

Northwestern Journal of International Law & Business

Volume 23

Issue 1 *Fall*

Fall 2002

The ABCs and NTBs of GMOs: The Great European Union-United States Trade Debate - Do European Restrictions on the Trade of Genetically Modified Organisms Violate International Trade Law

Sarah Lively

Follow this and additional works at: <http://scholarlycommons.law.northwestern.edu/njilb>



Part of the [Agriculture Law Commons](#), [Antitrust and Trade Regulation Commons](#), [Consumer Protection Law Commons](#), and the [International Law Commons](#)

Recommended Citation

Sarah Lively, The ABCs and NTBs of GMOs: The Great European Union-United States Trade Debate - Do European Restrictions on the Trade of Genetically Modified Organisms Violate International Trade Law, 23 Nw. J. Int'l L. & Bus. 239 (2002-2003)

This Comment is brought to you for free and open access by Northwestern University School of Law Scholarly Commons. It has been accepted for inclusion in Northwestern Journal of International Law & Business by an authorized administrator of Northwestern University School of Law Scholarly Commons.

The ABCs and NTBs of GMOs: The Great European Union-United States Trade Debate—Do European Restrictions on the Trade of Genetically Modified Organisms Violate International Trade Law?

*Sarah Lively**

The debate about the use of Genetically Modified technology continues, with daily news of claims about the safety or the risks. The public's reaction shows instinctive nervousness about tampering with nature when we do not know all the consequences. There are unanswered questions that need to be asked—about the need for GM food, its safety, the environmental consequences, consumer choice, and the usefulness to feed the world's growing population.

— The Prince of Wales¹

I. INTRODUCTION

Humans have been “tinkering” with agriculture for over ten thousand years.² Throughout the ages, we have poked and prodded to create the ideal agricultural product. Today, with advances in knowledge, science, and technology, scientists have nearly created what some believe to be the per-

* J.D. Candidate, May 2003, Northwestern University School of Law. The author would like to give special thanks to Professor Michael G. Schechter at Michigan State University, James Madison College, for sharing his wealth of knowledge on International Relations and for helping to get this article off the ground. She would also like to thank Richard E. Lively for his editing and re-editing of, not only this comment, but the hundreds of papers she has passed on to him throughout her life.

¹ The Prince of Wales, *Questions About Genetically Modified Organisms*, THE DAILY MAIL, June 1, 1999, available at <http://www.princeofwales.gov.uk/speeches/agriculture01061999.html>.

² Joshua M. Stone, *Restraints on Competition Through the Alteration of the Environment at the Genetic Level*, 8 N.Y.U. ENVTL. L.J. 704 (2000).

fect crop, and they have done so by altering individual plants at the genetic level.

The genetic engineering of agriculture has spurred a lively worldwide discussion, and the technology has found both enthusiastic fans and formidable foes. Specifically, the United States has signed on as a proponent of the genetic modification of agriculture.³ In fact, the United States has become the largest producer of genetically modified organisms ("GMOs") and is consequently the leading exporter of genetically modified goods.⁴ On the other side of this debate lies the European Community ("EC"). The European Community is much less enthusiastic about GMOs and effectively questions their presence in our environment and food products.⁵ The European Community has focused on the risks that GMOs potentially pose to environmental and human health, and accordingly, have regulated GMO trade. These markedly different positions have created strained trade relations between the United States and the European Community.

The European Community believes that, in light of the "scientific uncertainty"⁶ and consumer mistrust⁷ surrounding GMOs, it is of utmost necessity to regulate GM goods in order to protect and preserve consumer and environmental health.⁸ The United States points out that the risks posed by GMOs are only "potential," and that the prospective benefits of GM agriculture may be too great to sacrifice to precautionary measures.⁹ It appears, then, that the United States believes the European Community's GMO regulation scheme to be simply thinly veiled protectionism in violation of international trade law,¹⁰ which ultimately reigns supreme over Community

³ See generally John S. Fredland, *Unlabel Their Frankenstein Food!: 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 (2000).

⁴ See Bryan Endres, *GMO: Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and the European Union*, 22 LOY. L.A. INT'L & COMP. L. REV. 453, 459-60 (2000).

⁵ See European Commission, Advance Copy of Working Document of the Commission Services on Traceability and Labeling of GMOs and Products Derived From GMOs, ENV/620/2000, at http://europa.eu.int/comm/dgs/health_consumer/library/press/press63en.pdf (Nov. 6, 2000).

⁶ See generally David Byrne, *A Challenge for Europe*, at http://europa.eu.int/comm/commissioners/byrne/articles/kos-03-02_en.html (2001).

⁷ Daniel Pruzin, *Labeling: United States Reiterates Complaint to WTO on E.U. Labeling of Genetically Modified Foods*, BNA, Sept. 17, 1998, at LEXIS, News Library, BNAITD File.

⁸ See generally Byrne, *supra* note 6.

⁹ See generally Daniel Pruzin, *U.S. Submits Paper to WTO Citing Increase in Biotechnology Restrictions*, at http://www.biotech-info.net/U.S._submits_paper.html (June 27, 2000).

¹⁰ *Id.*; see also Ruth MacKenzie & Silvia Francescon, *The Regulation of Genetically Modified Foods in the European Union: An Overview*, 8 N.Y.U. ENVTL. L.J. 530, 531 (2000).

law.¹¹ Consequently, the United States has looked to the General Agreement on Tariffs and Trade ("GATT") and its accompanying Agreements, the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS") and the Agreement on Technical Barriers to Trade ("TBT"), to end the European Community's restriction on GMO trade and to demonstrate that Europe's protectionist measures amount to illegal Non-Trade Barriers ("NTBs") according to the current international trade regime.

