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Applying World Trade Organization Rules to the Labeling of Genetically Modified Foods

by

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APPLYING WORLD TRADE ORGANIZATION RULES TO THE LABELING OF GENETICALLY MODIFIED FOODS†

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I. Introduction

A. *Current Political Context Surrounding Genetically Modified Organisms and Genetically Modified Foods*

Genetically modified organisms (GMO) and genetically modified foods (GMF) are a topic much in the news of late. They arouse strong passions on the political front, and have proven a focus of passionate resistance by opponents and equally passionate support by those in favor. There have been violent pro-

tests against GMO and GMF at meetings of the World Trade Organization (WTO) in Seattle in 1999, at the International Monetary Fund meeting in Washington D.C. in 2000, and again at the World Bank meeting in Genoa in the summer of 2001.[1]

Consumer organizations and non-governmental organizations in many countries are seeking either an outright ban on GMO and GMF or, at the least, much stricter regulation.[2] There is a widespread movement in many countries aimed at destroying GMO crops.[3] Opponents cite concern for the long-term health effects of such products, and claim that the products are not adequately tested by independent scientists.[4] They are also concerned about destruction of bio-diversity, both of native plant species, and of animals and insects that feed on such crops.[5] Another concern frequently expressed is the lack of transparency of testing and regulation of such products.[6] The movement is also motivated by antipathy to large multi-national corporations and their perceived growing control over agriculture and food.[7] Concern for small farmers and moral reservations about manipulation of living things also play a role.[8]

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[1] *See* Dorothy Nelkin et al., *The International Challenge of Genetically Modified Organism Regulation,* 8 N.Y.U. ENVTL. L.J. 523, 524 (2000).

[2] One example is Brazil. *See, e.g.,* Reese Ewing, *Analysis: Brazil GMO Ban Seen in Place Till at Least 2003*, REUTERS NEWS, Feb. 5, 2002, *available at* http://www.planetark.org/dailynewsstory.cfm/newsid/14369/story.htm.

[3] *See, e.g., Farmers Advised to Destroy GM Crops*, BBC NEWS ONLINE, *at* http://news.bbc.co.uk/1/hi/uk-politics/766539.stm (May 27, 2000) (UK government advising farmers who accidentally planted GM crops to destroy them or dispose of them after they have been harvested).

[4] See generally Consumers Choice Council for articles, papers, and press releases on Genetically Engineered Food, *at* www.consumerscouncil.org (last modified Sept. 3, 2003); see also Public Citizen for more articles on GMO (search entire site using as a keyword "GMO"), *at* www.citizen.org (last visited Sept. 29, 2003).

[5] *See* Consumers Choice Council, *supra* note 4; *see also* John E. Losey et al., *Transgenic Pollen Harms Monarch Larvae*, 399 NATURE 214 (1999) (cited by many, including Brett Grosko, Note, *Genetic Engineering and International Law: Conflict or Harmony? An Analysis of the Biosafety Protocol, GATT, and the WTO Sanitary and Phytosanitary Agreement*, 20 VA. ENVTL. L.J. 295, 302 n.39 (2001)).

[6] *See* Grosko, *supra* note 5, at 318.

[7] *See generally* Consumers Choice Council, *supra* note 4; George E.C. York, Note, *Global Foods, Local Tastes and Biotechnology: The New Legal Architecture of International Agriculture Trade*, 7 COLUM. J. EUR. L 423, 432-33 (2001); Sean D. Murphy, *Biotechnology and International Law,* 42 HARV. INT'L L.J. 47, 65 (2001).

[8] *See* Nelkin et al., *supra* note 1, at 528.

Proponents of GMO and GMF present substantial arguments indicating that GMO are safe.[9] Proponents also claim huge potential benefits for the world's poor and underdeveloped countries.[10] GMO can be created, which requires less water, or grown in nutrient-poor soil.[11] GMO can be made to be pest-resistant, thus requiring fewer pesticides and herbicides than traditional varieties, while producing much larger yields.[12] GMO can also be created with heightened nutritional content, which proponents claim is a further benefit for the world's hungry and malnourished.[13]

B. *Distinction Between Genetically Modified Organisms and Genetically Modified Foods*

This paper distinguishes between GMO and GMF, as they involve different issues, different risks and often different regulations. GMO, in this context, refers to seeds and other agricultural products, grown as such. They are living organisms created through genetic engineering.[14] Scientists transplant the genes of one species into another to transfer desirable characteristics.[15] GMF is food made from GMO.[16] GMF may be a living organism, such as a tomato or potato, or a food product made from GMO ingredients.

Issues arising in the context of GMO include the potential spread of GMO into either organically grown or traditional varieties of crops.[17] This brings with it the danger of cross-pollination and the potential elimination of traditional and organic varieties, threatening bio-diversity.[18] There is also a danger of cross-pollination with weeds, creating "super-weeds," which are resistant to herbicides and pesticides to the same extent as the

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[9] *Id.* at 526.

[10] *See* York, *supra* note 7, at 431.

[11] *Id.*

[12] *See* Murphy, *supra* note 7, at 55-56; York, *supra* note 7, at 429-31.

[13] *See* Murphy, *supra* note 7, at 55-56; York, *supra* note 7, at 429-31.

[14] *See* Nelkin et al., *supra* note 1, at 523 ("GMO products [are defined as] the crops and other organisms that have been genetically modified by use of recombinant DNA technologies and food and other products containing such organisms").

[15] *See* Murphy, *supra* note 7, at 50.

[16] *See* York, *supra* note 7, at 430.

[17] *See* York, *supra* note 7, at 433.

[18] *Id.*

GMO.[19] Some GMO have been found to destroy beneficial fungus in the soil surrounding them.[20] While related to GMF, the range of issues and concerns about GMO, and their potential regulation, are not the focus of this paper.

GMF are foods derived from GMO.[21] GMF includes grains and other products such as corn (maize), wheat, rice, soybeans, sugar beets and rapeseed.[22] The grains can be used as animal feed or processed into food, e.g., oil, tofu, bean curd or other products eaten by humans. GMF also include produce eaten directly. GMF produce includes tomatoes, squash, potatoes, radicchio, and melon.[23] They have been modified for longer shelf life, slower ripening, resistance to freezing, resistance to pests and the like.[24]

Proponents of GMF claim that they are not proven to cause any ill effects to humans or animals. Increased yields, better field-to-market durability, better resistance to pests and improved appearance are benefits of GMF.[25] They cite particular benefits for developing countries, which need to feed their hungry and often lack the technology that makes possible the productivity achieved by the developed world.[26]

Opponents of GMF cite concerns which include those mentioned by opponents of GMO. Other concerns are more directly related to human consumption of such products.[27] Foremost is

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[19] *See, e.g.,* Thomas Hayden, *Bad Seeds in Court*, U.S. NEWS AND WORLD REPORT, Feb. 4, 2002 (concerning a lawsuit by an organic farmer whose crops were contaminated by GM canola); Ivan Noble, *Mexican Study Raises GM Concern*, BBC NEWS ONLINE, *at* http://news.bbc.co.uk/2/low/science/nature/1680848.stm (Nov. 28, 2001) (concerning the contamination of Mexican wild maize by GM plant varieties); Murphy, *supra* note 7, at 58; *see also* Consumers Choice Council, *supra* note 4.

[20] *See* Murphy, *supra* note 7, at 90.

[21] *See* York, *supra* note 7, at 430.

[22] *Id.*

[23] *Id.* at 429.

[24] *See, e.g.,* Andrew J. Nicholas, Comment, *As the Organic Food Industry Gets Its House in Order, the Time Has Come for National Standards for Genetically Modified* Foods, 15 LOY. CONSUMER L. REV. 277, 280 (2003); Steven H. Yoshida, *The Safety of Genetically Modified Soybeans: Evidence and Regulation*, *55* FOOD & DRUG L.J. 193, 193 (2000); York, *supra* note 7, at 429.

[25] *See* Murphy, *supra* note 7, at 55-56.

[26] *See* York, *supra* note 7, at 431.

[27] *See* Murphy, *supra* note 7, at 57; for an in-depth discussion of the concerns surrounding GMOs, see OECD Report of the Task Force for the Safety of Novel Foods and Feeds, C(2000)86/ADD1 (May 31, 2000), *at* http://www.olis.oecd.org/olis/

allergenicity, as when a gene from a product to which many people are allergic is inserted into another species.[28] Another concern is toxicity, especially where the product has a heightened vitamin content and the food is a staple of an area's diet.[29] Creation of antibiotic resistance by consumption of antibiotic resistant food is yet another issue raised.[30] While some scientists agree that "first generation" GMF might be considered safe, the "new generation GMF," which may include multiple gene manipulations and is therefore more complex, poses potentially graver risks.[31] Aside from general health-related concerns, opponents of GMF also resist them on grounds of moral or ethical scruples, and on the basis of the consumer's right to know what they are eating.[32]

Against this highly politically charged atmosphere, multinational fora and national governments have begun to take steps to regulate and, in some cases, ban GMF.

C. *Recent History of Regulation of Genetically Modified Foods*

The recent approach to regulation of GMF can be characterized as predominantly unilateral, with a fragmented international approach.[33] One reason for this is the speed with which the technology has been developed and commercialized.[34] The past ten years have seen a boom in the bio-technology industry and in the marketing of GMO and GMF.[35] International fora

2000doc.nsf/LinkTo/C(2000)86-ADD1 [hereinafter OECD Report]; and Gretchen L. Gaston & Randall S. Abate, *The Biosafety Protocol and the World Trade Organization: Can the Two Coexist?*, 12 PACE INT'L L. REV. 107, 118 (2000).

[28] One example is Brazil nut genes in tomatoes. People allergic to nuts would not normally look for danger in eating tomatoes. *See generally* OECD Report, *supra* note 27, at 13.

[29] *Id.*

[30] *Id.* at 17.

[31] *Id.* at 31.

[32] *Id* at 17; *see also* Nelkin et al., *supra* note 1, at 527-28.

[33] *See* Kim Brooks, *History, Change and Policy: Factors Leading to Current Opposition to Food Biotechnology;* 5 GEO. PUB. POL'Y REV. 153, 158-59 (2000).

[34] *Id.*

[35] *See generally id.* (describing the rapid advance of chemical companies into biotech seeds and food since 1992, with even more rapid expansion since 1997, and the increasing market dominance of Monsanto, Novartis, DuPont and Dow in the field).

have not kept pace with these developments, nor, in many instances, have the attitudes of consumers.[36]

The United States has been foremost in adopting the science, followed rapidly by other major grain-exporting countries, such as Brazil, Argentina, and Canada. By 2001, fifty varieties of genetically modified (GM) crops had been approved in the United States. Millions of acres of cropland in the United States are planted with GM crops.[37] Reports indicate the same for Brazil.[38] In such countries, there is a strong business and governmental interest in promoting export of GM crops, with corresponding liberal regulation of them.

Other countries have been slower and more reluctant to adopt the new biotechnology for crops. This is driven in part by consumer resistance,[39] and also in part perhaps by a more cautious attitude to novel foods. Regulation of GM foods is more restrictive in these countries, with both planting of GMO and use of GMF either banned or subject to significant restrictions.[40] The European Union (EU) has imposed a complete ban on the import of any GM products since 1998.[41] Japan, New Zealand, Australia, Switzerland, and the EU have all implemented or begun regulation of GMF, mostly through labeling schemes and an approval process for importation or commercialization of GMO and GMF.[42]

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[36] *Id.*

[37] *See* Murphy, *supra* note 7, at 55 (In the United States in 2000, 52% of approximately 75 million acres of soybeans, 56% of approximately 15.5 million acres of cotton and 25% of approx. 78 million acres of corn are planted with GM crops).

[38] *See* Richard Wright, *Paper Slams GM-free Claim*, FARMING NEWS, June 21, 2001, *available at* 2001 WL 10275849 (citing reports from a Brazilian newspaper *Valor* that thousands of acres of genetically modified soya is illegally being grown in Brazil, using seed imported illegally from Argentina. The State Seed Producers and Dealers organization claimed that GM crops will make up 45% of total crops in 2001, "whether or not it is authorized." The attraction for Brazilian farmers is the reduced cost of herbicides to grow GM crops); Raymond Colitt, *Brazil Set to Remove Block on GM Soya*, FINANCIAL TIMES (London) (Sept. 26, 2003), *at* LexisNexis (noting that the Brazilian government is expected to announce the legalization of genetically modified soybeans, which due to illegal planting already make up an estimated 15% of Brazil's total soybean harvest, opening one of the world's last GM-free agricultural frontiers).

[39] *See* Nelkin et al., *supra* note 1, at 523-24.

[40] *See* discussion *infra* Part II.

