

**Applying
World Trade Organization Rules
to Labeling of
Genetically Modified Food**

Michele Compton
Feb. 9, 2002

I. Introduction

- Current political context surrounding genetically modified organisms
- Distinction between genetically modified seeds and genetically modified food
- Recent history of regulation of genetically modified foods
- Potential trade conflicts involving genetically modified foods

II. Current State of GM Regulation

A. Multilateral approaches to and discussions of GMF

- UN Codex Alimentarius
- Cartagena Protocol on Biosafety to the Convention on Biological Diversity
- OECD Working Parties and discussions
- World Trade Organization Rules

B. Underlying principles

- Scientific Principle
- Precautionary principle
- Substantial equivalence

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

- Overview of measures adopted or proposed by
 - United States
 - Switzerland
 - European Union
 - Australia and New Zealand
 - Canada
 - South Korea
 - Brazil
 - Japan

III. Dispute before the World Trade Organization

A. Applicable Law

B. Agreement on Sanitary and Phytosanitary Measures

C. Agreement on Technical Barriers to Trade

IV. Conclusion

I. Introduction

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 protests 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 summer of 2001.

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. There is a widespread movement in many countries aimed at destroying GMO crops. Opponents cite concern for the long-term health effects of such products, and claim that the products are not adequately tested by independent scientists.¹ They also are concerned about destruction of bio-diversity, both of native plant species, and of animals and insects that feed on such crops.² Another concern frequently expressed is the lack of transparency of testing and regulation of such products.³ The movement is also motivated by antipathy to large multi-national corporations and their perceived growing control over agriculture and food.⁴ Concern for small farmers and moral reservations about manipulation of living things also play a role.⁵

Proponents of GMO and GMF cite studies which indicate that GMO are safe. Proponents also claim huge potential benefits for the world's poor and underdeveloped countries. GMO can be created which require less water, or grow in nutrient-poor soil. GMO can be made to be pest-resistant, thus requiring fewer pesticides and herbicides than traditional varieties, while producing much larger yields.⁶ GMO can also be created with heightened nutritional content, which proponents claim as a further benefit for the world's hungry and malnourished.⁷

Distinction between GMO and GMF

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. Scientists transplant the genes of one species into another to transfer desirable characteristics. GMF is food made from GMO. 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. This brings with it the danger of cross-pollination and the potential elimination of traditional and organic varieties, threatening bio-diversity. 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 GMO.⁸ Some GMO have been found to destroy beneficial fungus in the soil surrounding them.⁹ 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. GMF includes grains and other products such as corn (maize), wheat, rice, soybeans, sugar beets and rapeseed. 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. They have been modified for longer “shelf life”, slower ripening, resistance to freezing, resistance to pests and the like.¹⁰

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. They cite particular benefits for developing countries, which need to feed their hungry and often lack the technology which makes possible the productivity achieved by the developed world.¹¹

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.¹² Foremost is allergenicity, as when a gene from a product to which many people are allergic is inserted into another species.¹³ Another concern is toxicity, especially where the product has heightened vitamin content and the food is a staple of an area's diet.¹⁴ Creation of antibiotic resistance by consumption of antibiotic resistant food is yet another issue raised.¹⁵ 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.¹⁶ 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.¹⁷

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

A. Recent History of Regulation of GMF

The recent approach to regulation of GMF can be characterized as predominantly unilateral, with a fragmented international approach. One reason for this is the speed with which the technology has been developed and commercialized. The past ten years have seen a boom in the bio-technology industry and in the marketing of GMO and GMF.¹⁸ International fora have not kept pace with these developments, nor, in many instances, have the attitudes of consumers.¹⁹

The U.S. has been foremost in adopting the science, followed rapidly by other major grain-exporting countries, such as Brazil, Argentina and Canada. By 2001, 50 varieties of GM crops had been approved in the U.S. Millions of acres of cropland in the US are planted in GM crops.²⁰ Reports indicate the same for Brazil.²¹ 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, and also in part perhaps by a more cautious attitude to novel foods.²² 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.²³ The EU has imposed a complete ban on the import of any GM products since 1998. 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 import or commercialization of GMO and GMF.²⁴

International fora have begun to address the issues of GMF only relatively recently. One result of this 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 GMOs and GMF find themselves increasingly unable to export their products.²⁵ The largest and arguably most important potential dispute, and the one on which most commentary has centered, is between the US 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.²⁶ To analyze the potential outcome of such disputes, it is necessary to look in more detail at the current state of multilateral and national GM regulation.

II. Current State of GM Regulation

A. Multilateral approaches to and discussions of GMF

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 and the

WTO. Some potential regulations from 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 UN body which sets guidelines for food safety. It currently has working parties considering drafts on conducting risk assessments for foods derived from technology, and on food labeling.²⁷ As far as the Committee on Labeling of Foods Obtained through Biotechnology 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.²⁸ The Codex 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 US, 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)²⁹.

The Working Party 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. There is also strong concern for providing consumers with information about the food they eat, regardless of whether the food is considered healthy. The guidelines to the Working Party indicate that the overall objective is to facilitate consumer choice.³⁰

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.³¹ One concern voiced is whether the rules on labeling will be adopted by consensus, or by a majority vote. 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.³²

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

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity³³ (Protocol) was adopted in January 2000, with 67 countries and the EU as signatories. It is currently in the ratification process, and will come into effect after 50 countries have ratified it.³⁴ The US is not a party to the Protocol, although it was actively involved in the negotiation process.³⁵

The provisions of the Protocol refer primarily to seeds and agriculture, but there are provisions which also have relevance for GMF. The Protocol covers only live modified organisms (LMO), not processed foods, and as such will have limited application to regulation of GMO. 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 which are “intended as food or feed or for processing”.³⁶ Article 18 requires that GMOs 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. Although not denoted as such, the Protocol thus has established a labeling requirement for GMF which are commodities.³⁷ Annex II spells out what information must be contained in a required notification to a Biosafety Clearing House set up to monitor GMO. Countries are permitted to regulate GMO and GMF following a notification and decision-making procedure outlined in articles 8 through 12.³⁸ The Protocol specifically recognizes the precautionary principle, which is discussed below.³⁹

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.⁴⁰ However,

the Preamble also provides that “the above recital is not intended to subordinate this protocol to other international agreements.”⁴¹ 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 prevail⁴² The Protocol will apply to non-parties if they attempt to export to member parties,⁴³ which means that non-signatories such as the U.S. could be bound by the terms of the Protocol.