However, in light of the scientific uncertainty surrounding GM food and products, and thus, considering the real and potentially dangerous health and environmental risks posed by GMOs, this comment contends that European Community restrictions on GMO trade do not serve as NTBs under current international trade law (the GATT, SPS, and TBT Agreements). Such restrictions should not be considered NTBs in that current international trade law has failed to provide clear-cut rules governing genetically modified products that potentially pose environmental and human health risks. Furthermore, regardless of the ambiguity of such rules, Community restrictions on GMO trade do not currently overstep any international trade boundaries. Thus, despite an occasional trade-slowness effect, European restrictions on GMOs do not constitute NTBs as currently defined under international law. Rather, these restrictions seem to be part of a relatively sound policy that both embraces the potential of GMOs and confronts and controls the risks.

Ultimately, this comment will outline the lively trade debate between the European Community and the United States, and will do so by starting from the beginning. Part II will explain the science of GMOs and describe the technology's value to the "real world" of agriculture. Part III will highlight the potential risks of genetically modified organisms and outline the European regulatory regime that has developed in light of these risks. Part IV will then consider the specific effects of European GMO policies on trade with the United States and will summarize the resulting EC-U.S. trade debate. Part V shall discuss the current rules of international trade and

¹¹ Article 281 of the Treaty Establishing the European Community ultimately gives the European Community a singular legal personality under international law. Treaty Establishing the European Community, Feb. 7, 1992, art. 281, 1992 O.J. (C 224) 1, consolidated on Oct. 2, 1997, 1997 O.J. (C 340) 173 [hereinafter EC Treaty]. As an international actor, the Community has the general capacity, within its field of competence, to enter into obligations that bind it and its member states to the rules of international law. European Communities Committee Publication, Select Committees on the European Communities, Tenth Report, Appendix Four: Note of the Legal Adviser on Competence in the WTO, Sess. 1999-2000, available at <http://www.parliament.the-stationery-office.co.uk/pa/ld199900/ldselect/ldecom/76/7601.html>. Where the Community has bound itself to international law, it has effectively stated that those laws will reign supreme within the European Community. *Id.* The Community has entered into, and has therefore bound itself to the rules of the GATT, SPS, and TBT Agreements.

scrutinize the European position under each trade guideline set forth in, first, the GATT, second, the SPS, and lastly, the TBT. Part VI will comprehensively evaluate European GMO trade restrictions in view of current international trade law. Part VII will conclude that European Community GMO policies do not amount to NTBs.

II. GMOS EXPLAINED

A. The Science

Genetically modified agriculture is essentially those crops or plants that carry genetically modified organisms, or rather, strands of foreign genetic material within their cells.¹² Scientists insert these foreign genetic strands into a plant so that they may “change or supplement one or more of the plant’s traits,”¹³ thereby creating a plant that is potentially healthier, stronger, bigger, and overall, better. In order to genetically modify a crop, scientists must first isolate genetic material in a plant that is linked to the trait or process desired to be enhanced or changed.¹⁴ Then, scientists must incorporate “desirable” genetic material from some other organism into the plant that will be modified.¹⁵

Scientists incorporate the genetic material of one organism into another most commonly through a process known as “recombinant DNA.”¹⁶ The recombinant DNA process involves using plasmids or viruses to carry genetic material into a recipient cell’s nucleus.¹⁷ It is in the recipient cell’s nucleus that the new genetic material will, hopefully, be integrated with the recipient cell’s genes, eventually producing the desired trait.¹⁸

There are other experimental processes by which scientists insert the genetic material of one organism into another. These processes are known as, microinjection (new genetic material is directly injected into the recipient cell), electro and chemical poration (pores are created in the recipient cell membrane that allow new DNA to enter), and bioballistics (a gun-type instrument is used to shoot new DNA into the recipient cell).¹⁹

¹² Sophia Kolehmainen, *Precaution Before Profits: An Overview of Issues in Genetically Engineered Food and Crops*, 20 VA. ENVTL. L.J. 267, 269 (2001).

¹³ *Id.*

¹⁴ *Id.* at 271.

¹⁵ *See id.*

¹⁶ Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT’L L.J. 47, 51 (2001).

¹⁷ Michael K. Hansen, *Genetic Engineering is Not an Extension of Traditional Plant Breeding*, at http://www.biotech-info.net/wide_crosses.html (last visited Oct. 23, 2001).

¹⁸ *See* Kolehmainen, *supra* note 12, at 271.

¹⁹ Hansen, *supra* note 17; *see also* MARTIN TEITEL & KIMBERLY WILSON, *GENETICALLY ENGINEERED FOOD: CHANGING THE NATURE OF NATURE* 19 (1999).

B. The Application

Agricultural genetic engineering by means of recombinant DNA sequencing has truly “opened up a whole range of genetic exchanges that could never be possible without human interference”;²⁰ it has greatly expanded our ability to grow, cultivate and produce agriculture and certain agricultural products. According to many proponents, the technology has endless possibilities including the ability to improve the environment, enhance the nutritional qualities of food, and increase food production.²¹ Some of the GMO faithful even suggest that genetic modification may reduce human suffering and “improve the quality of life, particularly in the developing world.”²² These sweeping predictions seem quite idealistic considering the relative “novelty”²³ of agricultural genetic engineering by means of the recombinant DNA process. Nonetheless, scientists are expecting to achieve the “impossible” through agricultural genetic modification.

However, while some tout the potential of GMOs, others peddle a cautious skepticism. The potential benefits of GMOs are noble in nature and cause, yet these benefits are only the could-bes of the future. Many people have begun to fear all that is unknown about GMO technology. Agriculture has more effect on humans and the environment than any other industry; people consume its products everyday, and more than a third of the earth’s surface bears its fruits.²⁴ Because GMO technology is very new and still in its infant stages, it is impossible to accurately predict its effects on human and environmental health.²⁵ In 1906, Luther Burbank warned scientists to take care in the realm of genetic manipulation; he stated, “[w]e recently advanced our knowledge of genetics to a point where we can manipulate life in a way never intended by nature. We must proceed with utmost caution in the application of this new found knowledge.”²⁶ Many GMO opponents, including the citizens of Europe, have taken the words of Luther Burbank to heart and have applied them to the new technology.

²⁰ Kolehmainen, *supra* note 12, at 272.