[41] *See* Brooks, *supra* note 33, at 154.

[42] *See* discussion *infra* Part II.

D. *Potential Trade Conflicts Involving Genetically Modified Foods*

International fora have begun to address the issues of GMF only relatively recently. One result is that there are a number of potential trade conflicts brewing. These will occur between exporting and importing countries. Those countries which have most aggressively adopted GMO and GMF find themselves increasingly unable to export their products.[43] The largest and arguably most important potential dispute, and the one on which most commentary has centered, is between the United States and the EU. Both the Clinton and the current Bush administration have pressured the EU to modify or drop its proposed labeling requirements for GMF, pressure which the Europeans have staunchly resisted.[44] To analyze the potential outcome of such disputes, it is necessary to look at the current state of multilateral and national GM regulation in more detail.

II. CURRENT STATE OF GMF REGULATION

A. *Multilateral Approaches to and Discussions of Genetically Modified Foods*

There are four main fora which are involved in regulation of GMF, or in studying the current state of the field. Some are more directly concerned with GMO than GMF; however, all have discussed regulation of GMF. These include the UN Codex Alimentarius, the Cartagena Protocol to the Convention on Biological Diversity, the OECD Working Parties on Safety of Novel Foods (OECD) and the WTO. Some potential regulations from

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[43] *See, e.g., Corn Growers See Recent Events in Europe As Continuing the Controversy Over GMO Use in the USA: On-Farm Segregation Is Likely Result of Foreign Consumer Backlash,* American Corn Growers Association, *at* http://www.acga.org/news/2000/060100.htm (Jun. 1, 2000) (In marketing years 1998-1999, corn exports from the United States to Europe stood at 2 million metric tons. In 1998-1999, those exports dropped to 137,000 tons. Soybean sales showed a one-year drop in the same time period from 11 million tons to 6 million tons); Justin Sears, *Argentina Accuses Europe of Protectionism in GM Debate: Commodities,* LLOYD'S LIST INT'L, Jun. 18, 1999 (The head of Argentina's export body claimed that EU protectionism is behind its attempts to restrict import of GM soy, and constitutes a non-tariff barrier to trade. Argentina has about 60% of its soybean acreage planted with GM soy, and exported over 3.2 million tons of soy. Argentina also uses GM corn seeds extensively).

[44] *See* Alan Sipress & Marc Kaufman, *US Challenges EU's Biotech Food Standard,* THE WASHINGTON POST, Aug. 26, 2001, *available at* 2001 WL 23189504.

these fora could have significance for any trade violations claimed before the WTO. A brief overview of the relevant provisions is provided below.

1. *UN Codex Alimentarius*

The Codex Alimentarius (Codex) is the United Nations (UN) body which sets guidelines for food safety.[45] It currently has working parties considering drafts on conducting risk assessments for foods derived from technology, and on food labeling.[46] As far as the Committee on Labeling of Foods Obtained Through Biotechnology (Committee) is concerned, there is still no consensus on the approach to take, and the drafts were returned to the parties for further discussion and comments.[47] The Committee is discussing three options.

> Option 1: Label only if the food differs significantly from corresponding foods as to composition, nutritional value or intended use (preferred by the United States, Argentina and others).
> Option 2: Includes most of Option 1, with the addition that the labels must disclose the method of production of bio-technology-derived foods or ingredients.
> Option 3: Label required if any genetically-modified material is used at any time in the production process (proposed by Norway and India).[48]

The OECD is currently attempting to combine preferred aspects of Options 1 and 2. According to the Committee's report, there is still dispute over health concerns regarding GMF.[49] There is also strong concern for providing consumers with information about the food they eat, regardless of whether the food is

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[45] *See, e.g.*, Codex Alimentarius Commission, Report of Twenty-Eighth Session of the Codex Committee on Food Labelling, ALINORM 01/22 (2000), *at* http://www.fao.org/docrep/meeting/005/x7311e/x7311e00.htm; [hereinafter Codex 28th Sess. Report], and Report of Twenty-Ninth Session of the Codex Committee on Food Labelling, ALINORM 01/22A (2001), *at* http://www.fao.org/docrep/meeting/005/y0651e/y0651e00.htm [hereinafter Codex 29th Sess. Report].

[46] *See* Codex 28th Sess. Report, *supra* note 45; Codex 29th Sess. Report, *supra* note 45.

[47] *See* Anne A. MacKenzie, *The Process Of Developing Labeling Standards For GM Foods In The Codex Alimentarius*, 3 AGBIOFORUM 4, 203-208 (2000), *at* http://www.agbioforum.org/v3n4/v3n4a04-mackenzie.htm.

[48] *See* Codex 29th Sess. Report, *supra* note 45, app. 5, paras. 6-9.

[49] *Id.* paras. 49-78.

considered healthy.[50] The guidelines to the OECD indicate that the overall objective is to facilitate consumer choice.[51]

One potential problem for future resolution of trade disputes concerns the manner in which standards in the Codex are adopted. Traditionally they have been by consensus, but as the issues become more political, so does the decision-making process.[52] One concern voiced is whether the rules on labeling will be adopted by consensus, or by a majority vote.[53] The approach that Codex takes is significant for potential disputes under the WTO, as there is a presumption of WTO consistency for measures taken in conformity with international standards, by which Codex is meant.[54]

2. *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity[55] (Protocol) was adopted on January 29, 2000. The Protocol entered into force on September 11, 2003, ninety days after being ratified by fifty countries, as required by

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[50] *Id.* app. 5, para. 2.

[51] *Id.*

[52] *See* James F. Smith, *From Frankenfood to Fruit Flies: Navigating the WTO/SPS*, 6 U.C. DAVIS J. INT'L L. & POL'Y 1, 39 n.1 (2000) (The United States requested approval in Codex of the use of beef hormones as a safe process. Rather than a consensus, there was a vote. Thirty-three delegates voted in favor, twenty-nine opposed and seven abstained. Footnote 69 contains a detailed discussion of the politicized nature of the vote; the EU tried in vain to argue that the fact that a substantial minority had voted against the use of hormones indicated that their use was not widely regarded as safe).

[53] *See* Terence P. Stewart & David S. Johanson, *The SPS Agreement of the World Trade Organization and International Organizations: The Roles of the Codex Alimentarius Commission, the International Plant Protection Convention, and the International Office of Epizootics*, 26 SYRACUSE J. INT'L L. & COM. 27, 53 n.102 (1998) (Article provides an in-depth discussion of the role of the international standards in the functioning of the WTO agreements).

[54] *Id.* at 30.

[55] *See* Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 39 I.L.M. 1027 (2000), *available at* http://www.biodiv.org/biosafety/protocol.asp [hereinafter Protocol].

Article 37.[56] The United States is not a party to the Protocol, although it was actively involved in the negotiation process.[57]

The provisions of the Protocol refer primarily to seeds and agriculture, but there are also provisions which have relevance for GMF.[58] The Protocol covers only live modified organisms (LMO), not processed foods, and as such, will have limited application to the regulation of GMO.[59] However, many GMO are live foods. Produce such as GM tomatoes, squash or potatoes, and live GM, grains which could be used as feed or seed, could conceivably fall under the Protocol provisions.

Provisions relevant to GMF include labeling provisions which apply to GMO and which are "intended for direct use as food or feed, or for processing."[60] Article 18 requires that GMO which are "intended for direct use as food or feed, or for processing be clearly identified that they 'may contain' [GMO] and are not intended for intentional introduction into the environment."[61] Although not denoted as such, the Protocol has established a labeling requirement for GMF, which are commodities.[62] Annex II spells out what information must be contained in a required notification to a Biosafety Clearing House set up to monitor GMO.[63] Countries are permitted to regulate GMO and GMF following a notification and decision-making procedure outlined in Articles 8 through 12.[64] The Protocol

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[56] *See* Cartagena Protocol on Biosafety, Status of Ratification and Entry Into Force, *at* http://www.biodiv.org/biosafety/signinglist.aspx (last modified Aug. 11, 2003).

[57] For a discussion of the negotiations, see Lisa A. Tracy, *Does a Genetically Modified Rose Still Smell As Sweet? – Labeling of Genetically Modified Organisms Under the Biosafety Protocol,* 6 BUFF. ENVTL L.J. 129 (1999).

[58] *See* Gareth W. Schweizer, Note, *The Negotiation of the Cartagena Protocol on Biosafety,* 6 ENVTL. LAW. 577, 592 (2000).

[59] *See* Protocol, *supra* note 55, art. 1.

[60] *Id.* art. 18.

[61] *Id.*

[62] This issue was apparently very divisive for many in the negotiations for the Protocol. See Tracy, *supra* note 57, for a discussion of the positions taken and compromises made; *see* Schweizer, *supra* note 58, at 600 (stating unequivocally that importers have the option to label commodities as containing LMOs and consumers may thus choose whether to purchase them).

[63] *See* Protocol, *supra* note 55, Annex II.

[64] *Id.* arts. 8-12.

specifically recognizes the precautionary principle, which is discussed below.[65]

The Preamble to the Protocol specifically preserves the parties' rights under other international treaties, which means that in a dispute over whether the Protocol or the WTO control, the WTO would likely take precedence.[66] However, the Preamble also provides that "the above recital is not intended to subordinate this protocol to other international agreements."[67] One commentator has argued that despite the savings clause, in the case of a conflict between the Convention and the WTO, the Protocol provisions could prevail.[68] The Protocol will apply to non-parties if they attempt to export to member parties,[69] which means that non-signatories, such as the United States, could be bound by the terms of the Protocol.

3. *OECD Working Parties and Discussions*

At the request of the G8, the OECD convened a conference on GM Foods in Edinburgh at the end of February 2000.[70] It included more than 400 participants from governments, non-governmental organizations, and industry.[71] The report of the conference highlighted a number of conclusions and concerns on which there was general agreement among the majority of the participants. These include the need for a more open and transparent debate on the topic of GM foods, and a science-based approach to the issues raised.[72] Divisive issues on which there was little agreement included the extent to which participants regard issues surrounding GMF as inseparable from wider issues, such as environmental and moral concerns.[73] There was

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[65] *Id.* pmbl.; *see also* Jonathan A. Glass, Comment, *The Merits of Ratifying and Implementing the Cartagena Protocol on Biosafety,* 21 NW. J. INT'L. L. & BUS. 491, 510 (2001).

[66] *See* Protocol, *supra* note 55, pmbl.; Glass, *supra* note 65, at 510.

[67] Protocol, *supra* note 55, pmbl.

[68] For a discussion of whether the WTO or the Protocol would prevail, an issue that goes beyond the scope of this paper, see Gaston & Abate, *supra* note 27.

[69] *See* Protocol, *supra* note 55, art. 24.

[70] *See* Chairman of OECD Conference Calls For International Consultative Panel on GM Foods, Organization for Economic Co-operation and Development, *at* http://www1.oecd.org/media/release/nw00-23a.htm (Mar. 1, 2000).

[71] *Id.*

[72] *Id.*

[73] *Id.*

also continued disagreement about mandatory labeling of GMF, about the usefulness of feeding trials, and on the process of assessing consumer concerns.[74]

The Conference Chairman's report to the G8 included his view that labeling would provide consumers with the ability to choose whether to eat GMF or not.[75] He also acknowledged areas of concern about testing.[76] A review of the "substantial equivalence" tool was recommended, as was a re-examination of methods for testing GMF toxicity and allergenicity.[77]

As part of the conference, the OECD formed a number of working groups, building on a growing OECD expertise in biotechnology. The OECD applies a science and rules-based approach to its research. The reports of working groups sent to the G8 include:

- OECD Taskforce for the Safety of Novel Foods and Feeds, discussing the consumer safety issues addressed by food safety assessors, including on-going review and discussion of the principle of substantial equivalence as a safety assessment tool.[78] There is also specific mention of the need for greater post-market surveillance of GMF to assess potential human health issues.[79]
- OECD Working Group for the Harmonization of Regulatory Oversight in Biotechnology, reporting on environmental safety concerns regarding GM foods.[80]
- OECD Ad Hoc Group on Food Safety, reporting on national and international measures to address current and emerging food safety issues.[81]
- Summary reports from extensive consultations with Non-Governmental Organizations.[82]

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[74] *Id.*

[75] *See* Chairman's Report on OECD GM Food Safety Conference, Organization for Economic Co-operation and Development, *at* http://www1.oecd.org/media/release/nw00-31a.htm (Apr. 7, 2000).

[76] *Id.*

[77] *Id.*

[78] *Id.*

[79] *Id.*

[80] *See* Chairman's Report on OECD GM Food Safety Conference, *supra* note 75.