3. OECD Working parties and discussion

At the request of the G8, the OECD convened a conference on GM Foods in Edinburgh at the end of February, 2000. It included more than 400 participants from governments, non-governmental organizations, and industry.⁴⁴ 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.⁴⁵ 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. There was also continued disagreement about mandatory labeling of GMF, about the usefulness of feeding trials and on the process of assessing consumer concerns.⁴⁶

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. He also acknowledged areas of concern about testing. A review of the “substantial equivalence” tool was recommended, as was a re-examination of methods for testing GMF toxicity and allergenicity.⁴⁷

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. There is also specific mention of the need for greater post-market surveillance of GMF to assess potential human health issues.

OECD Working Group for the Harmonization of Regulatory Oversight in Biotechnology, reporting on environmental safety concerns regarding GM foods

OECD Ad Hoc Group on Food Safety, reporting on national and international measures to address current and emerging food safety issues

Summary reports from extensive consultations with Non-Governmental Organizations.⁴⁸

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

4. WTO Rules

The World Trade Organization'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. Founded after the Uruguay round of the GATT, the WTO was established by the Marrakesh Agreement Establishing the World Trade Organization.⁴⁹ The WTO is focused specifically on elimination of trade barriers. Its goals are non-discrimination, transparency, and a rules and science-based approach to resolution of trade disputes.⁵⁰ Harmonization of countries' trade measures is encouraged through reliance on international standards.⁵¹

The WTO rules establish a notification procedure, whereby countries notify the WTO Secretariat of potential measures which may directly or indirectly affect international trade. Other WTO members have the right to comment on such measures. Once the measures are in force, any country which 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 Panel 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.⁵² If the Panel or Appellate Body finds that a measure violates WTO trade rules, it recommends the nation concerned to modify the measure to bring it into compliance. If the country refuses, the affected exporting country is then justified in imposing retaliatory trade sanctions.⁵³

Two particular 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.⁵⁴ The SPS requires a scientific justification for the measure imposed, in the form of a risk assessment which is based on scientific evidence.⁵⁵ It encourages countries to follow international standards set by bodies such as the Codex Alimentarius.⁵⁶ If inadequate scientific evidence is available, the importing country may impose temporary measures.⁵⁷ In any event, the measure imposed may not case discriminate among countries, and must be the least trade-restrictive measure possible.⁵⁸

The Agreement on Technical Barriers to Trade⁵⁹ (TBT Agreement) applies to regulations and standards which regulate the production, processes, packaging, labeling, etc. of both agricultural and industrial products.⁶⁰ There are notice requirements to other members.⁶¹ Technical regulations may not discriminate between like products,⁶² and must not be more trade-restrictive than necessary to achieve their aims.⁶³ The TBT Agreement also encourages the use of international standards, as long as they are effective to achieve the importing country's objectives.⁶⁴ Members shall also, so far as possible, recognize other countries' regulations as equivalent.⁶⁵ Provision is made for deviation from some of the requirements when necessary to protect safety, health or the environment.⁶⁶ Members are required to adhere to a Code of Good Practice for the Preparation, Adoption and Application of Standards.⁶⁷

While many of their provisions are mirror images, the two Agreements are mutually exclusive. A measure cannot fall under both Agreements simultaneously.⁶⁸

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 verifiable⁶⁹. In multi-lateral regulation of GMF, the scientific principle is expressed as the requirement for a risk assessment based on sound science. All of the multi-lateral fora discussed above require some form of risk assessment or science-based approach.⁷⁰ Risk analysis includes three components: risk assessment, risk management and risk communication.

Risk analysis is a scientific assessment of the probability of risk, including determining what adverse effects could occur, and what the magnitude of the consequences could be.⁷¹ 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.⁷² 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.⁷³ Risk analysis is the subject of working committees to standardize approaches and assist developing countries with the technical aspects.⁷⁴

The second component is risk management, defined as the process of identifying, evaluating, selecting and implementing actions to reduce risk.⁷⁵ Risk management involves a decision regarding the acceptable level of risk, or what level of protection is deemed appropriate.⁷⁶ This decision is a sovereign one involving domestic considerations of policy.

Under SPS rules, countries are largely free to choose their acceptable level of risk, within the constraints of the SPS rules.⁷⁷ One goal of the SPS Agreement is harmonization of member countries' approaches to both risk assessment and risk management.⁷⁸ One way the SPS Agreement attempts to achieve this is strongly to promote reliance on rule making bodies such as Codex Alimentarius.⁷⁹ 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.⁸⁰ In the context of food safety, the European Union defines risk communication as making scientific opinions available as quickly and widely as possible. 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.⁸¹ One commentator argues strongly that adoption of science policies would increase transparency of the decisions underlying risk management, and this could also serve as risk communication.⁸²

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 law⁸³ and is an important principle in the Cartagena Protocol.⁸⁴ 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.⁸⁵ It may be described as a derogation from the scientific principle.

The European Union, among others, relies on this principle⁸⁶, while the U.S., among others, opposes its use in trade disputes over food safety.⁸⁷ The EU regards use of the precautionary principle as part of risk management, in determining how much risk is tolerable.⁸⁸ According to the EU, the precautionary principle plays no role in risk analysis, which must be science based.⁸⁹ Rather, the precautionary principle comes into play where the political decision must be made as to the acceptable level of risk. 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 factors) and examination of scientific developments.⁹⁰ The Codex Committee on General Principles is currently working on harmonization of the definition and application of the precautionary principle.⁹¹

3. Substantial equivalence.

The third principle often used to assess food safety is that of substantial equivalence. This concept is endorsed by the FAO and WHO of the United Nations, and favored by the OECD. 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.”⁹² One compares the trait encoded by the genetic modification, and compares it to an appropriate comparator in the traditional food.⁹³ Establishing the similarity to a traditional food which is safe indicates that the new food will also be safe. OECD views this approach as the most practical in assessing GMF for food safety.⁹⁴

Establishing substantial equivalence does not automatically mean that a novel food is safe, however. Substantial equivalence is not a safety assessment *per se*.⁹⁵ 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 be established, a testing program would have to be implemented on a case-by-case basis.⁹⁶

Substantial equivalence as a standard is under discussion in the Codex Alimentarius Committee on Food Labeling, with the US as a proponent.⁹⁷ Opponents of substantial equivalence point to the very fundamental difference of the product which contains DNA protein from another species. 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.⁹⁸

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 in brief below.

United States

The US 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 Department of Agriculture has responsibility for GM plants.⁹⁹ With respect to

GMF, in 1992 the FDA published its “Statement of Policy: Foods Derived from New Plant Varieties”.¹⁰⁰ 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. The company itself does the safety testing, and informs the FDA of its scientific and regulatory assessment of the food. FDA evaluates the submissions and if there are no difficulties noted, the product may be freely commercialized. Labeling is required only in exceptional circumstances, if the food differs significantly from the traditional variety. As of July 2001, the FDA website listed 50 GMF authorized for production and sale. The official FDA policy is that GMF are safe, unless proven otherwise. Companies conduct research, notify the FDA if there appear to be any problems, and bring their products to market.

