note 129, in which the panel found that the both the GATT and the SPS Agreement were applicable to the dispute, but that as the SPS Agreement contained commitments additional to the GATT, it was appropriate to analyze the case under the SPS Agreement first. Having found a violation of the SPS Agreement, the panel then found that an analysis under the GATT was unnecessary. The applicability of the GATT to the dispute was not raised on appeal.

[134] TBT Agreement, *supra* note 10, at Article 1.5; SPS Agreement, *supra* note 10, at Article 1.4. The relationship between the GATT and the TBT Agreement was raised in *US – Gasoline*, *supra* note 63. In this case, the panel chose to apply the GATT rather than the TBT Agreement, and upon finding a violation of the GATT did not find it necessary to proceed to a TBT analysis. In EC – Asbestos, the Appellate Body noted that the TBT Agreement is intended to "further the objectives of GATT 1994" and that it does so through a specialized legal regime that applies solely to a limited class of measures. It noted that "[f]or such measures the TBT Agreement imposes obligations on Members that seem to be *different* from and *additional* to, the obligations on Members under the GATT 1994." *EC – Asbestos*, *supra* note 65, at para. 80 [emphasis in original]. However in the *EC – Asbestos* case, the Appellate Body did not proceed to an analysis of Canada's claims under the TBT Agreement as there was no adequate factual basis on which to do so, since the panel had not examined these claims, *ibid*, at paras. 81-3.

objective behind the measure. What, in other words, is the risk that the measure is designed to protect against?

In the case law under the SPS Agreement to date, the Appellate Body has addressed and clarified a number of aspects of the agreement. It is beyond the scope of this article to go into these cases in detail, and the following paragraphs highlight some relevant findings in relation to the risk assessment and scientific uncertainty aspects of the SPS Agreement.[135] For example, the WTO Appellate Body has reaffirmed that countries retain the sovereign right to establish their own appropriate level of protection of human, animal, and plant health, which may be "zero risk."[136] While the appropriate level of protection is an objective, the SPS measure is an instrument selected to attain or implement that objective.[137]

The Appellate Body has strongly underscored the requirement for domestic SPS measures to be based on risk assessment and has explored the relationship between risk assessment, the appropriate level of protection, and the measure applied to achieve that level of protection. In addition, it has elaborated the meaning of science-based risk assessment and considered the factors to be taken into account in risk assessment. It has also considered the appropriate role of the WTO panels in evaluating whether measures that are the subject of complaint meet the requirements of the SPS Agreement. A risk assessment within Article 5.1 of the SPS Agreement must:

> i. identify the diseases (or pests) whose entry, establishment or spread a Member wants to prevent within its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these diseases;
> ii. evaluate the likelihood of entry, establishment or spread of these diseases (or pests), as well as the associated potential biological and economic consequences; and
> iii. evaluate the likelihood of entry, establishment or spread of these diseases (or pests) according to the SPS measures which might be applied.[138]

"Likelihood," in this case, corresponds to "probability," and it is insufficient merely to demonstrate the "possibility" of entry, establishment, or spread of pests or diseases.[139] The risk evaluated in the risk assessment must be an ascertainable risk rather than a theoretical uncertainty.[140]

While panels and the Appellate Body have characterized scientific risk assessment as a process characterized by "systematic, disciplined and objective enquiry and analysis, that

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[135] For a more detailed analysis, see, for example, Pauwelyn, (1999) 641; Charnovitz, (2000). Aspects of each of the first three SPS cases have been appealed.
[136] *Australia – Measures Affecting Importation of Salmon*, Report of the Appellate Body, 20 October 1998, Doc. WT/DS18/AB/R, at paras. 125, 199 [hereinafter *Australia – Salmon*]. See also, in the context of GATT 1994, *EC – Asbestos*, *supra* note 65, at para. 168.
[137] *Australia –Salmon*, *supra* note 153, at para. 200.
[138] *Ibid.*, at para. 121.
[139] *Ibid.*, at para. 123.
[140] *EC – Meat Hormones*, *supra* note 129, at para. 186; *Australia – Salmon*, *supra* note 145, at para. 125. But see also discussion of Article 5.7.

is, a mode of studying and sorting out facts and opinions,"[141] the Appellate Body has also indicated that the list of factors to be taken into account in risk assessments under Article 5.2 of the SPS Agreement is not necessarily a closed list. It has suggested that risk assessment might incorporate qualitative as well as quantitative analysis[142] and that "the risk is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world here people live and work and die."[143] It is not necessary that a member that adopts an SPS measure carries out its own risk assessment, however; it may be justified on the basis of an assessment carried out by another member or by an international organization.[144] Moreover, risk assessment need not necessarily rely solely on the majority view in the scientific community, but it can set out divergent views, which may in themselves reflect a state of scientific uncertainty.[145] There will be "scientific justification" for an SPS measure, within Article 3.3 of the SPS Agreement, if there is a "rational relationship" between the SPS measure and the risk assessment—that is, the results of the risk assessment must "sufficiently warrant" or "reasonably support" the SPS measure at stake—and this relationship will be assessed on a case-by-case basis.[146]

As noted earlier, under Article 5.7 of the SPS Agreement, provisional SPS measures may be applied in cases where scientific evidence is insufficient. This provision has been characterized as a reflection of the precautionary approach in the SPS Agreement. According to the Appellate Body, it operates as a qualified exemption from the obligation under Article 2.2 of the SPS Agreement not to maintain SPS measures without sufficient scientific evidence.[147] In *Japan – Measures Affecting Agricultural Products (Japan – Varietals)*, the Appellate Body confirmed that the four requirements set out in Article 5.7 are cumulative. Thus, a member may adopt an SPS measure provisionally only if this measure is:

(1) imposed in respect of a situation where "relevant scientific information is insufficient"; and
(2) adopted "on the basis of available pertinent information."

And it may only maintain such a measure if it:

(1) "seek[s] to obtain the additional information necessary for a more objective assessment of risk"; and

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[141] *EC – Meat Hormones*, *supra* note 129, at para. 187.
[142] *Ibid.*, at para. 187; and *Australia – Salmon*, *supra* note 153, at para. 124. The Appellate Body has made a similar finding in respect of Article XX(b) GATT in *EC – Asbestos*, *supra* note 65, at para. 167.
[143] *EC – Meat Hormones*, *supra* note 129, at para. 187.
[144] *Ibid.*, at para. 190.
[145] *Ibid.*, at para. 194.
[146] *Ibid.*, at para. 193; *Japan – Measures Affecting Agricultural Products*, Report of the Appellate Body, 22 February 1999, WTO Doc. WT/DS76/AB/R, at para. 80 [hereinafter *Japan – Varietals*]
[147] . *Japan -Varietals*, Report of the Appellate Body, *supra* note 163, at para. 79.

(2) "review[s] the ... measure accordingly within a reasonable period of time."[148]

The obligation actively to seek additional information is one of the more apparent points of difference between the SPS Agreement and the Biosafety Protocol. With respect to this obligation, the Appellate Body has observed that the SPS Agreement does not set out explicit requirements regarding the additional information to be sought or a specific procedure for collecting such information, nor does it specify the results to be achieved. However the information sought must be "germane to conducting risk assessment." What constitutes a "reasonable period of time" for Article 5.7 "has to be established on a case-by-case basis and depends on the specific circumstances of each case, including the difficulty of obtaining the additional information necessary for the review *and* the characteristics of the provisional SPS measure."[149]

In *EC Measures Concerning Meat and Meat Products (Hormones)* (*Meat Hormones* case), in which the EC did not seek to rely explicitly on Article 5.7 on the basis that the measure in question was not provisional, the Appellate Body noted that the precautionary principle is reflected in other provisions of the SPS Agreement that allow members to set their own level of protection and that 'representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned."[150]

The panels and Appellate Body have also addressed the issue of burden of proof in SPS cases and the proper role of the panels in assessing domestic SPS measures (the "standard of review"). The onus is on a complainant to make a *prima facie* case that the SPS measure at issue is inconsistent with a provision of the agreement—that is, that it is maintained without sufficient scientific evidence. Once this case is made, the burden of proof moves to the defending member to counter or refute the claimed inconsistency.[151] The standard of review goes to the extent to which the panels can undertake their own review of whether the member's risk assessment justifies a particular SPS measure and to what extent they should show deference to members. This issue goes to the crux of current debates over the role of the WTO in relation to national environmental and human health measures. The Appellate Body has observed that the standard of review "must reflect the balance established in the [SPS] Agreement between the jurisdictional competences conceded by Members to the WTO and the jurisdictional competences retained by the Members for themselves."[152] According to the Appellate Body, in accordance with the DSU, panels[153] must undertake "an objective assessment of the facts," and thus the applicable standard is neither one of *de novo* review nor one of "total

[148] *Ibid.*, at para. 89.
[149] *Ibid.*, at paras. 92-3.
[150] *EC – Meat Hormones*, *supra* note 129, at para. 124.
[151] Unless the measure in question conforms to an international standard and thus benefits from a rebuttable presumption of consistency with the SPS Agreement. *EC – Meat Hormones*, *supra* note 129, at para. 98.
[152] *Ibid*., at para. 115 [footnote omitted].
[153] Under the DSU, findings of fact, as distinguished from legal interpretations or conclusions, are in principle not subject to a review by the Appellate Body. However, *whether* a panel has made an objective assessment of the facts may in itself be a legal question that could fall within the scope of appellate review. *Ibid.*, at para. 132.

deference."[154] The level of protection selected by a member is not of itself subject to review by the WTO panels or the Appellate Body, rather it is the extent to which a measure designed to achieve that level of protection meets the other requirements of the SPS Agreement and other WTO rules that may be reviewed.

SPS measures challenged in the WTO to date have been found wanting, either on the basis that they were not based on a proper (or any) risk assessment or on the basis that a country implementing a provisional measure did not fulfil all the requirements under Article 5.7 of the SPS Agreement. Nonetheless, the approach taken by the Appellate Body suggests that there would be scope to defend a trade-based biosafety measure designed to address ascertainable environmental and health risks. However, the emphasis on the risk assessment procedure in the SPS Agreement, and now in the Biosafety Protocol, emphasizes the need for regulatory and administrative procedures capable of collecting or generating, and assessing, information on which to base domestic regulatory measures. In this regard, Charnovitz has noted that "the SPS Agreement—which was largely initiated by the US government—favours those countries that have a surfeit of administrative procedures. Governments that can produce a voluminous risk assessment, show that it was considered by regulators, and document each step of the regulatory process will probably do better as SPS defendants than countries with thinner regulatory structures."(Charnovitz 2000: 152; Victor 2000: 913-18)

As noted above, if a domestic biosafety measure does not fall within the SPS Agreement, it may be assessed under the TBT Agreement. The TBT Agreement applies to all measures affecting the trade in any products that are technical regulations or technical standards as long as these measures do not fall under the SPS Agreement. These measures may include trade restrictions on products containing certain substances.[155] There has so far been little analysis of the TBT Agreement in case law,[156] although the Appellate Body has observed that it imposes obligations on members that seem to be "*different* from and *additional* to, the obligations imposed on Members under the GATT 1994."[157]

In relation to a GATT analysis, a central aspect of any dispute in relation to GMOs may be whether or not they are deemed "like" their non-GM counterparts. Case law on Article III.4 of the GATT has identified four general criteria in analyzing "likeness" for the

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[154] *Ibid.*, at para. 117; DSU, *supra* note 103, at Article 11.