[81] *Id.*

[82] *Id.*

While non-binding, the OECD working groups reports provide a further indication of the extent to which governments and multi-national organizations see a need to address emerging GM issues.

4. *Rules of the World Trade Organization*

The WTO's regulatory scheme will be discussed in detail below. For the purposes of this section, a brief overview of the general background of the WTO and the regulatory framework is offered.

The WTO is the successor organization to the GATT.[83] Founded after the Uruguay round of the GATT, the WTO was established by the Marrakesh Agreement Establishing the World Trade Organization.[84] The WTO is focused specifically on elimination of trade barriers.[85] Its goals are non-discrimination, transparency, and a rules and science-based approach to resolution of trade disputes.[86] Harmonization of countries' trade measures is encouraged through reliance on international standards.[87]

The WTO rules establish a notification procedure, whereby countries notify the WTO Secretariat of potential measures that may directly or indirectly affect international trade.[88] Other WTO members have the right to comment on such measures. Once the measures are in force, any country that is negatively affected can request consultation with the member imposing the regulation. Should the consultations fail to be effective, the exporting country may then request that a WTO Panel (Panel)

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[83] *See* Smith, *supra* note 52, at 39 n.1.

[84] *Id.*

[85] *See* Marrakesh Agreement Establishing the World Trade Organization, LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND vol. 1, 33 I.L.M. 1144 (1994) [hereinafter WTO Agreement].

[86] *See* OAS Summary Description of the Uruguay Round Marrakesh Agreement Establishing the World Trade Organization Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Organization of American States, *at* http://www.sice.oas.org/summary/ur_round/ur7.asp (last visited Sept. 29, 2003).

[87] *See* Kevin C. Kennedy, *Resolving International Sanitary and Phytosanitary Disputes in the WTO: Lessons and Future Directions*, 55 FOOD DRUG L.J. 81, 85 (2000).

[88] *See generally*, WTO Rules of Conduct for the Understanding on Rules and Procedures Governing the Settlement of Disputes, WT/DSB/RC/1 (Dec. 11, 1996), *available at* http://www.wto.org/english/tratop_e/dispu_e/rc_e.htm.

be convened to adjudicate the dispute. If not satisfied with the Panel's decision, either country may request that an Appellate Body review the Panel's decision. If the Panel or Appellate Body finds that a measure violates WTO trade rules, it recommends that the nation concerned modify the measure to bring it into compliance. If the country refuses, the affected exporting country is then justified in imposing retaliatory trade sanctions.[89]

Two agreements under the WTO have particular relevance to potential disputes over labeling of GMF. They are sketched briefly here, and discussed in more depth below.

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) regulates measures taken to protect the life or health of humans, plants or animals.[90] The SPS Agreement requires a scientific justification for the measure imposed, in the form of a risk assessment which is based on scientific evidence.[91] It encourages countries to follow international standards set by bodies such as the Codex Alimentarius.[92] If inadequate scientific evidence is available, the importing country may impose temporary measures.[93] In any event, the measure imposed may not discriminate among countries, and must be the least trade-restrictive measure possible.[94]

The Agreement on Technical Barriers to Trade[95] (TBT Agreement) applies to regulations and standards which regulate the production, processes, packaging, labeling, etc. of both agricultural and industrial products.[96] There are notice require-

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[89] *See, e.g.*, York, *supra* note 7, at 461 (the United States took retaliatory measures against the EU, after the EU refused to modify its ban on import of beef treated with hormones, at a cost of $116.8 million).

[90] *See* Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, 1994 WL 761483, *available at* http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm (last visited Sept. 29, 2003) [hereinafter SPS Agreement].

[91] *Id.* art. 2.2.

[92] *Id.* arts. 3.1, 3.2.

[93] *Id.* art 5.7.

[94] *Id.* arts. 2.3, 5.5, 5.6.

[95] *See* Agreement on Technical Barriers to Trade, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND vol. 1 (1994), *available at* http://www.jurisint.org/pub/06/en/doc/16.htm (last visited Sept. 29, 2003) [hereinafter TBT Agreement].

[96] *Id.* art. 1.3, Annex 1.

ments to other members.[97] Technical regulations may not discriminate between like products,[98] and must not be more trade-restrictive than necessary to achieve their aims.[99] The TBT Agreement also encourages the use of international standards, as long as they are effective to achieve the importing country's objectives.[100] Members shall also, so far as possible, recognize other countries' regulations as equivalent.[101] Provision is made for deviation from some of the requirements when necessary to protect safety, health or the environment.[102] Members are required to adhere to a Code of Good Practice for the Preparation, Adoption and Application of Standards.[103]

While many of their provisions are mirror images, the two Agreements are mutually exclusive. A measure cannot fall under both Agreements simultaneously.[104]

B. *Underlying Principles*

Three underlying principles are recurring threads running through multilateral regulation of GMO and GMF. They are required for adoption of certain measures in some cases, and are offered as justification in others. They are also a source of conflict. These principles are the scientific principle, the precautionary principle and the principle of substantial equivalence.

1. *Scientific Principle*

The scientific principle requires that measures taken to restrain trade be based on neutral science. While "science" is not specifically defined, references to it generally imply scientific practices, evidence, and data that are verifiable.[105] In multilateral regulation of GMF, the scientific principle is expressed as the requirement for a risk assessment based on sound sci-

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[97] *Id.* arts. 2.9, 2.91, 2.92, 2.93, 2.94.

[98] *Id.* art. 2.1.

[99] TBT Agreement, art. 2.2.

[100] *Id.* art. 2.4.

[101] *Id.* art. 2.7.

[102] *Id.* art. 2.10.

[103] *Id.* art. 4, Annex 3.

[104] *See* Kennedy, *supra* note 87, at 91.

[105] *See* Vern R. Walker, *Keeping the WTO from Becoming the "World Transscience Organization": Scientific Uncertainty, Science Policy, and Factfinding in the Growth Hormones Dispute*, 31 CORNELL INT'L L.J. 251 (1998).

ence.[106] All of the multilateral fora discussed above require some form of risk assessment or science-based approach.[107] Risk analysis includes three components: risk assessment, risk management and risk communication.[108]

Risk assessment analyzes the probability of risk, including determining what adverse effects could occur, and what the magnitude of the consequences could be.[109] This first component also includes an assessment of the level of uncertainty as to the state of knowledge about both the adverse consequences and the likelihood of its occurrence.[110] Uncertainty derives from a general lack of knowledge, and also from uncertainty as to causation, choices of variables in the data collection and the experiments, samples drawn and mathematical models chosen.[111] Risk assesment is the subject of working committees to standardize approaches and assist developing countries with the technical aspects.[112]

The second component is risk management, defined as "the process of identifying, evaluating, selecting, and implementing actions to reduce risk."[113] Risk management involves a decision regarding the acceptable level of risk, or what level of protection

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[106] *Id.* at 256.

[107] *See, e.g.,* Report of the First Session of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology, Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, ALINORM 01/34 (2000), *at* ftp://ftp.fao.org/codex/alinorm01/A101_34e.pdf (last visited Sept. 30, 2003); Codex Alimentarius Commission, Draft Principles for Risk Analysis of Foods Derived from Modern Biotechnology, ALINORM, *at* http:// www.codexalimentarius.net/biotech/en/ra_fbt.htm (last visited Sept. 30, 2003); OECD Report, *supra* note 27; WTO Committee on Sanitary and Phytosanitary Measures, Summary Report on the SPS Risk Analysis Workshop, G/SPS/GEN/209 (Nov. 3, 2000) (discussing the fundamentals of risk analysis), *available at* http://www.wto.org/english/tratop_e/sps_e/risk00_e/risk00_e.htm [hereinafter WTO Summary Report]; Protocol, *supra* note 55, art. 15.

[108] *See* WTO Summary Report, *supra* note 107, para. 45.

[109] *Id.* para. 12.

[110] *Id.*; *see also* Walker, *supra* note 105, at 258.

[111] *See* WTO Summary Report, *supra* note 107, paras. 17-18; Walker, *supra* note 105, at 258.

[112] See WTO Summary Report, *supra* note 107, paras. 17-18 and further links at wto.org.

[113] Walker, *supra* note 105, at 255.

is deemed appropriate.[114] This decision is a sovereign one involving considerations of domestic policy.[115]

Under SPS rules, countries are largely free to choose their acceptable level of risk, within the constraints of the SPS rules.[116] One goal of the SPS Agreement is harmonization of member countries' approaches to both risk assessment and risk management.[117] One way the SPS Agreement attempts to achieve this is by promoting reliance on rule making bodies such as Codex Alimentarius.[118] Both risk assessment and risk management loom large in WTO cases to date on food, animal, and plant safety.

The third component is risk communication. There is little written on risk communication, either in the commentaries or in the official bodies' work on risk assessment. The notification requirements of SPS measures could conceivably be considered as part of risk communication. The EU has a position paper on Food Safety, including a section on risk communication.[119] In the context of food safety, the EU defines risk communication as making scientific opinions available as quickly and widely as possible.[120] The EU also stresses consumers' need to have access to information on these issues, and states that the consumer must be viewed as a fully recognized stakeholder in the debate on food safety.[121] One commentator argues strongly that adoption of science policies would increase transparency of the decisions underlying risk management, which could also serve as risk communication.[122]

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[114] *Id.* at 256; *see also* WTO Summary Report, *supra* note 107, para. 14.

[115] *See* Walker, *supra* note 105, at 256.

[116] *See* SPS Agreement, *supra* note 90, art 2.1; Walker, *supra* note 105, at 268-69.

[117] *See* Walker, *supra* note 105, at 256; WTO Summary Report, *supra* note 107, para. 9.

[118] *See* WTO Summary Report, *supra* note 107, paras. 9, 10; Walker, *supra* note 105, at 273-74.

[119] *See* Commission of the European Communities, White Paper on Food Safety, COM (1999) 719 final (Jan. 12, 2000), ch. 7, *available at* http:// europa.eu.int/comm/food/fs/intro/index_en.html [hereinafter White Paper].

[120] *Id.* at chs. 4, 7.

[121] *Id.* at ch. 7.

[122] *See* Walker, *supra* note 105, at 261, 271. Science policies are "default assumptions." *Id.* at 259 n.42. An example of a science policy is one that "prohibits the use of food additives that cause cancer in laboratory animals." *Id.* at 266.

2. *Precautionary Principle*

The precautionary principle is more controversial than the scientific principle, and is not yet firmly anchored in world trade regulation. It derives originally from environmental law[123] and is an important principle in the Cartagena Protocol.[124] Its basic premise is that a country may err on the side of caution in the face of large uncertainty as to potential risks or risks of uncertain magnitude, even without firm scientific evidence to support this.[125] It may be described as a derogation from the scientific principle.[126]

The EU, among others, relies on this principle,[127] while the United States, among others, opposes its use in trade disputes over food safety.[128] The EU regards use of the precautionary principle as part of risk management, in determining how much risk is tolerable.[129] According to the EU, the precautionary principle plays no role in risk analysis, which must be science based.[130] Rather, the precautionary principle comes into play where the political decision must be made as to the acceptable level of risk.[131] The EU states limits on the use of the precautionary principle, namely those which apply to risk management in general: proportionality, non-discrimination, consistency, cost/benefit analysis (including non-economic fac-

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[123] *See* Dr. Hans-Joachim Priess & Dr. Chistian Pitchas, *Protection of Public Health and the Role of the Precautionary Principle Under WTO Law: A Trojan Horse before Geneva's Walls?* 24 FORDHAM INT'L L.J. 519, 520, (2000); Konrad von Moltke, *The Dilemma of the Precautionary Principle in International Trade*, BRIDGES WEEKLY NEWS TRADE DIGEST, at 3-4, *available at* http:// ictsd.org/English/BRIDGES3-6.pdf (Jul-Aug. 1999) (discussing the origins of the precautionary principle in a German environmental law of 1968).

[124] *See* Protocol, *supra* note 55, art. 1 (referencing Article 15 of the Rio Declaration on Environment and Development).

[125] *See* Priess & Pitchas, *supra* note 123, at 520-24.

[126] *Id.* at 522.

[127] *See* White Paper, *supra* note 119, at executive summary, ch. 3.

[128] *See U.S., Europeans Pledge to Continue Work on Applying Precautionary Principle*, 17 INT'L TRADE REPORTER 16, 619 (Apr. 20, 2000); *Draft U.S. Position on Risk Analysis Biased Toward Trade, Consumer Group Comments*, 17 INT'L TRADE REPORTER 27, 1041 (Jul. 6, 2000); *U.S. Expects Codex Discussion on Proposal to Trace Biotech Crops*, 18 INT'L TRADE REPORTER 8, 304 (Feb. 22, 2001) (discussing the various controversial issues before the Codex Committees, including the precautionary principle).