In response to growing concerns among American scientists and consumers, in November 1999 the FDA convened public discussions about GMF.¹⁰¹ 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 producers¹⁰². However, there is growing public pressure for labeling in the US. Bills have been introduced in Congress to require mandatory labels.¹⁰³ Companies are beginning to label their products “non-GMO” in response to consumer demand.¹⁰⁴ The FDA has warned five natural food companies that their “GMO-free” labels are misleading consumers.¹⁰⁵ There is currently no approved text from FDA on what a label could say.¹⁰⁶ 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.¹⁰⁷

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

Switzerland

Switzerland appears to have been the earliest country to impose a comprehensive approval and labeling regime for GMF. In a 1992 referendum¹⁰⁸, the Swiss approved a constitutional amendment regulating GMO and providing a regulatory framework.¹⁰⁹ 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.¹¹⁰ 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.¹¹¹ 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 1% GMO.¹¹² The reason given is to prevent deceptive practices and to allow consumers choice of what they eat.¹¹³ 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 1% 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.¹¹⁴ 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% free of GM contamination.¹¹⁵

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. The labeling requirements are designed to prevent deceptive practices and provide choice to consumers.¹¹⁶

European Union

The European Union has passed legislation requiring mandatory labeling for GMF.¹¹⁷ It requires pre-marketing notification to the country of import before the product is placed on the market. Approval is based on an assessment of risk. A product must be considered “safe” to be imported. The scientific data needed for assessment is to be provided by the seller. Once a product is approved for sale by one EU member, it is free to circulate throughout the EU.

GMF food products approved for sale in the EU require labels. Labeling requirements are intended to provide information to consumers,¹¹⁸ for health reasons,¹¹⁹ for ethical reasons¹²⁰ and to prevent them from being misled.¹²¹ A label is required if the GMF is no longer equivalent to an existing food or ingredient, as determined by a scientific assessment, if the food contains GMO that may have health implications for parts of the population, or may cause ethical concerns.¹²² There does not appear to be a minimum threshold of GMO that trigger the labeling requirement. The criteria is whether the novel food is “no longer equivalent” to the existing food. In this case, a label is required. “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.¹²³

Negative labels are permitted. Food that does not contain GMO may be labeled as such.¹²⁴

New Zealand/Australia

The two countries have a Joint Food Safety Regulation which forms a comprehensive program regulating GMO and GMF in both countries.¹²⁵ 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.¹²⁶ Prior to convening the Royal Commission, no GMO or GMF had been approved for release. During the

study, a voluntary moratorium on introduction of GMO and GMF was in place. 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. These included human health, environmental concerns, including biodiversity, and cultural and ethical concerns, with particular reference to ethical concerns of indigenous peoples.¹²⁷

The Commission ended in July of 2001 and legislation in New Zealand regarding GMF has been passed. Regulation regarding GMF and GMO in New Zealand is governed by a number of laws, with different agencies having oversight over different areas.¹²⁸ These include the Hazardous Substances and New Organisms (HSNO) Act of 1996, which is intended to protect the environment and health of New Zealanders.¹²⁹

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.¹³⁰ If it contains a live GMO, such as a tomato with seeds, it must also be approved by the environmental agency.¹³¹ The food labeling rules came into effect in December 2001. As of December 7, 2001, any food that contains more than 1% genetically modified material must be labeled identifying its GM status.¹³² Food already in stores need not be retroactively labeled, nor must food sold in restaurants be labeled. The exemption also includes highly refined foods where refining removes novel DNA and/or protein. By December 7, 2002, any food with GM ingredients must be labeled.¹³³ The labeling regime is considered by New Zealand to be in line with that of the European Union.¹³⁴

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 2001,¹³⁵

despite its support by the Canadian Minister of Health.¹³⁶ The bill would have required labeling for any food containing more than 1% genetically modified ingredients.¹³⁷ 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.¹³⁸

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.¹³⁹ The Canadian Wheat Board (CWB) has recommended a moratorium on introduction of GM wheat in Canada, largely to protect potential markets.¹⁴⁰ The CWB's position statement acknowledges consumer concern, and that overseas customers have expressed a disinclination to purchase GM wheat. The inability to adequately segregate GM grain from traditional varieties plays an important role. The CWB is working with the government committee developing voluntary labeling rules.¹⁴¹ A broad coalition of groups in Canada supports this position. Its members include the National Farmers Union, the Keystone Agricultural Producers of Manitoba and Greenpeace of Canada.¹⁴² 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.

South Korea

South Korea implemented a labeling regime for GMF which came into effect on March 1, 2001. The regulations are designed to implement South Korea's commitment to the Cartagena Protocol.¹⁴³ The law follows the Protocol's "may contain" rule for possible GMO content.¹⁴⁴ The law makes approval mandatory for the importation, production or research of GMOs. 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.¹⁴⁵ The same provision applies to processed

foods based on GM beans, corn and bean sprouts as of July 2001. As of March, 2002, potatoes are also included.¹⁴⁶ According to the Ministry of Agriculture and Forestry, the purpose of the rule is to provide consumers with information on agricultural products,¹⁴⁷

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.¹⁴⁸ 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.¹⁴⁹ Despite such rulings, Brazil's agriculture minister is apparently finalizing plans to approve commercial use of five different types of GM soy.¹⁵⁰ His announcement prompted a warning from a federal judge that such products are still currently banned in Brazil.¹⁵¹ Other news reports indicate that there are large plantings of illegal GM grains in the growing areas of Brazil.¹⁵²

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 4%.¹⁵³ This decree was immediately challenged in court by the government's attorney general and a consumer group, as violating the Brazilian consumer defense code. The reason given was that it does not provide enough information or protection.¹⁵⁴ 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 US, Argentina and other growing countries in negotiations on labeling and regulation of GM foods.

Japan

Japan implemented a labeling program for GM foods as of April 1, 2001.¹⁵⁵ 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.¹⁵⁶ 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. In addition, 24 kinds of processed foods derived from these ingredients, such as tofu and bean curd, must also be labeled.¹⁵⁷ US-grown tomatoes will be included next.¹⁵⁸

Labels must state GM-free, GMO foods, unknown or undecided.¹⁵⁹ The threshold for being “GM-free”, for corn and soy products, is 5%. Anything over 5% requires a GMO foods label.

