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A Precautionary Tale: The International Trade Implications of Regulating Genetically Modified Foods in Australia and New Zealand

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A PRECAUTIONARY TALE: THE INTERNATIONAL TRADE IMPLICATIONS OF REGULATING GENETICALLY MODIFIED FOODS IN AUSTRALIA AND NEW ZEALAND

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Abstract: The current international debate surrounding the development of genetically modified ("GM") foods centers around the selection of appropriate regulations to control the new technology's potential food safety risks. Australia and New Zealand have used a precautionary approach to develop their regulatory system for GM foods—a system that will soon include a stringent labeling requirement for all foods containing GM ingredients. The United States, on the other hand, has rejected the precautionary approach to regulating GM foods and does not require mandatory labeling of most GM foods. These differing national regulations may lead to restrictions on the importation of many U.S. agricultural products to Australia and New Zealand. Rather than pursuing a trade dispute settlement through the World Trade Organization, the United States should drop its opposition to mandatory labeling and the use of precaution in food safety measures, and support the Codex Alimentarius Commission in its effort to develop harmonized international standards for GM foods.

I. INTRODUCTION

Growing international interest in the use of agricultural biotechnology to develop genetically modified ("GM") food has ignited intense concern and debate.[1] While this new technology holds the promise of helping to feed the world's expanding population,[2] it could also have food safety and environmental risks.[3] Responding to these risks, Australia and New Zealand

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[1] NEW ZEALAND MINISTRY OF FOREIGN AFFAIRS AND TRADE, THE INTERNATIONAL ASPECTS OF GENETIC MODIFICATION: BACKGROUND PAPER FOR ROYAL COMMISSION ON GENETIC MODIFICATION 1 (Aug. 2000), http://www.gmcommission.govt.nz/publications/background_papers_list.htm; EU-U.S. BIOTECHNOLOGY CONSULTATIVE FORUM, THE EU-U.S. CONSULTATIVE FORUM FINAL REPORT 5 (Dec. 2000) [hereinafter CONSULTATIVE FORUM], http://europa.eu.int/comm./external_relations/us/biotech.pdf; ORG. FOR ECON. CO-OPERATION AND DEV. ("OECD"), C(2000)86/ADD3, GM FOOD SAFETY: FACTS, UNCERTAINTIES, AND ASSESSMENT: THE OECD EDINBURGH CONFERENCE ON THE SCIENTIFIC AND HEALTH ASPECTS OF GENETICALLY MODIFIED FOODS 7 (May 2000), http://www.oecd.org/subject/biotech /g8_docs.htm [hereinafter OECD].

[2] CONSULTATIVE FORUM, *supra* note 1, at 7; OECD, *supra* note 1, at 4; Dan Ferber, *Food Fight: Risks and Benefits: GM Crops in the Cross Hairs*, 286 SCI. 1662, 1666 (1999); Agric. Dep't, Food and Agric. Org. of the U.S. ("FAO"), *Biotechnology in Agriculture*, AGRIC. 21 (Jan. 1999), http://www.fao.org/WAICENT/FAOINFO/AGRICULT/ magazine/9901sp1.htm [hereinafter FAO Agriculture Department]; U.S. NAT. ACAD. OF SCI. ET AL., TRANSGENIC PLANTS AND WORLD AGRICULTURE 6 (July 2000), http://www.nap.edu/html/ transgenic/pdf/transgenic.pdf.

[3] CONSULTATIVE FORUM, *supra* note 1, at 5, 7-8; *but see* Judith E. Beach, *No "Killer Tomatoes": Easing Federal Regulations of Genetically Engineered Plants*, 53 FOOD & DRUG L.J. 181, 182 (1998)

are currently implementing stringent standards for GM foods.[4] The United States has rejected such a precautionary regulatory system, in favor of what it terms a "science-based" approach.[5] Currently, there are no relevant international standards or guidelines specifically addressing the trade of GM agricultural products.[6] However, the United States, during a World Trade Organization ("WTO") committee meeting, expressed concern over the trade aspects of GM food labeling regulations developed by the European Union,[7] which are similar to those being developed in Australia and New Zealand.[8]

This Comment argues that instead of pursuing a trade dispute through the WTO, the United States should support the development of harmonized international standards for GM foods through the work of the Codex Alimentarius Commission.[9] Part II briefly discusses genetic modification ("GM") technology, as well as some of its benefits and risks. Part III compares the regulations of Australia and New Zealand with those of the United States. Part IV explores the international trade effects of these differing regulations. Part V demonstrates that the GM policies of the United States would be best served through the development of harmonized international standards. This Comment concludes that the United States would be in the best position to alleviate consumer distrust of the new technology and further the benefits of agricultural GM technology by allowing the use of the precautionary approach and mandatory labeling in nations where such consumer distrust is high.

(stating that most of the agencies in the United States responsible for regulating GMOs and GM foods have concluded "that genetically engineered plants are as safe as plants bred with traditional methodologies").

[4] *See infra* notes 52-112 and accompanying text.

[5] *See infra* notes 113-75 and accompanying text.

[6] *See* OECD, *supra* note 1, at 14. However, many international agencies are currently addressing the issue. *Id*; NEW ZEALAND MINISTRY OF FOREIGN AFFAIRS AND TRADE, *supra* note 1, at 1.

[7] Terence P. Stewart & David S. Johanson, *Policy in Flux: The European Union's Laws on Agricultural Biotechnology and Their Effects on International Trade*, 4 DRAKE J. AGRIC. L. 243, 286 (1999).

[8] In fact, the Australia New Zealand Food Authority ("ANZFA") characterized their labeling standards as "slightly more stringent" than that of the European Union. Fact Sheet, Australia New Zealand Food Authority, Labelling Genetically Modified Foods (Aug. 2000), *at* http://www.anzfa.gov.au/documents/fs036.asp [hereinafter ANZFA Fact Sheet].

[9] The Codex Alimentarius Commission, established under the World Health Organization and the Food and Agriculture Organization, develops international food standards. NEW ZEALAND MINISTRY OF FOREIGN AFFAIRS AND TRADE, *supra* note 1, at 6.

II. BENEFITS AND RISKS OF AGRICULTURAL GENETICALLY MODIFIED ORGANISMS AND GENETICALLY MODIFIED FOODS

The ongoing scientific and political debate over agricultural genetically modified organisms ("GMOs") and GM foods may currently be the most polarized debate in the international arena.[10] The main concern is over the relative weights of biotechnology's benefits and risks[11] and what level of precaution should be used in regulating the products of the new technology.[12] Proponents of the new technology believe that it is not any more risky than some other modern agricultural breeding methods[13] and therefore, precautionary regulations will only stifle new developments in an infant industry which has the potential of feeding the world's hungry.[14] Conversely, the opponents of agricultural biotechnology believe its risks far outweigh any benefit at this time, and thus advocate a highly cautious approach to the technology's regulation.[15] Outside of the United States, consumers have responded to GM technology with distrust[16] and have demanded an ability to make an informed choice of whether or not to consume GM foods.[17]

A. Genetic Modification Technology

Modern agricultural biotechnology or GM technology uses recombinant deoxyribonucleic acid ("rDNA") methods[18] to alter the

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[10] Ferber, *supra* note 2, at 1662.

[11] CONSULTATIVE FORUM, *supra* note 1, at 5.

[12] Jonathan H. Adler, *More Sorry Than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol*, 35 TEX. INT'L L.J. 173, 174 (2000).

[13] *Id.* at 177. The classic method of plant breeding is human selection of the seed from the best plants for the next season's planting, resulting in improvements in crop characteristics. ALAN MCHUGHEN, PANDORA'S PICNIC BASKET: THE POTENTIAL AND HAZARDS OF GENETICALLY MODIFIED FOODS 63 (2000). One modern (non-recombinant DNA) agricultural breeding method is crossing or hybridization, which consists of intentionally transferring superior pollen to the stigma another superior plant. *Id.* at 63. Another method, mutation breeding, involves exposing crop plants to radiation or other agents that will cause mutations. Any beneficial mutations will then be used in a breeding program. *Id.* at 65-66.

[14] Adler, *supra* note 12, at 174.

[15] *Id.* at 173-74.

[16] NUFFIELD COUNCIL ON BIOETHICS, GENETICALLY MODIFIED CROPS: THE ETHICAL AND SOCIAL ISSUES 82 (1999), http://www.nuffield.org/bioethics/publications/pub0000000310.html.

[17] *Id.* at 9.

[18] A detailed discussion of the science behind modern agricultural biotechnology is beyond the scope of this Comment; for further details see, for example, MCHUGHEN, *supra* note 13; Marc Van Motagu, *Plant Biotechnology: Historical Perspective, Recent Developments and Future Possibilities*, *in* BIOTECH., PATENTS & MORALITY 57 (Sigrid Sterckx ed., 1997).

characteristics of plants.[19] While there are a variety of rDNA methods,[20] generally, modern biotechnology works by inserting a gene from one organism into another.[21] In agricultural biotechnology, the use of GM technology results in a plant that is a GMO.[22] Examples of plant GMOs include the FlavrSavr™ tomato, which is a tomato with a longer shelf life due to the insertion of a modified tomato gene,[23] and *B.t.* corn, which is corn modified by the inclusion of a *Bacillus thuringiensis* ("*B.t.*") gene that codes for a protein toxic to some insects.[24] A portion of the GMO plant may be consumed whole, like the FlavrSavr™ tomato,[25] or it may be further processed to make other foods, such as tomato paste.[26] GM foods are the foods developed using GMOs, and would include both the whole tomato and the tomato paste.[27]

B. Benefits of Genetic Modification Technology

The potential benefits of agricultural biotechnology include both increasing crop productivity, thereby primarily aiding the farmer, and improving the nutritional value of the food itself, benefiting the consumer. Current GM technologies focus upon agricultural productivity by reducing the amount of herbicides or insecticides that need to be applied, or by increasing crop yield.[28] Future developments look to improve the nutritional quality of the foods themselves. For example, including a vitamin A precursor in rice could help reduce blindness and infections in developing countries.[29] Scientists are also developing vaccine-containing plants, intended to prevent many common diseases.[30] The Food and Agriculture

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[19] Henry I. Miller, *A Rational Approach to Labeling Biotech-Derived Foods*, 284 SCI. 1471, 1471. (1999). This Comment is limited to the discussion of plant biotechnology. Another area of agricultural biotechnology involves genetically modifying animals, and although many of the issues are similar, they are quite complex and beyond the scope of this comment.

[20] MCHUGHEN, *supra* note 13, at 9-10.

[21] *Id.* at 11.

[22] *Id.* at 9.

[23] *Id.* at 15.

[24] *Id.* at 108.

[25] *Id.* at 12.

[26] *Id.*

[27] *Id.* at 11-12.