[129] *See* Priess & Pitchas, *supra* note 123, at 530-31.

[130] *Id.*

[131] *Id.* at 531.

tors), and examination of scientific developments.[132] The Codex Committee on General Principles is currently working on harmonization of the definition and application of the precautionary principle.[133]

3. *Substantial Equivalence*

The third principle often used to assess food safety is that of substantial equivalence. This concept is endorsed by the Food and Agriculture Organization (FAO) and World Health Organization (WHO) of the UN, and favored by the OECD.[134] Substantial equivalence is defined by the OECD as the "idea that existing organisms used as food, or as a source of food, can be used as the basis for comparison when assessing the safety of human consumption of a food or food component that has been modified or is new."[135] One compares the trait encoded by the genetic modification to an appropriate comparator in the traditional food.[136] Establishing the similarity to a traditional food which is safe indicates that the new food will also be safe.[137] OECD views this approach as the most practical in assessing GMF for food safety.[138]

However, establishing substantial equivalence does not automatically mean that a novel food is safe. Substantial equivalence is not a safety assessment per se.[139] Once a substantial equivalence assessment has been made, there are three possible scenarios which could arise: (1) If the products are nearly identical, the novel product can be considered as safe as its traditional counterpart; (2) If equivalence is established apart from certain defined characteristics, risk analysis should focus on the identified differences; and (3) If no substantial equivalence can

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[132] *Id.* at 533.

[133] *See* Codex Alimentarius Commission, Report of the Fifteenth Session of the Codex Committee on General Principles, ALINORM 01/33 (2000), app. III, *at* http://www.fao.org/docrep/meeting/005/x7101e/x7101e00.htm [hereinafter Codex 15th Sess. Report].

[134] *See* OECD Report, *supra* note 27, at 5.

[135] *Id.* at 22.

[136] *Id.* at 21.

[137] *Id.* at 22.

[138] *Id.* at 22.

[139] *Id.*

be established, a testing program would have to be implemented on a case-by-case basis.[140]

Substantial equivalence as a standard is under discussion in the Codex Alimentarius Committee on Food Labeling, with the United States as a proponent.[141] Opponents of substantial equivalence point to the very fundamental difference of the product which contains DNA protein from another species.[142] They also point to the fact that many novel foods are patented as unique, and argue that they cannot then also be considered equivalent to non-GM varieties.[143]

There is an overlapping, sometimes inconsistent body of law regulating international trade, which will be applied to the potential disputes over labeling. There are also gaps in regulation due to the sometimes slow process of negotiating norms in multilateral bodies. In the absence of international norms specific to the topic, many countries have taken unilateral steps to regulate GMF.

C. *National Regulation of and Labeling Requirements for Genetically Modified Foods*

As might be expected from the foregoing, national regulation of GMF tends to divide along importer/exporter country lines, with exporting countries having little or no regulation of GMF, and importing countries attempting to restrict GMF. The regulatory schemes of the various countries, both those already adopted and those proposed, are outlined briefly below.

1. *United States*

The United States has an overlapping system of regulation of GMO and GMF, spread among a number of government agencies. The Food and Drug Administration (FDA) is charged with oversight of food safety, while the Environmental Protection Agency (EPA) is in charge of safety of pesticides, and the

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140 *Id.*

141 *See* Codex 28th Sess. Report, *supra* note 45, para. 43.

142 *See* Mathew Stilwell & Brennan Van Dyke, *An Activist's Handbook on Genetically Modified Organisms and the WTO*, Center for International Environmental Law, Consumers Choice Council (Jul. 1999), *at* www.consumerscouncil.org/policy/handbk799.htm.

143 *Id.*

Department of Agriculture has responsibility for GM plants.[144] With respect to GMF, in 1992 the FDA published its "Statement of Policy: Foods Derived from New Plant Varieties."[145] This policy implemented a registration procedure for companies which plan to bring such foods to market. The FDA recommends that developers consult with the FDA about bio-engineered foods under development.[146] The company itself does the safety testing, and informs the FDA of its scientific and regulatory assessment of the food.[147] FDA evaluates the submissions and if there are no difficulties noted, the product may be freely commercialized.[148] Labeling is required only in exceptional circumstances, if the food differs significantly from the traditional variety.[149] As of July 2001, the FDA had completed consultations with industry on more than fifty bioengineered plant products.[150] The official FDA policy is that GMF are safe, unless proven otherwise.[151] Companies conduct research, notify the FDA if there appear to be any problems, and bring their products to market.

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144 See the Food and Drug Administration (FDA) for an overview of food safety, *at* www.fda.gov (last visited Oct. 1, 2003); the Environmental Protection Agency (EPA) for EPA policy regarding GMO, *at* www.epa.gov/pesticides; the United States Department of Agriculture (USDA) for information on GMO, *at* www.usda.gov (last visited Oct. 1, 2003).

145 *See* Statement of Policy: Foods Derived from New Plant Varieties, Department of Health and Human Services, Food and Drug Administration, 57 FR 22984 (1992), *available at* http://www.cfsan.fda.gov/~lrd/fr92529b.html [hereinafter 1992 FDA Policy]

146 *Id.* at 22985.

147 *Id.* at 22985, 22989.

148 *Id.* at 22985.

149 *Id.* at 22991.

150 *See* Mitchell A. Cheeseman & James C. Wallwork, *FDA's Office of Food Additive Safety*, U. S. Food and Drug Administration, *reprinted from* Food Safety Magazine (Dec. 2002/Jan. 2003), *at* http://www.cfsan.fda.gov/~dms/opaofas.html (last modified Feb. 6, 2003).

151 *See* 1992 FDA Policy, *supra* note 145, at 22988 ("Foods derived from new plant varieties are not routinely subjected to scientific tests for safety, although there are exceptions. For example, potatoes are generally tested for the glycoalkaloid, solanine. The established practices that plant breeders employ in selecting and developing new varieties of plants, such as chemical analyses, taste testing, and visual analyses, rely primarily on observations of quality, wholesomeness, and agronomic characteristics. Historically, these practices have proven to be reliable for ensuring food safety. The knowledge from this past experience coupled with safe practices in plant breeding has contributed to continuous improvements in the quality, variety, nutritional value, and safety of foods derived from plants modified by a range of traditional and increasingly sophisticated techniques. Based on this record of safe development of new varieties of plants, FDA has not found it neces-

In response to growing concerns among American scientists and consumers, in November 1999 the FDA convened public discussions about GMF.[152] It has not yet made any changes in its policy or oversight based on this input, but issued a proposal in January 2001 for voluntary labeling guidelines for producers.[153] However, there is growing public pressure for labeling in the United States. Bills have been introduced in Congress to require mandatory labels.[154] Companies are beginning to label their products "non-GMO" in response to consumer demand.[155] The FDA has warned five natural food companies that their "GMO-free" labels are misleading consumers.[156] There is currently no approved text from FDA on what a label could say.[157] Another example of growing consumer concern is evidenced by a movement in three towns in Vermont to vote on whether GMF should be labeled, and whether there should be a moratorium on them while they are studied.[158]

Thus, while the official U.S. policy and law is that GMF need not be regulated or labeled, there is a movement among consumers and lawmakers in the United States to change this policy.

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sary to conduct, prior to marketing, routine safety reviews of whole foods derived from plants").

[152] *See, e.g.,* Statement of Rebecca Goldburg, of the Environmental Defense Fund, at the FDA Public Hearing on Genetically Engineered Foods, Environmental Defense, *at* http://www.environmentaldefense.org/documents/1662_Goldburg_FDA1999.pdf (Nov. 30, 1999). The Hearing was held during the World Trade Organization in Seattle, which may explain the lack of attention to the statements made at the hearing. *Id.* Rebecca Goldburg, a biologist with a Ph.D, commented on the food safety and regulation of genetically engineered foods. *Id.* She stated that the added substances in the foods may cause consumers to be allergic to foods they previously could consume safely. *Id.* She also stated that the FDA's current regulation did more to protect the biotechnology industry than consumers. *Id.*

[153] *See* York, *supra* note 7, at 441.

[154] *Id.* at 442 (Bills were introduced by Representative Dennis Kucinish (D-OH) in Nov. 1999 and Senator Barbara Boxer (D-CA) in Jan. 2000).

[155] *See* Scott Kilman, *FDA Warns of Misleading Labels On Genetic Modification in Foods*, THE WALL STREET JOURNAL, Dec. 20, 2001, *available at* 2001 WL-WSJ 29681303.

[156] *Id.*

[157] *Id.*

[158] *See Vermont Towns Begin Voting on Genetically Engineered Foods*, ASSOCIATED PRESS, Dec. 16, 2001, *available at* http://www.organicconsumers.org/gefood/vermont121801.cfm.

2. *Switzerland*

Switzerland appears to have been the earliest country to impose a comprehensive approval and labeling regime for GMF. In a 1992 referendum,[159] the Swiss approved a constitutional amendment regulating GMO and providing a regulatory framework.[160] A second referendum in 1995 brought about the adoption of regulations requiring that any GMF be approved before it is introduced into the market, and that all GMF be labeled.[161] In its approach to approval and labeling, the Swiss legislature appears to have closely followed WTO rules.

Approval for GMF will only be granted if there is certainty, based on actual scientific knowledge, that the product poses no threat to human health.[162] The Swiss regulations call for both positive and negative labeling. "Since June 1999, a food product must be labeled produced with GMO if any of its ingredients contain more than one percent GMO."[163] The reason given is to prevent deceptive practices and to allow consumers choice of what they eat.[164] The same rationale applies to negative labels. A product may only be labeled "produced without GMO" if three criteria are met: (1) none of its ingredients contain more than one percent GMO; (2) no GMO were used in the production or processing of the food; and (3) a similar GM food or ingredient has been approved for the Swiss market.[165] In other words, food may be labeled "non-GMO" only if there is danger of confusion with a GMF on the market. Labels proclaiming a product "GM-free" are not permitted, since it is believed that it is not possible to guarantee that a product is 100 percent free of GM contamination.[166]

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159 *See* Franz Xaver Perrez, *Taking Consumers Seriously: The Swiss Regulatory Approach to Genetically Modified* Food, 8 N.Y.U. ENVTL. L.J. 585 (2000) (noting that the Swiss system of government provides for mandatory and voluntary direct referenda, where the public directly approve laws, make changes to the constitution, and pass resolutions calling for lawmakers to pass legislation effectuating the wishes of the people expressed in the referendum).

160 *Id.*

161 *Id.* at 590-91.

162 *Id.* at 596.

163 *Id.* at 597.

164 Perez, *supra* note 159, at 597.

165 *Id.*

166 *Id.* at 598.

The Swiss regulations are intended to be fully compliant with WTO rules. Approval to introduce GMO or GMF into the Swiss market must be based on science. The regulations rely on international standards wherever they exist.[167] The labeling requirements are designed to prevent deceptive practices and provide choice to consumers.[168]

3. *European Union*

The EU has passed legislation requiring mandatory labeling for GMF.[169] It requires pre-marketing notification to the country of import before the product is placed on the market.[170] Approval is based on an assessment of risk.[171] A product must be considered "safe" to be imported.[172] The scientific data needed for assessment is to be provided by the seller.[173] Once a product is approved for sale by one EU member, it is free to circulate throughout the EU.[174]

GMF food products approved for sale in the EU require labels. Labeling requirements are intended to provide information to consumers,[175] for health reasons,[176] for ethical reasons[177] and to prevent them from being misled.[178] A label is required if the GMF is no longer equivalent to an existing food or ingredient, as determined by a scientific assessment; or if the food contains GMO that may have health implications for parts of the population or cause ethical concerns.[179] There does not appear to be a minimum threshold of GMO that triggers the labeling requirement. The criteria is whether the novel food is "no longer equivalent" to the existing food.[180] In this case, a la-

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[167] *Id.* at 599.

[168] *Id.* at 597.

[169] *See* Council Regulation 258/97 of 27 January 1997 Concerning Novel Foods and Novel Food Ingredients, art. 8, 1997 O.J. (L 43) 1 [hereinafter Novel Foods Regulation].

[170] *Id.* art. 4.

[171] *Id.* arts. 4, 6.

[172] *Id.* arts. 3.1, 6.

[173] *Id.* arts. 4.1, 6.1.

[174] Novel Foods Regulation, *supra* note 169, art. 4.

[175] *Id.* art. 8.

[176] *Id.* at eighth "whereas" clause.

[177] *Id.*

[178] *Id.* art. 3.1.

[179] *Id.* art. 8.