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.¹⁶⁰ The safety inspection is to be provided by third parties before the food is exported, and the Japanese Ministry of Health and Welfare will conduct spot audits to determine compliance.¹⁶¹

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 GM ingredients or GM processes.¹⁶² China, Taiwan, Russia, South Africa and Mexico are also mentioned in news reports as beginning to consider labeling for GMF.¹⁶³

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 1% to 5%, 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. The result of any dispute between GMF exporting countries and importing countries requiring labeling is thus 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.¹⁶⁴ 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.¹⁶⁵ Yet another discusses labeling requirements solely under GATT Art XX (b) and (g).¹⁶⁶ In discussing the potential of relying on GATT XX or GATT III, other commentators cite the principle of *lex specialis*, and argue that therefore the SPS Agreement would apply.¹⁶⁷ At least one official in the United States appears to assume that a challenge would be brought under TBT rules.¹⁶⁸

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 in Codex. The Cartagena Protocol has also provisions for labeling, but it is generally considered unlikely this would be considered an international standard on which labeling countries could rely, assuming they are signatories.¹⁶⁹ Some regulatory schemes, for instance South Korea's, are drafted to comply 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 whether they would withstand a challenge under either the SPS Agreement or the TBT Agreement.

B. SPS Agreement

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*¹⁷⁰ (*Hormones*), in 1998; *Australia – Measures Affecting Importation of Salmon*¹⁷¹ (*Salmon*), also in 1998, and *Japan – Measures Affecting Agricultural Products*¹⁷² (*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, *Agricultural Products* concerned a phytosanitary measure to protect plants against pests. Many of the same issues were litigated in all three cases, and there is thus 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. The measures taken were also not based on the risk assessment that was performed.¹⁷³

Application of SPS Agreement

A threshold issue is whether the SPS Agreement applies to labeling regulations intended primarily for consumer information purposes. Art. 1.1 of the SPS states that it applies to “all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade.”¹⁷⁴ 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 plant 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.¹⁷⁵

The SPS 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.¹⁷⁶ 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, 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 is generally stated to be to allow consumer choice, provide consumer information, health information or information for those with religious or ethical considerations.

Approval Processes

Proceeding from the definition provided in Annex A, it is open to discussion whether the approval regulations fall under the SPS Agreement.¹⁷⁷ 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 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 measures are not intended to protect against one of the named risks, then the measure is not an SPS measure.¹⁷⁸

The most likely definition of GMO would be as an additive, if a Panel wanted to view the definitions expansively.¹⁷⁹ 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.

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.¹⁸⁰ 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.¹⁸¹ A violation of either of these rules may provide the exporting country with a legitimate complaint under GATT rules.¹⁸² 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 art. III (4) makes clear that GMF and traditional foods are not “like”.¹⁸³ The argument is that the genetic modification creates a completely new product, and is thus correctly distinguished from the traditional product.

There is also a health and safety exception to the GATT non-discrimination rules. Art XX provides a list of exceptions. In the case of the approval process for GMF, the importing country would most likely rely on GATT art. XX(b), the health and safety exception that was the forerunner of the SPS Agreement. The art. 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....¹⁸⁴

The requirements for imposing the art. XX (b) exception are thus that it be “necessary”, not discriminate arbitrarily and not be a disguised restriction on international trade.¹⁸⁵ In order for a measure to be considered “necessary” it must be the least trade restrictive alternative available.¹⁸⁶ 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 environmental 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.¹⁸⁷ The approval processes are designed to be rules and science based, which should eliminate the argument that they are discriminatory. 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.¹⁸⁸ All GMF are regulated the same. Opponents of the approval requirements will certainly argue that since there is little to 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 domestic traditional production.

The GATT practice has traditionally been to construe Art XX narrowly in favor of trade and against nontariff barriers to trade. 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 art. XX, but on balance, the approval processes should withstand the challenge.

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 is intended to prevent the introduction or spread of pests, diseases etc. Nor are they intended to regulate or prevent the presence of contaminants, toxins, additives or disease-causing organisms. Unlike the *Hormones, Salmon and Agricultural Products* cases, which cited specific dangers the measures in question sought to avert, 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.¹⁸⁹ The purpose of the South Korean regulation is to provide information to consumers.¹⁹⁰ The only regulation with an overt reference to safety is the EU¹⁹¹, 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.¹⁹² This presumably refers to the allergenicity issue. The EU also states that its legislation is intended to prevent consumers from being misled.¹⁹³

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. 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 art. XX(b) exception of the GATT discussed above.¹⁹⁴ This then raises the issue of whether the labeling regulations would be regulated under the TBT Agreement.

C. TBT Agreement

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.¹⁹⁵ 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.¹⁹⁶ 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 art. III:4 (discussed above) However, comments by the Appellate Body in *Asbestos* give some insight into factors they might consider important in the future.

Application of the TBT Agreement

The TBT Agreement applies to both industrial and agricultural products.¹⁹⁷ It covers technical rules related to product characteristics, processes, production methods, packaging and labeling.¹⁹⁸ The TBT Agreement is intended to prevent such technical regulations from being a disguised barrier to trade.¹⁹⁹ Legitimate objectives to be achieved by technical regulations are listed in Art. 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”.²⁰⁰ This is not a closed list, and other legitimate objectives are possible.²⁰¹ While health and safety are mentioned, these are not the main focus of the TBT Agreement. If the measures are designed solely to protect health and safety, then the SPS Agreement is the proper rule.²⁰² Regulations are defined in Annex 1, Art. 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.²⁰³

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.

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, Art. 1. From the apparent intent of the various labeling framers as well, they should be considered technical regulations.

Legal Requirements

To conform to 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.²⁰⁴ Second, regulations must be no more trade restrictive than necessary to achieve their objectives.²⁰⁵ 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.²⁰⁶ If there is no standard, or the technical regulation in place derogates from it, there is a requirement to notify other members what the regulation requires.²⁰⁷ Fourth, with a view to harmonizing measures, countries must recognize other members’ measures as technically equivalent, if those measures meet the stated objectives.²⁰⁸ Fifth, members shall ensure that all technical regulations adopted are promptly published.²⁰⁹ Sixth, members are responsible for ensuring that all subsidiary governments conform to the TBT Agreement if they also set technical regulations.²¹⁰ 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.²¹¹ 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.

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?

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. 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.²¹² Although the Appellate Body did not consider “likeness” in the context of TBT Agreement, the Appellate Body did outline the criteria which it, and other panels, have used in determining whether products are “like”.

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. “Likeness” is a flexible word, and expands and shrinks like an accordion depending on the context. 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.²¹³

The Appellate Body then noted an approach for analyzing “likeness” that was developed in the context of GATT, and followed and developed by several panels and the Appellate Body since.²¹⁴ The approved approach uses four general criteria in analyzing “likeness”: i) the properties, nature and quality of the products; ii) the end-uses of the product; iii) consumer’s tastes and habits in respect of the products and iv) the tariff classification of the products.²¹⁵ 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.²¹⁶ These criteria are interrelated.²¹⁷ The Appellate Body stressed that this is not the only means to approach

“likeness”, nor a closed list of considerations. Nevertheless, it is apparently an approach accepted by many panels and Appellate Bodies.²¹⁸ In the context of the *Asbestos* case, the Appellate Body paid particular attention to the chemical composition of the products involved, which differed significantly, and to their differing levels of carcinogenicity. 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 US, and the reason they are freely marketed there. The TBT Agreement also requires that where possible, technical regulations should be based on product requirements in terms of performance, not characteristics,²¹⁹ and GMF “perform” the same as traditional counterparts. 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.