[28] Ferber, *supra* note 2, at 1665-66; .U.S. NAT. ACAD. OF SCI. ET AL., *supra* note 2, at 7. However, one study has found that herbicide use increased with the use of herbicide-resistant soybeans. Ferber, *supra* note 2, at 1666.

[29] Ferber, *supra* note 2 at 1666.

[30] *Id.* Over 800 million people in the world today are chronically undernourished and many peoples' diets lack essential nutrients such as protein, vitamins, and minerals. CONSULTATIVE FORUM, *supra* note 1, at 7.

Organization of the United Nations ("FAO") believes that biotechnology could help developing countries by solving a variety of agricultural problems,[31] thus feeding a world population that is expected to reach eight billion by 2020.[32]

C. *Risks of Genetic Modification Technology*

Some argue that along with the benefits, there are scientific risks associated with whether a particular agricultural GMO is safe to introduce into the environment and whether the GM food is safe for human consumption.[33] Environmental questions revolve around the possibilities that the new genes will spread to wild plants creating "super weeds," negatively affecting biodiversity by displacing native species,[34] or that the increased use of plants with pesticidal characteristics will create new strains of resistant insects.[35] Another environmental concern, highlighted by studies indicating that *B.t.* corn pollen may harm Monarch butterflies,[36] is that agricultural GMOs with insecticidal characteristics may threaten beneficial insects, as well as the targeted pests.[37] Food safety questions revolve around the consumption of GM foods. For example, there are questions about whether the new GM foods will produce unexpected allergic reactions or long-term toxic effects.[38] Many consumers are deeply concerned about both the environmental and food safety risks.[39]

Ethical, social, and other non-scientific concerns also play a role in the debate over GM foods.[40] In this area, personal values and beliefs enter

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[31] Biotechnology could increase agricultural productivity in the developing world by increasing crop yields, developing crops resistant to pests, drought, salinity, and disease, and by increasing nutritional values. CONSULTATIVE FORUM, *supra* note 1, at 18.

[32] FAO Agriculture Department, *supra* note 2.

[33] MCHUGHEN, *supra* note 13, at 11.

[34] Ferber, *supra* note 2, at 1665.

[35] MCHUGHEN, *supra* note 13, at 108.

[36] Ferber, *supra* note 2, at 1663-65.

[37] *Id.* at 1665.

[38] McHughen, *supra* note 13, at 11, 160-61.

[39] Arthur E. Appleton, *The Labeling of GMO Products Pursuant to International Trade Rules*, 8 N.Y.U. ENVTL. L.J. 566, 567-68 (2000). Consumers in Europe, Japan, and, increasingly, the United States, have objected to GM crops and food. Kim Brooks, *History, Change and Policy: Factors Leading to Current Opposition to Food Biotechnology*, 5 GEO. PUB. POL'Y REV. 153, 154 (2000); *see also* Lara Beth Winn, *Special Labeling Requirements for Genetically Engineered Food: How Sound Are the Analytical Frameworks Used by FDA and Food Producers?*, 54 FOOD DRUG L.J. 667, 679 (discussing public opinion against GM foods in Europe). For a discussion of the increasingly negative public opinion about GM foods in the United States, see generally Paul Raeburn, *Clamor Over Genetically Modified Food Comes to the United States*, 8 N.Y.U. ENVTL. L.J. 610 (2000). This Comment does not address the environmental effects of GM foods other than in the context of consumer concern.

[40] CONSULTATIVE FORUM, *supra* note 1, at 5. As the Nuffield Council on Bioethics put it:

the debate.[41] Some believe that the technology is unnatural and, as such, unacceptable.[42] Others are concerned that the consumption of GM plants modified by the inclusion of animal genes will lead to a violation of ethical or religious beliefs.[43] Many believe that the domination of GM technology expertise by large corporations means that legitimate risks will be ignored in the drive to realize the profits of the new technology.[44] Additionally, while agricultural biotechnology could increase crop productivity in the developing world, the economic and cultural aspects of its use in these regions are hotly debated.[45] Finally, there is a deep distrust in the ability of regulatory agencies to provide meaningful oversight for GM technologies and food development.[46]

While all of these risks tend to be of deep concern to the public, the non-scientific aspects fall outside of the normal purview of regulatory agencies, which tend to focus on the purely scientific risks to the environment and human health.[47] And while the natural sciences cannot

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> The part played by food in human life is much larger than its role as fuel for physical activity. Food features prominently in religious rituals and in the small rituals of everyday life; we welcome friends with food; and our credentials as good parents rest partly on what we feed our children and under what circumstances. Although the overriding interests of consumers in the developed world are first, safety and second, informed choice, we are very conscious that the cultural meanings of food are more elaborate. Any parent will remember teaching children to 'eat properly', and recall their children's adamant refusal to eat even the most nutritious food if it was declared to be 'yucky.' Powerful adult emotions are aroused when age and infirmity makes it harder for us to 'eat properly.' The public's concern about the introduction of genetically modified (GM) foods into their diets is therefore not surprising, even to those who think GM foods pose little risk to health.
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> NUFFIELD COUNCIL ON BIOETHICS, *supra* note 16, at 82.

[41] OECD, *supra* note 1, at 2.

[42] NUFFIELD COUNCIL ON BIOETHICS, *supra* note 16, at 7. This concern was expressed by the Prince of Wales in a commentary published in June 1998. John Stephen Fredland, Note, *Unlabel Their Frankenstein Foods!: Evaluating a U.S. Challenge to the European Commission's Labeling Requirements for Food Products Containing Genetically-Modified Organisms*, 33 VAND. J. TRANSNAT'L L. 183, 187 (2000) (citing H.R.H Charles, Prince of Wales, *Seeds of Disaster: HRH the Prince of Wales, Who Farms Organically, Says the Genetic Modification of Crops is Taking Mankind into Realms That Belong to God, and God Alone*, DAILY TELEGRAPH, June 8, 1998, at 16).

[43] DONNA U. VOGT & MICKEY PARISH, CRS REPORT TO CONGRESS: FOOD BIOTECHNOLOGY IN THE UNITED STATES: SCIENCE, REGULATION, AND ISSUES (1999), http://usinfo.state.gov/topical/global/biotech/crsfood.htm.

[44] CONSULTATIVE FORUM, *supra* note 1, at 5.

[45] NUFFIELD COUNCIL ON BIOETHICS, *supra* note 16, at 133; OECD, *supra* note 1, at 4; CONSULTATIVE FORUM, *supra* note 1, at 17.

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

[47] *Id.* at 526. Additionally, consumers are likely to assess food safety risks quite differently than regulators. NEW ZEALAND MINISTRY OF CONSUMER AFFAIRS, SUBMISSION TO THE ROYAL COMMISSION ON GENETIC MODIFICATION 4 (2000), *available at* http://www.gmcommission.govt.nz/publications/Govt_submissions.html.

provide all of the answers to the debate, each of the concerns is legitimate.[48] The resulting debate over the correct balance of benefits and risks leads to regulations for GM foods that vary significantly from nation to nation, as illustrated by the differences between the regulations of the United States and those of Australia and New Zealand.

III. NATIONAL REGULATION OF GM FOODS

As the use of products developed through biotechnology has exploded over the last decade, the need to provide safety to consumers without over-regulating an industry in its infancy has challenged national regulatory systems.[49] Ideally, each nation's regulations will assess and control the risks associated with human consumption of GM foods.[50] Additionally, many consumers are deeply concerned about the risks of the new technology and wish to have a choice in whether to purchase and consume GM foods, a choice that may be provided by regulations requiring the labeling of GM foods.[51]

A. GENETICALLY MODIFIED FOODS REGULATION IN AUSTRALIA AND NEW ZEALAND

1. Background

Because of the risks associated with GM foods, Australia and New Zealand have implemented precautionary regulatory programs. Their precautionary approach to GM technologies has international support.[52] For example, Principle 15 of the Rio Declaration on Environment and Development states:

> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for

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[48] CONSULTATIVE FORUM, *supra* note 1, at 5.

[49] Franz Xaver Perrez, *Taking Consumers Seriously: The Swiss Regulatory Approach to Genetically Modified Food*, 8 N.Y.U. ENVTL. L.J. 585, 589 (2000).

[50] CONSULTATIVE FORUM, *supra* note 1, at 8.

[51] Appleton, *supra* note 39, at 567-68.

[52] *See* David Freestone & Ellen Hey, *Origins and Development of the Precautionary Principle*, *in* THE PRECAUTIONARY PRINCIPLE AND INT'L LAW: THE CHALLENGE OF IMPLEMENTATION 3, 3 (David Freestone & Ellen Hey eds., 1996).

> postponing cost-effective measures to prevent environmental degradation.[53]

The precautionary approach has been described as implementing such common sense ideas as "better safe than sorry,"[54] "an ounce of prevention is worth a pound of cure,"[55] or even "regulate first, assess the risks later."[56] Unfortunately, while these adages adequately describe the general approach for the purposes of conversation, the concept is not that simple.[57] It is expressed in several different formulations, with effects ranging from reversing the burden of proof [58] to requiring an environmental impact statement.[59] These issues lead many to question the "practical utility"[60] of the precautionary approach as a regulatory standard.[61] However, the precautionary approach does have the "potential to be worked up into a practical way to accommodate the new approaches of consumers, the public at large, special interest groups, and scientists."[62]

In both Australia and New Zealand, existing agencies were initially given the responsibility to regulate GMOs and GM products, with a general focus on the end use of the item.[63] As the development and use of GMOs

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[53] Rio Declaration on Environment and Development, June 14, 1992, 31 I.L.M. 874. This declaration is non-binding. DAVID HUNTER ET AL., INTERNATIONAL ENVIRONMENTAL LAW AND POLICY 306 (1998). The United States recently recognized the "wide-spread recognition and international agreement on Principle 15 of the 1992 Rio Declaration." U.S. Dep't of State, International Information Programs, U.S. States Position on Precaution at Pollutants Meeting (Dec. 4, 2000) *at* http://usinfo.state.gov/topical/global/environ/latest/00120407.htm.

[54] Frank B. Cross, *Paradoxical Perils of the Precautionary Principle*, 53 WASH. & LEE L. REV. 851, 851 (1996).

[55] Daniel Bodansky, *Scientific Uncertainty and the Precautionary Principle*, ENV'T, Sept. 1991, at 4.

[56] Adler, *supra* note 12, at 194.

[57] Jutta Brunnee, Book Review and Note, *The Precautionary Principle and International Law: The Challenge of Implementation*, 91 A.J.I.L. 210, 210 (1997) (reviewing THE PRECAUTIONARY PRINCIPLE AND INTERNATIONAL LAW: THE CHALLENGE OF IMPLEMENTATION (David Freestone & Ellen Hey eds., 1996)).