[180] Novel Foods Regulation, *supra* note 169, art. 8.

bel is required.[181] "No longer equivalent" is defined as a scientific determination that there are characteristics that are different, having regard to the natural limits of variation for such characteristics.[182]

Negative labels are permitted.[183] Food that does not contain GMO may be labeled as such.[184]

4. *New Zealand and Australia*

New Zealand and Australia have a Joint Food Safety Regulation which forms a comprehensive program regulating GMO and GMF in both countries.[185] The New Zealand Ministry of the Environment is the lead government agency administering the programs. For space reasons, only the New Zealand program will be described in detail here.

A Royal Commission in New Zealand was convened to study the various issues surrounding the introduction of GMO and GMF.[186] Prior to convening the Royal Commission, no GMO or GMF had been approved for release.[187] During the study, a voluntary moratorium on introduction of GMO and GMF was in place.[188] In addition to potential economic, medical and other benefits to be derived from GMO and GMF, the Royal Commission also inquired into areas of public concern.[189] These included human health, environmental concerns, including biodiversity, as well as cultural and ethical concerns, with particular reference to ethical concerns of indigenous peoples.[190]

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[181] *Id.*

[182] *Id.*

[183] *Id.*

[184] *Id.* at tenth "whereas" clause.

[185] *See* Terms of Reference (the Warrant), Report of the Royal Commission on Genetic Modification, Environmental Risk Management Authority, New Zealand (Jul. 27, 2001), *at* http://www.gmcommission.govt.nz/intro/warrant_eng.html [hereinafter Terms of Reference]. The full report of the Royal Commission is available at http://www.gmcommission.govt.nz/RCGM/rcgm_report.html.

[186] *Id.*

[187] *See* Royal Commission of Inquiry into Genetic Modification, Frequently Asked Questions about Genetic Modification and the Governments decisions, Environmental Risk Management Authority, New Zealand, *at* http://www.ermanz.govt.nz/news-events/focus/royal-commission-govt-qa.asp (Oct. 2001) [hereinafter Frequently Asked Questions].

[188] *Id.*

[189] *See* Terms of Reference, *supra* note 185.

[190] *Id.*

The Commission ended in July of 2001 and legislation in New Zealand regarding GMF has been passed.[191] Regulation regarding GMF and GMO in New Zealand is governed by a number of laws, with different agencies having oversight over different areas.[192] One such agency is the Hazardous Substances and New Organisms (HSNO) Act of 1996, which is intended to protect the environment and health of New Zealanders.[193]

GMF introduced into New Zealand are regulated under the Food Act of 1981 and a joint Australia New Zealand Food Standard (ANZFS). New Zealand requires GMF be assessed for safety by the Australia New Zealand Food Authority (ANZFA) and in most cases labeled, before it can be sold.[194] If it contains a live GMO, such as a tomato with seeds, it must also be approved by the environmental agency.[195] The food labeling rules came into effect in December 2001.[196] As of December 7, 2001, any food that contains more than one percent genetically modified material must be labeled identifying its GM status.[197] Food already in stores need not be retroactively labeled nor must food sold in restaurants be labeled.[198] The exemption also includes highly refined foods where refining removes novel DNA and/or protein.[199] By December 7, 2002, any food with GM ingredients

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[191] *Id.*

[192] *See* Understanding the Royal Commission on Genetic Modification – a simple guide to the process and recommendations, Environmental Risk Management Authority, New Zealand, *at* http://www.mfe.govt.nz/issues/organisms/commission (last visited Oct. 2, 2003).

[193] *See* Terms of Reference, *supra* note 185.

[194] *See* Ten Facts About Genetic Modification, No. 5, Genetic Modification, Ministry for the Environment, New Zealand, *at* http://www.gm.govt.nz/facts.shtml (last visited Oct. 17, 2003).

[195] *See* GM Topics: How Genetic Modification Is Regulated?, Genetic Modification, Ministry for the Environment, New Zealand, *at* http://www.gm.govt.nz/topics-food-regulated.shtml (last visited Oct. 17, 2003).

[196] *See* Labeling: Australia New Zealand, Transgenic Crops: An Introduction and Resource Guide, *at* http://www.isaaa.org/kc/issues/labeling/country/australia.htm (2003).

[197] *See* Frequently Asked Questions, *supra* note 187.

[198] *Id.*

[199] *See* Labelling Genetically Modified Foods, Food Standards: Australia New Zealand, *at* http://www.foodstandards.gov.au/mediareleasespublications/factsheets/factsheets2000/labellinggenetically29.cfm (Aug. 2000) [hereinafter Labelling Genetically Modified Foods].

must be labeled.[200] The labeling regime is considered by New Zealand to be in line with that of the EU.[201]

5. *Canada*

At present, Canada does not require labeling of GMF. There appears to be quite a volatile debate within the government and among the citizens on whether labeling should be required. A bill requiring mandatory labeling on GMF sponsored by a private member was defeated in Parliament in October 2001,[202] despite its support by the Canadian Minister of Health.[203] The bill would have required labeling for any food containing more than one percent genetically modified ingredients.[204] In August 2001, the Canadian Biotechnology Advisory Committee released an interim report that recommended a voluntary system of labeling, but the Minister of Health noted that there was no consensus on acceptable standards, such as the percentage of GM that would trigger a label.[205]

Debate on GMF continues among various sectors of Canadian society. An independent scientific panel of the Royal Society of Canada made a number of recommendations to the government regarding safety of GMO and GMF.[206] The Canadian Wheat Board (CWB) has recommended a moratorium on introduction of GM wheat in Canada, largely to protect potential markets.[207] The CWB's position statement acknowledges consumer concern, and that overseas customers have expressed

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[200] *See* Frequently Asked Questions, *supra* note 187.

[201] *See* Labelling Genetically Modified Foods, *supra* note 199.

[202] *See Debate Erupts After Canada Parliament Votes Against GE Food Labels*, THE OTTAWA CITIZEN, Oct. 18, 2001, *available at* http://www.organicconsumers.org/gefood/mplabels102901.cfm.

[203] *See* Robert Fife, *Canada Minister of Health Wants Mandatory Labels on GE Food*, NATIONAL POST (Canada), Oct 5, 2001, *available at* http://www.organicconsumers.org/gefood/canadalabel.cfm.

[204] *See Debate Erupts After Canada Parliament Votes Against GE Food Labels*, *supra* note 202.

[205] *See* Fife, *supra* note 203.

[206] *See* Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada, The Royal Society of Canada, *at* http://www.rsc.ca/foodbiotechnology/indexEN.html (Jan. 2001).

[207] *See* CWB Draws Attention to Concerns Over GM Wheat, Canadian Wheat Board (Apr. 4, 2001) *at* http://www.cwb.ca/en/news/releases/2001/040301.jsp. (Apr. 4, 2001).

a disinclination to purchase GM wheat.[208] The inability to adequately segregate GM grain from traditional varieties plays an important role.[209] The CWB is working with the Royal Society of Canada to develop voluntary labeling rules. A broad coalition of groups in Canada support this position. Its members include the National Farmers Union, the Keystone Agricultural Producers of Manitoba, and Greenpeace of Canada.[210] Canada is a signatory to the Cartagena Protocol and, as such, bound by its terms.

Although the current state of legislation in Canada does not require labeling for GMF, it appears that this might change in the future.

6. *South Korea*

South Korea implemented a labeling regime for GMF which came into effect on March 1, 2001.[211] The regulations are designed to implement South Korea's commitment to the Cartagena Protocol.[212] The law follows the Protocol's "may contain" rule for possible GMO content.[213] The law makes approval mandatory for the importation, production or research of GMO.[214] The law also requires retailers of genetically modified beans, corn and bean sprouts to label packing material, or lay signs beside them identifying them as genetically modified, if they are not packaged.[215] The same provision applies to processed foods based on GM beans, corn and bean sprouts as of July 2001.[216] As of March 2002, potatoes are also included.[217] According to the Ministry of Agriculture and Forestry, the pur-

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208 *See Canadian Coalition Calls for GE Wheat Ban*, ASSOCIATED PRESS (Canada), Jul. 31, 2001, *at* http://www.organicconsumers.org/patent/gewheat080301.cfm.

209 *See* CWB Draws Attention to Concerns Over GM Wheat, *supra* note 207.

210 *See Canadian Coalition Calls for GE Wheat Ban*, *supra* note 208.

211 *See Korea to Enforce Labeling of GMO Products From March 1 Deadline*, ASIA PULSE, Feb. 27, 2001, *available at* LexisNexis.

212 *See* James Lim, *South Korea Strengthens Regulations Covering GMO Production, Movement*, 18 INT'L TRADE REPORTER 11, 434 (Mar. 15, 2001) [hereinafter Lim, *South Korea Strengthens Regulations*].

213 *See* James Lim, *South Korea to Impose Agricultural Label Requirements for Genetically Modified Foods*, 18 INT'L TRADE REPORTER 28, 1104 (Jul. 12, 2001).

214 *See* Lim, *South Korea Strengthens Regulations*, *supra* note 212, at 434.

215 *Id.*

216 *Id.*

217 *Id.*

pose of the rule is to provide consumers with information on agricultural products.[218]

7. *Brazil*

The situation regarding GM foods and products in Brazil appears to be confused and fraught with political struggles. The sale of GM products is currently forbidden, although there are areas where experimental plantings are permitted.[219] Brazil is one of the few grain-exporting countries to have such a ban. Sale of GM products was banned by a court order of 1998, until their impact and safety could be better studied.[220] Despite such rulings, Brazil's agriculture minister is apparently finalizing plans to approve commercial use of five different types of GM soy.[221] His announcement prompted a warning from a federal judge that such products are still currently banned in Brazil.[222] Other news reports indicate that there are large plantings of illegal GM grains in the growing areas of Brazil.[223]

A presidential decree issued mid-July of 2001 provided that effective January 2002, labeling on GM foods would be required if the percentage of GM ingredients is over four percent.[224] This decree was immediately challenged in court by the government's attorney general and a consumer group, as violating the Brazilian Consumer Defense Code.[225] The reason given was that it does not provide enough information or protection.[226] It is thus unclear what direction Brazil will eventually take, given the political struggles between consumers and judges on one hand, and the government on the other. Brazil has traditionally sided with the United States, Argentina, and other growing countries in negotiations on labeling and regulation of GM foods.

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[218] *See Korea to Enforce Labeling of GMO Products From March 1 Deadline*, *supra* note 211.

[219] *See* Michael Kepp, *Brazilian Agency, Consumer Group File Suit Over Decree on GM Foddstuffs*, 18 INT'L TRADE REPORTER 34, 1345 (Aug. 23, 2001).

[220] *See Brazilian Court Bars Cultivation of Genetically Modified Soy Beans*, AGENCE FRANCE-PRESSE, Aug. 9, 2000, *available at* 2000 WL 24686842.

[221] *See* Kepp, *supra* note 219, at 1346.

[222] *Id.*

[223] *See* Wright, *supra* note 38.

[224] *See* Kepp, *supra* note 219, at 1345.

[225] *Id.*

[226] *Id.*

8. *Japan*

Japan implemented a labeling program for GM foods as of April 1, 2001.[227] The stated purpose is to provide consumers with the information they demand about GM status of the food they buy, in response to their growing concerns about GMF.[228] The labeling program includes both positive and negative labels. From April 1, 2001, soybeans, corn, rapeseed, cottonseeds and potatoes must be labeled as to their GM status.[229] In addition, twenty-four kinds of processed foods derived from these ingredients, such as tofu and bean curd, must also be labeled.[230] Tomatoes grown in the United States will be included next.[231]

Labels must state "GM-free," "GMO foods," "unknown" or "undecided."[232] The threshold for being "GM-free," for corn and soy products, is five percent.[233] Anything over five percent requires a GMO foods label.[234]

In addition to the GMF labeling program, the Ministry of Health and Welfare has instituted a mandatory food safety inspection program, replacing the previous voluntary program. The purpose is to determine whether imported food is GMF or contains GM ingredients.[235] The safety inspection is to be performed by third parties before the food is exported, and the Japanese Ministry of Health and Welfare will conduct spot audits to determine compliance.[236]

9. *Other Countries*

There are reports of other countries beginning to consider GMF labeling. At the most recent Codex meeting, India indicated that it is developing a labeling scheme in line with its proposal to the Codex, *i.e.*, labeling required for any food containing

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[227] *See Japan to Increase Inspections of GMO, GM Food Imports; Details Coming Soon*, 17 INT'L TRADE REPORTER 18, 709 (May 4, 2000) [hereinafter *Japan to Increase Inspections*].

[228] *Id.* at 710.

[229] *See* Declan Conroy, *Regulation of Biotech Foods Worldwide Characterized by Confusion, Uncertainty,* 18 INT'L TRADE REPORTER 28, 1091 (Jul. 2001).