[155] TBT Agreement, *supra* note 10, at Article 1(2); Annex 1(1); *EC – Asbestos*, *supra* note 65, at paras. 63-76. In the *EC – Asbestos* case, the Appellate Body found that although in principle a decree relating to the ban on imports of asbestos and asbestos-containing products did constitute a technical regulation, it did not have an adequate factual basis on which to properly examine Canada's claims under the TBT Agreement (para. 75-83).

[156] See *EC – Asbestos*, *supra* note 65, at para. 81: "[T]he meaning of the different obligations in the TBT Agreement has not previously been the subject of any interpretation or application by either panels or the Appellate Body. Similarly the provisions of the Tokyo Round *Agreement on Technical Barriers to Trade*, which preceded the TBT Agreement and which contained obligations similar to those in the TBT Agreement, were also never the subject of even a single ruling by a panel." See now *European Communities – Trade Description of Sardines*, Report of the Appellate Body, 26 September 2002, Doc. WT/DS231/AB/R.

[157] *EC – Asbestos*, *supra* note 65, at para. 80 [emphasis in original].

purposes of the like products test. These are: (1) the properties, nature, and quality of the products; (2) the end-uses of the products; (3) consumers' tastes and habits—more comprehensively termed consumers' perceptions and behaviour—with respect to the products; and (4) the tariff classification of the products. In *EC – Measures Affecting Asbestos and Asbestos-Containing Products*, the Appellate Body emphasized that these criteria are simply tools to assist in the task of sorting and examining the relevant evidence. They are neither a treaty-mandated nor a closed list of criteria that will determine the legal characterization of products.[158] The Appellate Body also found in this case that health risks associated with a product may be pertinent in an examination of "likeness" under Article III.4, as were consumer tastes and preferences, including as they relate to health risks.[159]

If a domestic biosafety measure were to be assessed under the GATT, it is likely that the country imposing it would seek to justify it under paragraphs (b) or (g) of Article XX, the general exceptions provision.[160] The member defending the measure bears the burden of provisionally justifying it under one of the policy objectives enumerated in the subparagraphs of Article XX, including showing it as being *necessary* to the protection of "human, animal or plant life or health" (Article XX(b)) and, under certain conditions, *related to* the conservation of natural resources (Article XX(g)). If a member succeeds with its provisional justification, it must then demonstrate that the measure is not being *applied* in an arbitrary or unjustifiable manner and is not a disguised restriction on trade. Measures taken under the Biosafety Protocol to regulate GMOs that "may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health,"[161] would appear, as a general matter, to be necessary or related to the objectives of the protection of human, animal, or plant life or health or of the conservation of natural resources.

The GATT and WTO panels and the Appellate Body have elaborated on the interpretation of Article XX(b) and (g) in case law. In relation to Article XX(b), according to the Appellate Body, a measure would not be considered necessary if an alternative measure, which the member could reasonably be expected to employ and which is not inconsistent with other GATT provisions, is available to that member. "By the same token, in cases where a measure consistent with other GATT provisions is not reasonably available, a Member is bound to use, among the measures reasonably available to it, that which entails the least degree of inconsistency with other GATT provisions."[162] The question of whether a particular measure meets this "least degree of

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[158] *Ibid.*, at para. 101-2.
[159] *Ibid.*, at para. 120-2.
[160] The following section, on GATT Article XX, is drawn from Mackenzie *et al.*, *supra* note 26, at Appendix.
[161] *Ibid.*
[162] *United States – Section 337 of the Tariff Act of 1930*, GATT Panel Report, 7 November 1989, BISD 36S/345, at para. 5.26. A similar reasoning was followed in *Thailand – Restrictions on Importation of and Internal Taxes on Cigarettes*, GATT Panel Report, 7 November 1990, Doc. BISD 37S/200, at para. 75. Both cases are quoted in para. 6.24 of the Report of the Panel in *US – Gasoline*, *supra* note 63. The panel's interpretation of Article XX(b) of the GATT was not appealed and was thus not reviewed by the Appellate Body.

inconsistency" test, will require a case-by-case analysis. The Appellate Body has held that when determining whether a less trade restrictive measure was "reasonably available," it will assess the extent to which the measure "contributes to the realization of the end pursued."[163] It has also observed that "[t]he more vital or important [the] common interests or values" pursued by the measure, the easier it would be to accept as "necessary" measures designed to achieve those ends."[164] The international recognition, in the Biosafety Protocol, of the special character of GMOs and of the need to protect biological diversity, may provide relevant evidence of "common interests and values."

In relation to Article XX(g), the following criteria need to be met: (1) the policy objective behind the measure must fall within the range of policies related to the conservation of exhaustible natural resources; (2) the measure must be "related to" the conservation of exhaustible natural resources; and (3) the measure must be "made effective in conjunction with restrictions on domestic production or consumption."[165] A measure is considered "related to" the conservation of natural resources, if there is a "substantial relationship" between the general structure and design of the measure at stake and the policy objective it purports to serve. The second criterion is met if "the means are, in principle, reasonably related to the ends."[166] The third criterion, concerning the restrictions on domestic production or consumption, requires the demonstration of "even-handedness" in the imposition of the trade restrictions.[167] Restrictions on the production or consumption of imported GMOs must be in the context of similar restrictions on domestically produced GMOs.

If a member defending a challenged measure is able to justify that measure under Article XX(b) or (g), it would then need to show that the measure also conforms to the requirements of Article XX's "chapeau," which is intended to prevent the abuse of the "limited and conditional"[168] exceptions in Article XX. It lays down three standards. The member would have to demonstrate that the application of its measure does not constitute arbitrary discrimination between countries where the same conditions prevail; unjustifiable discrimination between countries where the same conditions prevail; or a disguised restriction on international trade. According to the Appellate Body, the application of these criteria must strike a balance "between the right of a Member to invoke an exception under Article XX and the rights of other Members under varying [GATT] substantive provisions."[169] The Appellate Body has acknowledged that this balance can be assessed only on a case-by-case basis.[170] Measures that have failed to meet the chapeau test in the past have included those that have been applied in a unilateral manner, that did not offer a sufficient and equal opportunity for affected trading

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[163] *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, Report of the Appellate Body, 10 January 2001, WTO Doc. WT/DS161/AB/R and WT/DS169/AB/R, at para. 163 [hereinafter *Korea – Beef*], cited in *EC – Asbestos, supra* note 65, at para. 172.
[164] *Korea – Beef, supra* note 181, at para. 162, cited in *EC – Asbestos*, *supra* note 65, at para. 172.
[165] *US – Gasoline*, *supra* note 63, at para. 6.35.
[166] *US – Shrimp-Turtle*, *supra* note 63, at paras. 136-42.
[167] *Ibid*., at para. 143.
[168] *Ibid*., at para. 157.
[169] *Ibid*., at para. 157.
[170] *Ibid*., at para. 159.

partners to agree to a common solution; and, in an inflexible manner, that did not allow other members sufficient latitude to demonstrate compliance with the measure. A measure that is required or authorized under the Biosafety Protocol, which is a multilaterally agreed instrument, open for signature to all WTO members, may be more likely to pass these tests.[171]

Case law on Article XX has related to unilateral environmental measures, rather than to trade measures taken pursuant to MEAs. Despite concerns about the relationship between the WTO and MEAs, no trade measures adopted pursuant to a MEA have so far been challenged in the WTO. However, the Appellate Body of the WTO has demonstrated its willingness to consider MEAs in disputes that come before it. For example, in *United States – Import Prohibition of Certain Shrimp and Shrimp Products* (*US – Shrimp-Turtle* case), it referred to the Convention on International Trade in Endangered Species of Wild Fauna and Flora in considering the definition of "exhaustible natural resources" for the purposes of Article XX(g).[172] More generally, the WTO has emphasized the importance of adopting multilateral solutions to transborder environmental problems.[173]

The Appellate Body has also acknowledged the evolving context in which the WTO agreements operate. Originally adopted in 1947, the GATT must now be read in light of contemporary developments and concerns. In the *US – Shrimp-Turtle* case, the Appellate Body noted that:

> 152. At the end of the Uruguay Round, negotiators fashioned an appropriate preamble for the new *WTO Agreement*, which strengthened the multilateral trading system by establishing an international organization, *inter alia*, to facilitate the implementation, administration and operation, and to further the objectives, of that Agreement and the other agreements resulting from that Round. In recognition of the importance of continuity with the previous GATT system, negotiators used the preamble of the GATT 1947 as the template for the preamble of the new *WTO Agreement*. Those negotiators evidently believed, however, that the objective of "full use of the resources of the world" set forth in the preamble of the GATT 1947 was no longer appropriate to the world trading system of the 1990's. As a result, they decided to qualify the original objectives of the GATT 1947 with the following words:
>
> > … while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development.
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> 153. We note once more that this language demonstrates a recognition by WTO negotiators that optimal use of the world's resources should be made in accordance with the objective of

[171] See, generally, *US – Shrimp-Turtle*, *supra* note 63.

[172] *Ibid*., at para. 132. Convention on International Trade in Endangered Species of Wild Fauna and Flora, 993 UNTS 243. The Appellate Body also made reference to the United Nations Convention on the Law of the Sea, 21 ILM 1261 (1982); the CBD, *supra* note 22; Agenda 21, *supra* note 14; and the Convention on the Conservation of Migratory Species of Wild Animals, which can be accessed at <http://sedac.ciesin.org/pidb/texts-menu.html> (*US – Shrimp-Turtle*, *supra* note 63, at para. 130).

[173] *US – Shrimp-Turtle*, *supra* note 63, at para. 166; *Report (1996) of the Committee on Trade and Environment*, 12 November 1996, Doc. WT/CTE/1, para. 171; and *Section VII of the Report of the General Council to the 1996 Ministerial Conference*, 26 November 1996, Doc. WT/MIN(96)/2.

> sustainable development. As this preambular language reflects the intentions of negotiators of the *WTO Agreement*, we believe it must add colour, texture and shading to our interpretation of the agreements annexed to the *WTO Agreement*, in this case, the GATT 1994.[174]

This statement suggests a need to interpret rights and obligations under the WTO agreements in a manner that reflects evolving international understandings of issues of sustainable development, including issues relating to food security and the right to food.

One question that emerges from this brief overview of the existing case law is whether limited regulatory monitoring or enforcement capacity might provide grounds for a developing country to adopt a "protective" trade measure in relation to biosafety, under the general provisions of the agreements (for example, GATT Article XX(b) or (g), or the SPS/TBT Agreements). While this issue has not specifically come before it, the Appellate Body has recognized, in relation to the SPS Agreement, that risk may be evaluated in qualitative, and not merely quantitative, terms and that the risk to be evaluated is risk in a "real world" context.