[58] *See* Charmian Barton, Note, *The Status of the Precautionary Principle in Australia: Its Emergence in Legislation and as a Common Law Doctrine*, 22 HARV. ENVTL. L. REV. 509, 519 (2000). Under a non-precautionary system, the regulator must prove that harm has occurred or will occur to stop the action, while under a burden-shifting precautionary system, the proponent of the action must prove that the action is safe prior to proceeding. *Id.*

[59] *Id.* at 521.

[60] Nelkin et al., *supra* note 46, at 526.

[61] Bodansky, *supra* note 55, at 5.

[62] OECD, *supra* note 1, at 12.

[63] Generally, the regulation encompasses the intended use of the product. For example, GM medicines are regulated by the agencies that have responsibilities for medicines in general. *See* HELEN ATKINS & PHILLIPS FOX, THE LEGAL ASPECTS OF GENETIC MODIFICATION: BACKGROUND FOR ROYAL COMMISSION ON GENETIC MODIFICATION 9, 16-17 (2000), *at* http://www.gmcommission.govt.nz/publications/background_papers_list.html. For a general discussion of New Zealand's GMOs regulations and the institutions responsible for enforcing them see ROYAL COMMISSION ON GENETIC MODIFICATION:

and GM foods increased, however, both Australia and New Zealand responded with new regulations addressing biotechnology with increasing precaution.[64]

Even so, the use of agricultural GMOs in Australia is prevalent and expected to increase.[65] At this time, almost thirty percent of the Australian cotton crop is genetically modified[66] and this could rise to eighty percent by 2005.[67] Aventis, a major biotechnology company, predicts that almost the entire canola crop in Australia will be genetically modified by 2005.[68] Responding to concerns about the increasing use of the technology, Australia enacted a comprehensive regulatory scheme for GMOs, the Gene Technology Act 2000, on December 21, 2000.[69] The Act establishes an independent agency to regulate GMOs, the Gene Technology Regulator,[70] and explicitly adopts a precautionary approach to the regulation of GMOs.[71]

There are no GMOs approved for release in New Zealand.[72] New Zealand's Environmental Risk Management Authority ("ERMA"), under the Hazardous Substances and New Organisms ("HSNO") Act 1996,[73] must approve the import of agricultural GMOs.[74] While the HSNO Act explicitly adopts a precautionary approach for the regulation of GMOs,[75] New Zealand also imposed a voluntary moratorium on the environmental release of new

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ROLE OF AGENCIES, INSTITUTIONAL AND REGULATORY FRAMEWORK (2000), *at* http://www.gmcommission.govt.nz/publications/Govt_submissions.html.

[64] *See* Gene Technology Act 2000 (no. 169, 2000) (Austl.), *at* http://scaleplus.law.gov.au/html/pasteact/browse/TOCGE.htm; Warrant, Royal Commission on Genetic Modification, 2000 (NZ), *at* http://www.gmcommission.govt.nz/intro/warrant_eng.html.

[65] Bills Digest No. 11 2000-01, Gene Technology Bill 2000, Parliament of Australia, http://wopared.aph.gov.au/library/pubs/bd/2000-01/01BD011.htm.

[66] *Id.* (citing Andrew Stevenson, *Fearful or Not, There is Nowhere to Hide*, SYDNEY MORNING HERALD, July 25, 2000). Cottonseed oil is used in food production. AUSTRALIA NEW ZEALAND FOOD AUTH., ANZFA OCCASIONAL PAPER SERIES NO. 1: GM FOODS AND THE CONSUMER: ANZFA'S SAFETY ASSESSMENT PROCESS FOR GENETICALLY MODIFIED FOODS 15 (2000), *at* http://www.anzfa.gov.au/Documents/pub02_00.pdf [hereinafter ANZFA'S GM FOODS AND THE CONSUMER].

[67] *See* Bills Digest No. 11 2000-01, *supra* note 65 (citing Andrew Fraser, *Most Cotton Will be GM by 2005: Marketer*, AUSTRALIAN, July 25, 2000).

[68] *See id.* (citing James Woodford, *Crop Target 2005, A Million Hectares*, SYDNEY MORNING HERALD, July 24, 2000).

[69] Therapeutic Goods Admin.—Gene Technology, *What's New*, *at* http://www.health.gov.au/tga/genetech.htm (last modified Jan. 15, 2001).

[70] Gene Technology Act 2000, *supra* note 64, § 25.

[71] A precautionary approach is incorporated in Section 4 of the Act. It "provides that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation." *Id.* § 4(aa).

[72] New Zealand Ministry of Health, *News and Issues: GM Foods 2—Regulatory Control in New Zealand*, http://www.moh.gov.nz/moh.nsf/wpg_index/News+and+Issues-Index (last visited Jan. 17, 2001).

[73] Hazardous Substances and New Organisms Act 1996 (N.Z.), http://rangi.knowledge-basket.co.nz/gpacts/public/text/1996/AN/030.html.

[74] ATKINS & FOX, *supra* note 63, at 5.

[75] Hazardous Substances and New Organisms Act 1996, *supra* note 73, § 7.

GMOs in June 2000,[76] while a Royal Commission conducts a year-long detailed inquiry into the new technology.[77]

The Australia New Zealand Food Authority ("ANZFA") regulates GM foods in Australia and New Zealand.[78] ANZFA's standards for the approval and labeling of GM food reflect the precautionary approach of Australia's Gene Technology Act 2000 and New Zealand's Royal Commission inquiry.[79] ANZFA's standards are characterized as among the strictest in the world.[80]

ANZFA was implemented as a result of a treaty agreement signed by Australia and New Zealand on December 5, 1995.[81] The purpose of the treaty was to establish a joint system for developing food standards in the two countries.[82] In Australia, the statutory authority for ANZFA is an amendment to the Australia New Zealand Food Authority Act 1991.[83] In New Zealand, the authority is the New Zealand Food Amendment Act 1996.[84] Moreover, ANZFA is organized as a partnership between the

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[76] NEW ZEALAND MINISTRY FOR THE ENV., GUIDE TO THE VOLUNTARY MORATORIUM 1 (2000), *at* http://www.mfe.govt.nz/new/geneticthing.pdf.

[77] Media Release, Hon. Marian Hobbs, Minister for the Environment, Royal Commission on Genetic Modification (Apr. 17, 2000), *at* http://www.mfe.govt.nz/media_17_04_00.htm. The Royal Commission will be examining many issues, including "human health, environment, economic, cultural and ethical concerns." Royal Comm. on Genetic Modification, Opening Address of Counsel Assisting The Commission (2000), at 1, *at* http://www.gmcommission.govt.nz/inquiry/FormalOpeningStatement.pdf. The Maori are also very interested in the implications of GM technology and the Royal Commission will also examine issues raised by Maoris. TE PUNI KOKIRI [NEW ZEALAND MINISTRY OF MAORI DEV.], SUBMISSION TO THE ROYAL COMMISSION ON GENETIC MODIFICATION 2-3 (2000), http://www.gmcommission.govt.nz/publications/Govt_submissions.html.

[78] Ian Lindenmayer, Managing Director Australia New Zealand Food Authority, Speech on Regulating Genetically Modified Food prepared for the APEC Techomart III Conference (Nov. 3, 1999), *at* http://www.anzfa.gov.au/documents/sp008_99.asp; *see* Australia New Zealand Food Authority, Foods Standards Code A18—Food Produced using Gene Technology (effective May 13, 1999), http://www.anzfa.gov.au/foodstandardscode/code/parta/A18.htm.

[79] ANZFA's GM FOODS AND THE CONSUMER, *supra* note 66, at 4.

[80] ANZFA Fact Sheet, *supra* note 8.

[81] Agreement Between the Government of New Zealand and the Government of Australia Establishing a System for the Development of Joint Food Standards, Dec. 5, 1995, Austl.-N.Z., http://www.dfat/gov.au/geo/new_Zealand/11-FOOD.pdf [hereinafter Joint Food Standards Agreement].

[82] *Id.* art. 2. This agreement was developed under the Australia New Zealand Closer Economic Trade Agreement. AUSTRALIA NEW ZEALAND FOOD AUTHORITY, SUBMISSION TO THE ROYAL COMMISSION ON GENETIC MODIFICATION 3 (2000), *at* http://www.gmcommission.govt.nz/publications/Govt_submissions.html [hereinafter ANZFA SUBMISSION].

[83] Australia New Zealand Food Authority Act 1991 (no. 118, 1991, as amended by National Food Authority Amendment Act 1995, no. 152) (Austl.-NZ), § 6, http://scaleplus.law.gov.au/html/pasteact/browse/TOCAU.htm.

[84] Food Amendment Act 1996 (no. 041, 1996) (N.Z.), § 11B(b), http://rangi.knowledge-basket.co.nz/gpacts/public/text/1996/se/041se9.html.

Australian Commonwealth, and its states and territories, along with the New Zealand government.[85]

2. *Genetically Modified Food Approval Process*

ANFZA develops GM food standards under its regular food standard process.[86] The GM food standard became effective in both countries only after approval by the Australia New Zealand Food Standards Council ("ANZFSC"), which is composed of the Health Ministers of the ten governments involved.[87] The health administrations of New Zealand and the Australian states and territories enforce the joint GM food standard.[88] While the Gene Technology Act generally continues the current regulatory regime under ANZFA for GM foods,[89] the Gene Technology (Consequential Amendments) Act 2000 amended the Australia New Zealand Food Authority Act to require consultation with the Gene Technology Regulator during the ANZFA's normal food approval process.[90]

Under ANZFA's standard for GM foods, no GM food can be sold in either country without a pre-market safety assessment[91] conducted by ANZFA and approved by ANZFCS.[92] This standard, Food Standard A18: Food Produced Using Gene Technology, became effective on May 13, 1999.[93] The approval process for GM foods applications includes a public comment period and a pre-market safety assessment,[94] conducted by ANZFA and reviewed by an external panel of independent experts.[95] Under this process, ANZFCS has approved seven varieties of GM food as of

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[85] ANZFA SUBMISSION, *supra* note 82, at 6. A total of ten governments participate in the arrangement. Lindenmayer, *supra* note 78.

[86] ANZFA SUBMISSION, *supra* note 82, at 1.

[87] Australia New Zealand Food Authority Act 1991, *supra* note 83, § 20.

[88] Lindenmayer, *supra* note 78.

[89] *See* Bills Digest No. 10 2000-01, Gene Technology (Consequential Amendments) Bill 2000, Parliament of Australia, http://wopared.aph.gov.au/library/pubs/bd/2000-01/01BD010.htm.

[90] Gene Technology (Consequential Amendments) Act 2000 (no. 170, 2000) (Austl.), § 12, http://scaleplus.law.gov.au/html/pasteact/browse/TOCGE.htm.