²¹ Murphy, *supra* note 16, at 47.

²² *Id.*

²³ The recombinant DNA process only became a “theoretical” reality in the late 1970’s. The New Zealand Royal Commission on Genetic Modification, *Genetic Modification: An Overview for Non-Scientists*, at <http://www.gmcommission.govt.nz/RCGM/pdfs/report/GMOverview.pdf> (last visited Jan. 17, 2002). And, it was not until 1994 that this method was successfully applied to plants. *Id.* Thus, the recombinant DNA process is “novel” in the sense that it is still a relatively new process.

²⁴ See WORLD RESOURCES INSTITUTE, WORLD RESOURCES 1994-1995, 149 (1995).

²⁵ See Fredland, *supra* note 3, at 184-85.

²⁶ Thomas P. Redick et al., *Private Legal Mechanisms for Regulating the Risks of Genetically Modified Organisms: An Alternative Path Within the Biosafety Protocol*, 4 ENVTL. L. 1, 11-12 (1997).

III. EUROPEAN FEARS AND THE CONSEQUENT REGULATION OF GMOs

European citizens are relatively skeptical and generally wary of any product containing genetically modified organisms.²⁷ In fact, many European citizens have “expressed fear that the so-called ‘Frankenstein Foods’ may be harmful to health and the environment.”²⁸ Ultimately, European fears are quite legitimate, as there is much scientific uncertainty surrounding GMOs, “[t]hough scientists have the skill to remove and insert gene sequences in living things, they are not able to control the many variables in the process.”²⁹

A. The Risks

GMOs undoubtedly open a realm of wondrous possibilities, yet they also pose serious, life-threatening risks. Specifically, GMOs pose three known risks to human health. First, experiments have shown that genetically modified food can “take on the allergenic properties of transferred foreign genetic material.”³⁰ For example, in an attempt to enhance the nutritional quality of soybeans, a group of scientists injected certain DNA from a brazil nut into a soybean cell.³¹ Researchers ultimately found that the genetically modified soybean not only obtained positive nutritional qualities found in the brazil nut, but also the negative quality which makes some people deathly allergic to the nut.³² Accordingly, consumers allergic to the brazil nut would also be allergic to the genetically modified soybean.

Second, in order to track the success of genetic modification, scientists will often introduce a third foreign gene into the process.³³ This gene is called the “marker gene,” and is generally a bacterial gene that is known to resist certain antibiotics.³⁴ A bacterial gene is used because if scientists expose the genes of the genetically modified organism to antibiotics and the cell survives, then scientists may assume that the antibiotic resistant gene, accompanied by the desirable piece of DNA, successfully implanted itself in the recipient cell.³⁵ Ultimately, the antibiotic resistant trait in the newly

²⁷ Endres, *supra* note 4, at 460.

²⁸ Fredland, *supra* note 3, at 183 (citing James Walsh, *Alien Seed?: As Genetically Engineered Crops Begin to Enter the Food Chain, Europe Remains a Holdout Against What Eco-Warriors Call “Frankenstein Foods,”* TIME INT’L, Aug. 24, 1998, at 38 (giving an overview of the European reaction to genetically-modified agriculture)).

²⁹ Kolehmainen, *supra* note 12, at 275.

³⁰ *Id.* at 278; see also Julie A. Nordlee et al., *Identification of a Brazil-Nut Allergen in Transgenic Soybeans*, 334 NEW ENGL. J. MED. 688 (1996).

³¹ See generally Nordlee et al., *supra* note 30.

³² *Id.*

³³ Richard Caplan & Ellen Hickey, *Weird Science: The Brave New World of Genetic Engineering*, at <http://www.pirg.org/ge/press/wierdscience> (last visited Mar. 7, 2002).

³⁴ *Id.*

³⁵ Kolehmainen, *supra* note 12, at 277.

modified organism may be transferred to bacteria within the human body and the environment.³⁶ Thus, new strains of antibiotic resistant bacteria could develop, making disease much harder to control.³⁷

Third, in order to accelerate the activation of foreign genes inside the recipient cell, and ultimately to achieve desired results at a faster pace, scientists will often inject what is known as the “cauliflower mosaic virus” into the recipient plant.³⁸ The use of this viral promoter is problematic in that the cauliflower mosaic virus has demonstrated that it is highly likely to promote the horizontal transfer of genes between species.³⁹ This has raised questions as to whether or not the cauliflower mosaic virus might aid in bringing about new super-strains of viruses as it advances the inter-species transfer of genes.⁴⁰

Fourth, GMOs also pose serious threats to wildlife. For example, it is known that certain types of genetically modified plants can kill beneficial insects.⁴¹ Specifically, pesticide resistant plants have been known to kill Monarch butterflies.⁴² Beneficial insects, such as the Monarch butterfly, feed on harmful pests that regularly destroy thousands of acres of crops each year.⁴³ Therefore, if GM crops poison useful insects, it is possible that pest populations would increase, thereby decreasing “biological diversity among insects.”⁴⁴

Finally, genetically modified organisms have the potential to affect ecological stability. Some scientists “warn that crops engineered to resist pesticides and herbicides could pass those traits on to weeds, resulting in herbicide and pesticide-tolerant ‘superweeds’.”⁴⁵ Both American and Danish scientists have already demonstrated that “an herbicide-tolerance gene readily passed from cultivated canola plants to closely-related wild plants, like wild mustard, in nearby fields.”⁴⁶ Ultimately, scientists cannot accurately predict the results and effects of nature’s interaction with genetically modified plants.⁴⁷ Thus, there is no way of knowing what kinds of migrations, reproductions, and mutations will occur.

³⁶ *Id.*

³⁷ *Id.*

³⁸ Hansen, *supra* note 19.

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ See generally J.E. Losey et al., *Transgenic Pollen Harms Monarch Larvae*, 399 NATURE 214 (1999).

⁴² See generally *id.*

⁴³ Murphy, *supra* note 16, at 59.