[230] *See Japan to Increase Inspections*, *supra* note 227, at 709.

[231] *Id.*

[232] *Id.*

[233] *See* Conroy, *supra* note 229, at 1091.

[234] *Id.*

[235] *See Japan to Increase Inspections*, *supra* note 227, at 709.

[236] *Id.*

GM ingredients or GM processes.[237] China, Taiwan, Russia, South Africa and Mexico are also mentioned in news reports as beginning to consider labeling for GMF.[238]

D. *Summary*

Overall, there is a growing trend toward labeling, especially for purposes of consumer information and choice. Safety concerns are also a factor. The labeling schemes in general appear to parallel the more moderate proposals being considered in the Codex Alimentarius working parties. They are also often framed to comply with the Cartagena Protocol. The threshold requirements to trigger labeling range from one to five percent, and include both GM food eaten directly and food made with GM ingredients. Those countries requiring labeling make up a large percentage of the food importing countries in terms of volume. Thus the result of any dispute between GMF exporting countries and importing countries requiring labeling is likely to have widespread consequences.

III. Dispute Before the World Trade Organization

A. *Applicable Law*

In a dispute over labeling of GMF brought before the WTO, which would be the applicable law? Either the TBT Agreement or the SPS Agreement could conceivably be applied, depending on the terms of the complaint and the regulatory framework that is challenged. Commentators do not appear to have a uniform opinion. One argues that the TBT Agreement would appear to apply to any labeling mandated for general consumer information.[239] Others suggest that either the TBT Agreement or the SPS Agreement could conceivably be used, but that in the end, only the SPS Agreement could apply.[240] Yet another dis-

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[237] *See* Codex 29th Sess. Report, *supra* note 45, para. 75.

[238] *See* Conroy, *supra* note 229, at 1091.

[239] *See* Steve Charnovitz, *The Supervision of Health and Biosafety Regulation by World Trade Rules,* 13 Tul. Envtl. L.J. 271, 296 (2000).

[240] *See* Robert Howse & Petros C. Mavroidis, *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, 321 (2000); Julie Teel, Comment, *Regulating Genetically Modified Products and Processes: An Overview of Approaches,* 8 N.Y.U. Envtl. L.J. 649, 687 (2000) ("While labeling of GMOs is likely to be covered by Annex A1 of the SPS Agreement . . . , the two agreements have parallel provisions").

cusses labeling requirements solely under GATT Article XX (b) and (g).[241] In discussing the potential of relying on GATT XX or GATT III, other commentators cite the principle of *lex specialis*, and argue that the SPS Agreement would apply.[242] At least one official in the United States appears to assume that a challenge would be brought under TBT rules.[243]

In discussing a potential dispute, there is one important unknown: This is which international standard would be applied, if any. The standard is significant because of the WTO presumption of compliance if parties rely on international standards in drafting measures. The Codex has not yet finalized its rules on labeling, as they are still being debated. The labeling battle may well be won in this arena, rather than before the WTO. The labeling rules described above could enjoy a presumption of compliance, depending on which labeling option is chosen by the Codex. The Cartagena Protocol also has provisions for labeling, but it is generally considered unlikely that this would be an international standard on which labeling countries could rely, assuming they are signatories.[244] Some regulatory schemes, for instance South Korea's, are drafted to comply

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[241] *See* Philip Bentley Q.C., *A Re-assessment of Art XX, Paragraphs (b) and (g) of GATT 1994 in the Light of Growing Consumer and Environmental Concern about Biotechnology*, 24 FORDHAM INT'L L.J. 107, 127-28 (2000) (apparently assuming that labeling regimes are not safety-driven, and the ethical considerations at their root would allow a country to rely on GATT rather than one of the more specialized rules).

[242] *See* Howse & Mavroidis, *supra* note 240, at 321-22.

[243] *See* Sharynne Nenon, Presentation to the Third Annual Roundtable on the Liability and Labeling of Genetically Modified Organisms (May 26, 1999), *at* http://www.cast-science.org/cast-science.lh/0002abab.htm. "If our trading partners decide to require mandatory labeling of agricultural products made with biotechnology, we expect them to abide by their international obligations contained in the World Trade Organization agreement on Technical Barriers to Trade (TBT Agreement). . . . The United States is unlikely to challenge biotech labeling rules based on their objective, *i.e.* consumer information. However, we could choose to challenge the specific measures that countries adopt based on the obligations of Art. 2.2 of the TBT Agreement or other provisions of the General Agreement on Tariffs and Trade." *Id.*; Edward Alden & Michael Mann, *US Again Threatens EU on Frankenfoods Moratorium*, FINANCIAL TIMES (London), Dec. 18, 2001, *available at* http://www.organicconsumers.org/gefood/eumoratorium122001.cfm (where a "U.S. industry official" is quoted as saying that unless Europeans can show they have a workable system in place to approve applications for GMOs, it is a technical barrier to trade).

[244] *See* Gaston & Abate, *supra* note 27, at 120 (arguing that under certain circumstances, the Protocol would take precedence over the WTO, in case of conflict;

with the Protocol provisions. A labeling country could make a case that reliance on the Protocol's rules should provide the same presumption of compliance as reliance on the Codex rules. If a case is brought before the Codex has issued its labeling rules, uncertainty as to outcome is increased.

The relevant provisions of both the SPS Agreement and the TBT Agreement, as well as the case law interpreting them, are discussed below to determine under which provision a challenge to labeling regulations should be brought. Thereafter, the provisions of the labeling regimes described above are analyzed for their conformity to the applicable Agreements, and a determination is made on whether they would withstand a challenge under either the SPS Agreement or the TBT Agreement.

B. *Agreement on Sanitary and Phytosanitary Measures*

The first agreement under which a challenge to labeling regulations could be brought is the SPS Agreement. To date, only three cases have been decided by the WTO under this Agreement: *EC Measures Concerning Meat and Meat Products*[245] (*Hormones*), in 1998; *Australia – Measures Affecting Importation of Salmon*[246] (*Salmon*), also in 1998, and *Japan – Measures Affecting Agricultural Products*[247] (*Agricultural Products*), in 1999. All three concerned import bans of products under health and safety regulations of the importing country. *Hormones* involved sanitary measures designed to protect human health, *Salmon* involved measures to protect animal health, and *Agricultural Products* concerned a phytosanitary measure to protect plants against pests. Many of the same is-

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Grosko, *supra* note 5 (discussing the relationship between the WTO and the Protocol).

[245] *See* WTO Appellate Body Report, EC Measures Concerning Meat and Meat Products (Hormones), WT/DS26/AB/R, (Jan. 16, 1998), *available at* www.wto.org/english/tratop_e/dispu_e/ab_reports_e.htm [hereinafter Hormones Appellate Body Report].

[246] *See* WTO Appellate Body Report, Australia – Measures Affecting Importation of Salmon, WT/DS18/AB/R, (Oct. 20, 1998), 1998 WL 731009, *available at* www.wto.org/english/tratop_e/dispu_e/ab_reports_e.htm [hereinafter Salmon Appellate Body Report].

[247] *See* WTO Appellate Body Report, Japan – Measures Affecting Agricultural Products, WT/DS76/AB/R, (Feb. 22, 1999), *available at* www.wto.org/english/tratop_e/dispu_e/ab_reports_e.htm [hereinafter Agricultural Products Appellate Body Report].

sues were litigated in all three cases, thus there is a body of case law interpreting the SPS Agreement. In all three cases, the importing country lost, and its measures were found to be not in compliance with WTO rules. Broadly speaking, lack of a proper risk assessment in each case was found.[248] The measures taken were also not based on the risk assessment that was performed.[249]

1. *Application of SPS Agreement*

A threshold issue is whether the SPS Agreement applies to labeling regulations intended primarily for consumer information purposes. Article 1.1 of the SPS Agreement states that it applies to "all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade."[250] Sanitary and phytosanitary measures are defined in Annex A of the SPS Agreement. They include any measure applied:

> 1. to protect animal or plant life or health . . . from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
> 2. to protect human or animal life or health . . . from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
> 3. to protect human life or health . . . from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
> 4. to prevent or limit other damage . . . from the entry, establishment or spread of pests.[251]

The SPS Agreement is thus intended to regulate measures that limit the importation of disease and pests and their spread, and to protect against risks arising from contaminants, additives, and the like. The Annex defines "contaminants" to include pesticide and veterinary drug residues and extraneous matter.[252]

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[248] *See* Hormones Appellate Body Report, *supra* note 245, para. 6; Salmon Appellate Body Report, *supra* note 246, para. 279(d); Agricultural Products Appellate Body Report, *supra* note 247, para. 143(f).

[249] *See* Hormones Appellate Body Report, *supra* note 245, para. 6; Salmon Appellate Body Report, *supra* note 246, paras. 135-36; Agricultural Products Appellate Body Report, *supra* note 247, paras. 113-14.

[250] SPS Agreement, *supra* note 90, art. 1.1.

[251] *Id.* Annex A.

[252] *Id.* art. 1 n.4.

The first question is whether the labeling regulations discussed above include such measures and therefore fall under the SPS Agreement.

Those countries whose labeling regulations are described above generally regulate GMF in two different ways. The first is an approval process governing the import, marketing and research of GMO and GMF, which requires a risk assessment by the importing country to determine if they are safe. The second is a separate regulation requiring labeling of GMF once they are approved for import or commercialization. Switzerland, the EU, Australia/New Zealand and Korea all have separate requirements for approval and for labeling. Japan has a food inspection regulation to determine GMO status, and a separate labeling regulation. In analyzing whether labeling regulations fall under the SPS Agreement, it is necessary to distinguish them from the accompanying rules regarding GMO or GMF approval.

The approval processes described in the regulations above are all based on "science" or a risk assessment, presumably to conform to the WTO rules as outlined in the *Hormones, Salmon*, and *Agricultural Products* cases. The labeling rules, on the other hand, do not appear to be safety- or science-based, and their purpose apparently is to allow consumer choice, and to provide consumer information, health information, or information to those with religious or ethical concerns.

2. *Approval Process*

Proceeding from the definition provided in Annex A, it is open to discussion whether the approval regulations fall under the SPS Agreement.[253] The regulating countries do not appear to be regulating because they consider GMO a pest, disease or disease-causing organism. The approval regulations are thus not caught by definition 1, 2, or 4. Nor do labeling countries appear to consider GMO a contaminant, toxin, disease-causing organism or additive, and they are thus most likely not caught by definition 3. Transgenic products are *sui generis*, which may be either a curse or a blessing, in terms of litigation before the WTO. They are new and different, and are not included in the

[253] *See* Charnovitz, *supra* note 239, at 276-77 (in agreement, stating that dangers from bio-engineered foods are not covered by the SPS Agreement because genetic modification is not listed in the above categories).

traditional categories of dangers regulated under the WTO rules. In the multilateral standard-setting bodies, GMO and GMF are also not being discussed in terms of contaminants, etc. It would be difficult for producing countries to argue that GMO and GMF fall under these categories, as they claim that GMF are equivalent to traditional foods and completely safe. It is difficult to picture how the complaint would be framed if a violation of the SPS Agreement is claimed. According to at least one commentator, if the measure is not intended to protect against one of the named risks, then the measure is not an SPS measure.[254]

The most likely definition of GMO would be as an additive if a Panel wanted to view the definitions expansively.[255] Approval to sell, import or research could be refused under the regulations outlined, and a challenge of this decision brought before the WTO. Assuming *arguendo* that the regulations requiring approval to import or market GMO and GMF are covered by the SPS Agreement, this does not necessarily mean that the labeling regulations which accompany them are also subject to the terms of the SPS Agreement.

3. *GATT Regulations*

If there is a gap in the SPS Agreement, a complaining country could still fall back on the GATT provisions. SPS case law indicates that such an approach is possible, and commentators have also addressed the GMF issue in terms of GATT requirements. The GATT provisions strive for equal treatment of imported goods through application of non-discrimination principles.[256] There are two aspects to these: (1) non-discrimination by an importing country among importers; and (2) non-discrimination between imported goods and domestic like-products.[257] A violation of either of these rules may provide the exporting country with a legitimate complaint under GATT

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[254] *See* Kennedy, *supra* note 87, at 84; John Stephen Fredland, Note, *Unlabel Their Frankenstein Foods!: Evaluating a U.S. Challenge to the European Commission's Labeling Requirements for Food Products Containing Genetically-Modified Organisms*, 33 VAND. J. TRANSNAT'L L. 183, 212 (2000) (reaching a similar conclusion).

[255] *See* Bentley, *supra* note 241, at 127.

[256] *Id.* at 81-82.