[91] ANZFA's pre-market safety assessment involves using scientific information submitted by the food developer augmented by other detailed information to evaluate the risks of the GM food to ensure the food is safe, providing "all the benefits of conventional foods and no additional risks." ANZFA'S GM FOODS AND THE CONSUMER, *supra* note 66, at 6-8. For a general discussion of safety assessments for GM foods, see OECD, C(2000)86/ADD1, Report of the Task Force for the Safety of Novel Foods and Feeds (2000), http://www.oecd.org/subject/biotech/report_taskforce.pdf.

[92] Australia New Zealand Food Authority, *Update on Foods Produced Using Gene Technology* (Nov. 1999), *at* http://www.anfza.gov.au/Documents/gen25_99.asp [hereinafter *Update on Foods Produced Using Gene Technology*].

[93] ANZFA SUBMISSION, *supra* note 82, at 13.

[94] *Update on Foods Produced Using Gene Technology*, *supra* note 92.

[95] ANZFA'S GM FOODS AND THE CONSUMER, *supra* note 66, at 8.

November 24, 2000, including insect-protected corn and herbicide-resistant canola, soybeans, and corn.[96]

3. *Genetically Modified Food Labeling Requirements*

ANZFA's present Food Standard A18 also contains a labeling requirement for GM foods.[97] This standard does not require the labeling of all GM foods, but does require labeling when "the nature of the food has been significantly changed with respect to its nutritional quality, composition, allergenicity, or end use."[98] This standard will change, however, under the new, more stringent labeling standards for GM foods approved by ANZFSC on July 28, 2000.[99] The revised Food Standard A18, containing the new labeling requirements, will be effective December 8, 2001.[100] ANZFA characterizes the new GM food labeling standard as "one of the most rigorous and progressive" in the world.[101]

Under the revised Food Standard A18, if the genetic material or protein is present in the final food, it must be identified on the label.[102] Additionally, foods with altered characteristics must also be labeled.[103] There are several exemptions from this requirement, including highly refined foods where the GM material is removed, food processing aids and additives (unless GM material is present in the final food), and foods prepared at restaurants and hotels.[104] Finally, if the food was not intended to have a GM ingredient in the final product, a one percent tolerance is allowed.[105] This is not a blanket exemption since it only applies to

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[96] Media Advisory, Australia New Zealand Food Standards Council, Health Ministers Make Historic Decision on Food Regulation (Nov. 24, 2000), *at* http://www.anzfa.gov.au/documents/mr33_00.asp.

[97] *Update on Foods Produced Using Gene Technology*, *supra* note 92.

[98] *Id.*

[99] ANZFA Fact Sheet, *supra* note 8.

[100] Press Release, Australia New Zealand Food Authority, New Labeling Requirements for GM Foods to Take Effect in 12 Months (Dec. 7, 2000), *at* http://www.anzfa.gov.au/documents/mr35_00.asp; Australia New Zealand Food Authority: Draft Compliance Guide to Standard A18, Labelling Genetically Modified Foods (2000), at 2, http://www.anzfa.gov.au/Documents/gen31_00.pdf.

[101] ANZFA Fact Sheet, *supra* note 8.

[102] ANZFA News Special Edition, Australia New Zealand Food Authority (Oct. 2000), http://www.anzfa.gov.au/documents/news_speced_oct00.htm; ANZFA Fact Sheet, *supra* note 8.

[103] ANZFA Fact Sheet, *supra* note 8.

[104] *Id.*

[105] *Id.*

accidental inclusion of GM ingredients.[106] Any intended inclusion of GM food ingredients, no matter the level present, must be listed on the label.[107]

These labeling requirements are not based upon safety concerns about GM foods, but are instead based on the consumer's right to exercise a choice of whether to consume GM foods.[108] In a media release announcing the approval of two GM foods, ANZFA stated that "[t]o date, ANZFA has found no evidence that GM foods are less safe than their conventionally produced counterparts."[109] So, this new labeling requirement was "based largely on the wish of many consumers to be able to make an informed choice about whether to buy food containing genetically modified material."[110] Outside of scientific considerations, cultural, economic, and other social factors may influence consumer choice.[111] Therefore, in addition to the regulatory precaution practiced by Australia and New Zealand in the food approval process, the new labeling requirements provide the consumer with information that allows the practice of precaution on an individual level.[112]

B. *Comparison of the U.S. Science-Based Approach to the Precautionary Approach of Australia and New Zealand*

1. *Background*

The United States rejects the precautionary approach, advocating instead a "science-based"[113] policy for the regulation of GM foods.[114] While

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[106] Pattrick Smellie & Chelsey Martin, *GM Food Hit With World's Toughest Rules*, AUSTL. FIN. REV., July 29, 2000, at 1.

[107] Australia New Zealand Food Authority, Draft Food Standards Code A18—Food Produced using Gene Technology, provision 5, http://www.anzfa.gov.au/FoodStandardsCode/code/parta/A18.htm (last visited Jan. 10, 2001).

[108] Lindenmayer, *supra* note 78.

[109] Media Release, Australia New Zealand Food Authority, More GM Foods Pass ANZFA Safety Assessment (Oct. 4, 2000), *at* http://www.anzfa.gov.au/documents/mr26_00.asp.

[110] Lindenmayer, *supra* note 78.

[111] Nelkin et al., *supra* note 46, at 526.

[112] Appleton, *supra* note 39, at 570.

[113] U.S. officials use the term "science-based" as the alternative to the precautionary approach in GM food regulatory systems. *See, e.g.*, Fact Sheet, Office of Communications, White House, Strengthening Science-Based Regulation: Clinton Administration Agencies Announce Food and Agricultural Biotechnology Initiatives: Strengthening Science-Based Regulation and Consumer Access to Information (May 3, 2000), *at* 2000 WL 553837 (White House) [hereinafter Announcement of Agricultural Biotechnology Initiatives]; Alan Larson, U.S. Undersecretary of State for Economic, Business and Agricultural Affairs, Remarks at the Presentation of the World Food Prize (Oct. 12, 2000) (on file with author); Merle D. Kellerhals, Jr., U.S. Dep't of State, International Information Program, Biotechnology Initiative Expands Regulatory Process (May 3, 2000), *at* http://usinfo.state.gov/topical/global/biotech/00050302.htm.

the United States has recently responded to some public concerns about the safety of GM food products by announcing the implementation of new requirements for the pre-market GM food review process[115] and a voluntary labeling standard for GM foods,[116] it simultaneously reaffirmed its commitment to the science-based approach.[117] The U.S. opposition to the precautionary approach stems from its "vague definition and departure from the science-based criteria"[118] as well as the belief that there is "strong scientific evidence that biotech foods are as safe as other foods."[119] The United States, like many who are critical of the precautionary approach in the context of GM foods, feel that its application allows the fear of new technology to overshadow its benefits.[120]

The United States, like Australia and New Zealand, began its regulation of agricultural biotechnology within a framework of statutes and agencies focused on the end use of the product.[121] In 1986, the Office of Science and Technology Policy ("OSTP"), a White House office providing scientific and technical analysis to the President,[122] issued the Coordinated Framework for Regulation of Biotechnology ("Coordinated Framework").[123] The Coordinated Framework provides for the review and regulation of biotechnology products through existing federal statutes and agencies.[124]

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[114] Larson, *supra* note 113.

[115] Announcement of Agricultural Biotechnology Initiatives, *supra* note 113; Proposed Rule: Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4,706 (Jan. 18, 2001).

[116] Announcement of Agricultural Biotechnology Initiatives, *supra* note 113; Notice of Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4,839 (Jan. 18, 2001) [hereinafter Draft Guidance for Industry].

[117] Kellerhals, *supra* note 113. Additionally, one U.S. official stated, "If we blindly reject this technology out of fear, then we will never know what could have been. Similarly, we must recognize that the application of this technology does pose potential risks and real challenges to the food chain and to our environment." Dan Glickman, U.S. Secretary of Agriculture, Remarks to the Third Meeting of the Advisory Committee on Biotechnology (Nov. 29, 2000), *at* http://usinfo.state.gov/topical/global/biotech/00112901.htm. Another official concluded that, since cross-breeding will not be enough to feed the growing world population, biotechnology will be necessary to meet future world food requirements. Larson, *supra* note 113.

[118] Kellerhals, *supra* note 113.

[119] Alan Larson, Undersecretary of State for Economic, Business and Agricultural Affairs, Remarks at the Foreign Press Center on Enhancement of U.S. Biotechnology Initiatives (May 3, 2000), *at* http://usinfo.state.gov/topical/global/biotech/00050303.htm.

[120] Adler, *supra* note 12, at 174. "The precautionary principle seems to suggest that the choice is between risk and caution, but often the choice is between one risk and another." Bodansky, *supra* note 55, at 43. Here, foregoing the potential benefits of GM foods can be viewed as a risk. Adler, *supra* note 12, at 174.

[121] *See supra* note 63 and accompanying text.

[122] *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

[123] *Id.*

[124] *Id.*

There are no U.S. statutes that specifically address agricultural biotechnology.[125] Therefore, GM foods are regulated under the laws and by the agencies that have primary responsibility for similar non-GMO products, reflecting the U.S. attitude that biotechnology is simply an extension of current products and does not fundamentally change them.[126] The primary agencies that regulate GM foods are the Food and Drug Administration ("FDA") and the Environmental Protection Agency ("EPA").[127]

Under the Coordinated Framework, the development and use of GM foods has flourished in the United States.[128] Over fifty crops of GM foods have been through the U.S. regulatory process and "thousands of foods" containing GM ingredients are currently in the U.S. market.[129] In the United States, at least forty-five percent of cotton, thirty-eight percent of soybeans, and twenty-five percent of corn grown are crops altered with GM technologies.[130] As of November 2000, seventy million acres in the United States were planted with GM crops.[131]

In an effort to maintain and improve consumer confidence, the White House announced a new round of biotechnology initiatives on May 3, 2000.[132] However, these initiatives do not change the regulatory responsibilities created by the Coordinated Framework, unlike the recent initiatives in Australia and New Zealand, which have implemented biotechnology-specific regulations.[133] The objectives of the biotechnology initiatives are to "strengthen our science-based regulatory system and

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[125] *See* Stewart & Johanson, *supra* note 7, at 247; Alek P. Szecsy, *From the Test Tube to the Dinner Table in Record Time: Liberalizing Effects on Domestic and International Regulatory Frameworks for Controlled Environmental Introduction of Genetically Engineered Agricultural Organisms*, 2 DICK. J. ENVTL. L. & POL'Y 177, 182 (1993). *See also*, Adler, *supra* note 12, at 181.

[126] Stewart & Johanson, *supra* note 7, at 247.