Overall, there are provisions in the agreements, and guidance in the case law, that would enable a country to mount a defence to a challenge of a domestic biosafety measure adopted on environmental, health, and potentially socio-economic, grounds (see discussion below).[175] However, there remains a significant degree of uncertainty inherent in relying upon dispute settlement to find favourable outcomes.[176] As noted by Charnovitz and others, despite the guidance given by the Appellate Body so far on the SPS Agreement in particular, there remain many areas of uncertainty and, hence, unpredictability. For example, what precisely would be deemed a sufficiently "rational relationship" between a risk assessment and an SPS measure?[177] Given the scope for interpretation of the agreements, there is a possibility of *de facto* policymaking through dispute settlement in the WTO, and it remains uncertain to what extent the dispute settlement process would take account of other relevant international rules and principles. The lack of certainty and predictability may also render countries designing and applying national biosafety frameworks more susceptible to external pressures to adopt specific approaches.

IV. SOCIO-ECONOMIC CONSIDERATIONS IN THE REGULATION OF MODERN BIOTECHNOLOGY

Despite the intensity of international activity, there are still significant gaps in the international framework on modern biotechnology. The emphasis both in the norms adopted to date and in those under development remains on technical and procedural requirements for harmonizing risk assessment procedures in relation to risks to human health and to the environment posed by GMOs. Developing countries have emphasized

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[174] *US – Shrimp-Turtle*, *supra* note 63, at paras. 152-3 [footnotes omitted]. See also, *US – Gasoline*, *supra* note 63, at 17, observing that "the General Agreement is not be to read in clinical isolation from public international law."

[175] See, for example, Howse and Mavroidis, (2000), assessing the potential compatibility of existing and proposed EC regulations with the requirements of the SPS Agreement.

[176] Victor (2000: 898) notes the high transaction costs of interpreting the SPS Agreement through cases

[177] *ibid*., at 915.

the need to address impacts of modern biotechnology more broadly, for example, by considering socio-economic issues, liability and redress, as well as technology transfer. These have been addressed only partially and in ambiguous terms to date.

In light of the international regulatory context outlined in Sections II and III above, what space exists for taking food security and related socio-economic considerations into account in decision-making on biotechnology and biosafety? Much of the debate around the role of biotechnology in promoting food security in developing countries has focused on socio-economic impacts, in particular, on the conditions under which GMOs might be made available (for example, licensing arrangements and impacts on the ability of farmers to save and re-use seed) (Yamin 2003) and on the potential impacts of GM crops on traditional crop varieties. Concerns have also been expressed that developments in modern biotechnology could give rise to substitutions of crops traditionally exported from developing countries, thus reducing export revenues. In some circumstances, the potential impacts of a particular GMO upon biological diversity, plant or animal life or health, or human health may give rise directly to related food security or socio-economic concerns. In others, socio-economic concerns not specifically related to direct impacts on biodiversity or health might be raised by the potential use of GM crops. Thus, food security concerns related to the use of GMOs in agriculture might emanate directly from concerns about environmental/biodiversity or human health risks associated with a GMO, from concerns about potential impacts on other agricultural crops, or from broader concerns about socio-economic impacts in regard to food production patterns and access to seeds and so on. In some respects, international agreements and instruments that have been adopted to date on biotechnology may constrain the consideration of some of these broader concerns, with their emphasis on "science-based" decision-making procedures. This section examines the way in which socio-economic considerations have thus far been integrated into the international regulatory framework for GMOs and the opportunities that have arisen to expand the role of food security concerns into domestic decision-making on GMO imports and use.

Given the extent to which socio-economic issues have been raised in the debate, it is perhaps surprising that the role and impact of socio-economic considerations in decision-making on imports and the use of GMOs remains relatively undefined in international instruments. While it is recognized that decisions on imports of GMOs should take into account the assessment of risks on human health, on the environment, and on plant health, little detailed prior evaluation of the potential socio-economic impacts of the use of a specific GMO in the country concerned has been provided for. Yet if modern biotechnology is to be promoted as a tool to contribute to food security, it would seem logical to undertake a specific analysis of potential food security and other socio-economic impacts *before* the technology or specific products are introduced. Such an analysis could reasonably incorporate not only the potential impacts on agricultural productivity but also the broader distributive impacts.

As observed above, food security is not expressly mentioned in the Biosafety Protocol, although it was raised as a concern in discussions concerning socio-economic considerations. During the negotiation of the protocol, many developing countries

proposed that socio-economic considerations should be part of the risk assessment procedure. The original draft Protocol submitted by the African group contained extensive provisions on socio-economic considerations. An early proposal listed the parameters of a risk assessment to include the following socio-economic considerations: (1) anticipated changes in the existing social and economic patterns; possible threats to biological diversity, traditional crops or other products, and, in particular, farmers' varieties and sustainable agriculture; (2) impacts likely to be posed by the possibility of substituting traditional crops, products, and indigenous technologies through modern biotechnology outside of their agro-climatic zones; (3) anticipated social and economic costs due to the loss of genetic diversity, employment, market opportunities, and, in general, means of livelihood of the communities; (4) disruptions to social and economic welfare; and (5) possible effects contrary to the social, cultural, ethical and religious values of communities.[178] The remit of this proposal was unacceptable to most developed countries, although some, such as Norway, were prepared to see socio-economic concerns reflected in the Biosafety Protocol in some way. Other countries, such as Bolivia and Mexico, emphasized the importance of economic impacts on centres of origin and genetic diversity.[179] Early in the Protocol negotiations, in preparation for the second meeting of the BSWG in 1997, the Secretariat was asked to prepare a bibliography on potential socio-economic impacts of biotechnology,[180] but further studies were not conducted as part of the negotiation process.

While the Biosafety Protocol does address socio-economic considerations in Article 26, it remains unclear how far this provision goes in meeting broader concerns that have been raised around biotechnology products, such as ethical concerns and issues of property rights or local preferences. The scope of Article 26 remains to be defined, both in national legislation and in practice, and perhaps in further elaboration by the meeting of the Parties to the Protocol. While Article 26 would appear to extend to the impacts on local crop varieties used by indigenous and local communities (and potentially to related, but indirect, impacts),(Stabinsky 2000) it is more debatable whether it would extend to more general socio-economic impacts of the use of GMOs in a country—for example, such as what happens to local/national food production patterns as a whole and how this affects different groups. In addition, the phrase "consistent with their international obligations" indicates that a country's conduct in relying upon Article 26 can be tested against other applicable international agreements, including WTO agreements.

The lack of data and analysis on the socio-economic impacts of modern biotechnology makes it difficult to foresee the impact of Article 26. Some parallels may perhaps be seen

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[178] *Compilation of the Views of Governments on the Contents of the Future Protocol*, Doc. UNEP/CBD/BSWG/2/2, 18 March 1997. See also *Government Submissions, Comments from Kenya on the Revised Consolidation Text of Draft Articles*, 5 July 1998, Doc. UNEP/CBD/BSWG/5 Inf.2, suggesting that users "should take due account of the long observation periods that socio-economic impacts may require to manifest such adverse consequences as genetic erosion and associated loss of income and dislocation of traditional farmers and farm products."

[179] For example, *Compilation of the Views of Governments on the Contents of the Future Protocol*, Doc. UNEP/CBD/BSWG/2/2, 18 March 1997, at 73.

[180] *Potential Socio-Economic Effects of Biotechnology: A Bibliography*, Doc. UNEP/CBD/BSWG/2/4, 6 March 1997.

with the provisions of the TRIPS Agreement and the CBD on intellectual property rights. At the time of the negotiation of the TRIPS Agreement, little analysis was available on the interlinkages between biological diversity and intellectual property rights.(Yamin 2003) Subsequent attempts to raise these issues within the CBD itself have been inconclusive, but they have prompted calls from the COP to the CBD for case studies and analysis of the interrelationship.

In addition to Article 26, there are other provisions in the Biosafety Protocol that may support the consideration of food security concerns within the context of decision-making on imports of GMOs. For example, in general terms, during the AIA procedure, Parties are to consider the potential impacts of the GMO on biological diversity in their territory. Under these provisions, Parties may consider in the context of risk assessment the possible impact of introduced GMOs on other agricultural and non-agricultural biological diversity. The preamble to the Biosafety Protocol refers to the importance of centres of origin and centres of genetic diversity. Information on such centres is also to be provided in notifications under the AIA procedure and in relation to LMO-FFPs and to be taken into account in the risk assessment process. These types of considerations have been of particular concern in the recent case of apparent "contamination" of traditional maize varieties in Mexico with the *Bt* gene. Finally, Article 16(5) of the Protocol, which provides for collective action by Parties in relation to certain GMOs or traits, may provide some scope for action related to food security concerns where these concerns arise out of adverse effects of LMOs on the conservation and sustainable use of biological diversity or risks to human health.

Given the lack of firm guidance on the scope of acceptable socio-economic considerations, it is difficult to predict how governments will implement Article 26. Stabinsky notes that as both quantitative and qualitative data are used in social impact analysis and that to an extent it is therefore subjective, "[a]ny [social impact assessment] is likely to be highly contested, in particular when the benefits and costs of the impacts are not evenly distributed, and a finding goes against the interests of either the major beneficiaries or those bearing the largest burdens of impact."(Stabinsky 2000:269) In this context, she notes that "the subjectivity of the results will make them easy targets for challenge at the WTO."(ibid:270) At least one GATT panel has rejected trade restrictions that were justified solely on the grounds that cheap imports would undermine the traditional livelihoods of a certain minority population.[181]

As noted earlier in this paper, under Article 5.3 of the SPS Agreement, members are to take into account certain relevant economic factors in assessing the risk to animal or plant life or health (but not to human health) and in determining the measure to be applied for achieving the appropriate level of protection from such risk. The factors enumerated in Article 5.3 are: "the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness

[181] *Japanese Measures on Imports of Leather*, GATT Panel Report, 2 March 1984, Doc. BISD 31S/94, at 44; see also *EC – Quantitative Restrictions against Imports of Certain Products from Hong Kong*, GATT Panel Report, 1983, Doc. BISD 30S/129. See Mackenzie *et al.*, *supra* note 26, at appendix.

of alternative approaches to limiting risks." During the negotiation of the SPS Agreement, there was debate over whether "other economic considerations and genuine consumer concerns" should be a factor in risk assessment (for example, where standards are imposed against the weight of scientific evidence but in accordance with widespread consumer concern).(Stewart 1993:vol 1 201) While there is nothing in Article 5.3 to suggest that this is an exhaustive list of "relevant economic factors," the freedom for action of WTO members is circumscribed by the other provisions of the SPS Agreement described in Section II above. There has been no specific case law on Article 5.3 since the adoption of the SPS Agreement, although, as noted in Section III, the Appellate Body has referred to the inclusion of potential economic consequences of the entry, establishment, or spread of pests or diseases in risk assessment under the SPS Agreement.[182] Again, it may be difficult to extend the scope of this provision to encompass broader socio-economic concerns relating to GMOs, such as the general impacts on traditional agriculture and the conditions under which GM seeds are made available.