⁴⁴ *Id.*

⁴⁵ Public Citizen, *Genetically Modified Organisms*, at http://www.citizen.org/publications/release.cfm?ID=5102#N_6 (Mar. 1999).

⁴⁶ *Id.*

⁴⁷ *Id.*

The European Community has wisely taken account of these potential risks. In fact, several European polls have indicated that “high percentages of European citizens desire the complete segregation of genetically-modified foods from organically-grown products, and some of those polled favor banning GMOs altogether.”⁴⁸ In general, European consumers bear a highly negative attitude toward GM food and products,⁴⁹ although attitudes vary between countries. For example, Germany and Denmark appear to be more averse toward genetic modification than Britain and Italy.⁵⁰ Yet, not one EC country has come forward in full support of GM foods and products.⁵¹ Therefore, EC policy-makers have made the political choice to develop a safety first approach to GMOs.⁵² The European Commission has had the difficult task of creating GMO legislation that not only addresses consumer concerns, but also addresses international trade obligations.⁵³

B. The European Regulatory Regime

In light of a number of potential risks and a general fear of GMOs, the European Community seems to have selected the “Precautionary Principle” approach in dealing with GMOs and international trade obligations.⁵⁴ The Precautionary Principle was adopted in 1992 at the Rio Declaration on Environment and Development.⁵⁵ Principle Fifteen of the Rio Declaration essentially states that “lack of full scientific certainty” should not be used as an excuse to delay “cost effective measures” that may aid in preventing environmental degradation.⁵⁶ The purpose of the Precautionary Principle is to shift the burden of proof to the proponents of potentially environmentally

⁴⁸ Fredland, *supra* note 3, at 186.

⁴⁹ See Europa, *Consumer Attitudes and Decision-Making with Regard to Genetically Modified Food Products*, at <http://europa.eu.int/comm/research/quality-of-life/gmo/04-food/04-01-project.html> (last visited Jan. 19, 2003).

⁵⁰ *Id.*

⁵¹ *Id.* It is quite clear that the majority of European consumers bear adverse feelings toward GM food and products. *Id.* To be sure, there are a few European constituencies that would like to see GM production flourish. However, these constituencies tend to be the employees and major shareholders of large GMO producing companies such as the Cebeco Groep, Pfizer, CHR Hansen, etc. See Northern Light, *Major Industry Players*, at <http://special.northernlight.com/gmfoods/> (last visited Feb. 21, 2002); see also Daniel Boy, Centre National de la Recherche Scientifique, *Biotechnology and GMOs in Europe: Results of Eurobarometer 2000*, at <http://www.cnrs.fr/cw/en/pres/compress/ogm/ogmevolution.html> (Apr. 27, 2000).

⁵² Endres, *supra* note 4, at 458.

⁵³ MacKenzie & Francescon, *supra* note 10, at 532.

⁵⁴ See Jeffrey K. Francer, *Frankenstein Foods or Flavor Savers?: Regulating Agricultural Biotechnology in the United States and European Union*, 7 VA. J. SOC. POL’Y & L. 257, 278 (2000).

⁵⁵ See generally U.N. Conf. on Env’t and Dev., Rio Declaration on Environment and Development, Principle 15, U.N. Doc. A/Conf.151/5 (1992), reprinted in 31 I.L.M. 874 (1992).

⁵⁶ *Id.*

damaging products, and to require them to demonstrate that their products will not harm or severely damage the environment.⁵⁷ Ultimately, Principle Fifteen's "sense of precaution is reflected in the EC regulations,"⁵⁸ and the Community believes that such an approach to GMOs both protects its citizens and environment from potential risks and fits within international trade constraints.

The European Community originally enacted Council Directive⁵⁹ 90/220 to generally regulate the "deliberate release" of GMOs into the environment.⁶⁰ Directive 90/220 was designed to protect both human health and the environment from any risks of genetic alteration.⁶¹ Directive 90/220 was also developed as an aid in avoiding the creation of "unequal conditions of competition or barriers to trade in products containing [modified] organisms" within the EC common market.⁶²

In general, the Directive requires that member states take appropriate precautions to ensure that "any person"⁶³ seeking to "release" a GMO notify the relevant regulatory authority of the state "within whose territory" the GMO will be released.⁶⁴ This notification must include information necessary for evaluating the foreseeable risks that the GMO may pose to human and/or environmental health.⁶⁵ When the competent authority of the member state receives GMO notification, the authority must submit a summary of the notification to the European Community, which immediately distributes summaries to the authorities of other member states.⁶⁶ The member state that received pre-market notification then has ninety days in which to approve or reject that notification.⁶⁷ If the competent authority finds that

⁵⁷ See Francer, *supra* note 54, at 278 (citing Charmian Barton, *The Status of the Precautionary Principle in Australia: Its Emergence in Legislation and as a Common Law Doctrine*, 22 HARV. ENVTL. L. REV. 509 (1998)).

⁵⁸ *Id.*

⁵⁹ Directives are binding on all member states, but a member state may choose the Directive's form of implementation. See GEORGE A. BERMAN ET AL., CASES AND MATERIALS ON EUROPEAN COMMUNITY LAW 50-68 (1993) [hereinafter CASES AND MATERIALS].

⁶⁰ See generally Council Directive 90/220 on the Contained Use of Genetically Modified Micro-Organisms, part A, art. 2, 1990 O.J. (L 117) 15. It is important to note that Council Directive 90/220 will be replaced by Council Directive 2001/18, effective October 17, 2002. Directive 2001/18 bears the same structure and purpose as 90/220 but clarifies and improves upon the "deliberate release" procedures instituted by 90/220. See Council Directive 2001/18 on the Deliberate Release Into the Environment of Genetically Modified Organisms, 2001 O.J. (L 106) 1. Moreover, Directive 2001/18 intertwines ethical, scientific, and legal concerns in a more coherent and practical manner. See *id.*

⁶¹ See generally Council Directive 90/220, *supra* note 60.

⁶² *Id.* at Preamble.