[127] Fact Sheet, U. S. Department of State, Food Safety—Regulating Plant Agricultural Biotechnology in the U.S. (Aug. 9, 2000), *at* http://usinfo.state.gov/topical/global/biotech/00080901.htm [hereinafter U.S. Food Safety Fact Sheet].

[128] In 1996 several crops of GM foods began to be used widely. Sara M. Dunn, Comment, *From Flav'r Sav'r to Environmental Saver? Biotechnology and the Future of Agriculture, International Trade, and the Environment*, 9 COLO. J. INT'L ENVTL. L. & POL'Y 145, 150 (citing Peter Fritsch et al., *Seed Money: Huge Biotech Harvest Is a Boom for Farmers and for Monsanto Co.*, WALL ST. J. EUR., Oct. 28, 1996, at 1).

[129] U.S. Food Safety Fact Sheet, *supra* note 127.

[130] Adler, *supra* note 12, at 177 (citing Siobhan Gorman, *Future Pharmers of America*, NAT'L J., Feb. 6, 1999, at 355).

[131] Glickman, *supra* note 117.

[132] Announcement of Agricultural Biotechnology Initiatives, *supra* note 113, at 1.

[133] However, bills proposing to amend the Federal Food, Drug, and Cosmetic Act ("FFDCA") to address GM food issues have been introduced in both the House of Representatives and the Senate: the Genetically Engineered Food Safety Act (H.R. 3883, 106th Cong. (2000); S. 2315, 106th Cong. (2000)), and the Genetically Engineered Food Right to Know Act (H.R. 3377, 106th Cong. (1999); S. 2080, 106th Cong. (2000)). Karen A. Goldman, *Genetic Technologies: Bioengineered Food—Safety and Labeling*, 290 SCI. 457, 457 (2000) [hereinafter *Safety and Labeling*].

facilitate reliable, voluntary labeling practices."[134] These initiatives continue to emphasize the U.S. commitment to science-based regulation for GM foods.[135]

This approach reflects the U.S. preference for product specific regulation rather than biotechnology process specific regulation. This conclusion is drawn from the evaluation that the "genetic engineering processes are not per se risky"[136] and that the products are simply extended by biotechnology, not fundamentally changed.[137] In comparison, the express incorporation of the precautionary approach in Australia's Gene Technology Act and New Zealand's HSNO Act, as well as the precaution implicit in the New Zealand's Royal Commission Moratorium and ANZFA's Food Standard A18, demonstrate a more cautious approach, reflecting concerns about the technology itself.[138]

2. *Genetically Modified Food Approval Process*

The U.S. process for GM food approval is much less stringent than that of Australia and New Zealand's ANZFA.[139] While ANZFA requires that each GM food must undergo a complete premarket safety assessment, including a period of public comment, prior to its sale in Australia and New Zealand,[140] the United States primarily relies upon manufacturers' voluntary consultations with the FDA to ensure food safety.[141] The FDA regulates most food safety issues, including the safety of GM foods, through the Federal Food, Drug, and Cosmetic Act ("FFDCA")[142] and the Public Health Service ("PHS") Act.[143]

In 1992, the FDA issued an updated policy statement for foods derived from GM plants.[144] Under this policy, the FDA regulates foods based upon the "characteristics of the food product."[145] The FDA has not conducted a comprehensive review of a GM food since its approval of the

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[134] Announcement of Agricultural Biotechnology Initiatives, *supra* note 113, at 1.
[135] Kellerhals, *supra* note 113.
[136] Szecsy, *supra* note 125, at 193-94.
[137] Stewart & Johanson, *supra* note 7, at 247.
[138] *See supra* notes 63-112 and accompanying text.
[139] *See supra* notes 78-96 and accompanying text.
[140] *See supra* notes 91-96 and accompanying text.
[141] *See infra* notes 144-54 and accompanying text.
[142] Beach, *supra* note 3, at 184 (citing 21 U.S.C. §§ 301 et seq. (1994)); Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,985 (May 29, 1992).
[143] Beach, *supra* note 3, at 184 (citing 42 U.S.C. §§ 262-263a (1994)).
[144] Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. at 22,984.
[145] *Id.*

first GMO that was marketed in the United States, the FlavrSavr™ tomato.[146] The FDA has implemented a voluntary premarket notification and consultation procedure for manufacturers of food produced with GMOs, but does not otherwise impose regulatory requirements.[147] As a part of the premarket process, the GM food developer submits a "Summary of the Safety and Nutritional Assessment" for the food, which includes detailed information about the genetic modification, its purpose, and how it is expected to affect the food's characteristics.[148] Notwithstanding the consultation, the FDA does not approve the GM food and the responsibility for the food's safety lies with the developer.[149] Even under the White House's new biotechnology initiative requiring a GM food developer to consult with the FDA on a mandatory basis prior to placing a GM food on the market, the FDA will not provide approval of GM foods.[150]

Under the FFDCA, the EPA is responsible for regulating GMOs with pesticidal characteristics intended to be food crops.[151] The EPA exercises more caution for the pesticidal GM foods under its authority than the FDA has done under the FFDCA.[152] The EPA uses a formal approval process and, if necessary, sets tolerance levels for the pesticidal protein in the final GM food products.[153] This approval process is subject to public comment for each new plant pesticide.[154]

In contrast to the FDA's consultation procedures, ANZFA's Food Standard 18 specifically requires pre-market approval by both ANZFA and ANZFCS for any GM food sold in Australia and New Zealand.[155] ANZFA only grants its approval following a safety assessment, which includes an opportunity for public comment and independent expert review.[156] Although the EPA provides approval for GM foods with pesticidal characteristics,[157] many GM foods in the United States are within the authority of the FDA only. As a result, many GM foods entering the U.S. market will do so

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[146] Beach, *supra* note 3, at 185 (citing Biotechnology of Food, FDA Backgrounder (May 18, 1994)).

[147] Adler, *supra* note 12, at 182.

[148] Beach, *supra* note 3, at 185 (citing CFSAN, FDA, Guidance on Consultation Procedures for Food Derived from New Plant Varieties (Oct. 1997), at 2).

[149] Proposed Rule: Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. at 4,707 (reaffirming the statement of the 1992 Policy, 57 Fed. Reg. at 22,985).

[150] *Id.*

[151] VOGT & PARISH, *supra* note 43.

[152] Adler, *supra* note 12, at 182.

[153] U.S. Food Safety Fact Sheet, *supra* note 127.

[154] *Id.*

[155] *See supra* notes 91-93 and accompanying text.

[156] *See supra* notes 94-95 and accompanying text.

[157] *See supra* notes 151-54 and accompanying text.

without any regulatory approval.[158] The FDA will soon require pre-market notifications for GM foods being introduced into the food supply. While this is more stringent than the voluntary pre-market notifications available prior to the initiative, it remains less stringent than the ANZFA requirements, since public consultation is not required and the FDA will still not provide approval.[159]

2. *Genetically Modified Food Labeling Requirements*

The U.S. GM food labeling requirements, like the U.S. GM food approval requirements, are much less stringent than those that will soon be required in Australia and New Zealand. While ANZFA's labeling standards will soon require the labeling of all foods containing GM ingredients,[160] the United States resists mandatory labeling and has only recently begun development of voluntary labeling guidelines.[161]

In the United States, labeling of GM foods is regulated under the same provisions of the FFDCA as other foods not produced by modern biotechnology.[162] Since the FDA does not regulate the method of food production, but rather the food's characteristics, the fact that a food is produced by GM technology is immaterial for labeling purposes.[163] Thus, if genetic modifications have not significantly altered the food's characteristics, special labeling is not appropriate.[164] However, if the food's characteristics have been changed to display characteristics different from what a consumer would expect, then the FDA requires appropriate labeling to inform consumers.[165] While reaffirming its decision not to require mandatory labeling of all GM foods, the FDA has recently announced that it will work with industry and consumer groups to develop standards for voluntary labeling of foods.[166] This will provide a standard for

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[158] Marian Burros, *Eating Well: Labeling Foods with Designer Genes*, N.Y. TIMES, Jan. 3, 2001, at F-2.

[159] *See supra* note 150 and accompanying text.

[160] *See supra* notes 99-112 and accompanying text.

[161] *See infra* notes 166-67 and accompanying text.

[162] Draft Guidance for Industry, *supra* note 116, at 4,839.

[163] Beach, *supra* note 3, at 186.

[164] *Id.* at 186-87.

[165] For example, the FDA would require labeling for the introduction of a peanut protein that would function as an allergen for some people. Beach, *supra* note 3, at 187.

[166] Draft Guidance for Industry, *supra* note 116, at 4,840.

manufacturers who wish to provide labeling in response to the current international and national consumer demand for GM food labeling.[167]

In contrast, Australia and New Zealand, in response to consumer concerns, will soon require labeling of GM foods solely because they were produced using GM technology.[168] ANZFA's new labeling requirement is premised on the notion that the consumer has a right to choose whether or not to consume GM foods.[169] In the United States, however, the concept of consumer disclosure may not be sufficient to force a manufacturer to label GM foods "in the absence of health and safety concerns."[170] In *Stauber v. Shalala*, a case concerning milk products from cows treated with a genetically engineered growth hormone,[171] a federal court held that consumer opinion alone is not enough to require labeling under the FFDCA when a treated product does not differ materially from a non-treated product.[172] Similarly, in *International Dairy Foods Association v. Amestoy*, the Second Circuit Court of Appeals concluded that a Vermont law requiring the labeling of the same types of milk products,[173] which was "based solely on consumer right-to-know, violated the First Amendment commercial speech rights of the manufacturers, who had been compelled to label their food products with the equivalent of a warning."[174] These cases indicate that mandatory labeling of GM foods may not be allowed where there is a lack of scientific evidence of a potential health risk.[175] Thus, despite the precautionary approach to food labeling by Australia and New Zealand, the United States continues to advocate a science-based approach that is based on the premise that GM foods are as safe as any other type of food and that non-scientific concerns do not justify mandatory GM food labeling.

IV. INTERNATIONAL TRADE OF GM FOODS

The differences between the U.S. regulations and those of Australia and New Zealand, especially with regard to labeling requirements, are

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[167] Karen A. Goldman, *Labeling of Genetically Modified Foods: Legal and Scientific Issues*, 12 GEO. INT'L ENVTL. L. REV. 717, 758 (2000).

[168] *See supra* notes 102-07 and accompanying text.

[169] Lindenmayer, *supra* note 78.

[170] *Safety and Labeling*, *supra* note 133, at 459.

[171] Stauber v. Shalala, 895 F. Supp. 1178 (W.D. Wis. 1995).

[172] Goldman, *supra* note 167, at 731.

[173] Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996).

[174] Goldman, *supra* note 167, at 757; Stewart & Johanson, *supra* note 7, at 251-52.