The TBT Agreement, in Article 2.2, requires that technical regulations imposed by members are not prepared, adopted, or applied with a view to, or with the effect of, creating unnecessary obstacles to international trade and are not more restrictive than necessary to fulfil a legitimate objective. A non-exhaustive list of legitimate objectives is provided, including national security requirements, the prevention of deceptive practices, the protection of human health or safety, animal or plant life or health, or the environment. A more appropriate route for accommodating socio-economic concerns may be through provisions of the WTO agreements on special and differential treatment or through enhancing the assessment of broader development implications of the agreements. In this regard, certain debates and proposals in the context of the Agreement on Agriculture negotiations may be instructive, along with the declarations and objectives of other international policy fora.

Codex Alimentarius principles on the elaboration of food standards also provide for the consideration of certain "other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade".[183] Such factors may be identified in the risk management process, but are not to affect the scientific basis of risk analysis.[184] The Codex Alimentarius Commission has stated that the feasibility of risk management options due to the nature and particular constraints of the production or processing methods, transport and storage, especially in developing countries, may be considered; and that concerns related to economic interests and trade issues in general should be substantiated by quantifiable data.[185] In its fourth session, the Codex Task

[182] See Section II earlier in this paper, and *Australia –Salmon, supra* note 153, at para. 121.
[183] Statements Of Principle Concerning The Role Of Science In The Codex Decision-Making Process And The Extent To Which Other Factors Are Taken Into Account, Decision of the 21st Session of the Codex Alimentarius Commission, 1995.
[184] Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle, Decision of the 24th Session of the Commission, 2001.
[185] *Ibid.* The Codex Decision further states that the integration of other legitimate factors in risk management should not create unjustified barriers to trade; particular attention should be given to the impact on developing countries of the inclusion of such other factors.

Force on Foods Derived from Biotechnology considered possible future work on such foods within the Codex. Among the proposals for future work were discussions of broader issues related to genetically modified food such as ethics and socio-economic considerations; other legitimate factors related to modern biotechnology; and special needs of developing countries.[186] Economic impacts of plant pests have been considered in the IPPC, and in 2003 the Interim Commission on Phytosanitary Measures adopted guidance on the term "potential economic importance".[187]

Other international processes have provided alternative fora for countries to raise socio-economic concerns, including food security, associated with biotechnology. However, these processes have to date generated incomplete or non-binding outcomes. For example, the (CGRFA) draft 1993 Code of Conduct for Biotechnology[188] appears to contain a more wide-ranging concept of socio-economic considerations than either the Biosafety Protocol or the SPS Agreement. The aim of the code was to maximize the positive effects and minimize the possible negative effects of biotechnology. Work on the draft code was suspended pending the completion of the Biosafety Protocol and the revision of the International Undertaking on Plant Genetic Resources[189] (which were completed in 2000 and 2001 respectively). Article 8 of the draft code, on prevention and mitigation of possible negative effects provides:

> 8.1 In order that they can act to foresee and prevent possible negative socio-economic effects of agro and food biotechnologies, Governments and international organizations should develop, as part of their procedures for Technology Assessment, monitoring and assessments of the socio-economic impacts of biotechnologies, in particular on developing countries and local communities.
>
> …
>
> 8.4 Governments should consider the establishment of mechanisms to provide technical and financial assistance to affected farming communities and countries to mitigate adverse socio-economic effects due to particular developments in biotechnology.

Further, Article 10 provides for research on criteria and indicators of the contribution of biotechnology to sustainability in agriculture and the use of plant genetic resources, noting that such criteria should include both scientific and socio-economic aspects (for example, whether innovations suit local farming systems).

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[186] *Report of the Fourth Session of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology*, Yokohama, 11-14 March 2003, Doc. ALINORM 03/34A, paras. 81-86. Some delegations expressed the view that future work on genetically modified food in Codex should focus on food safety issues and should not address issues that fell outside the Codex mandate, *ibid*, paras. 84-85. The question of future work on genetically modified food by the Codex Alimentarius will be considered at the 26th meeting of the Commission in July 2003.

[187] *Report of the Fifth Session of the Interim Commission on Phytosanitary Measures*, Rome 7-11 April 2003, Doc. ICPM 03/Report, Appendix III, Supplement No. 2 to ISPM No. 5 (*Glossary of Phytosanitary Terms*), Guidelines on the Understanding of Potential Economic Importance and Related Terms Including Reference to Environmental Considerations.

[188] Draft Code of Conduct for Biotechnology, 1993, Doc. CGRFA -9/02/18/Annex (CPGR/93/9).

[189] International Undertaking on Plant Genetic Resources, Resolution 8/83, Twenty Second Session of the FAO Conference, Rome 1983, available at http://www.fao.org/ag/cgrfa/IU.htm

The status of the draft code was reviewed at the most recent session of the CGRFA in October 2002. A number of FAO members had supported continued work on the code, notwithstanding the adoption of the Protocol and the International Treaty on Plant Genetic Resources, suggesting a wide range of possible issues that could be addressed, such as the socio-economic impacts of biotechnological advances on agricultural practices and food security, ethical issues, the substitution of traditional agricultural products, the control of the global agro-food system, liability issues, and incentives to promote appropriate biotechnologies. Some FAO members and stakeholders opposed further development of the code.[190]

More generally, issues regarding biotechnology are being debated in other international fora concerned with food security, the right to food, and ethics in food and agriculture. These fora encompass a range of bodies concerned with issues of human rights, ethics, and equity. Such initiatives, while not solely focused on the role of biotechnology in contributing to food security, can provide useful inputs to broaden the debate. They include the work of the UN Special Rapporteur on the Right to Food, appointed by the Commission on Human Rights, and the FAO Panel of Eminent Experts on Ethics in Food and Agriculture. The work of the UN special rapporteur, Jean Ziegler, has been controversial. He has been vocal in calling for the integration of the right to food, and international human rights law, into international agricultural trade. His reports have expressed particular concern about the impacts on the right to food of developments in modern biotechnology, including related intellectual property rights issues, noting that "[t]he right to food implies not only access to food, but also access to the means of producing it."[191] The special rapporteur has also criticized the emphasis on free trade and biotechnology as key ways of reducing hunger in the final declaration of the World Food Summit: Five Years Later[192] and has recommended that alternative policy options be given greater attention at the international level.[193] The declaration called on the FAO, in conjunction with the CGIAR and other international research institutes, to advance agricultural research and research into new technologies, including biotechnology.[194] The comments of the special rapporteur on GM food aid provoked strong criticism from the United States.[195] The biotech debate may also feature on the agenda of the newly created Intergovernmental Working Group, which was established by the FAO Council as a subcommittee of the Committee on World Food Security to craft voluntary guidelines to support member states efforts to achieve the progressive realization of the right to

[190] See 2(16) *Bridges Trade BioRes* (24 October 2002). The status of the draft code will be reviewed at the next session of the Commission on Genetic Resources for Food and Agriculture in 2004.

[191] Jean Ziegler, *Report by the Special Rapporteur on the Right to Food*, 7 February 2001, UN Doc. E/CN.4/2001/53, submitted in accordance with Commission on Human Rights Resolution 2000/10, para. 73.

[192] Declaration of the World Food Summit: Five Years Later, *supra* note 15.

[193] *Note by the Secretary General transmitting the report of the Special Rapporteur of the Commission on Human Rights on the right to food*, 27 July 2002, UN Doc. A/57/356, at para. 19.

[194] Declaration of the World Food Summit: Five Years Later, *supra* note 15, at para. 25.

[195] *Statement of Ambassador Sichan Siv, US Representative to the Economic and Social Council on the Report of Mr. Jean Ziegler, Special Rapporteur on the Right to Food, at the 57th Session of the UN General Assembly, in the Third Committee, November 11, 2002*, 11 November 2002, USUN Press Release no. 189(02), available at <http://www.un.int/usa/02-189.htm>.

adequate food. This action is intended to follow up paragraph 10 of the Declaration of the World Food Summit: Five Years Later.[196]

The issues of biotechnology and biosafety did not feature as prominently as might have been expected in the formal outputs of the WSSD in 2002, although they were the focus of significant debate and discussion at events taking place around the summit. The WSSD Plan of Implementation invites all states that have not already done so to ratify the CBD and the Biosafety Protocol and calls for enhanced scientific and technical cooperation on biotechnology and biosafety, including exchanging experts, training human resources, and developing research-oriented institutional capacities.[197]

Some countries have already sought to accommodate in their national legislation socio-economic concerns associated with modern biotechnology and have thus adopted national regulations on biotechnology/biosafety, which go beyond environmental and health risks to also address socio-economic and/or ethical concerns. For example, the Norwegian Gene Technology Act states that its purpose is "to ensure that the production and use of genetically modified organisms takes place in an ethically and socially justifiable way, in accordance with the principle of sustainable development and without detrimental effects on health and the environment."[198] Consideration for the approval of deliberate releases of GMOs into the environment take into account whether the release represents a benefit to the community.(Stabinsky 2000:270) EC Directive 2001/18 on the Deliberate Release into the Environment of Genetically Modified Organisms recognizes that member states may take into consideration ethical aspects when GMOs are deliberately released or placed on the market as or in products.[199] However, the directive does not accord a specific role to ethical issues in the risk assessment and decision-making process—this being within the preserve of the member states. The directive also provides for consultation of an Ethics Committee.[200] The first report on the operation of the directive, which is due in 2003, will include an assessment of the socio-economic implications of deliberate releases and placing on the market of GMOs.[201] The New Zealand Act on Hazardous Substances and New Organisms also requires as part of the approval process for release of a GMO, information on potential socio-economic impacts, including its impacts on indigenous communities, culture, and traditions.[202]

V. IMPLEMENTATION ISSUES

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[196] *Report of the 123rd Meeting of the FAO Council*, 28 October-1 November 2002, Doc. CL123-REP-Revised, at Appendix D.
[197] WSSD, *supra* note 14, at paras. 42(r) and (t).
[198] Act relating to the Production and Use of Genetically Modified Organisms (Gene Technology Act), Act No. 38 of 2 April 1993, section 1, available at http://www.ub.uio.no/ujur/ulovdata/lov-19930402-038-eng.pdf>.
[199] EC Directive 2001/18 on the Deliberate Release into the Environment of Genetically Modified Organisms, OJ L 106, 17 April 2001, 1, at recital 9.
[200] *Ibid.*, at Article 29.
[201] *Ibid.*, at Article 31.
[202] New Zealand Act on Hazardous Substances and New Organisms, available at <http://www.mfe.gov.nz/laws/hsno.html>, see Stabinsky, *supra* note 200, at 270.