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.²²⁰ At the least, consumers wish to be able to distinguish between the two before making a purchasing decision. The counterargument 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 this could be significant, and noted that ultimate consumers may have a different view of a product's "likeness" than the inventor or producers of the product.²²¹ .

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.

Are GMF discriminated against?

Article 2.1 TBT requires that "like" products be treated no less favorably than products of national origin, or like products originating from another country. As discussed above, 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. The only criteria most of the regulatory schemes have for labeling seems to be the percentage threshold which triggers labeling. The EU requires labeling only for products not substantially equivalent, but again does not discriminate between domestic or imported GMF.

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. Labels providing information about the environmentally friendly practices of the producer are permitted.²²² 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 less favorable”, solely in the context of the TBT. The GATT and WTO Panels and Appellate Bodies have discussed this requirement in the context of GATT art. III. While the text of the TBT Agreement appears to focus solely on the issue of protection of domestic product against 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.²²³ The counterargument 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.

Least restrictive trade measure

The technical rules put in place must be the least trade restrictive possible to achieve the desired objective.²²⁴ The stated objective of most of the regulations examined is 1) 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.²²⁵

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 that they see the wisdom of this point. Others ask whether such labels are not akin to a warning symbol on the product.²²⁶

The labeling requirement in many countries replaces a complete ban on GMO and GMF²²⁷, and for others will provide for increased marketing of GM products. 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.

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.²²⁸

The labeling requirements studied vary in their approach. The Protocol requires that food or feed to be processed be labeled “may contain GMO”.²²⁹ 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,²³⁰ while others have also noted the necessity for clarifying the intersection of the WTO and multi-lateral environmental agreements.²³¹

Many of the other labeling countries have gone beyond the Protocol standard in the level of detail they demand and the threshold imposed. TBT Art 2.4 allows members to derogate from international standards if they would be inappropriate or ineffective in fulfilling the member’s legitimate objectives. 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.

Conclusion

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 “like, “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.

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 US and the EU, in fact labeling regimes are in place 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.

¹ See generally the Consumers Council Website, www.consumerscouncil.org and links there to other anti-GMO and Green websites, databases and news articles. (visited 8/28/2001). See generally also www.citizen.org, another website devoted to consumer awareness and opposition to GMO and GMF.

² Id. John E. Losey et al, *Transgenic Pollen Harms Monarch Larvae*, 399 *nature* 214, (May 20, 1999), cited by many, including Brett Grosko, *Genetic Engineering and International Law; Conflict or Harmony? An Analysis of the Biosafety Protocol, GATT and the WTO Sanitary and Phytosanitary Agreement*, 20 *Va. Env'tl. L.J.* 295 (2001) at FN 39. The Monarch butterfly study itself generated controversy, with other researchers coming up with other findings.

³ Id.

⁴ See generally Consumers Council, *supra* note 3; George E.C. York, *Global Foods, Local Tastes and Biotechnology: the New Legal Architecture of International Agricultural Trade*, 7 *Colum.J.Eur.L.* 423, 432 (2001); Sean D. Murphy, *Biotechnology and International Law*; 42 *harv. Int'l L.J.* 47, 65 (2001)

⁵ Dorothy Nelkin, Philippe Sands, Richard B. Stewart, *The International Challenge of Genetically Modified Organism Regulation*, 8 *N.Y.U. Env'tl. L.J.* 527 (2000)

⁶ Murphy at 55-56 (2001); York at 429-431

⁷ Id.

⁸ See, e.g. *U.S. News and World Report*, Feb 4, 2002, “Bad Seeds in Court”, regarding a lawsuit by an organic farmer whose crops are contaminated by GM canola; *BBC News Online*, 11/29/2001 about the contamination of Mexican wild maize, considered the birthplace of maize, by GM plant varieties; Murphy at 58, generally Consumers Council website (*supra*).

⁹ Murphy at 90

¹⁰ See FDA website for a complete list of genetically modified foods approved for commercialization in the U.S. www.fda.gov and links there.

¹¹ York at 431

¹² Murphy at 57; for an in-depth discussion of a multiplicity of concerns see OECD Report of Task Force for the Safety of Novel Foods and Feeds (hereafter OECD Report), at OECD website, www.oecd.org, visited 10/11/2001; and Gretchen Gaston and Randall S Abate, *The Biosafety Protocol and the World Trade Organization, Can the Two Coexist?*, 12 Pace Int'l L. Rev. 118 (2000)

¹³ One example is Brazil nut genes in tomatoes. People allergic to nuts would not normally look for danger in eating tomatoes.

¹⁴ OECD Report

¹⁵ Id.

¹⁶ OECD Report of the Task Force for the Safety of Novel Foods and Feeds, C(2000)86/ADD1, 17 May 2000, at para. 128,

¹⁷ Id.; Nelkin at 527-28

¹⁸ Kim Brooks, *History, Change and Policy: Factors Leading to Current Opposition to Food Biotechnology*; 5 Geo. Public Pol'y Rev. 159 (2000), 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.

¹⁹ Id.

²⁰ In the US in 2000, 52% of approximately 75 mio acres of soybeans, 56% of approximately 15.5 mio acres of cotton and 25% of approx. 78 million acres of corn are planted with GM crops.

Murphy at 55.

²¹ *Paper Slams GM-free Claim*, Farming News, June 21, 2001, 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 top 3.5 mio acres (45% of total crops) in 20 01, "whether or not it is authorized." The attraction for Brazilian farmers is the reduced cost of herbicides to grow GM crops.

²² Nelkin at 161

²³ See below for more information on individual countries' regulatory schemes.

²⁴ Id.

²⁵ 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*, PR Newswire, May 31, 2000. In marketing years 1998-1999, corn exports from the US to Europe stood at 2 mio 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 mio tons to 6 mio tons. *Argentina Accuses Europe of Protectionism in GM Debate: Commodities*. Lloyd's List, June 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 m tones of soy. Argentina also uses GM corn seeds extensively

²⁶ *Bush Administration Threatens EU on New GE Food Labeling Law*, The Washington Post, Aug 26, 2001

²⁷ Codex Working Party Reports 01/22 – 28th Session (Chiba, Japan, March 2001), and 01/22A – 29th Session, Ottawa, Canada, May 2001. www.codexalimentarius.net (visited 4/7/2001)

²⁸ Id.