⁶³ *Id.* at part B, art. 5.

⁶⁴ See *id.*

⁶⁵ See *id.* at art. 5(a).

⁶⁶ See *id.* at art. 9.

⁶⁷ See Council Directive 90/220, *supra* note 60, at art. 6(2).

the GMO is safe for humans and the environment, the authority must notify the European Community and other member states.⁶⁸ If it finds that the GMO is unsafe, the competent authority may reject the notification and the application for use throughout the Community.⁶⁹

If the GMO is ultimately approved, and another member state has not objected within sixty days of the approval, then the approving state must give written consent for use of the GMO throughout the Community.⁷⁰ If another member state objects to the introduction of a GMO, the European Community must decide whether or not to consent to the general use of the GMO.⁷¹ If the European Community approves a GMO over a member state's continued disapproval, that member state may temporarily restrict marketing.⁷² The European Community then has three months to approve or reject the restriction.⁷³ If the European Community rejects the member state's restriction, and yet the Community member continues to restrict marketing of the GMO, legal proceedings can be instituted against that member state.⁷⁴ Nonetheless, the objecting member state may still have a valid defense against lifting its particular restriction; the member state may argue that its restrictions are justified on grounds that its policy is necessary for the "protection of health and life of humans, animals, or plants."⁷⁵

The European Community has also mandated that "food products containing genetically-modified agricultural products be labeled as such."⁷⁶ European policies suggest that "labeling is a mechanism for risk sharing" between producers and consumers. "[R]egulation through labeling empowers the consumer in the management of risk."⁷⁷ In fact, the European Community stated that "it is important [for European consumers] to be informed about the use of additives or flavourings genetically modified or produced by genetic engineering."⁷⁸ Thus, "the most satisfactory solution . . . will be to draw up a Community [labeling] provision."⁷⁹

The European Community has enacted two Regulations⁸⁰ to cope with

⁶⁸ See *id.* at art. 3(8).

⁶⁹ See *id.* at arts. 12(1), 12(2)(b).

⁷⁰ See *id.* at art. 13(2).

⁷¹ See *id.* at arts. 13(3), 21.

⁷² See *id.* at art. 16.

⁷³ See Council Directive 90/220, *supra* note 60.

⁷⁴ See generally, EC TREATY, *supra* note 11.

⁷⁵ See *id.* at art. 36.

⁷⁶ Fredland, *supra* note 3, at 183.

⁷⁷ See Francer, *supra* note 54, at 265, n.77.

⁷⁸ Commission Decision 98/613/EC Concerning a Draft Decree of the Republic of Austria on the Identification of Genetically Modified Additives and Flavourings Used as Food Ingredients, ¶ 6, 1998 O.J. (L 291) 35 [hereinafter Commission Decision 98/613/EC].

⁷⁹ *Id.* at ¶ 10.

⁸⁰ E.U. Regulations are binding in their entirety as law for a member state. See CASES AND MATERIALS, *supra* note 59, at 74-75.

the issue of labeling. First, Regulation 258/97 states that a product containing novel ingredients (which are those products containing GMOs, or those that have a modified molecular structure) must somehow make consumers aware that there is an ingredient within the product that is “not present in an existing equivalent foodstuff.”⁸¹ Second, Regulation 1139/98, which applies to GM maize varieties and GM soy varieties not covered by 258/97, requires that the list of ingredients (or some other clear location on the product) include the words “produced from genetically modified soya,” or “produced from genetically modified maize,” etc.⁸²

IV. THE EFFECTS OF EUROPEAN LEGISLATION ON INTERNATIONAL TRADE

The volume of trade between the United States and the European Community is larger than that of any other trading relationship in the world.⁸³ Certainly, such a relationship is not without its troubles, but these trading partners have never encountered such a problematic issue as GMOs. The United States, as the leading producer of GMOs,⁸⁴ has continually touted their potential benefits. The European Community, on the other hand, has shown its trepidation by enacting both Directives and Regulations governing the use of GMOs. The United States believes that EC legislation has shut its agricultural goods out of the Community market.⁸⁵ As such, a trade impasse has developed between the United States and the European Community over GMOs.

A. The Effects of EC Legislation on Trade with the United States

The United States is the leading developer and exporter of genetically modified agriculture and products.⁸⁶ In fact, approximately sixty million acres of U.S. farmland are covered in genetically modified corn, soybeans, canola, and cotton.⁸⁷ GMO crops account for “at least forty-five percent of cotton, thirty-eight percent of soybeans, and twenty-five percent of corn

⁸¹ Council Regulation 258/97 Concerning the Novel Foods and Novel Food Ingredients, art. 8(1)(c), 1997 O.J. (L 43) 1, 5.

⁸² Council Regulation 1139/98 Concerning the Compulsory Indication of the Labeling of Certain Foodstuffs Produced from Genetically Modified Organisms of Particulars Other Than Those Provided for in Directive 79/112/EEC, art. 2(3)(a)-(b), 1998 O.J. (L 159) 4, 6 [hereinafter Council Regulation 1139/98].

⁸³ Terence P. Stewart & David S. Johanson, *Policy in Flux: The European Union's Laws on Agricultural Biotechnology and Their Effect on International Trade*, 4 DRAKE J. AGRIC. L. 243, 246 (1999).

⁸⁴ Endres, *supra* note 4, at 459.

⁸⁵ Jennifer Coderre, *Biotechnology: Agriculture Officials Urge Outreach to Convince Europe of GMOs' Benefits*, BNA, Mar. 5, 1999, at LEXIS, News Library, BNAITD File.

⁸⁶ Endres, *supra* note 4, at 459.

⁸⁷ Kolehmainen, *supra* note 12, at 269.

grown.”⁸⁸ And, “within a few years virtually one hundred percent of U.S. agricultural commodity exports will be genetically modified or mixed with GMO products.”⁸⁹

It is clear that the presence of GMOs is generally accepted by American food producers⁹⁰ and is advocated by large technology companies like DuPont, Dow AgroSciences, and Aventis. Such companies and producers rely heavily on the export and purchase of genetically modified crops and goods in order to generate higher profits and to finance research and development.⁹¹ But, the European Community, which is a major market for U.S. agricultural products, “has a ‘slow unpredictable process for approving new U.S. agricultural products developed through advanced biotechnology.’”⁹² Consequently, European restrictions on GMO trade have created several problems for U.S. agricultural producers and major technological companies.