[257] *Id.*

rules.[258] The question would then arise whether the approval provisions discussed above are discriminating between "like" products or among importers. At least two commentators argue that in the case of GMF, there would be no discrimination, since a proper reading of GATT Article III (4) makes clear that GMF and traditional foods are not "like."[259] The argument is that the genetic modification creates a completely new product, which is correctly distinguished from the traditional product.[260]

There is also a health and safety exception to the GATT non-discrimination rules. Article XX provides a list of exceptions. In the case of the approval process for GMF, the importing country would most likely rely on GATT Article XX(b), the health and safety exception that was the forerunner of the SPS Agreement. The Article XX exception states:

> Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: b) necessary to protect human, animal or plant life or health. . . .[261]

The requirements for imposing the Article XX(b) exception are that it be "necessary," not discriminate arbitrarily, and not be a disguised restriction on international trade.[262] In order for a measure to be considered "necessary" it must be the least trade restrictive alternative available.[263] The question to be resolved would be whether the approval processes outlined above constitute unnecessary or discriminatory measures, or a disguised barrier to trade.

The arguments could conceivably take a number of different tacks. Many of the approval processes are modeled on the procedures required under the Protocol. It is open to question whether measures which comply with a multi-national environ-

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[258] *See* Kennedy, *supra* note 87, at 82.

[259] *See* Howse & Mavroidis, *supra* note 240, at 319-20; Gaston & Abate, *supra* note 27, at 143.

[260] *See* Gaston & Abate, *supra* note 27, at 143.

[261] *See* General Agreement on Tariffs and Trade, Oct. 30, 1947, art. XX(b), 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194 [hereinafter GATT].

[262] *See* Kennedy, *supra* note 87, at 82.

[263] *Id.*

mental treaty can be considered discriminatory, even against a country which is not a party to it. Regarded in this light, they would not be considered unilateral measures, which has been important to the GATT panels in the past.[264] The approval processes are designed to be rules and science based, which should eliminate the argument that they are discriminatory.[265] Certain commentators argue that such measures would be considered merely the operational requirements of a non-protectionist scheme for health regulation, and that there is no element of discrimination between domestic products and imports.[266] All GMF are regulated the same. Opponents of the approval requirements will certainly argue that since there is little or no domestic production of GMF in the regulating countries, the measures are clearly a disguised barrier to trade. By regulating only GMF, the importing countries are giving an unfair advantage to traditional domestic production.

The GATT practice has traditionally been to construe Article XX narrowly in favor of trade and against non-tariff barriers to trade.[267] Crucial issues will be whether the approval processes are considered discriminatory and whether the GMF are considered "like" traditional counterparts. It is thus possible that the approval measures could fail a challenge under GATT Article XX, but on balance, the approval processes should withstand the challenge.

4. *Labeling Requirements*

The labeling requirements which are the focus of this paper must be analyzed separately from the approval processes. None of the labeling regulations described are intended to prevent the introduction or spread of pests, diseases, etc. Nor are they intended to regulate or prevent the presence of contaminants, tox-

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[264] *See, e.g.*, WTO Appellate Body Report on U.S. Import Prohibitions of Certain Shrimp and Shrimp Products, WT/DS58/AB/R (Oct. 12, 1998), *available at* http://www.wto.org (WTO case involving U.S. restrictions on shrimp imports designed to protect endangered sea turtles from accidental harvesting. The WTO Appellate Body determined that the United States had the right under the WTO to regulate the conditions of shrimp harvesting in foreign waters, but ruled that the regulations adopted by the Department of Commerce constituted an impermissibly arbitrary and discriminatory exercise of that regulatory power).

[265] *See* Kennedy, *supra* note 87, at 83.

[266] *See* Howse & Mavroidis, *supra* note 240, at 320.

[267] *See* Kennedy, *supra* note 87, at 82.

ins, additives or disease-causing organisms. Unlike the *Hormones, Salmon*, and *Agricultural Products* cases, which cited specific dangers the measures in question sought to avert,[268] the regulations discussed above make no mention of any of these specifically. There is a common provision in each regulation that once the GMF is approved for sale or production within the country, it is presumed safe. Labeling is a separate issue done for different reasons.

The Swiss regulation is intended to prevent deceptive practices.[269] The purpose of the South Korean regulation is to provide information to consumers.[270] The only regulation with an overt reference to safety is the EU,[271] which requires a label if the novel food contains material not present in an equivalent food, and which may have health implications for certain sectors of the population.[272] This presumably refers to the allergenicity issue. The EU also states that its legislation is intended to prevent consumers from being misled.[273]

Based on the definition of sanitary measures in Annex A to the SPS, and the specific terms of the labeling regulations considered, it is doubtful that the SPS Agreement would apply to the labeling regimes proposed. The measures covered by the SPS Agreement are those intended specifically to combat disease, pests and the like, and to regulate toxins, additives, and contaminants.[274] The labeling provisions proposed do not address these issues, and are intended to serve a different purpose. The labeling provisions considered alone are not subject to the SPS Agreement, and also do not appear to be covered under the Article XX(b) exception of the GATT discussed above.[275]

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[268] *See* Hormones Appellate Body Report, *supra* note 245, paras. 1-8; Salmon Appellate Body Report, *supra* note 246, paras. 1-5; Agricultural Products Appellate Body Report, *supra* note 247, paras. 1-5.

[269] *See* Perrez, *supra* note 159, at 597.

[270] *See* James Lim, *South Korea Finalizes Guidelines for Labeling GMOs Starting Next Year*, 17 INT'L TRADE REPORTER 8, 710 (May 4, 2000).

[271] *See generally* Council Directive 90/220/EEC of 23 April 1990 on the Deliberate Release Into the Environment of Genetically Modified Organisms, 1990 O.J. (L 117) 15 (making labeling compulsory for all new products containing or consisting of genetically modified organisms).

[272] *Id.*

[273] *See* Novel Foods Regulation, *supra* note 169, art. 3.

[274] *See* SPS Agreement, *supra* note 90, Annex A.1.

[275] *See* Kennedy, *supra* note 87, at 84 ("If a measure is not intended to protect against one of these risks, then the measure is not an SPS measure").

This then raises the issue of whether the labeling regulations would be regulated under the TBT Agreement.

C. *Agreement on Technical Barriers to Trade*

To date, there have been no cases brought before the WTO under the TBT Agreement, which leaves a number of open questions as to its potential interpretation.[276] Not only has the TBT Agreement itself not yet been the subject of interpretation, its precursor, the Tokyo Round Agreement on Technical Barriers to Trade, was also never the subject of a ruling by a panel.[277] There is thus little indication how some of the more important provisions might be interpreted. The only case linked to the TBT Agreement is the *Asbestos* case, which was ultimately not decided on the basis of the TBT Agreement, but rather on GATT Article III(4) (discussed above).[278] However, comments by the Appellate Body in *Asbestos* give some insight into factors they might consider important in the future.

1. *Application of TBT Agreement*

The TBT Agreement applies to both industrial and agricultural products.[279] It covers technical rules related to product characteristics, processes, production methods, packaging, and labeling.[280] The TBT Agreement is intended to prevent such technical regulations from being a disguised barrier to trade.[281] Legitimate objectives to be achieved by technical regulations are listed in Article 2.2. These include: "protection of national security, prevention of deceptive practices, protection of human health or safety, animal or plant life or health, or the environment."[282] This is not a closed list, and other legitimate objectives are possible.[283] While health and safety are mentioned,

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[276] *See* WTO Appellate Body Report on European Communities – Measures Affecting Asbestos And Asbestos-Containing Products, WT/DS135/AB/R, para. 81, (Mar. 12, 2001), 40 I.L.M. 1193 (2001) [hereinafter Asbestos Appellate Body Report].

[277] *Id.*

[278] *Id.* paras. 192-93.

[279] *See* TBT Agreement, *supra* note 95, art. 1.3.

[280] *Id.* Annex 1.

[281] *Id.* pmbl.

[282] *Id.* art. 2.2.

[283] *Id.* (The objectives are listed as "inter alia," which implies that others are possible).

they are not the main focus of the TBT Agreement.[284] If the measures are designed solely to protect health and safety, then the SPS Agreement is the proper rule.[285] A regulation is defined in Annex 1.1 as a

> document which lays down product characteristics or their related processes and production methods, . . . with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method.[286]

The labeling regimes in question are mandatory, and they apply to both the product characteristics and to the production method of the GMF in question.[287]

From a textual standpoint, the TBT Agreement covers mandatory labeling requirements. They would be considered a technical regulation under the definition provided in Annex 1, Article 1. From the apparent intent of the various labeling framers as well, they should be considered technical regulations.

2. *Legal Requirements*

To conform with the TBT Agreement, a regulation must meet six legal criteria. First, imported products must be treated no less favorably than "like" domestic products, and "like" products from other countries.[288] Second, regulations must be no more trade restrictive than necessary to achieve their objectives.[289] Third, the regulations must be based on international standards, to the extent they exist or are imminent, unless they would not permit the achievement of the objectives sought.[290] If there is no standard, or the technical regulation in place derogates from it, there is a requirement to notify other members

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[284] *Id.*

[285] SPS Agreement, *supra* note 90, art. 1.1 ("This agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade"); *see also id.* Annex A, which defines in more detail SPS measures.

[286] *See* TBT Agreement, *supra* note 95, Annex 1.1.

[287] *Id.*

[288] *Id.* art. 2.1.

[289] *Id.* art. 2.2.

[290] *Id.* art. 2.4.

what the regulation requires.[291] Fourth, with a view to harmonizing measures, countries must recognize other members' measures as technically equivalent, if those measures meet the stated objectives.[292] Fifth, members shall ensure that all technical regulations adopted are promptly published.[293] Sixth, members are responsible for ensuring that all subsidiary governments conform to the TBT Agreement if they also set technical regulations.[294] In addition, members are responsible for ensuring that their government standard-setting bodies adhere to the Code of Good Practice for the Preparation, Adoption and Application of Standards.[295] Of these, only the first three are likely to be the object of dispute if a case is brought before the WTO. The remaining three are more housekeeping measures, and should not be cause for conflict.

3. *Application to Labeling Schemes*

The next point is consideration of the labeling rules discussed above, with regard to whether they meet the legal requirements of the TBT Agreement. In case of challenge, on what basis could they be overturned?

4. *Are They "Like"?*

"Likeness" of products will doubtless be one of the most difficult points argued. What is "like"? Is it substantial equivalence, or something else? There is no Panel or Appellate Body decision interpreting "likeness" under the TBT Agreement. However, "likeness" is a term that is used throughout the GATT, and the Appellate Body in *Asbestos* was at pains to discuss the concept of "likeness" in detail.[296] As the Panel hearing *Asbestos* declined to consider Canada's claims under the TBT Agreement, and made no findings of fact, the Appellate Body was unable to rule on potential violations of the TBT Agreement.[297] Although the Appellate Body did not consider "likeness" in the context of the TBT Agreement, the Appellate Body

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[291] *Id.* arts. 2.9 - 2.9.4.
[292] TBT Agreement, *supra* note 95, art. 2.7.
[293] *Id.* art. 2.11.
[294] *Id.* art. 3.
[295] *Id.* art. 4, Annex 3.
[296] *See* Asbestos Appellate Body Report, *supra* note 276, paras. 85-92.
[297] *Id.* paras. 81, 82.

did outline the criteria which it, and other panels, have used in determining whether products are "like."[298]

The Appellate Body began by determining that "likeness" has no specific definition, but must be determined through a case-by-case consideration of the provision which requires "likeness" and the circumstances which surround it.[299] "Likeness" is a flexible word, and expands and shrinks like an accordion depending on the context.[300] The Appellate Body rejected the ordinary (dictionary) meaning of "like," since it does not resolve three issues of interpretation: (1) which qualities or characteristics are important in assessing "likeness"; (2) the degree or extent to which products must share qualities or characteristics in order to be "like"; and (3) from whose perspective "likeness" is determined.[301]

The Appellate Body then noted an approach for analyzing "likeness" that was developed in the context of GATT, and subsequently followed and developed by several panels and the Appellate Body.[302] The approved approach uses four general criteria in analyzing "likeness": (1) the properties, nature, and quality of the products; (2) the end-uses of the products; (3) consumer's tastes and habits in respect of the products; and (4) the tariff classification of the products.[303] The Appellate Body elaborated on these categories, explaining that properties refers to physical properties, and that consumers' tastes means the extent to which consumers perceive and treat the products as alternative means of performing particular functions to satisfy a demand.[304] These criteria are interrelated.[305] The Appellate Body stressed that this is not the only means to approach "likeness," nor a closed list of considerations.[306] Nevertheless, it is apparently an approach accepted by many Panels and Appellate Bodies.[307] In the context of the *Asbestos* case, the Appellate

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[298] *Id.* para. 85.
[299] *Id.* para. 88.
[300] *Id.* para. 88 n.59.
[301] Asbestos Appellate Body Report, *supra* note 276, para. 92.
[302] *Id.* para. 104.
[303] *Id.* para. 85.
[304] *Id.* para. 101.
[305] *Id.* para. 102.
[306] *Id.*
[307] Asbestos Appellate Body Report, *supra* note 276, paras. 101, 102.