²⁹ Id.

³⁰ Id.

³¹ The US 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. James F. Smith, *From Frankenfoods to Fruit Flies: Navigating the WTO/SPS*, U.C.Davis Journal of Int'l L & Pol., 6:1 at 17(2000). 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.

³² 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, this article provides an in-depth discussion of the role of the international standards in the functioning of the WTO agreements.

³³ Cartagena Protocol on Biosafety to the convention on biological diversity, 26 Feb 2000; hereinafter "Protocol", available on the United Nations website, www.unitednations.org

³⁴ Art. 37 Protocol

³⁵ 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. Env't'l L.J. 129 (1999)

³⁶ Art. 18, Protocol, Annex II, Protocol

³⁷ This issue was apparently very divisive for many in the negotiations for the Protocol. See Tracy, note 35, supra, for a discussion of the positions taken and compromises made. Gareth W. Schweizer, *The Negotiation of the Cartagena Protocol on Biosafety*, 6 Env't'l. Law. 577, 600 (2000) states unequivocally that importers have the option to label commodities as containing LMOs and consumers may thus choose whether to purchase them.

³⁸ Id.

³⁹ Preamble, Protocol; Article 11,

⁴⁰ Preamble, Protocol; Jonathan A. Glass, *The Merits of Ratifying and Implementing the Cartagena Protocol on Biosafety*, 21 J. Intl. L. Bus. 491, 510 (2001)

⁴¹ Preamble to Cartagena Protocol on Biosafety to the Convention on Biological Diversity

⁴² For a discussion of whether the WTO or the Protocol would prevail, an issue that goes beyond the scope of this paper, see Gaston and Abate, supra.

⁴³ Art 24 Protocol

⁴⁴ News Release, Paris, March 1, 2000, found at OECD, website www.oecd.org/media/release (visited 10/11/2001)

⁴⁵ Id.

⁴⁶ Id.

⁴⁷ Chairman's Report on OECD GM Food Safety Conference, Paris, 7 April, 2000, on OECD website, www.oecd.org/media/release (visited 10/11/2001)

⁴⁸ Id.

⁴⁹ James F. Smith, *From Frankenfoods to Fruit Flies: Navigating the WTO/SPS*, 6:1 U.C.Davis J. Internat'l L. & Pol. 3 (2000)

⁵⁰ Marrakesh Agreement Establishing the World Trade Organization at WTO website, www.wto.org

⁵¹ Kevin C. Kennedy, *Resolving International Sanitary and Phytosanitary Disputes in the WTO: Lessons and Future Directions*, 55 Food Drug L.J. 81,85 (2000)

⁵² Id.

⁵³ E.g., the U.S against the E.U, after the E.U refused to modify its ban on import of beef treated with hormones, at a cost of \$116.8 mio. York at 461.

⁵⁴ Agreement on the Application of Sanitary and Phytosanitary Measures, (SPS Agreement), available on the WTO website: www.wto.org (visited 10/11/2001); GATT Secretariat, the Results of the Uruguay Round Trade Negotiations, The Legal Texts 5, 5-19 (1994); 33 I.L.M. 1140, Annex 1A (1994)

⁵⁵ Art. 2.2, SPS Agreement

⁵⁶ Art 3.1 and 3.2, SPS Agreement

⁵⁷ Art. 5.7, SPS Agreement

⁵⁸ Art. 2.3, Art. 5.5 and 5.6, SPS Agreement

⁵⁹ Agreement on Technical Barriers to Trade (TBT Agreement), www.wto.org (visited 10/11/2001)

⁶⁰ Art. 1.3; Annex 1, TBT Agreement

⁶¹ Art. 2.9, 2.91, 2.92, 2.93, 2.94 TBT Agreement

⁶² Art. 2.1 TBT Agreement

⁶³ Art. 2.2 TBT Agreement

⁶⁴ Art. 2.4 TBT Agreement

⁶⁵ Art. 2.7 TBT Agreement

⁶⁶ Art. 2.10 TBT Agreement

⁶⁷ Art. 4 and Annex 3, TBT Agreement

⁶⁸ Kennedy at 91

⁶⁹ Vern R. Walker, *Keeping the WTO from Becoming the "World Trans-science Organization": Scientific Uncertainty, Science Policy, and Factfinding in the Growth Hormones Dispute*; 31 Cornell Int'l L.J. 252 (1998)

⁷⁰ Codex Working Principles for Risk Analysis, Codex website, supra.; OECD Report of the Task Force for the Safety of Novel Foods and Feeds, C(2000)86/ADD1; WTO Summary Report on the SPS Risk Analysis Workshop, 19-20 June 2000, G/SPS/GEN/209 (hereafter WTO Summary Report) at www.wto.org; Cartagena Protocol Art. 15

⁷¹ WTO Summary Report para. 12

⁷² Id.; Walker at 258.

⁷³ Walker at 258; WTO summary report at para 17-18.

⁷⁴ See, e.g. WTO Summary Report further links at WTO website

⁷⁵ Walker at 256

⁷⁶ Id.; SPS Summary Report para. 14.

⁷⁷ SPS Agreement Art 5.5; Walker at 270-271

⁷⁸ Walker at 256; SPS Summary Report para. 9 & 14; Walker at 272-274.

⁷⁹ WTO Summary Report para. 9 & 10; Walker at 272-274.

⁸⁰ Commission of the European Communities, *White Paper on Food Safety*, Brussels, 12 January 2000, G/SPS/GEN/169, (hereafter White Paper on Food Safety)

⁸¹ *White Paper on Food Safety*, at page 17, para 17 and 96

⁸² Walker at 260, 270-271. Science policies are "default assumptions". An example of a science policy would be "An additive that causes cancer in animals is not safe for humans".

⁸³ See: Dr. Hans-Joachim Priess and Dr. Chistian Pichas, *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*, at Bridges website,, discussing the origins in German environmental law of 1968.

⁸⁴ Protocol Preamble with reference to Art 15 of the Rio Declaration on Environment and Development.

⁸⁵ Priess, 520-21

⁸⁶ White Paper on Food Safety, p 5 and page 11

⁸⁷ U.S., *Europeans Pledge to Continue Work on Applying Precautionary Principle* 17 ITR, No 16, p. 619, 4/20/2000; *Draft U.S. Positions on Risk Analysis Biased toward Trade, Consumer Group Comments*, 17 ITR No.27,p.1041, July 6, 2000; *U.S. Expects Codex Discussion on Proposal to Trace Biotech Crops*, 18 ITR No 8, p. 304, Feb 22, 2001, discussing the various controversial issues before the Codex Committees, including the precautionary principle.

⁸⁸ Priess at 520.

⁸⁹ Id.