The Biosafety Protocol is premised upon a system of national biosafety frameworks and upon information exchange. National biosafety frameworks need to be capable, *inter alia*, of dealing with applications for the import and use of LMOs, assessing and managing risks associated with LMOs, policing "illegal" transboundary movements and unauthorized use of LMOs, and monitoring the actual impact of authorized LMOs in the receiving environment. It is far from clear that the situation on the ground in many countries will enable these requirements to be met (Dhar 2003; Odame *et aI* 2003) The adoption of the Biosafety Protocol has given rise to a wide range of international capacity-building initiatives that are aimed, in the first instance, at assisting developing countries to develop "national biosafety frameworks"—that is, to develop or to adapt a set of laws, institutions, and regulations on biosafety. These initiatives derive from diverse sources—international organizations, such as UNEP and the GEF as well as CGIAR bodies such as the International Service for National Agricultural Research, bilateral donors, NGOs, and the private sector. The ICCP has recommended a capacity-building action plan.[203] These efforts focus primarily, to date at least, on putting into place legal and administrative measures and on risk assessment procedures, while some focus more specifically on biotechnology as such.[204] There has been debate as to the appropriate role of the private sector in capacity building.

Significant efforts are also underway to promote capacity in the development and application of international food safety standards, given the enhanced role of the Codex Alimentarius in the WTO SPS Agreement. At the WTO Doha Ministerial Conference, the WTO, the FAO, the International Office of Epizootics, the WHO, and the World Bank issued a statement on strengthening the ability of developing countries to establish and implement science-based sanitary and phytosanitary requirements of trading partners and to participate fully in the work of standard-setting organizations (see Section VI below). The organizations are to undertake technical assistance activities and investment in infrastructure and to explore new technical and financial mechanisms for coordination and resource mobilization.[205]

Influences on the development of national biosafety frameworks are coming from a number of sources. In addition to seeking to comply with their various international obligations, countries are coming under pressure from domestic constituencies, seeking more or less stringent arrangements, and from the multinational biotech enterprises (Newell and Glover 2003) as well as from other countries seeking to secure a reflection of their own regulatory models elsewhere. Numerous examples have been publicized of

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[203] *Recommendation 3/5 of the Intergovernmental Committee for the Cartagena Protocol*, Doc. UNEP/CBD/ICCP/3/10, 27 May 2002, at annex.

[204] For example, the ongoing work of the International Centre for Genetic Engineering and Biotechnology. USAID increased its spending on agricultural biotechnology activities from US $7-8 million in 2000 to US $19 million in 2001, with a further increase in 2002: *The Future of Agricultural Biotechnology in World Trade: The Promise and the Challenges*, Statement by Alan P. Larson, Under Secretary for Economic, Business and Agricultural Affairs, at the Agricultural Outlook Forum 2002, 21 February 2002, available at <http://www.state.gov>.

[205] *Agencies to Boost Developing Countries' Participation in Setting Food Safety and Related Norms*, 11 November 2001,WTO Press Release, Press/254; *Capacity Building for Food Standards and Regulations*, 21 October 2002, Doc. G/SPS/GEN/344,.

bilateral pressure apparently being brought to bear on developing countries, in particular by the United States, as they prepare national GMO regulations. Examples include Bolivia, China, Sri Lanka, and Croatia.[206] Such influence may be high level and may be exercised in a range of bilateral fora, including trade and investment negotiations as well as, in some instances, through bilateral biotech capacity-building initiatives. For example, President George Bush raised US concerns with China's proposed regulations on agricultural biotechnology with the Chinese leadership, resulting in a change to interim regulations to avoid the disruption of US agricultural exports.[207] The US Under Secretary for Economic, Business and Agricultural Affairs has stated that "US foreign policy is also devoted to a longer-term struggle to gain world acceptance of agricultural biotechnology products."[208] In 2002, the United States and Thailand entered into a bilateral trade agreement including cooperation, *inter alia,* on biotechnology policy.[209]

Pressure may also be applied in the context of consultations under the WTO SPS and TBT transparency provisions.[210] This pressure is all the more real since, as discussed earlier, it may be backed up by the threat of challenge through the WTO's dispute settlement system. While such trade diplomacy is hardly unusual, it seems problematic when it occurs in the context of a new technology for which many developing countries do not yet have in place adequate risk management infrastructure, in terms of environmental and health risks, and the socio-economic impacts of which are uncertain but are likely to be uneven. Linking capacity building in biotechnology and biosafety to specific policy and regulatory options forecloses domestic public consultation and debate on the appropriate role of biotechnology in agriculture. It has also been suggested that countries are influenced less directly when they take into account the preferences or regulatory systems of their export markets in making their own regulatory choices about biotechnology. In this regard, the US Under Secretary has, for example, criticized EC proposed regulations on the basis, *inter alia,* that they threaten to hamper the development of agricultural biotechnology in developing countries.[211]

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[206] See, for example, Friends of the Earth International (2002); Kruszewska (Winter 2001/2002).

[207] *Agriculture and Biotechnology in US Foreign Policy*, Statement by Alan P. Larson, Under Secretary for Economic, Business and Agricultural Affairs, to the Commodity Club of Washington DC, 10 April 2002, available at <http://www.state.gov>.

[208] *Ibid.*

[209] 6(37) *Bridges Weekly Trade News Digest* (31 October 2002).

[210] See, for example, the comments of the United States, Canada, and Argentina regarding China's food safety regulations affecting agricultural products produced from modern biotechnology. Committee on Sanitary and Phytosanitary Measures, *Summary of the Meeting Held on 25-26 June 2002*, 2 August 2002, Doc. G/SPS/R/27, at paras. 21-3. Significant discussions have also taken place in WTO committees over the GMO approval process in the EC, and new proposals for an EC regulation on traceability and labelling of GMOs.

[211] *Agriculture and Biotechnology in US Foreign Policy*, Statement by Alan P. Larson, Under Secretary for Economic, Business and Agricultural Affairs, to the Commodity Club of Washington DC, 10 April 2002, available at <http://www.state.gov>. Similar allegations have been made in the context of the request by the US for WTO consultations in respect of EC biotech measures in May 2003, see *supra* note 109, and Office of the US Trade Representative and US Department of Agriculture, Press Release 13 May 2003, "US and Cooperating Countries File WTO Case Against EU Moratorium on Biotech Food Crops: EU's Illegal, Non-Science based Moratorium Harmful to Agriculture and the Developing World", available at <http://www.ustr.gov/releases/2003/05/03-31.pdf>.

Debates about the proper scope of regulation of GMOs, and about the removal of trade barriers to the entry of GMOs, are intensified given the absence of specific legal norms and certainty regarding responsibility for any damage that may arise from the import and use of GMOs. In the absence of specific rules, general legal principles on liability and redress apply, but they may not be appropriate to the kinds of scenarios that may arise.[212] Most countries have no specific liability rules in place, and developing countries and communities have expressed concerns about their ability to obtain redress in the event of damage. There is still no agreement as to whether or not international rules and procedures on liability and redress should be adopted under the Protocol.[213] More specific debates concern what types of damage may be covered by any such regime if it is established and who should be liable for any damage.[214] The biotechnology industry has argued that only biodiversity damage should be covered. Others, including some NGOs and developing countries, have suggested that any damage arising from GMOs should be covered by international liability rules, including potential socio-economic damage. In terms of channelling liability, many developing countries have so far expressed a preference for a system of strict State liability, so that in the event of any damage, the State of export of the GMO would be liable without proof of fault. This approach is founded on the difficulties that individuals and communities in developing countries may experience in seeking to bring claims against multinational corporations. Others have proposed strict liability of the exporter of the GMO for any damage.

VI. PROCESS AND PARTICIPATION

The previous sections have outlined the international regulatory framework for modern biotechnology and the scope for considering potential socio-economic impacts of GMOs more squarely within domestic regulatory processes, as well issues that influence the development and implementation of national biosafety frameworks. While numerous international fora have given attention and priority to food security and socio-economic issues in the context of sustainable development, overall, the international regulatory framework for biotechnology appears to overlook these issues or to address them in a relatively vague manner. What opportunities exist for developing countries to influence the international regulatory framework in a way that would provide more policy space for food security concerns? This section briefly examines decision-making and participation in the relevant fora.

Much attention has been paid to the ability of developing countries to participate effectively in international institutions. These concerns have been perceived to be particularly acute in the WTO, as evidenced, specifically, by the events at the Seattle ministerial meeting. They have more recently been raised in relation to international

[212] These issues are addressed in more detail in Newell and Glover, *supra* note 232.

[213] Biosafety Protocol, supra note 2, at Article 27; on further discussions on liability and redress under the protocol, see Recommendations 2/1 and 3/1 of the Intergovernmental Committee for the Cartagena Protocol, available at <http://www.biodiv.org>.

[214] See generally, Mackenzie, (2002); *Report of the Workshop on Liability and Redress in the Context of the Cartagena Protocol on Biosafety*, 14 December 2002 Doc. UNEP/CBD/BS/WS-L&R/1/3; and Singh, (n.d.) See also the reports of the meetings in September 2001 and April 2002, organized by the Meridian Institute, on liability and redress under the Biosafety Protocol, available at <http://www.merid.org>.

standard-setting bodies. By contrast, developing countries played an active role in the Biosafety Protocol negotiations, although complaints arose regarding the lack of transparency at certain stages of the negotiating process.

Each of the main institutions considered in this paper tends to operate in practice by consensus. The Biosafety Protocol was negotiated under the rules of procedure of the CBD, for which it has not been possible to agree on a rule on voting in relation to substantive decisions.[215] Thus, by default, consensus is required. In practice, this procedure, coupled with the strategic importance and bargaining power of the major exporters or potential exporters of GMOs and GM commodities, meant that the Miami Group countries[216] were able to block the adoption of the Biosafety Protocol in Cartagena in 1999. A similar rule has operated in relation to the adoption of the recommendations of the ICCP, and it will operate at meetings of the Parties to the Protocol unless, as seems unlikely, this body is able to agree upon a voting rule.

In the WTO, if it is not possible to reach consensus, decisions may be taken by the majority of votes cast, on the basis of one-member-one-vote, except where other specific decision-making rules are set out.[217] In practice, however, decision-making is once again by consensus.[218] Few, if any, countries appear to have proposed a change in the consensus-based procedures. The decision-making process can work against members that are not represented in Geneva, as remains the case for some developing countries (see the further discussion below).

The Codex Alimentarius Commission also seeks to operate largely by consensus, although where efforts to reach consensus fail decisions may be taken by the majority of votes cast, based on one-member-one-vote.[219] Every effort must be made to reach decisions on the adoption or amendment of standards by consensus, and voting may only occur if these efforts fail.[220] Standards and guidelines are generally elaborated through a committee procedure mandated by the commission, and similar rules apply to decision-making in such committees.[221] Under the IPPC, parties again are to attempt to reach decisions by consensus, failing which decisions can be taken by a two-thirds majority of parties present and voting.