[175] *Safety and Labeling*, *supra* note 133, at 459; *but see* Winn, *supra* note 39, at 671-72 (the FDA requires labeling for irradiated foods, finding that irradiation is material information for labeling purposes "even in the absence of safety concerns").

important because these differences will affect the trade of agricultural products between the three countries.[176] Although there is currently no trade agreement that explicitly regulates GM foods,[177] the multinational trade rules of the World Trade Organization will play an important role in decisions about the regulation of GM foods in the three countries.[178] Furthermore, the work of the Codex Alimentarius Commission, since it is developing international standards for GM foods, will affect the development of national regulations in Australia and New Zealand, as well as in the United States.[179]

A. How Australia and New Zealand's GM Food Regulations May Affect Trade with the United States

Many agricultural products, including non-GM products, exported from the United States may be affected by Australia and New Zealand's precautionary regulatory requirements, resulting in restrictions on trade.[180] This impact could be significant, because while the balance of trade with the United States favors Australia and New Zealand, the United States still exported agricultural products valuing over $300 million to Australia and over $100 million to New Zealand in 1999.[181] Since the United States takes the position that GM foods are generally as safe as other foods, concern exists that the application of the conservative regulations are thinly disguised protectionist trade policies, rather than policies designed to protect human

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[176] Jeffrey K. Francer, Note, *Frankenstein Foods or Flavor Savers?: Regulating Agricultural Biotechnology in the United States and the European Union*, 7 VA. J. SOC. POL'Y & L. 257, 308 (2000).

[177] Stewart & Johanson, *supra* note 7, at 287 (explaining that the WTO trade rules have not specifically addressed biotechnology products). Once it is in force, the Convention on Biological Diversity, through its Cartagena Protocol on Biosafety, will regulate the international trade of some. *See* Richard J. Mahoney, *Opportunity for Agricultural Biotechnology*, 288 SCI. 615 (2000). The Biosafety Protocol will not regulate food safety issues. Fact Sheet, U.S. Dep't of State, Office of the Spokesman, The Cartagena Protocol on Biosafety, Feb. 16, 2000, *available at* http://www.state.gov/ www/global/oes/fs-cart_prot_biosaf_000216.html. However, the protocol is not a factor in this trade analysis, as Australia and the United States have not signed the Protocol, and New Zealand has signed, but not ratified it. Secretariat, Convention on Biological Diversity, Cartagena Protocol of Biosafety to the Convention on Biological Diversity, List of Signatories (Feb. 2, 2001), *at* http://www.biodiv.org/ biosafety/signinglist.asp.

[178] Francer, *supra* note 176, at 308.

[179] *See infra* notes 229-47 and accompanying text.

[180] *Biotechnology: Australia, New Zealand Health Ministers Approve Resolution for Labeling GMO Foods*, INT'L ENV'T DAILY (BNA), Aug. 9, 2000.

[181] U.S. Dep't of Agric., U.S. Exports of Agricultural, Fish & Forestry Products to Australia, *at* http://www.fas.usda.gov/scriptsw/bico/bico.asp?Entry=lout&doc=372 (last visited Feb. 7, 2001); U.S. Dep't of Agric., U.S. Exports of Agricultural, Fish & Forestry Products to New Zealand, *at* http://www.fas.usda.gov/scriptsw/bico/bico.asp?Entry=lout&doc=504 (New Zealand) (last visited Feb. 7, 2001).

health and the environment.[182] For this reason, U.S. officials indicated to New Zealand that implementation of the new ANZFA regulations would threaten the development of a free trade agreement between the two countries.[183]

1. Divergent GM Food Approval Processes

Australia and New Zealand's differing food approval processes may affect their food trade with the United States.[184] Some agricultural GMOs used extensively in the United States[185] are not approved for use by ANZFA.[186] Since the United States does not segregate its GM and non-GM crops,[187] a planned bulk corn shipment to Australia or New Zealand could contain a single type of GM corn not approved for import by ANZFA, thus rendering the entire shipment "unmarketable."[188] While the United States could implement segregation of GM and non-GM crops to overcome this problem, it has been unwilling to do so thus far.[189] This refusal is primarily based upon the expense[190] associated with segregating crops, which would result in higher food costs.[191] The United States regards the expense scientifically unjustified.[192] In fact, the U.S. Secretary of Agriculture has stated that "segregating crops and processed products on the basis of GMO characteristics is scientifically unfounded and commercially impossible."[193] The higher cost would arise from the fact that segregation would be required

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[182] Undersecretary of State, Stuart Eizenstat, suggested that the European Union's restrictions were only a "pretense 'to justify keeping its trade restrictions in place.'" Adler, *supra* note 12, at 204 (citing Ehsan Masood, *Europe and US in Confrontation Over GM Food Labelling Criteria*, 398 NATURE 641, 641 (1999)).

[183] Julie Teel, Note, *Regulating Genetically Modified Products and Processes: An Overview of Approaches*, 8 N.Y.U. Envtl. L.J. 649, 682 (citing Marie Woolf, *Revealed: How U.S. Bullies Nations Over Genetic Food*, INDEPENDENT, Nov. 22, 1998).

[184] Thomas P. Redick & Christina G. Bernstein, *Nuisance Law and the Prevention of "Genetic Pollution": Declining a Dinner Date with Damocles*, 30 ENVTL. L. REP. 10328, 10328 (2000).

[185] *Id.*

[186] Over fifty different GMOs have been through the U.S. regulatory process. *See supra* note 129 and accompanying text. ANZFA has approved only seven. *See supra* note 96 and accompanying text.

[187] Stewart & Johanson, *supra* note 7, at 292.

[188] Redick & Bernstein, *supra* note 184, at 10329.

[189] Beach, *supra* note 3, at 187 (citing *EU May Strengthen Labeling Requirements for Genetically Modified Soybeans and Corn*, FOOD LABELING & NUTRITION NEWS, Dec. 11, 1997 at 10).

[190] Implementation of segregation of GM from non-GM corn and soybeans in the United States could increase the total cost of the commodities by ten to twenty-five percent. J. Howard Beales, III, *Modification and Consumer Information: Modern Biotechnology and the Regulation of Information*, 55 FOOD DRUG L.J. 105, 115 (2000).

[191] Appleton, *supra* note 39, at 569-70.

[192] Beach, *supra* note 3, at 187.

[193] *Id.* (A. Novotny, EU Directive on Labeling Genetically Modified Organisms Creates Confusion for U.S. Industry, Government, FOOD LABELING & NUTRITION NEWS, July 10, 1997, at 3-4).

"throughout all phases of production, including planting, harvesting, processing, and retail distribution."[194]

2. *ANZFA's Strict Labeling Standards*

The U.S. food trade with Australia and New Zealand may also be affected by ANZFA's stringent labeling standards.[195] Because ANZFA's new standard will require "all reasonable steps be taken to ascertain the status of the food," the mandatory labeling requirement will necessitate expensive laboratory testing or detailed tracking and segregation of the food to establish its origin.[196] Again, this will result in increased consumer costs.[197] Additionally, labeling could affect the trade of GM foods by leading consumers in Australia and New Zealand to reject the foods containing GM ingredients.[198] Expressing this concern, a U.S. official stated that mandatory labeling will "stigmatize a technology that has had no demonstrable ill effects."[199] As one commentator has also stated, the "debate between scientific justification and protectionism [is] at the heart of the controversy surrounding the labeling of products made with genetically modified organisms."[200] ANZFA bases its food labeling requirement in the consumer's right to know about the presence of GM foods, rather than in food safety concerns.[201] For this reason, the lack of a science-based foundation for ANZFA's new labeling requirement could form the basis for a U.S. challenge at the World Trade Organization ("WTO").[202]

B. *The Role of the World Trade Organization*

The WTO's[203] goal is to develop trade rules that facilitate free, predictable international trade by eliminating trade barriers.[204] The WTO

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[194] Goldman, *supra* note 167, at 722.

[195] *Biotechnology: Australia, New Zealand Health Ministers Approve Resolution for Labeling GMO Foods*, *supra* note 180.

[196] Lindenmayer, *supra* note 78.

[197] Appleton, *supra* note 39, at 569-70.

[198] *Id.* at 569.

[199] Ambassador David L. Aaron, U.S. Undersecretary of Commerce For Trade, Remarks before the Conference On Biotechnology: The Science and the Impact at The Hague, Netherlands (Jan. 21, 2000), *at* http://usinfo.state.gov/topical/global/biotech/00012103.htm.

[200] Appleton, *supra* note 39, at 566.

[201] *See supra* notes 109-10 and accompanying text.

[202] Stewart & Johanson, *supra* note 7, at 286.

[203] Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 33 I.L.M. 1144 (1994) [hereinafter WTO Agreement].

operates through agreements developed in formal trade negotiations and has implemented formal dispute resolution procedures.[205] The agreements that are relevant to the trade and national regulation of GM agricultural products include the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement")[206] and the Agreement on Technical Barriers to Trade ("TBT Agreement").[207]

1. WTO Dispute Resolution

If a country believes that a regulation of another country is adversely affecting its rights under either the SPS Agreement or the TBT Agreement, it may bring a complaint to the WTO using the mechanisms of the WTO Dispute Settlement Understanding.[208] The WTO dispute settlement process has not yet been used to resolve any disputes about agricultural biotechnology.[209] Because biotechnology has not been addressed expressly in any of the WTO Agreements,[210] there is some debate about whether the TBT Agreement or the SPS Agreement would apply to a dispute over the trade of GM foods.[211] However, if the WTO should determine that the disputed GM trade restriction fails to comply with either agreement, the losing nation must then bring the restriction into conformity with the agreement or face retaliatory trade action.[212]

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[204] Stephanie Carlsten, *Trade and the Environment: The World Trade Organization Millennium Conference in Seattle: The WTO Recognizes a Relationship Between Trade and the Environment and Its Effect on Developing Countries*, 1999 COLO. J. INT'L ENVTL. L. & POL'Y 33, 35 (1999).

[205] NEW ZEALAND MINISTRY OF FOREIGN AFFAIRS AND TRADE, *supra* note 1, at 3.

[206] Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, WTO Agreement, Annex 1A, 1994 WL 761483 [hereinafter SPS Agreement].

[207] Agreement on Technical Barriers to Trade, Apr. 15, 1994, WTO Agreement, Annex 1A, 1994 WL 761483 [hereinafter TBT Agreement]; Stewart & Johanson, *supra* note 7, at 287-88; NEW ZEALAND MINISTRY OF FOREIGN AFFAIRS AND TRADE, *supra* note 1, at 4.

[208] Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, WTO Agreement, Annex 2, 33 I.L.M. 1226 (1994); NEW ZEALAND MINISTRY OF FOREIGN AFFAIRS AND TRADE, *supra* note 1, at 1.

[209] Stewart & Johanson, *supra* note 7, at 285. The United States has threatened to bring a WTO complaint against the European Union, but thus far has not. *Id.* at 286.