The European Community’s general regulatory scheme has made it very difficult for the United States to export products to the European market.⁹³ The approval process may involve long delays and millions of dollars lost in what were potential exports. For example, in 1996, the United States exported \$3 billion in genetically modified and conventional corn and soybeans to the European Community.⁹⁴ Due to the introduction of EC Direc-

⁸⁸ Jonathan H. Adler, *More Sorry Than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol*, 35 TEX. INT’L L.J. 173, 177 (2000).

⁸⁹ Endres, *supra* note 4, at 459-460 (quoting a U.S. State Department Official during testimony before the Senate Finance Subcommittee on International Trade).

⁹⁰ Symposium, *Transgenic Agriculture: Biosafety and International Trade*, 4 B.U. J. SCI. & TECH. L. 4, 29 (1998).

⁹¹ See Northern Light, *supra* note 51. American consumers, it seems, also support the presence of GMOs in food and food products; after all, American supermarkets tend to sell genetically modified products with ease – the shelves are restocked with GM products each night. It may be that Americans are simply unaware that they are buying genetically modified products. In 1992, the Food and Drug Administration (“FDA”) determined that it would not treat GM foods any differently than “natural” foods. Donna U. Vogt & Brian A. Jackson, *Labeling of Genetically Modified Foods*, at http://www.agriculturelaw.com/aglibrary/articles/label_mar20_00.htm (last visited Feb. 21, 2002). Thus, there has not been much debate over, or advertising about, GMOs in the consumer realm. Moreover, producers are not required to place special labels upon their GMO products. Consequently, the average American consumer is unfamiliar with GMOs and may be unaware that she is buying a genetically modified product. See *id.*

⁹² Endres, *supra* note 4, at 460 (quoting Ambassador David L. Aaron, Under Secretary of Commerce for International Trade).

⁹³ Fredland, *supra* note 3, at 191.

⁹⁴ Ved P. Nanda, *Genetically Modified Food and International Law – The Biosafety Protocol and Regulations in Europe*, 28 DENV. J. INT’L L. & POL’Y 235, 237-38 (2000). EC restrictions on GM imports have cost the U.S. \$300 million in corn exports alone. See Gary G. Yerkey, *E.U. Likely to Begin Clearing Imports of GMO Products This Fall, Official Says*, INT’L TRADE REP., March 7, 2002, at 408.

tive 90/220, these exports dropped to approximately \$1 billion in 1999.⁹⁵ Even if a GM export is approved by the Commission, European states can make the introduction of GM products difficult in their individual markets.⁹⁶ The result appears to be another hindrance to trade.

The European Community's labeling requirements also create at least three problems for U.S. agricultural producers.⁹⁷ First, labeling requirements force U.S. producers to "brand products in a fashion that will be certain to repulse a significant portion of the European populace."⁹⁸ Second, U.S. producers find it extremely difficult to separate, for labeling purposes, products containing GMOs from those that are considered "organic"; GM crops look the same as organic crops, and therefore, separating the two during "harvesting, storage, and transport is difficult."⁹⁹ Third, it is very difficult to create purely organic crops or foodstuffs and, because the European Community has failed to specify criteria for testing for the presence of GMOs, U.S. producers have been left confused as to whether their products meet European specifications.¹⁰⁰

B. The Trade Debate Brewing Between the European Community and the United States

Considering the effect that EC GMO legislation has had upon U.S. exports, the United States has "tended to see E.U. measures, and their application in practice, as thinly disguised protectionism."¹⁰¹ On the other hand, some Europeans see EC legislation as "foisting genetically modified products onto unwilling consumers."¹⁰² The European Community appears to have passed its requirements without express protective intent—there does not seem to be a conspiracy aimed at protecting European farmers.¹⁰³ Nonetheless, EC legislation may make U.S. farmers less competitive in the European market. Therefore, the U.S. has turned to the GATT¹⁰⁴ and its accompanying Agreements, the SPS¹⁰⁵ and the TBT,¹⁰⁶ for aid in this trade

⁹⁵ Nanda, *supra* note 94, at 237-38.

⁹⁶ Francer, *supra* note 54, at 281.

⁹⁷ Fredland, *supra* note 3, at 191.

⁹⁸ *See id.*

⁹⁹ *Id.*

¹⁰⁰ *See id.*

¹⁰¹ MacKenzie & Francescon, *supra* note 10, at 531.

¹⁰² *Id.*

¹⁰³ Fredland, *supra* note 3, at 183.

¹⁰⁴ *See generally* General Agreement on Tariffs and Trade, Oct. 30, 1947, TIAS No. 1700, 55 U.N.T.S. 194 [hereinafter GATT].

¹⁰⁵ *See* Agreement on the Application of Sanitary and Phytosanitary Measures, Dec. 15, 1993, 1867 U.N.T.S. 493 [hereinafter SPS Agreement].

¹⁰⁶ *See* Agreement on Technical Barriers to Trade, Dec. 15, 1993, 1868 U.N.T.S. 120 [hereinafter TBT Agreement].

conflict.