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[215] See CBD COP, Decision I/1, as amended by Decision V/20. Rule 40(1) on voting on matters of substance remains in square brackets. It remains to be seen how this issue will be resolved. Controversy arose at the last COP to the CBD in the Hague in April 2002 when a decision on alien invasive species was adopted by consensus over the formal objection of the delegation of Australia, based, *inter alia*, on perceived potential inconsistencies between the elements of that decision and international trade rules; see 9(239) *Earth Negotiations Bulletin* (22 April 2002).

[216] *Supra* note 32.

[217] For example, under Article IX of the WTO Agreement, *supra* note 110[], certain decisions must be taken by three fourths majority; the DSU sets out a "reverse consensus" rule for the adoption of panel and Appellate Body reports by the dispute settlement body.

[218] WTO Agreement, *supra* note 110, at Article IX.

[219] *Codex Alimentarius Procedural Manual*, Rules of Procedure of the Codex Alimentarius Commission, Rule VI.2, available at <http://www.codexalimentarius.net>.

[220] *Ibid*., at Rule X.2.

[221] *Ibid*., at Rule IX.11.

A number of factors affect the ability of developing countries to participate effectively in international negotiations, including the human and financial resources to attend meetings, the capacity to prepare adequately for international meetings, the rules that govern the formal procedures of international negotiating meetings, and the informal or conventional practices affecting the transparency of proceedings.

Developing countries played an active role in the Biosafety Protocol negotiations. (Bail *et al* 2002: Ch10-16) The African group submitted a full text of a draft Protocol in the early stages of the negotiations, which to some extent appears to have galvanized the negotiation process, prompting other textual proposals. Later in the negotiations, the mechanism of the Like-Minded Group (in effect, the G-77 and China minus Argentina, Chile, and Uruguay) was effective in giving a voice to the concerns of many developing countries. Nonetheless, issues of participation, transparency, and power did arise. For much of the negotiations, many developing countries were represented by only one delegate, who was funded by voluntary contributions from the developed countries. Often these delegates only became aware that they could attend a negotiating session shortly before that session was due to take place, as it became apparent that resources were available, thus hampering preparations. As the negotiations became more complex, it was clearly difficult for one-person delegates to cover, either in terms of substance or mere presence, the many issues under discussion, which covered technical issues, such as definitions of "living modified organisms," regulatory processes, and trade and liability issues, especially as the number of smaller negotiating groups proliferated and met late into the night for several days running. In Cartagena, many developing country delegates, particularly those who had not been central players in the Like-Minded Group or who had not attended many of the sessions of the BSWG, found it difficult to obtain information as to the location and timing of meetings, let alone to gain access to them. While the Like-Minded Group operated on the basis of information sharing and cooperation (for example, in covering simultaneous meetings), it is questionable whether this practice effectively accorded parity to the developed and developing country negotiators. The resource-based limitation on the size of delegations has been raised as an issue in many CBD fora, with developing countries seeking to have funding for two delegates per meeting incorporated into the core budget of the convention.

The issue of the lack of transparency in the negotiations was addressed with some success by the adoption of what has become known as the "Vienna Setting" by the President of the Extraordinary Meeting of the Conference of the Parties (ExCOP) in Cartagena and later in the second session of the ExCOP in Montreal.[222] The Vienna Setting enabled the core negotiating groups to each be represented by spokespeople while other delegates observed the negotiations. Nonetheless, the final contentious issue in the negotiations, which related to the identification requirements for shipments of GM commodities, was still resolved essentially on a bilateral basis between the EC and the Miami Group.

[222] *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*, Doc. UNEP/CBD/ExCOP/1/3, 20 February 2000, Part Two, para. 11.

While the strength of the Like-Minded Group enhanced the role of developing countries in the Protocol negotiations, the effectiveness of such mechanisms may be challenged as the interests of developing countries in relation to biotechnology and biosafety policy-making diversify. Anecdotal evidence emerging during the Biosafety Protocol negotiations suggested that serious efforts were made to split countries away from the Like-Minded Group,(Third World Network 1999) and it is by no means clear that in future negotiations on the implementation of the Protocol the same unity of interest will prevail.

With the enhanced significance of international standards in the WTO agreements, concerns have also arisen with respect to the participation of developing countries in standard-setting processes of the Codex Alimentarius.[223] Both the SPS and TBT Agreements contain provisions calling for enhanced participation in international standard-setting activities. Within the Codex, it has been noted that participation of developing countries is especially weak at the committee level—that is, at the point in the process at which standards are actually formulated. By contrast, participation in the Commission itself, at the stage of the adoption of standards, is stronger.[224]

One problem is the sheer number of standing and ad hoc committees through which the standard-formulation process takes place. As noted earlier in this paper, there are at least three committees in which work relevant to the safety assessment and labelling of GM foods has been taking place. Under the procedures of the Codex, these committees are "hosted" by Codex members, and the meetings generally take place in the host country. Committees are almost exclusively hosted by developed countries, which meet the operating costs of the meetings.[225] The Codex Commission has identified two major constraints to effective participation: (1) the lack of effective infrastructures at the national level for the evaluation of draft standards and the formulation of positions in consultation with all interested parties; and (2) the cost of travel and other means of participation in the Codex meetings.[226] Some attempts have been made to hold more meetings in developing countries, and the Codex is also seeking to accelerate technical assistance at the national level.[227] Differences in formal and absolute participation

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[223] See, for example, *International Harmonisation of SPS Standards*, Submission by India, 25 September 1998, Doc. G/SPS/GEN/94, at para. 3, stating that "[d]espite the efforts that are being made by some of the international organizations to encourage and broaden participation of countries in standardization activities, the participation of developing countries in the activities of these organizations continues to be marginal. Only a few developing countries are able to participate actively in the meetings of the technical committees."

[224] *Note on Developing Country Participation in Codex Bodies*, Submission by the FAO/WHO *Codex Alimentarius* Commission, 9 March 2001, Doc. G/SPS/GEN/236. However, even in this case, participation may be nominal as the meetings are usually attended by the permanent representatives to the FAO (in Rome) or the World Health Organization [hereinafter WHO] (in Geneva) rather than by an expert in Codex matters, (at para. 5).

[225] *Note on Developing Country Participation in Codex Bodies, supra* note 253, at para.18.

[226] In February 2003, a FAO/WHO Trust Fund for the Participation of Developing Countries and Countries in Transition in the Work of the Codex Alimentarius Commission was launched. *Report of the 25th (Extraordinary) Session of the Codex Alimentarius Commission*, 13-15 February 2003, Doc. ALINORM 03/25/5.

[227] *Note on Developing Country Participation in Codex Bodies, supra* note 253, at paras. 19-20.

between developed and developing countries are apparent in the participation to date in the Task Force on Foods Derived from Modern Biotechnology. At the first meeting, of the thirty-three participating countries, twenty were developed and thirteen were developing.[228] Developed countries had 106 representatives, and developing countries had forty-six.[229] This pattern was broadly reflected at the second and third meetings of the Task Force.[230]

The issue of improving developing country participation has been taken up in the Codex Strategic Framework of 2003-7, with an emphasis on resource constraints and capacity building. This Strategic Framework also takes up the issue of external transparency and participation, stressing the fact that the Codex Commission needs to promote and facilitate the participation of consumers and public interest groups in its processes at the international level in order to build public confidence in international standards.[231] In practice, industry(Newell and Glover 2003) and consumer groups have participated in the Codex, both as representatives on country delegations and as observers. As observers, they are entitled to put forward views at all stages of the process, except at the final decision-making stage, which remains the preserve of member governments. The majority of organizations on the list of NGOs with observer status are industry associations.[232]

Wide-ranging debates have taken place on issues of internal and external transparency in the WTO, and they are the subject of extensive literature and recommendations.(Narlikar 2001; Michalopoulos 1999; Oxfam 2000; Krajewski 2000; Marceau and Pedersen 1999) These debates relate both to policy and decision-making and to the dispute settlement procedure. Since the Uruguay Round, developing countries have become much more active in participating in world trade negotiations.[233] A significant proportion of proposals before the Seattle Ministerial Conference in 1999 came from developing countries, and many States have been active in submitting proposals in the context of the post-Doha negotiations. However, as noted above, the practice of operating by consensus coupled with extensive reliance on informal processes for reaching decisions has tended to limit

[228] Using the Codex criterion of G-8 or OECD membership as the criterion to identify a "developed country."

[229] This is somewhat skewed by the high number of participants from the host country, Japan (twenty-eight representatives) and other differences in the size of developed country delegations. Thus, for example, the United States had a delegation of twenty-one at the meeting (including industry and a non-governmental organization representative), while the United Kingdom had a one-person delegation. Twenty-nine of the forty-six developing country representatives were from three countries: Brazil, China, and Thailand.

[230] At the second meeting, twenty-two developed countries (120 representatives) and fourteen developing countries (thirty-five representatives) attended; at the third meeting, twenty-three developed countries (121 representatives) and twelve developing countries (thirty-eight representatives), see Doc. ALINORM 01/34A and Doc. ALINORM 03/34.

[231] *Codex Strategic Framework 2003-2007*, Objective 5, paras. 16-17, available at <http://www.c*odexalimentarius*.net>.

[232] See <http://www.*CodexAlimentarius*.net/organizations_ngo.stm> and the Principles Concerning the Participation of International Non-Governmental Organizations in the Work of the *Codex Alimentarius* Commission, which are contained in the Codex Procedural Manual (12th edition, FAO/WHO 2000), available at http://www.codexalimentarius.net and http://www.fao.org/DOCREP/005/Y2200E/Y2200E00.HTM.

[233] For an analysis of developing countries' involvement in the WTO, see Page, 2002.

effective and extensive developing country participation. Informal processes play a significant role in decision-making in the WTO. While some of these informal consultations involve the entire WTO membership, for example, meetings of the heads of delegations,(Narlikar 2001) smaller group negotiations, such as the Green Room meetings, have also often been used to reach consensus.(ibid) Informal consultations are also used at the levels of the councils, committees, and working parties, which again work partly by invitation and partly by self-selection.(ibid) These problems are exacerbated by a lack of Geneva representation for some developing countries, which, given the intensity of the WTO negotiating process and the meeting schedule, results in their marginalization from preparatory processes and from the day-to-day business of the organization.[234]

In light of the negative experiences of many developing country delegations in the preparations for, as well as at, the Seattle Ministerial Conference, discussions on internal transparency in the General Council focused on three areas: overriding questions, day-to-day consultations, and the preparation and organization of ministerial conferences.[235] While it was generally recognized that the preparations for the Doha meeting represented an improvement, some problems still emerged, with developing countries complaining that the draft ministerial declaration forwarded to Doha did not adequately accommodate the views expressed by developing countries in the preparatory process.[236]

The Doha Ministerial Declaration requires that negotiations are to be conducted in a transparent manner in order to facilitate effective participation by all.[237] Minutes of the meetings of the Trade Negotiations Committee and of other negotiating bodies are to be circulated expeditiously, and the WTO Secretariat is to take steps to ensure the prompt dissemination of information relating to the negotiations to non-resident delegations. In addition, the constraints of smaller delegations are to be taken into account when scheduling meetings.[238] In light of the experience in the ministerial conferences to date, a number of developing countries, have proposed basic principles and procedures to ensure that the preparatory process and the conduct of the ministerial conference are more transparent, inclusive, and predictable.[239] These proposals focus in large part on eliminating the Green Room-type procedures that have dominated previous meetings. In relation to the preparatory process, they include the principle that all consultations should

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[234] The WTO holds periodic "Geneva weeks" for non-resident delegations. The last such meeting, which was held in November 2002, was attended by representatives from twenty-two member governments and eight observer states as well as secretariats of regional trade organizations. WTO Press Release, 8 November 2002, Doc. Press/321.