[210] *Id.* at 287. Although proposals for biotechnology's formal consideration were made at the Seattle Ministerial Conference in 1999, no agreement was reached to proceed with negotiations. NEW ZEALAND MINISTRY OF FOREIGN AFFAIRS AND TRADE, *supra* note 1, at 4.

[211] Stewart & Johanson, *supra* note 7, at 287.

[212] NEW ZEALAND MINISTRY OF FOREIGN AFFAIRS AND TRADE, *supra* note 1, at 4.

2. *The SPS Agreement*

The SPS Agreement allows nations to implement health and safety measures to protect human, animal, and plant life.[213] The SPS Agreement is purely a trade agreement in that it does not require nations to take health and safety measures. It is only concerned when a nation's use of such a measure acts as a trade barrier.[214] The SPS Agreement requires that a valid national health measure (like a food safety measure) must be based in science and risk assessment principles.[215] Further, the measure cannot be a disguised barrier to trade.[216] The SPS Agreement allows provisional or temporary measures in the absence of conclusive scientific evidence, but the member nation must take steps to seek further information.[217] Finally, the SPS Agreement requires nations to base their health and safety measures on international codes, specifically the Codex Alimentarius Commission ("Codex") standards for food safety measures.[218] However, in the matter of agricultural biotechnology, use of the Codex standards is complicated by the fact that the Codex has not yet developed GM-specific provisions.[219]

3. *The TBT Agreement*

The TBT Agreement's overall goal is to avoid unnecessary barriers to trade,[220] while acknowledging that WTO member nations should not be prevented from taking measures to pursue legitimate objectives, such as the prevention of deceptive trade practices or the protection of human health and safety, animal or plant life, and the environment.[221] The TBT Agreement provides that these measures cannot restrict trade any more than is necessary to achieve a legitimate objective.[222] Further, the measures must be applied

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[213] Stewart & Johanson, *supra* note 7, at 288.

[214] Steve Charnovitz, *The Supervision of Health and Biosafety Regulation by World Trade Rules*, 13 TUL. ENVTL. L.J. 271, 276 (2000).

[215] Stewart & Johanson, *supra* note 7, at 288.

[216] NEW ZEALAND MINISTRY OF FOREIGN AFFAIRS AND TRADE, *supra* note 1, at 6.

[217] OECD, C(2000)86/ADD2, REPORT OF THE WORKING GROUP ON HARMONIZATION OF REGULATORY OVERSIGHT IN BIOTECHNOLOGY 133 (2000), http://www.oecd.org/subject/biotech/report_workgroup.pdf.

[218] NEW ZEALAND MINISTRY OF FOREIGN AFFAIRS AND TRADE, *supra* note 1, at 6.

[219] *See infra* notes 230-47 and accompanying text.

[220] Stewart & Johanson, *supra* note 7, at 288.

[221] NEW ZEALAND MINISTRY OF FOREIGN AFFAIRS AND TRADE, *supra* note 1, at 5.

[222] Stewart & Johanson, *supra* note 7, at 288 (citing TBT Agreement, *supra* note 207).

in a non-discriminatory way.[223] The TBT Agreement would apply to mandatory and voluntary labeling requirements for GM foods.[224]

Like the United States in its GM regulatory scheme, the TBT Agreement focuses on product characteristics rather than methods of production and encourages reliance on international standards, like the Codex food labeling standards, as much as possible.[225] While many national GM food labeling regulations are designed with the goal of providing consumer information, providing consumer information is not listed as a legitimate objective of the TBT Agreement.[226] If the provision of consumer information is not a legitimate objective of the TBT Agreement, then mandatory labeling as a response to consumer fears may have an unjustifiable effect on trade.[227] This issue is further complicated by the fact that the Codex has not yet developed a standard governing the labeling of GM foods.[228]

C. *Codex Alimentarius Commission*

The Codex Alimentarius Commission establishes international food standards with the aim of protecting human health without unnecessarily restricting trade.[229] Several committees within the Codex are currently developing standards and guidelines for the international regulation of GM foods.[230] Once developed, these standards will be used as the basis for determining whether a national GM food regulation violates the provisions of the SPS or TBT Agreements.[231]

The Codex established the Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology ("Task Force"), which conducted its first meeting in March 2000.[232] The major work of the Task Force is the

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[223] NEW ZEALAND MINISTRY OF FOREIGN AFFAIRS AND TRADE, *supra* note 1, at 5.

[224] *Id.*

[225] *Id.*

[226] *Id.* at 6. Switzerland has characterized the reason for its GM labeling requirement as the prevention of deceptive practices, a legitimate objective under the TBT Agreement. Perrez, *supra* note 49, at 602-03.

[227] Stewart & Johanson, *supra* note 7, at 291.

[228] *See infra* notes 230-47 and accompanying text.

[229] The Codex was established under the World Health Organization and the Food and Agriculture Organization. Beach, *supra* note 3, at 188; NEW ZEALAND MINISTRY OF FOREIGN AFFAIRS AND TRADE, *supra* note 1, at 6.

[230] Notice of International Standard-Setting Activities, 65 Fed. Reg. 34,637; 34,641-42; 34,645 (May 31, 2000).

[231] Merle D. Kellerhals, Jr., U.S. Dep't of State, International Information Programs, U.S. Codex Delegation Seeks Science-Based Food Safety Guidelines (Apr. 6, 2000), *at* http://usinfo.state.gov/topical/global/biotech/00040603.htm.

[232] NEW ZEALAND MINISTRY OF FOREIGN AFFAIRS AND TRADE, *supra* note 1, at 7.

development of two documents: the first will include a set of broad principles for risk analysis and the second will provide specific guidance on the conduct of risk assessments for GM foods.[233] The Task Force has also noted that work in other Codex committees regarding labeling, the use of the precautionary approach, and the consideration of legitimate, non-science factors would affect its work.[234] However, the Task Force will not present the finalized guidelines to the Codex until 2003.[235]

At the last meeting of the Codex Committee on General Principles ("CCGP") in April 2000, the committee considered the roles of precaution and non-scientific factors in the analysis of food safety risks.[236] The United States objected to the final adoption of two proposals that would incorporate precaution into the analysis food safety risks.[237] Additionally, in contrast to other CCGP delegations, the United States took the position that non-scientific factors that are "not relevant to the protection of consumers' health and the promotion of fair practices of trade were not within the mandate of Codex."[238] Because no agreement on either precaution or non-scientific factors could be reached, both proposals were deferred to the next meeting of the CCGP in 2001.[239]

The Codex Committee on Food Labeling ("CCFL") is also considering the international standards for GM foods.[240] At the last meeting of the CCFL, in 2000, the committee considered three options for mandatory labeling on GM foods.[241] The first approach would require labeling only when there is a "change in composition, nutritional value, or intended use" between the GM food and the analogous conventional food.[242] Another

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[233] CODEX ALIMENTARIUS COMMISSION, ALINORM 01/34, REPORT OF THE FIRST SESSION OF THE CODEX AD HOC INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY 5 (2000), ftp://ftp.fao.org/codex/ALINORM01/AI01_34e.pdf.

[234] *Id.* at 6.

[235] NEW ZEALAND MINISTRY OF FOREIGN AFFAIRS AND TRADE, *supra* note 1, at 7.

[236] CODEX ALIMENTARIUS COMMISSION, ALINORM 01/33, REPORT OF THE FIFTEENTH SESSION OF THE CODEX COMMITTEE ON GENERAL PRINCIPLES 5-7, 11-12 (2000), ftp://ftp.fao.org/codex/ALINORM01/AI01_33e.pdf [hereinafter CODEX REPORT OF GENERAL PRINCIPLES].

[237] Catherine Woteki, U.S. Under Secretary of Agriculture, U.S. Reports from Codex Meeting (Apr. 17, 2000), *at* http://usinfo.state.gov/topical/global/biotech/00041702.htm.

[238] CODEX REPORT OF GENERAL PRINCIPLES, *supra* note 236, at 11.

[239] *Id.* at 7, 12.

[240] NEW ZEALAND MINISTRY OF FOREIGN AFFAIRS AND TRADE, *supra* note 1, at 7.

[241] *Id.*

[242] CODEX ALIMENTARIUS COMMISSION, ALINORM 01/22, REPORT OF THE TWENTY-EIGHTH SESSION OF THE CODEX COMMITTEE ON FOOD LABELLING 5 (2000), ftp://ftp.fao.org/codex/ALINORM01/AI01_22e.pdf [hereinafter CODEX REPORT ON FOOD LABELING]; CODEX ALIMENTARIUS COMMISSION, CX/FL 00/6, RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH BIOTECHNOLOGY (PROPOSED DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS) 9 (2000), ftp://ftp.fao.org/codex/olddocs/committees/ccfl28/fl00_06e.pdf [hereinafter CODEX LABELING RECOMMENDATIONS].

option, advocated by "many delegations,"[243] requires mandatory labeling for most GM foods.[244] The delegation from Japan presented a third option, where the labeling ideas of the second option would be developed as a Codex guideline. This would allow a country to implement mandatory labeling on a voluntary basis, thereby allowing for flexible application of labeling concepts in national legislation.[245] The United States proposed that the CCFL should consider "all the implications of labelling [sic] of foods derived from biotechnology as regards enforcement, methodology, economic cost, and consumer perception" prior to implementing any mandatory labeling requirements.[246] The CCFL decided, in light of the varying attitudes within the committee, to return the labeling text to a working group to continue to formulate draft labeling standards and present to the CCFL at its next meeting.[247] The United States, by its opposition to the precautionary approach and mandatory labeling in the CCFL, as well as the CCGP, has delayed the development of harmonized Codex standards.

D. *International Debate Over the Regulation of Genetically Modified Foods*

The international debate about regulating GM foods is illustrated by the differences between the United States and the countries of the European Union ("EU"). In 1998, the United States expressed its opposition to a labeling provision for GM foods adopted by the European Union in a meeting of the WTO Technical Barriers to Trade ("TBT") Committee.[248] The EU regulation in question requires the labeling of foods containing certain GM corn and soy varieties.[249] The United States expressed concern about the regulation's potential impact on trade, as well as the precedents that the regulation might set.[250] While the United States acknowledged that providing consumers with food safety information was a legitimate

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[243] The report does not specify which delegations advocated this option. CODEX REPORT ON FOOD LABELING, *supra* note 242, at 5.

[244] *Id.*; CODEX LABELING RECOMMENDATIONS, *supra* note 242, at 10-13.

[245] CODEX REPORT ON FOOD LABELING, *supra* note 242, at 6.

[246] *Id.* at 5.

[247] *Id.* at 6.

[248] Stewart & Johanson, *supra* note 7, at 286.

[249] *Id.* (citing Regulation (EC) No. 1139/98).