V. THE RULES OF INTERNATIONAL TRADE: THE GATT, SPS, AND TBT

The United States believes that European measures against GMOs serve as non-trade barriers ("NTBs") against U.S. produced agriculture. NTBs violate international trade law, specifically Article III of the GATT. In general, the GATT promotes the international economy by reducing barriers to trade through the elimination of protective treatment of domestic goods.¹⁰⁷ In particular, Article III (the "National Treatment" Clause) prohibits internal taxes and regulations that protect domestic production.¹⁰⁸ Article III, however, is excepted by Article XX, which allows members to make regulations that otherwise violate the GATT when such restrictions are "necessary to protect human, animal or plant life or health."¹⁰⁹ The European Community, it appears, has relied on Article XX in asserting that its regulatory measures are absolutely necessary to protect European consumers from the potential risks posed by GMOs.¹¹⁰ However, the 1994 Uruguay Round produced two Agreements, the SPS and TBT Agreements, which restrict the use of Article XX defenses.¹¹¹

A. The SPS Agreement

The SPS Agreement attempts to clarify Article XX by describing situations in which trade discrimination is permissible to protect health and the environment.¹¹² The SPS Agreement requires that protective measures concerning human, animal, or plant life be scientifically supported, not be arbitrary or unjustifiable, and ultimately follow internationally accepted standards of regulation.¹¹³ The United States has challenged EC GMO legislation in light of the SPS Agreement.

First, the United States suggests that EC Directive 90/220 does not meet the "scientifically supported" requirement of the SPS Agreement.¹¹⁴ This requirement appears to be two-pronged.¹¹⁵ These two prongs call for protective measures that are: (1) "based on" a risk assessment and not

¹⁰⁷ See generally GATT, *supra* note 104.

¹⁰⁸ See generally *id.* at art. III.

¹⁰⁹ *Id.* at Art. XX(b), ¶ I(b).

¹¹⁰ See Fredland, *supra* note 3, at 196-200.

¹¹¹ See Rick Franzen, *Will GATT Take a Bite Out of the Organic Food Production Act of 1990?*, 7 MINN. J. GLOBAL TRADE 399, 409 (1998).

¹¹² See Layla Hughes, *Limiting the Jurisdiction of Dispute Settlement Panels: The WTO Appellate Body Beef Hormone Decision*, 10 GEO. INT'L ENVTL. L. REV. 915, 917 (1998).

¹¹³ See generally SPS Agreement, *supra* note 105.

¹¹⁴ *Id.* at arts. 2, ¶ 2, 5 ¶ 1-3.

¹¹⁵ See Vern R. Walker, *Keeping the WTO From Becoming the "World Trans-Science Organization": Scientific Uncertainty, Science Policy and Factfinding in the Growth Hormones Dispute*, 31 CORNELL INT'L L.J. 251, 271-72 (1998).

“maintained without sufficient scientific evidence” and, (2) “necessary” in order to achieve the regulator’s selected level of protection, while minimizing collateral effects on international trade.¹¹⁶

A proper risk assessment would, or should, generally involve investigating all “available scientific evidence.”¹¹⁷ As far as GMOs, no existing scientific evidence shows that GMOs positively pose serious threats to human or environmental health. However, the evidence does not show that there are no risks either. In general, there is great scientific uncertainty surrounding GMOs:

One of the greatest concerns about genetically engineered crops and food is the fact that so much is unknown and, at this time, unknowable. Though scientists have the skill to remove and insert gene sequences in living things, they are not able to control the many variables in the process.¹¹⁸

Genetic engineering of agriculture is still in its infant stages and we do not know if GMOs will positively, negatively, or neutrally affect our health and environment. Nonetheless, we do know that GMOs potentially pose real threats. For example, a study conducted by Dr. Arnpad Pusztai, formerly of the Towett Research Institute, found that rats who were fed genetically modified potatoes suffered weight loss, internal organ damage, and suppression of their immune systems after a certain period of consumption.¹¹⁹

Ultimately, scientific experimentation has proved the potential for dangerous health¹²⁰ (allergenic, antibiotic resistance, and virus promotion) and environmental¹²¹ (genetic pollution and harm to wildlife) risks. The other side cannot negate this potential, but can only say, with equal scientific uncertainty, that they do not believe the potential risks will manifest themselves in a significant way. In the end, each side of the debate can find scientific evidence that supports its point of view and seems to refute that of its opponents.¹²² Thus, the question becomes, how much risk is too much risk, and who gets to draw that line? In the face of such scientific uncertainty, the European Community has drawn its line, and “based” Directive

¹¹⁶ See *id.* at 271; see also SPS Agreement, *supra* note 105, at art. 2, ¶ 2.

¹¹⁷ SPS Agreement, *supra* note 105, at art. 5, ¶ 2.

¹¹⁸ Kolehmainen, *supra* note 12, at 275.

¹¹⁹ See *id.* at 276; see also Fredland, *supra* note 3, at 188.

¹²⁰ See Discussion in Section III(A) of this Comment; see also Martin Enserink, *Preliminary Data Touch Off Genetic Food Fight*, 283 SCI. 1094 (1999).

¹²¹ See *id.*; see also Kolehmainen, *supra* note 12, at 276-77.

¹²² Compare *GM Foods Debate Needs a Recipe for Restoring Trust*, 398 NATURE 175 (1999) with Union of Concerned Scientists, *Risks of Genetic Engineering*, at http://www.ucsusa.org/food_and_environment/biotechnology/page.cfm?pageID=346 (last modified Oct. 30, 2002).

90/220 on an appropriate risk assessment by considering *all* the “available scientific evidence.”¹²³

The next question under the SPS Agreement is whether the European Community’s Directive is “necessary” in order to achieve its selected level of protection while minimizing collateral effects on international trade.¹²⁴ First, if items subject to regulation do not, in reality, have a known harmful effect on human health or the environment, then the regulations in question cannot be considered “effective” for achieving their protective goal and therefore, are not necessary.¹²⁵ Certainly, one could argue that as of yet, the world has not seen any major GMO-caused disasters. Nonetheless, real life has shown that plants modified to produce pesticide ultimately kill beneficial insects like Monarch butterflies.¹²⁶ We also know that, in reality, individuals allergic to brazil nuts would also be allergic to, for example, soybeans modified with brazil-nut DNA.¹²⁷

Ultimately, science has shown us that GMOs are risky and do have some very harmful effects. And, while every human activity bears some risk, those risks are often relatively minimal compared to the life-threatening and life-altering risks posed by GMOs. For example, potential ecological disaster through the destruction of Monarch butterflies unquestionably poses greater risks to humans and the environment than, for instance, consuming caffeine. And, if an activity does potentially pose a severe risk, like GMOs, the world generally tends to take every precaution necessary. Thus, it seems that EC legislation is, for now, correctly responding to both perceived and real risks, and therefore effectively protecting humans and the environment from these risks.