⁹⁰ Priess at 533

⁹¹ See Codex site for details, www.codexalimentarius.net, visited 4/7/2002

⁹² OECD report para 84.

⁹³ Id at para 82

⁹⁴ Id at para 83

⁹⁵ Id at para. 84

⁹⁶ Id. at para. 84-85.

⁹⁷ Report of the 28th Session of the Codex Report on food Labeling, Ottawa, Canada, 5-9 May 2000, www.fao.org/codex/ALINORM01 (visited 4/7/2002)

⁹⁸ Mathew Stilwell and Brennan Van Dyke, *An Activist's Handbook on Genetically Modified Organisms and the WTO*, Center for International Environmental Law, July 1999, found at www.consumerscouncil.org/policy/handbk799 (visited 8/28/2001)

⁹⁹ See the USDA website for information on GMO: www.aphis.usda.gov/biotech (visited 1/3/2002). See FDA website for a complete package of the rules, registration requirements and a lists of those products currently allowed for commercialization.www.fda.gov (visited 1/3/2002).

See the EPA website for EPA policy and the list of pesticides used in GMO.

www.epa.gov/pesticides.

¹⁰⁰ The 1992 Policy, FDA website, www.fda.gov; or 57 FR 22984

¹⁰¹ Held the same day as the WTO meeting in Seattle, this fact may explain the lack of attention to the statements made at the hearing. At this hearing, consumers and scientists spoke in particular about the dangers to consumers of allergic reactions to GMF, and the lack of oversight exercised by the FDA in this regard. For an example of statements delivered, see www.environmentaldefense.org/pubs/filings/FDAhearing (visited 10/4/2001)

¹⁰² York at 441

¹⁰³ Bills have been introduced by Representative Dennis Kucinich (D-OH) in Nov. 1999 and Senator Barbara Baxter (D-CA) in January 2000. cited in York at 442.

¹⁰⁴ *FDA Tries to Intimidate Companies Using GMO-Free Labels*, Wall Street Journal, 12/20/2001

¹⁰⁵ Id.

¹⁰⁶ Id.

¹⁰⁷ *Vermont Towns Begin Voting on Genetically Engineered Foods*, Associated Press, Dec 16, 2001, found at Organic Consumers website, www.OrganicConsumers.org/gefood (visited 1/16/2002)

¹⁰⁸ The Swiss system of government provides for mandatory and voluntary direct refenda, 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

¹⁰⁹ For a discussion of the Swiss regulations in English, see Franz Xaver Perrez, *Taking Consumers Seriously: The Swiss Regulatory Approach to Genetically Modified Food*, 8 N.Y.U. Env'tl. L.J. 585 (2000). For the laws and regulations, see the Swiss government website, www.ch.gov

¹¹⁰ Bundesgesetz uber Lebensmittel und Gebrauchsgegenstande (LMG), art. 9 (SR 817.0, October 1992); Lebensmittelverordnung (LMV), arts. 15 and 22 (SR 817.02, march 1, 1995); Verordnung ober das Bewilligungsverfahren fur GVO-Lebensmittel, GVO-Zusatzstoffe and GVO-Verarbeitungshilfsstoffe (VBGVO, SR 817.021.35, Nov 19, 1996)

¹¹¹ Perrez at 597

¹¹² Id.

¹¹³ Id

¹¹⁴ Id

¹¹⁵ Id.

¹¹⁶ Perrez at 600.

¹¹⁷ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients

¹¹⁸ Regulation 258/97, Art. 8

¹¹⁹ Id, at Whereas Clause 8

¹²⁰ Id

¹²¹ Id, Art 3

¹²² Id., Art 8

¹²³ Id.

¹²⁴ Id at Whereas Clause 10

¹²⁵ See the Terms of Reference for the Royal Commission, and the Royal Commission Simple Guide to Genetic Modification at the New Zealand government website:

www.mfe.govt.nz/new/GMinfo (visited 1/16/2002). The full report of the Royal Commission is available at www.gmcommission.govt.nz.

¹²⁶ Terms of Reference, Royal Commission

¹²⁷ Id.

¹²⁸ See: *Understanding the Royal Commission on Genetic Modification – a simple guide to the process and recommendations*, New Zealand Ministry for the Environment, at www.mfe.govt.nz/new/GMComInfo (visited 1/16/2002)

¹²⁹ Id.

¹³⁰ Id.

-
- ¹³¹ Id
- ¹³² See: *Frequently Asked Questions about Genetic Modification and the Government's Decisions*, New Zealand Ministry for the Environment, at www.mfe.govt.new/public (visited 1/16/2002)
- ¹³³ Id.
- ¹³⁴ *Understanding the Royal Commission on Genetic Modification*, supra.
- ¹³⁵ *Debate Erupts After Canada Parliament Votes Against GE Food Labels*, The Ottawa Citizen, Oct 18, 2001.
- ¹³⁶ *Canada Minister of Health Wants Mandatory Labels on GE Food*, National Post (Canada), Oct 5, 2001.
- ¹³⁷ *Debate Erupts ...*, The Ottawa Citizen, supra
- ¹³⁸ Id.
- ¹³⁹ *Regulations of Food Biotechnology in Canada*, at www.rsc.ca
- ¹⁴⁰ *CWB Biotechnology Position Statement*, April 4, 2001, at www.cwb.ca (visited 1/16/2002)
- ¹⁴¹ Id.
- ¹⁴² *Canadian Coalition Calls for GE Wheat Ban*, The Associated Press, (Canada), July 31, 2001, found at www.OrganicConsumers.org. (visited 1/16/2002)
- ¹⁴³ *South Korea Strengthens Regulations Covering GMO Production, Movement*, 18 ITR 11, p 434, March 15, 2001. For regulations and discussions about purpose and methods, see the English links on the S Korean Food and Drug Administration and Ministry of Agriculture and Fisheries websites: www.kfda.go.kr and www.maf.go.kr
- ¹⁴⁴ *South Korea to Impose Agricultural Label Requirements for Genetically Modified Foods*, 18 ITR 28, p 1104, July 212, 2001
- ¹⁴⁵ *Korea to Enforce Labeling of GMO Products from March 1*, Asia Pulse, Feb 27, 2001
- ¹⁴⁶ Id.
- ¹⁴⁷ Id.
- ¹⁴⁸ 18 ITR 34, p 1345, Aug 23, 2001
- ¹⁴⁹ Id; Agence France Presse, Aug 9, 2000, *Regional Federal Court of Brasilia bars cultivation of Monsanto Gm soybeans until their environmental impact is better studied*
- ¹⁵⁰ 18 ITR 34, Aug 23, 2001
- ¹⁵¹ Id
- ¹⁵² Farming News, June 21, 2001, *Paper Clams GM-free Claim*
- ¹⁵³ 18 ITR 34, Aug 23, 2001
- ¹⁵⁴ Id.
- ¹⁵⁵ For rules, see Japan ministries websites: Ministry of Agriculture, Forestry and Fisheries, www.maff.go.jp (visited 1/3/2002); www.mhw.go.jp (visited 1/2/2002).
- ¹⁵⁶ MAFF website
- ¹⁵⁷ Id; 17 ITR No 18, p 709, May 4, 2000
- ¹⁵⁸ 17 ITR No 18, p 709, May 4, 2000
- ¹⁵⁹ Id.
- ¹⁶⁰ Id
- ¹⁶¹ Id.
- ¹⁶² See Codex website for reports of the meetings of the Food labeling committees, the various proposals
- ¹⁶³ Declan Conroy, *Regulation of Biotech Foods Worldwide Characterized by Confusion, Uncertainty*, BNA/ITR Vol 18, No. 28, P. 1091, July 12, 2001
- ¹⁶⁴ Steve Charnovitz, *The Supervision of Health and Biosafety Regulation by World Trade Rules*, 13 Tul.Envntl. L.J.296 (2000)
- ¹⁶⁵ 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. 321 (2000); Julie Teel, *Regulating Genetically Modified Products and Processes: an Overview of Approaches*, 8 N.Y.U. Envntl. L.J. 687 (2000)
- ¹⁶⁶ 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. 127-128 (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;