[250] The United States submitted a formal letter to the TBT Committee, requesting that the European Union address its concerns. *Id.* (citing World Trade Organization, Committee on Technical Barriers to Trade, European Council Regulation No. 1139/98 Compulsory Indication of the Labelling of Certain Foodstuffs Produced from Genetically Modified Organisms: Submission by the United States, G/TBT/W/94 (Oct. 16, 1998), http://docsonline.wto.org/gen_search.asp [hereinafter U.S. TBT Committee Submission]).

objective, it suggested that providing GM information when there was no risk to human health would amount to a deceptive practice.[251] The United States questioned the EU's conviction that the presence of a GM ingredient distinguished a product of biotechnology from a traditional product, as it was "unaware of any evidence that would demonstrate that genetically modified varieties as a class differ from conventional varieties in composition, nutritional value, or nutritional effects."[252] In 1999, the United States, while not commenting on any specific concerns, did submit another letter to the TBT Committee, drawing the committee's attention to a number of other national regulations governing GM foods, including those of Australia and New Zealand.[253]

In May 2000, President Prodi of the European Union and President Clinton of the United States commissioned the EU-U.S. Biotechnology Consultative Forum ("Biotechnology Forum")[254] to examine "the full range of issues of concern" presented by modern agricultural biotechnology in the European Union and the United States.[255] The White House, in its announcement of the Biotechnology Forum, stated that the "paralysis" in the EU's GM foods approval system was leading to "uncertainty in markets around the world and harming U.S. farm exports."[256] The Biotechnology Forum was part of an effort to "make progress on regulatory issues and to avoid and resolve trade problems."[257]

The Biotechnology Forum was composed of a diverse group of biotechnology experts, ten from the United States and ten from the European Union, representing scientists, environmentalists, biotechnology industry representatives, and farmers.[258] Representatives from the United States included Dr. Norman Borlaug, winner of the Nobel Peace Prize in 1970 for work in improving agricultural methods, and Dr. Cutberto Carza, the chair of the Food and Nutrition Board at the National Academy of Sciences, as well as eight other distinguished members from academia, industry, the

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[251] U.S. TBT Committee Submission, *supra* note 250.

[252] *Id.*

[253] World Trade Organization, Committee on Technical Barriers to Trade, Genetically Modified Agricultural and Food Products: Submission from the United States, G/TBT/W/115 (June 17, 1999), *at* http://docsonline.wto.org/gen_search.asp.

[254] CONSULTATIVE FORUM, *supra* note 1, at 4.

[255] *Id.*

[256] Fact Sheet, Office of the Press Secretary, White House, U.S.-EU Cooperation on Biotechnology (May 31, 2000), *at* http://usinfo.state.gov/topical/global/biotech/00053102.htm.

[257] *Id.*

[258] Merle D. Kellerhals, Jr., U.S. Dep't of State, International Information Program, U.S.-EU Panel Recommends Review, Labeling of Biotech Foods, (Dec. 19, 2000), *at* http://usinfo.state.gov/topical/global/biotech/00121903.htm.

farming community, and environmental groups.[259] The Biotechnology Forum's final report, released in December 2000, called for greater precaution in the GM food approval process, as well as mandatory labeling of GM foods.[260]

This report, along with the other legitimate concerns demonstrated by the more precautionary regulations of most of the other developed countries, including Australia and New Zealand, indicates that the United States should work with the international community to develop standards governing the trade in GM foods that are more precautionary than the ones that they have advocated so far.

V. THE UNITED STATES SHOULD WORK TO DEVELOP HARMONIZED INTERNATIONAL STANDARDS

The development of harmonized international standards for food derived from biotechnology through the Codex will provide a better solution to the U.S. debate over GM foods regulation in Australia and New Zealand than a WTO dispute settlement action. Given U.S. resistance to Australia and New Zealand's precautionary approach, the United States may protest some of the GM food standards in the WTO arena. Proponents of the U.S. science-based approach argue that "excessive precautionary regulation could, for example, limit the introduction of high-yield crops, nutritionally-enhanced foodstuffs, or new vaccines."[261] While the United States may perceive that the benefits of Australia and New Zealand's new regulations are so low and the cost to U.S. farmers so high that some action must be taken,[262] the Biotechnology Forum demonstrates that there is support for the precautionary approach to agricultural biotechnology and mandatory labeling of GM foods even among experts within the United States.[263] The United States could file a complaint under the WTO dispute resolution process, yet given the concern about agricultural GMOs and GM foods internationally, as well as within the United States,[264] this effort would be better spent in arriving at harmonized international standards for GM products through the Codex.

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[259] CONSULTATIVE FORUM, *supra* note 1, at 23-24; Burros, *supra* note 158.

[260] Kellerhals, *supra* note 258.

[261] Adler, *supra* note 12, at 174.

[262] Stewart & Johanson, *supra* note 7, at 294.

[263] *See supra* notes 258-60 and accompanying text.

[264] Office of the Spokesman, U.S. Dep't of State, Report of the U.S.-EU Biotechnology Consultative Forum (Dec. 19, 2000), *at* http://usinfo.state.gov/topical/global/biotech/00121901.htm.

A. International Trade Dispute Complaint

Australia, New Zealand, and the United States, as members of the WTO, have an obligation to comply with the trade agreements and rules designed to facilitate international trade.[265] It is possible that the United States would be successful in a WTO complaint against Australia or New Zealand.[266] However, the consequences of a favorable ruling might include backlash from consumers in those countries as well as others that support greater regulation of agricultural GMOs and GM foods, such as Europe.[267] The United States has also shown a desire to settle the issues on a "government-to-government level."[268]

Since Australia and New Zealand approve GMOs and GM products using science-based risk assessments, this practice would appear to be in compliance with the requirements of the SPS Agreement.[269] If the United States protested the disapproval of a GMO or GM product in Australia or New Zealand, the basis of this dispute could be that the assessment used inaccurate information or that the risk assessment was not conducted properly in violation of the obligations of the SPS Agreement.[270]

For a dispute concerning Australia and New Zealand's mandatory labeling, where ANZFA has determined that the GM product is safe but is providing only consumer information, the United States' most likely argument would be that the nations are violating the TBT Agreement.[271] Since consumer information is the aim of the ANZFA labeling requirements, the United States would maintain that the ANZFA labeling requirements are not technical regulations with a legitimate objective under the TBT Agreement.[272] This argument would be strengthened if the United States can maintain that the ANZFA labeling requirements will require segregation of GM from non-GM products to import any food product into Australia or New Zealand.[273] However, Australia may argue that the labeling does have a legitimate objective of preventing deceptive practices by identifying an ingredient that the consumer wishes to avoid.[274] As was recently

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[265] NEW ZEALAND MINISTRY OF FOREIGN AFFAIRS AND TRADE, *supra* note 1, at 1.
[266] Stewart & Johanson, *supra* note 7, at 293; Fredland, *supra* note 42, at 218.
[267] Fredland, *supra* note 42, at 219.
[268] Office of the Spokesman, *supra* note 264.
[269] Stewart & Johanson, *supra* note 7, at 290.
[270] *Id.*
[271] *Id.* at 289.
[272] *Id.* at 290.
[273] *Id.* at 292.
[274] Perrez, *supra* note 49, at 602.

demonstrated by the results of the Biotechnology Forum,[275] U.S. experts do not completely support the official rejection of the precautionary approach and mandatory labeling in the United States.[276] Additionally, a U.S. official acknowledged that "whether it improves food safety or not, it is going to be hard in the end to avoid satisfying the consumer's demand to know."[277] Another indicated that U.S. companies were "prepared to try to meet the one percent threshold for incidental contamination" in the European Union labeling standard.[278] It appears that, while still objecting to mandatory labeling requirements, the United States is not prepared to officially protest them in a WTO forum.

B. Development of Codex Alimentarius Commission Standards

The Codex, which is currently assessing several issues associated with agricultural biotechnology, is an ideal forum for the development of harmonized standards.[279] The advantage to working within the Codex is that, while accommodating the more precautionary approaches of the other countries, the United States may still achieve uniform rules in a stable international trade regime, allowing U.S. biotechnology companies to continue the development of innovative GMOs.[280] The United States, in light of the Biotechnology Forum recommendations, should cease objecting to the incorporation of a precautionary approach into risk assessments.[281] Additionally, the United States should assent to the Codex labeling standards that the Japanese delegation suggested that allow, but do not require, nations to implement mandatory labeling standards for GM foods.[282]

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[275] CONSULTATIVE FORUM, *supra* note 1.

[276] *Id.* at 13-14. In fact, in the context of international negotiations to address persistent organic pollutants, the United States stated its support for the precautionary approach in Principle 15 of the Rio Declaration. U.S. Dep't of State, *supra* note 53.

[277] Frank Loy, U.S. Undersecretary of State for Global Affairs, Remarks at the Center on Environmental and Land Use Law's Colloquium on the Risks and Regulations of Genetically Modified Organism (GMO) Food Products, New York University School of Law, Statement on Biotechnology: A Discussion of Four Important Issues in the Biotechnology Debate (Oct. 1999), *reprinted in* 8 N.Y.U. ENVTL. L.J. 605, 607 (2000).

[278] Aaron, *supra* note 199.

[279] Appleton, *supra* note 39, at 573.

[280] The Head of Regulatory and Government Affairs at Novartis Seeds, a major seed production company involved with the development of GM technologies, stated, "the industry has a vital interest in regulatory harmony throughout the world." Willy De Greef, *Regulatory Conflicts and Trade*, 8 N.Y.U. ENVTL. L.J. 579, 582 (2000).

[281] CONSULTATIVE FORUM, *supra* note 1, at 13-14; OECD, *supra* note 1, at 12.

[282] CONSULTATIVE FORUM, *supra* note 1, at 15-16; OECD, *supra* note 1, at 3.

VI. CONCLUSION

The United States has consistently rejected the precautionary approach as it has been applied to agricultural biotechnology and GM foods. Additionally, since it believes that there is no scientific basis for separating GM and non-GM foods, the United States also objects to mandatory labeling of GM foods. However, the U.S. science-based approach neglects other legitimate factors such as economic, cultural, and social issues–those issues with which consumers are currently concerned. While the United States may have a valid claim against the more stringent regulations of Australia and New Zealand within the WTO dispute resolution arena, a WTO trade complaint would only serve to exacerbate those consumer concerns. Additionally, the U.S. opposition to precaution and mandatory labeling has slowed the development of harmonized international standards under the Codex. Given the diminishing support for the U.S. position even within the country, as demonstrated by the results of the Consultative Forum, the United States should cease its opposition to these concepts and support the Codex in its development of uniform international standards, thus giving the technology the stable regulatory environment which it needs to further develop in a manner sensitive not only to science, but to economics, society, and culture.