Body paid particular attention to the chemical composition of the products involved, which differed significantly, and to their differing levels of carcinogenicity.[308] This might give insight into how a Panel or Appellate body would view the underlying characteristics of GMF.

Whether GMF have similar physical properties to traditional foods of the same type will likely be vigorously disputed. It will be argued that the mere fact that there are proteins from foreign genes makes their physical characteristics very different. Indeed, the very reason they are bio-engineered is to have different physical characteristics. The fact that they are often patented also indicates that they are not "like" ordinary food of the same type, or they would not be unique enough to qualify for patent protection. The potential allergens and toxic elements they contain also indicates that their physical properties are not "like" traditional foods. Particularly, second generation GMF, which involve multiple gene transplants, are far removed from traditional counterparts.

The counter-argument will be that GMF are substantially equivalent to traditional foods of the same type. They have almost all of the same characteristics, indeed all of the key characteristics, and are simply enhanced. This is the position of the FDA in the United States, and the reason they are freely marketed there.[309] The TBT Agreement also requires that where possible, technical regulations should be based on product requirements in terms of performance, not characteristics.[310] The resolution of this will be a question of fact for the Panel.

Discussion of and resolution of whether substantial equivalence of GMF is accepted as the standard in Codex is an important consideration here. If substantial equivalence becomes the standard, then the "like" issue could be resolved against labeling countries. This highlights once again the importance of the Codex rules, and the intensity with which countries on different sides of this debate will attempt to influence the discussions in Codex.

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[308] *Id.* para. 114.

[309] *See* Emily Robertson, *Finding a Compromise in the Debate Over Genetically Modified Food: An Introduction to a Model State Consumer Right-to-Know Act*, 9 B.U. J. SCI. & TECH. L. 156, 159 (2003).

[310] *See* TBT Agreement, *supra* note 95, art. 2.8.

In regard to the second criteria, GMF are put to the same end-uses as traditional counterparts. There should be no dispute about this.

The third criteria, consumer perception, will also likely be a sticking point. The growing consumer demand worldwide for labeling indicates quite clearly that consumers do not perceive GMF and traditional counterparts as the same, and do not perceive GMF as an acceptable alternative to traditional food.[311] At the least, consumers wish to be able to distinguish between the two before making a purchasing decision. The counter-argument is that this is based on irrational fears and has nothing to do with the reality of the science behind GM products. The rules are not provided for consumers to make irrational decisions. Consumer perceptions need not be based in science, nor does there appear to be a rational basis criteria for consumer perceptions. In the *Asbestos* case, the Appellate Body did look at how consumers viewed the two products, at least from a relative safety standpoint, and noted that ultimate consumers may have a different view of a product's "likeness" than the inventor or producers of the product.[312]

The last criteria, tariff classification, does not appear likely to be disputed.

On balance, relying on criteria number one and three, a panel could justifiably find that GMF and traditional counterparts are not "like." If they are not "like," a claim under the TBT Agreement should fail. However, if other criteria are used, or these criteria are interpreted differently, and a finding of "likeness" is made, the question then becomes whether the regulation discriminates against "like" products.

5. *Are Genetically Modified Foods Discriminated Against?*

TBT Article 2.1 requires that "like" products be treated no less favorably than products of national origin, or like products originating from another country.[313] As discussed above,

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[311] Some chemical companies are recognizing this and are supporting voluntary labeling guidelines, to protect markets and soothe consumer fears. *See, e.g.*, Dilemma – Food Labeling, Monsanto, *at* http://www.monsanto.com/monsanto/layout/our_pledge/dialogue/food_labeling.asp (last visited Oct. 25, 2003); *see also* Asbestos Appellate Body Report, *supra* note 276, para. 102.

[312] *See* GATT, *supra* note 261, para. 92.

[313] *See* Asbestos Appellate Body Report, *supra* note 276, para. 87.

whether GMF will be considered "like" is open to doubt, based on both the physical characteristics and consumer perception criteria. However, the TBT also applies a non-discrimination test.

The labeling rules discussed above describe a uniform policy regarding all GMF, both domestic and imported. No distinction is made between imported GMF and domestic GMF, to the extent GMF is grown or produced domestically. For most of the regulatory schemes, the sole criteria which triggers labeling is the percentage threshold.

The labeling rules do treat GMF differently from traditional counterparts, by requiring labels on GMO status. The question is whether this is discrimination under the terms of the TBT Agreement. If a country requires only "GMF" labels, is it more discriminatory than if they allow both "GMF" and "GMO-free" labels on all food, because they are singling out only GMF? Under this analysis, the Swiss and the Japanese regulations would not be discriminatory. Under the EU rules, as well, GMO-free labels are acceptable but apparently not required. It has long been accepted practice under GATT rules that countries can require labeling of country of origin on food and other products.[314] Labels providing information about the environmentally friendly practices of the producer are permitted.[315] So are labels with information provided for religious purposes, such as kosher for observant Jews, hallal for devout Muslims or vegetarian for Hindus. If these are acceptable, an argument could be made that labels as to GMO status are also acceptable.

There is as yet no WTO panel interpretation of "treatment no less favorable," as defined in GATT Article III(4) solely in the context of the TBT. The GATT and WTO Panels and Appellate Bodies have discussed this requirement in the context of GATT Article III. While the text of the TBT Agreement appears to focus solely on the issue of protection of domestic product against

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[314] *See* GATT, *supra* note 261, art. IX.

[315] *See, e.g.*, FAQ, StarKist, *at* http://www.starkist.com/ (stating that StarKist will not purchase any tuna caught in association with dolphins or caught with devices, which are known to be dangerous to many forms of marine life, and that StarKist tuna is labeled with a special "Dolphin Safe" logo); Fishing For Answers, Bumble Bee, *at* http://www.bumblebee.com/faq.jsp (stating that all of Bumble Bee's tuna products are certifiably dolphin-safe, indicated by the "dolphin-safe" symbol).

imported competition, it is likely that a WTO Panel would interpret this requirement along the same lines as GATT Panels have done in the past. The requirements have traditionally been interpreted narrowly, in favor of trade and against non-tariff barriers.[316] The counter-argument is likely to be that since the regulating countries have little to no domestic production of GMF, the labels are a disguised barrier to trade, implemented to protect importing countries' domestic agriculture and products. It is thus possible that the labeling requirements could fail under this analysis. Only if the regulating countries can convince a panel that there is no discriminatory effect could the labeling requirements pass this hurdle.

6. *Least Restrictive Trade Measures*

The technical rules put in place must be the least trade restrictive possible to achieve the desired objective.[317] The stated objective of most of the regulations examined is to provide consumers with information about the food they buy and eat and, (for some countries) to provide safety and/or ethical information. By definition, labeling is the most likely means to provide such information to consumers; an alternative does not come to mind. If the TBT Agreement is interpreted similarly to the SPS Agreement, the burden of proof is on the complaining party to establish that there is another, less restrictive measure possible.[318]

Even if a label is the least restrictive measure, another question arises. How much information is required on a label? At what point is there too much information, and how much information do consumers really need to have? Would it be adequate merely to put the country of origin on the label, or would this harm those exporters who are GM free as well as those who are not? One argument made in favor of labels is that once consumers get accustomed to eating GM foods, their confidence in the products will grow; they would thus be a benefit to the GM industry. That some biotech companies are beginning to voluntarily label their products indicates they see the wisdom of this

316 *See* Kennedy, *supra* note 87, at 82.

317 *See* TBT Agreement, *supra* note 95, art. 2.2.

318 *See* Kennedy, *supra* note 87, at 87.

point.[319] Others ask whether such labels are not akin to a warning symbol on the product.[320]

The labeling requirement in many countries replaces a complete ban on GMO and GMF[321] and for others will provide for increased marketing of GM products.[322] Labeling could therefore be viewed as a measure promoting trade in GM products. It is unlikely a complaining party would succeed if challenging this provision.

D. *Conformance to International Standards*

The lack of labeling rules from Codex has already been discussed. Rules from Codex can hardly be said to be "imminent," since Codex only meets every two years. In the absence of international standards, members are forced to set their own standards. However, the SPS case law has shown that there are risks to this approach.

The labeling requirements studied vary in their approach. The Protocol requires the label "may contain GMO" for food or feed which is processed.[323] South Korea has implemented this standard. In the context of the TBT Agreement, the question also arises whether adherence to the Cartagena Protocol rules would qualify a country for the presumption of compliance discussed in TBT Article 2.4. As discussed above, the short answer is "most likely not." However, at least one commentator has argued that despite the savings clause, under a narrow interpretation the Protocol could prevail,[324] while others have also noted the necessity for clarifying the intersection of the WTO and multi-lateral environmental agreements.[325]

Many of the other labeling countries have gone beyond the Protocol standard in the level of detail they demand and the threshold imposed. TBT Article 2.4 allows members to derogate from international standards if they would be inappropriate or

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[319] *See e.g.,* Dilemma – Food Labeling, *supra* note 311.

[320] *See* Kennedy, *supra* note 87, at 81.

[321] *See* discussion *supra* Part II.

[322] *See Id.*

[323] Protocol, *supra* note 55, art. 18.

[324] *See* Gaston & Abate, *supra* note 27, at 120-22 (discussing Vienna Convention interpretation of the two treaties).

[325] *See* Kennedy, *supra* note 87, at 103.

ineffective in fulfilling the member's legitimate objectives.[326] Thus a country appears to be free to set a higher threshold than that required by international standards if necessary. Under what standard a Panel would interpret such a threshold is another open question under the TBT agreement, and underscores yet again the importance of leveraging the Codex standard-setting process to achieve a workable standard.

E. *Summary*

The TBT Agreement probably does apply. There is a textual argument to be made for its application. Labels are specifically mentioned as a technical regulation, and other labels are regulated here (nutrition, national origin, etc. . .), although there is no specific provision in the TBT for consumer rights. However, the list of objectives cited is not a closed list. There is an assumption by some opponents that the TBT Agreement applies. Issues likely to be litigated are discrimination of "like" products and international standards. There are also fundamental disputes about the extent of consumers' right to know. While the labeling regimes are declared to be for the benefit of consumers, labeling opponents argue that their purpose is merely to serve as a non-tariff barrier.

It is doubtful that opponents of labeling could prevail on the issue of "likeness," an issue which could prove to be decisive. Labels are more likely to be viewed as a non-tariff barrier, at least under the GATT jurisprudence to date. The lack of international standards makes it even more difficult to predict the outcome. The labeling rules as they are written appear designed to comply with the TBT Agreement, and on balance, should withstand a challenge.

IV. Conclusion

The issue of labeling GMF is politically divisive and likely to lead to trade frictions between countries which produce and export GMF and those importing countries which are attempting to restrict GMF. A potential dispute before the WTO looms. While often framed in terms of a conflict solely between the United States and the EU, in fact labeling regimes are in place

[326] *Id.* at 86.

in many other countries, and thus the scope of a potential conflict extends beyond a trans-Atlantic dispute. Consumers from many countries, including an increasing number in GMF-producing countries, are requiring more information about whether the food they eat contains GMF.

Which WTO rules would apply to such a dispute is uncertain, although either the SPS Agreement or the TBT Agreement would be implicated. The labeling rules examined in this paper appear to have been drafted to take account of the WTO case law to date, and to comply with multinational environmental treaties on GMF. The labeling schemes would likely not fall under the SPS Agreement, as at least facially, the rules are not designed to deal with health or safety-related issues. The TBT Agreement has never been applied in a WTO dispute situation, so many questions about its interpretation and application must remain open. A country disputing the validity of labeling regulations would challenge most successfully on grounds that they are a disguised barrier to trade. Based on prior GATT jurisprudence, however, and dicta from other cases, a country bringing a complaint against a labeling scheme could find a heavy burden of proof. The best defense for countries implementing labeling will be the issue of whether GMF are considered "like" traditional counterparts. Resolution of this question will turn largely on questions of fact and science presented to the Panel adjudicating. Physical properties and the underlying makeup of the product are likely to be significant. In addition, indications in the prior case law are that the WTO is inclined to give at least some weight to consumer views in regard to "likeness." This may well prove to be a critical factor, as the avowed purpose of the labeling rules is to provide consumers with the information they need to make an informed choice about the food they purchase.