¹⁶⁷ Howse at 321-22.

¹⁶⁸ “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.” Speech of Sharynne Nenon, U.S. Department of Agriculture, Report of 3rd Annual Roundtable *Liability and Labeling of Genetically Modified Organisms*, May 26, 1999, St. Louis Missouri. Speech reported at www.cast-science.org (visited 8/28/2001). *US Again Threatens EU on Frankenfoods Moratorium*, Financial Times, London, Dec 18, 2001, where a “US 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.

¹⁶⁹ Gaston at 120-122 argues that under circumstances, the Protocol would take precedence over the WTO, in case of conflict. See also Grosko, note 2, *supra*, for a discussion of the relationship between the WTO and the Protocol.

¹⁷⁰ WTO Appellate Body Report, EC Measures Concerning Meat and Meat Products (Hormones), AB-1997-4, WT/DS26/AB/R (16 January 1998) [hereinafter Hormones], available at www.wto.org/dispute (visited 9/5/2001)

¹⁷¹ WTO Appellate Body Report, Australia – Measures Affecting Importation of Salmon, AB-1998-5, WT/DS18/AB/R (Oct. 20, 1998) [hereinafter Salmon], available at www.wto.org/dispute (visited 9/5/2001)

¹⁷² WTO Appellate Body Report, Japan – Measures Affecting Agricultural Products, AB-1998-8, WT/DS76/AB/R (Feb. 22, 1999) [hereinafter Agricultural Products], available at www.wto.org/dispute (visited 9/6/2001)

¹⁷³ Hormones, para. 197, 208; Salmon, para. 135-136; Agricultural Products para 113-114

¹⁷⁴ SPS Agreement, art. 1.1

¹⁷⁵ Annex A, Art. 1, SPS Agreement

¹⁷⁶ Note 4, Annex 1, SPS Agreement

¹⁷⁷ Charnovitz agrees, and states that dangers from bio-engineered foods are not covered by the SPS because genetic modification is not listed in the above categories. Charnovitz at 276-277.

¹⁷⁸ Kennedy at 84; See also John Stephen Fredland, *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) for a similar conclusion.

¹⁷⁹ Although there could be problems with this approach. GMF and GMO are not treated as such in US, for approval purposes. The FDA doesn't require the same approvals for GMF as for new additives)

¹⁸⁰ Kennedy at 81-82

¹⁸¹ *Id.*

¹⁸² Kennedy at 82

¹⁸³ Howse at 319-320, Abate at 143

¹⁸⁴ General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194, art. XX (b)(hereinafter GATT XX(b))

¹⁸⁵ Kennedy at 82

¹⁸⁶ *Id.*

¹⁸⁷ e.g. Sea Turtles, where the US lost because it was a unilateral measure to protect the endangered species.

¹⁸⁸ Howse at 320

¹⁸⁹ Perrez at 597

¹⁹⁰ See BNA/ITR Vol 17, No. 18, pg 710, May 4, 2000, James Lim, *South Korea Finalizes Guidelines for Labeling GMOs Starting Next Year*; see also the South Korean Ministry of Agriculture and Fisheries website for press releases, position statements on labeling.

¹⁹¹ Directive 90/220, Art. 8.1[c]
¹⁹² Id.
¹⁹³ Regulation 258/ Art. 3
¹⁹⁴ Kennedy at 84: “If a measure is not intended to protect against one of these risks, then the measure is not an SPS measure.
¹⁹⁵ Asbestos at para. 81
¹⁹⁶ Id
¹⁹⁷ TBT Art. 1.3;
¹⁹⁸ Annex 1, para. 1
¹⁹⁹ TBT preamble
²⁰⁰ TBT art. 2.2
²⁰¹ Id. The objectives are listed as “*inter alia*”, which implies that others are possible.
²⁰² SPS Art. 1.1 “This agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade.” Also see Annex A, SPS Agreement, which defines in more detail SPS measures.
²⁰³ Annex 1, Art. 1
²⁰⁴ TBT Art. 2.1
²⁰⁵ TBT Art. 2.2
²⁰⁶ TBT Art. 2.4
²⁰⁷ TBT Art. 2.9, 2.9.1, 2.9.2, 2.9.3, 3.9.4
²⁰⁸ TBT Art. 2.7
²⁰⁹ TBT Art. 2.11
²¹⁰ TBT Art. 3
²¹¹ Art. 4 and Annex 3: Code of Good Practice
²¹² Asbestos para. 81 and 82
²¹³ Asbestos para. 92
²¹⁴ Asbestos para. 101
²¹⁵ Id
²¹⁶ Id
²¹⁷ Asbestos para. 102
²¹⁸ Asbestos para 101-102.
²¹⁹ TBT 2.8
²²⁰ Some chemical companies are recognizing this and acquiescing in labeling, to protect markets and soothe consumer fears. Monsanto is one.
²²¹ Asbestos analysis of “likeness” under GATT art. III:4 at para, 101 – 104; para 93, and para 130
²²² See tuna cans in supermarkets
²²³ Kennedy at 82
²²⁴ TBT Art. 2.2
²²⁵ Salmon at para. 211.
²²⁶ Kennedy at 81
²²⁷ EU de facto; New Zealand, Switzerland
²²⁸ Kennedy at 99
²²⁹ Protocol Art. 18
²³⁰ Gaston at 120-122, discussing Vienna Convention interpretation of the two treaties.
²³¹ Kennedy at 102