[235] See, for example, *Minutes of the Meeting of the General Council*, 17-19 July 2000, Doc. WT/GC/M/57; *General Council Annual Report (2000)*, 12 February 2001, Doc. WT/GC/44,.

[236] See, for example, *Statement by the Honourable Murasoli Maran, Minister of Commerce and Industry, India*, 10 November 2001, Doc. WT/MIN(01)/ST/10, at para. 3.

[237] Doha Ministerial Declaration, *supra* note 87, at para. 10.

[238] *Statement by the Chairman of the General Council at the First Meeting of the Trade Negotiations Committee*, 4 February 2002, Doc. TN/C/1,.

[239] *Preparatory Process in Geneva and Negotiating Procedure at the Ministerial Conferences*, Communication from Cuba, Dominican Republic, Egypt, Honduras, India, Indonesia, Jamaica, Kenya, Malaysia, Mauritius, Pakistan, Sri Lanka, Tanzania, Uganda, and Zimbabwe, 24 April 2002, Doc. WT/GC/W/471,.

be transparent and open-ended; that draft agendas should be drawn up only after members have had an opportunity to express their views; and that there should be frequent formal meetings of the General Council, with minutes circulated to non-resident delegations. In relation to the ministerial conferences themselves, again it has been proposed that consultations should be at open-ended meetings only, with schedules announced at least a few hours in advance, that negotiating texts and draft decisions should be introduced only in open-ended meetings, and that all members should be given equal opportunity to express their views in consultations. It has also been suggested that all future ministerial conferences might be held in Geneva to avoid additional costs for developing country members. Other members have expressed concern at the potential loss of flexibility in WTO procedures if these types of recommendations are taken up.[240] These debates are ongoing in the General Council.[241]

Some problems of the dispute settlement system for developing countries have been referred to in earlier sections of this article. Nonetheless, the use of the dispute settlement mechanism by developing countries has increased since the adoption of the DSU.(Romano 2002) In the context of the review of the DSU, some developing countries have called for a more specific focus on development issues in the dispute settlement process, requiring, for example, panels to consider and make specific findings on the development implications of issues raised in a dispute where a developing or least-developed country is party to that dispute and to do so in consultation with the relevant development institutions.[242] Proposals have also been put forward to improve the effectiveness of remedies for developing and least-developed countries, for example, by allowing for the collective retaliation by WTO members where such a member has been a successful complainant.[243] Effective involvement of developing countries in the dispute settlement process is significant, given the role of the panels and the Appellate Body in interpreting the WTO agreements and, hence, in contributing to their evolution.

VII. CONCLUSIONS

The main conclusion that can be drawn from the survey in this paper is that overall the WTO seems at present to play a central role in shaping the direction of international governance of GMOs. The disciplines imposed by the relevant WTO agreements

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[240] *Preparatory Process in Geneva and Negotiating Process at Ministerial Conferences*, Communication from Australia, Canada, Hong Kong, China, Korea, Mexico, New Zealand, Singapore, and Switzerland, 28 June 2002, Doc. WT/GC/W/477,.

[241] *Minutes of the Meeting of the General Council, 8 and 31 July 2002*, 27 September 2002, Doc. WT/GC/M/75,.

[242] *Text for the African Group Proposals on Dispute Settlement Understanding Negotiations*, Communication from Kenya, 24 January 2003, Doc. TN/DS/W/42; *Negotiations on the Dispute Settlement Understanding*, Proposal by the African Group, 25 September 2002, Doc. TN/DS/W/15; and *Negotiations on the Dispute Settlement Understanding*, Proposal by the LDC Group, 9 October 2002, Doc. TN/DS/W/17.

[243] *Negotiations on the Dispute Settlement Understanding*, *supra* note 264. This issue has also been raised by India in the context of special and differential treatment provisions, *Concerns Regarding Implementation of Provisions Relating to Differential and More Favourable Treatment of Developing and Least-Developed Countries in Various WTO Agreements*, Communication from India, 13 November 1998, Doc. WT/GC/W/108, para. 29(h).

underpin and shape the biotech regulation debate both internationally and nationally. Interactions where they occur are primarily WTO driven (even if they are initiated by other bodies)—for example, both through policymaking bodies, such as the role of the CTE in the trade and environment debate, and through the dispute settlement system. Yet it is by no means clear that this trend is in the interests of developing (or other) countries, given the primacy accorded to the objective of trade liberalization in the WTO agreement. The WTO agreements provide some scope for countries to take trade measures, under certain conditions, on grounds of protecting human, animal, or plant life or health, to conserve exhaustible natural resources, or for other legitimate objectives. However, it is not clear that they, or other relevant international instruments primarily relevant to the domestic regulation of GMOs, adequately accommodate the consideration of the potential socio-economic impacts of GMOs on countries at different stages of development and in which different conditions and priorities prevail. More robust provisions on socio-economic considerations in the Biosafety Protocol may have been helpful in this case.

There remains a degree of uncertainty and unpredictability regarding the scope for countries take into account socio-economic considerations in decision-making on imports of GMOs. Uncertainty and ambiguity still exist with regard to how domestic environmental and health measures must be designed and applied if they are to be deemed to be consistent with the relevant WTO agreements. This situation arises out of ambiguities within the WTO agreements themselves, uncertainties regarding the relationship between the Biosafety Protocol and the WTO and between the WTO and MEAs, the lack of international consensus on the benefits and risks of GMOs in different contexts, and on how to accommodate different views and circumstances in international regulation. While the uncertainty and ambiguity in the international legal framework on GMOs may present some flexibility and space for countries as they develop and implement their own national biosafety frameworks, it may also present certain risks. Unpredictability in the outcome of possible disputes surrounding domestic GMO regulations can render developing countries vulnerable to additional pressure from powerful trading partners and give rise to delayed or weakened national regulations.

To date, in three cases involving SPS measures, the Appellate Body has found that the challenged measure did not meet all the requirements of the SPS Agreement, and it has required the member concerned to bring the measure into compliance. Statements of the Appellate Body emphasizing state sovereignty in setting the appropriate level of protection have failed to assuage concerns about the perceived role of the WTO in setting the bar for domestic environmental and health regulations. Where differences exist between members in regard to the appropriate measures to achieve the desired levels of sanitary and phytosanitary protection within their borders, and where the relevant agreements contain gaps or uncertainties, the strength of the dispute settlement system appears to allow for the possibility for policymaking through dispute settlement.(Walker 1998; Oxfam 2000:15) While the panels are intended to make an "objective assessment of facts" and are not to undertake a *"de novo* review" or risk assessment on their own part, concerns have been expressed that, in effect, in determining whether a "rational relationship" exists between a risk assessment and an SPS measure, the panels and

Appellate Body may assume the role of "domestic regulator." In this regard, Charnovitz has raised the question: "Who would bear the cost of the WTO panel being wrong about the danger of alien pathogens?" while observing that at present "defendant countries .. . have nothing to gain from SPS litigation and plaintiff countries ... have nothing to lose."(Charnovitz 2000) This fear might be heightened where other relevant international agreements, such as the Biosafety Protocol, do not contain clear guidance on the appropriate outcomes and given the lack of international agreement on issues of liability and redress.

The prospect of a developed country bringing a case against a developing country in relation to a biosafety measure may be slim. Public opinion, and the significance of developing country markets for GM products, may argue against bringing such a case, even where an exporting country feels that trade measures are being applied in a manner that violates WTO rules. Nonetheless, the threat of WTO litigation is powerful, particularly for developing countries, and the dispute between the EC and the United States and others in the WTO seems certain to have broad ramifications for all countries engaged, or potentially engaged, in international trade in GMOs.

The concerns about the power of the WTO dispute settlement system arise in part, of course, due to the relative weakness of corresponding mechanisms in international environmental agreements, including the Biosafety Protocol. Dispute settlement mechanisms in MEAs tend largely to be non-mandatory or, where mandatory, to be non-binding.[244] The Protocol itself contains no specific provisions on dispute settlement and thus relies upon the provisions of its parent treaty, the CBD. This fact, in turn, provides for optional recourse to the International Court of Justice or to international arbitration by the mutual consent of the parties to the dispute, or for mandatory recourse to non-binding conciliation, by the request of one party to a dispute.[245] These provisions, in common with similar arrangements in other MEAs, have not been invoked. The Protocol also provides for the establishment of a compliance mechanism, which is to be based on "cooperative procedures and institutional mechanisms to promote compliance ... and to address cases of non-compliance."[246] However, the opportunity to develop a strong compliance mechanism within the Protocol appears, for the present, to have been foregone.[247]

While the WTO agreements make provision for special and differentiated treatment of developing country members, the scope of these provisions has not been agreed upon. Work is ongoing under the Doha mandate to clarify and strengthen the S&DT obligations. One question that arises, for example, is whether limited regulatory, monitoring or enforcement capacity might provide grounds for a developing country to adopt a "protective" trade measure in relation to biosafety, either under the general provisions of the agreements, provisions for exceptions (for example, Article XX of the

[244] See Sands and Mackenzie, (2001); and Romano, (2000).
[245] CBD, *supra* note 22, at Article 27.
[246] Biosafety Protocol, *supra* note 2, at Article 34.
[247] See ICCP, Recommendation 3/2, Doc. UNEP/CBD.ICCP/3/10, at annex.

GATT) and provisional measures (Article 5.7 of the SPS Agreement), or S&DT provisions.

The complexity of the issues raised by the possible integration of modern biotechnology into developing country agricultural settings suggests that time and space is needed to consult on, and to develop, nationally driven regulatory frameworks for GMOs. Nevertheless, there is increasing evidence from countries such as Sri Lanka, Bolivia, and China that they are coming under bilateral pressure to avoid the implementation of stringent regulations on GMOs and GM foods. This pressure is visited through diplomatic channels and through bilateral trade and investment negotiations, and it is backed up by the "stick" of the WTO dispute settlement mechanism. The elaboration of national biosafety frameworks, which many countries have recently initiated, represents an important opportunity to consider and address many of these issues. It is important that these processes and their outputs are comprehensive, deliberative, and responsive to the complexity of national circumstances and interests. Of critical interest will be whether and how countries decide to incorporate socio-economic considerations into their decision-making or whether these considerations will end up being addressed in other policy-making settings.

The prominent role given in the WTO to international standards promulgated by institutions such as the Codex Alimentarius, the IPPC, and the International Office of Epizootics, as well as the issues that remain to be addressed in the Biosafety Protocol, have also emphasized the need for full, informed, and effective participation in these processes by developing countries. At present, such participation is in effect often limited to a few representatives, or to a few countries, or to certain stages of the decision-making process. In some cases, as in the TRIPS Agreement, the need and interests of developing countries were only fully articulated after the deal was done. Without such participation, it is difficult to resist the conclusion that international biosafety regulation will remain a forum principally for the United States and the EC, as well as powerful stakeholders within those jurisdictions—each attempting to secure accommodation of their own interests.

However, the broader, and more pressing, question emerging from this survey is whether the harmonized approaches to risk regulation are really capable of accommodating diverse national and local priorities and realities in developing countries, especially bearing in mind the differences in agricultural practices between and among developed and developing countries, and the vastly different stages of development and take-up of agricultural biotechnology in developing countries to date. The Biosafety Protocol and the Codex Alimentarius focus primarily on a relatively narrow set of environmental and human health concerns. Yet concerns over the use of biotechnology in agriculture are more far-reaching, encompassing, alongside health and environmental concerns, ethical and socio-economic issues which demand analysis and public consultation and debate at the national level. Moreover, regulatory policy needs to look to the real world conditions under which GMOs will be used. How are any approved GMOs to be monitored and assessed on an ongoing basis; will risk management measures be identified, such as conditions as to geographic use, work in the field; what sections of the community might

benefit or lose out from the use of GMOs in place of traditional crop varieties; and how will any unforeseen health, environmental, or socio-economic impacts be addressed? Given this diversity of conditions, interests, experience, and capacity, some additional flexibility in the application of international trade disciplines would appear to be desirable in any assessment of biosafety measures applied by developing countries. Accommodating national diversity in the face of a relatively new technology represents a challenge not only for the Biosafety Protocol and for national biosafety authorities, but also for the international trade regime.

Bibliography

Bail, Marquard and Falkner (eds.), (2002) *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment and Development*

Charnovitz, (2000). "The Supervision of Health and Biosafety Regulation by World Trade Rules", 13 *Tul. Envtl. L. J.* 271

Chaytor, (1998), "Dispute Settlement under the GATT/WTO: The Experience of Developing Nations", in Cameron and Campbell (eds.), *Dispute Resolution in the World Trade Organisation* Cameron and May

Chaytor, Palmer, and Werksman, (2003), *Interactions with the World Trade Organisation: The Cartagena Protocol on Biosafety and the International Commission for the Conservation of Atlantic Tunas*, paper prepared for a project on Institutional Interaction: How to Prevent Conflicts and Enhance Synergies between International and EU Environmental Institutions, available at <http://www.ecologic.de/interaction/>.

Chinkin and Mackenzie, (2002) "Intergovernmental Organisations as "Friends of the Court"," *in* Boisson de Chazournes, Romano, and Mackenzie (eds.), *International Organizations and Dispute Settlement: Trends and Prospects* 135 Transnational

Christoforou, (2000) "Settlement of Science-Based Trade Disputes in the WTO: A Critical Review of the Developing Case Law in the Face of Scientific Uncertainty", 8 *N.Y.U. Envtl. L. J.* 622, 630

Dhar, (2003) *Regulating Biotechnology in India*

Eggers and Mackenzie, (2000), "The Cartagena Protocol on Biosafety", 3(3) *J. Int'l Econ. L.* 534

Falkner, (2000), "Regulating Biotech Trade: The Cartagena Protocol on Biosafety", 76(2) *Int'l Affairs* 299

Food and Agriculture Organization [FAO], 2001, *Report of the Panel of Eminent Experts on Ethics in Food and Agriculture*, first session, 26-8 September 2000, available at http://ftp.fao.org/docrep/fao/003/X9600e/X9600e00.pdf, Rome.

French, (2001) "The International Regulation of Genetically Modified Organisms: Synergies and Tensions in World Trade", 3 *Envtl. Liability* 127, 138

Friends of the Earth International, (2002) *Us Steps Up Pressure to Force Acceptance of Genetically Modified Organisms Worldwide*, Briefing Paper, April;

Gupta, (2000) "Governing Trade in Genetically Modified Organisms: The Cartagena Protocol on Biosafety", 42(4) *Environment* 23

Howse and Mavroidis, (2000), "Europe's Evolving Regulatory Strategy for GMOs—The Issue of Consistency with WTO Law: Of Kine and Brine", 24 *Fordham Int'l L. J.* 317

Howse and Meltzer, "The Significance of the Protocol for WTO Dispute Settlement", in Bail, Marquard, and Falkner, *supra* note 33, at 482, 494-6.

Kennedy, (2000) "Resolving International Sanitary and Phytosanitary Disputes in the WTO: Lessons and Future Directions", 55 *Food Drug Cosm. L.J.* 81, 100).

Krajewski, (2000), *From Green Room to Glass Room: Participation of Developing Countries and Internal Transparency in the WTO Decision Making Process*, Tradewatch Paper.

Kruszewska, (Winter 2001/2002). *US Government Threatens WTO Action if Croatia Bans GMOs*, Northern Lights

Mackenzie, (2002) *"Environmental Damage and Genetically Modified Organisms"*, in Bowman and Boyle, (eds.), *Environmental Damage in International and Comparative Law: Problems of Definition and Valuation* 63 (Oxford University Press,);

Mackenzie, Burhenne-Guilmin, La Vina and Werksman, in cooperation with Ascencio, Kinderlerer, Kummer and Tapper, (2003), *Explanatory Guide to the Cartagena Protocol on Biosafety*, IUCN Environmental Law and Policy Paper no. 46

Mackenzie, (2001) *Mapping Paper on International Organisations and GMOs*, draft report January 2001 (unpublished, copy on file with the author).

Marceau and Pedersen, (1999). "Is the WTO Open and Transparent? A Discussion of the Relationship of the WTO with Non-Governmental Organisations and Civil Society's Claims for more Transparency and Public Participation", 33(1) *J. World Trade 5*

Marceau and Trachtman, (2002), "The Technical Barriers to Trade Agreement, the Sanitary and Phytosanitary Measures Agreement, and the General Agreement on Tariffs and Trade: A Map of the World Trade Organization Law of Domestic Regulation of Goods", 36(5) *J. World Trade* 811, 840

Michalopoulos, (1999), "The Developing Countries in the WTO", 22(1) *World Economy*

Narlikar, (2001), *WTO Decision-Making and Developing Countries*, South Centre, Working Paper no. 11, November 2001, available at <http://www.southcentre.org/publications/pubindex.htm>

Newell and Glover, (2003), *Business and Biotechnology: Regulation and Politics of Influence* IDS Working Paper, Biotech Policy Series, no. 17,

Newell and Mackenzie, (2000) "The Cartagena Protocol on Biosafety: Legal and Political Dimensions", 10 *Global Envtl. Change* 313

Odame, Kameri-Mbote, and Wafula, (2003), *Globalisation and the International Governance of Modern Biotechnology: Implications for Food Security in Kenya* IDS Working Paper, Biotech Policy Series, no. 20.

Oxfam, (2000), *Institutional Reform of the WTO*, Oxfam GB Discussion Paper, March 2000;

Page, (2002), *Developing Countries in GATT/WTO Negotiations*, ODI Working Paper.

Pauwelyn, (1999), "The WTO Agreement on Sanitary and Phytosanitary (SPS) Measures as Applied in the First Three SPS Disputes", 2(4) *J. Int'l Econ. L.*

Pythoud, (2002),*Commodities*, in Bail, Marquard and Falkner (eds.), *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment and Development*

Romano, (2002), "International Justice and Developing Countries: A Quantitative Analysis", 1(2) *Law and Practice of Int'l Courts and Tribunals* 367

Romano, (2000), *Peaceful Settlement of Environmental Disputes* Kluwer

Safrin, (2002). "Treaties in Collision? The Biosafety Protocol and the World Trade Organization Agreements", 96(3) *Am. J. Int'l L.* 606, 618-21

Sands and Mackenzie, (2001), "Guidelines for Negotiating Dispute Settlement Clauses for Multilateral Environmental Agreements", in International Bureau of the Permanent Court of Arbitration (ed.), *International Investment and the Protection of the Environment: the Role of Dispute Resolution Mechanisms*

Sands, Mackenzie and Shany, (1999), *Manual on International Courts and Tribunals*, Chapter 5 Butterworths

Scoones, (2002), *Agricultural Biotechnology and Food Security: Exploring the Debate*, IDS Working Paper 145

Silverglade, (2000). "The WTO Agreement on Sanitary and Phytosanitary Measures: Weakening Food Safety Regulations to Facilitate Trade", 55 *Food Drug Cosm. L.J*. 517, 521

Singh, (n.d.) *Developing a Liability and Redress Regime under the Cartagena Protocol on Biosafety for Damage Resulting from the Transboundary Movement of Genetically Modified Organisms*, Third World Network (undated), available at <http://www.twnside.org.sg/title/blp.pdf>.

Stabinsky, (2000), "Bringing Social Analysis into a Multilateral Environmental Agreement: Social Impact Assessment and the Biosafety Protocol", 9(3) *J. Env't & Dev.* 260

Stewart, (1993). *The GATT Uruguay Round: A Negotiating History* (1986-1992), vol. 1, 175 Kluwer

Stoll, (2000), "Controlling the Risks of GMOs: the Cartagena Protocol and the SPS Agreement", 11 *Y.B.Int'l Envtl. L.* 118

Third World Network, (1999) *Key Issues and Key Elements Needed in the Biosafety Protocol*, TWN Position Paper for the Sixth and Final Biosafety Negotiations in Cartagena, 14-19 February 1999, available at <http://www.twnside.org.sg/title/key-cn.htm>.

TMC Asser Institute and Amsterdam Center for International Law, (2002), *Report of the First Meeting of the Legal Platform for Consumer Concerns and International Trade in Food and Agriculture*, The Hague, 15-16 February 2002, 26, (2002).

Trebilcock and Howse, (1999). *The Regulation of International Trade*, Chapter 6 2nd edition, Routledge

Victor, (2000), "The Sanitary and Phytosanitary Agreement of the World Trade Organization: An Assessment after Five Years", 32 *N.Y.U. J. Int'l L. & Pol.* 865, 872

Walker, (1998), "Keeping the WTO from Becoming the "World Trans-Science Organization": Scientific Uncertainty, Science Policy, and Fact-Finding in the Growth Hormones Dispute", 31(2) *Cornell Int'l L. J.*

Yamin, (2003), Intellectual Property Rights, Biotechnology and Food Security IDS Working Paper, Biotechnology Policy Series, No. 22,

Zarilli, (2000) *International Trade in Genetically Modified Organisms and Multilateral Negotiations: A New Dilemma for Developing Countries*, 5 July 2000, Doc. UNCTAD/DITC/TNCD/1, at para. 135.

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