The second part of the “necessary” test involves the issue of whether or not EC legislation minimizes collateral effects on international trade. Currently, the EC Directive is at least less harmful to international trade than individual restrictions proposed by individual states would have been; for example, Norway banned all products coming from crops that contained antibiotic-resistant marker genes.¹²⁸ In light of this, the fact that GM engineering is in its infant stages, and that real risks do exist, it is possible that the EC’s Directive is “necessary” to protect human health, the environment, and to facilitate at least some trade in GMOs. At this juncture, scientific evidence has not provided us with the ability to know what is necessary and what is not, and therefore, which GMO restrictions will or will not be “ef-

¹²³ SPS Agreement, *supra* note 105, at art. 5, ¶ 2.

¹²⁴ Walker, *supra* note 115, at 271.

¹²⁵ *Id.*

¹²⁶ See generally Losey, *supra* note 41.

¹²⁷ See generally Nordlee et al., *supra* note 30.

¹²⁸ Nigel Williams, *Agricultural Biotech Faces Backlash in Europe*, 281 Sci. 768, 768 (1998).

fective” in achieving human and environmental protection.

Second, it seems the United States believes that the EC Directive fails to fulfill the arbitrary or unjustifiable distinction¹²⁹ requirement of the SPS Agreement, which condemns measures that “result in discrimination or disguised restriction on trade.”¹³⁰ Any restrictions on trade should only be found “arbitrarily or unjustifiably discriminate” in the “most blatant and unexplainable cases.”¹³¹ In the current GMO trade dispute, “[n]o equally obvious counterpart to genetically-modified agriculture is permitted to enter the European markets unscathed by regulations.”¹³² More importantly, the same restrictions must be applied to GM agriculture produced in the European Community.¹³³ Therefore, EC measures against GM agriculture do not seem to arbitrarily, unjustifiably or blatantly discriminate against international trade.

Third, it seems the United States believes that the EC Directive may violate the internationally-accepted standards¹³⁴ requirement of the SPS Agreement.¹³⁵ The Agreement defines internationally-accepted standards (for measures aimed at protecting human health and the environment) as those found in the Codex Alimentarius Commission.¹³⁶ The Codex recommends special treatment for products in which genetic modification has created a material difference from non-modified products.¹³⁷ Essentially, the presence of “marker genes and powerful promoters, the insertion of genes from other species . . . into plants that could never come together in nature, and even the technology itself” provide evidence that GM products are materially different from “traditional” agricultural products.¹³⁸ Moreover, common sense tells us that, for example, a plant modified to internally produce the *Bacillus thuringiensis* (B.t.) insecticide is materially different from the original plant that does not naturally produce any insect toxin.¹³⁹ Also, a soybean modified to demonstrate brazil nut properties is materially different from a soybean that naturally demonstrates only soybean properties.¹⁴⁰ If we are not convinced by common sense, science tells us that the introduction of foreign genetic material alters a plant’s genetic makeup, creating an

¹²⁹ SPS Agreement, *supra* note 105, at art. 2, ¶ 3.

¹³⁰ *Id.* at art. 5, ¶ 5.

¹³¹ Fredland, *supra* note 3, at 205 (citing Walker, *supra* note 115, at 270).

¹³² *Id.* at 215.

¹³³ *See id.* at 191.

¹³⁴ SPS Agreement, *supra* note 105, at art. 3, ¶ 1-3.

¹³⁵ Pruzin, *supra* note 9.

¹³⁶ SPS Agreement, *supra* note 105, at Annex A, ¶ 3.

¹³⁷ Fredland, *supra* note 3, at 215.

¹³⁸ Kolehmainen, *supra* note 12, at 284.

¹³⁹ *See id.* at 273.

¹⁴⁰ *See id.* at 278.

entirely new plant with its own unique genetic structure.¹⁴¹ Thus, GMO products are materially different from their “natural” counterparts and, under the Codex, can be accorded special treatment.

B. The TBT Agreement

The TBT Agreement also attempts to clarify GATT, Article XX by ensuring that technical regulations used to “protect human, animal or plant life or health,”¹⁴² do not create “unnecessary obstacles to international trade.”¹⁴³ More importantly, the TBT Agreement states that technical regulations must “fulfill a legitimate objective.”¹⁴⁴

The United States has challenged the European labeling regulations under the TBT Agreement. First, the United States appears to believe that EC labeling requirements fail to fulfill a legitimate objective.¹⁴⁵ However, the TBT Agreement may consider a state’s desire for uniform regulation as a legitimate goal.¹⁴⁶ As several different European governments had, in the past, passed individual legislation regulating the labeling of products containing GMOs,¹⁴⁷ the European Community’s current labeling requirements have helped to promote legal uniformity and have harmonized legislative differences that were “liable to impede the free movement of [GMOs] and thereby adversely affect the functioning of the internal market.”¹⁴⁸ In light of this, it seems the EC’s regulations have achieved legitimate objectives – uniformity and harmonization – and have thus satisfied this requirement of the TBT Agreement.

Second, the United States seems to believe that EC labeling requirements are unnecessary obstacles to trade. Yet, while EC regulations are not perfectly conducive to the complete free-flow of international trade, one might hesitate to call them *unnecessary obstacles*. Considering the world as it exists, *free-flowing* trade is somewhat of a misnomer. Each trade item confronts at least one obstacle at some point during its route; these trade obstacles vary in difficulty and include customs, quotas, and quarantines. The question becomes whether the obstacles pertaining to GMOs are too difficult to hurdle—are they too excessive or unnecessary?

Certainly, EC labeling regulations may create obstacles to trade in that

¹⁴¹ Union of Concerned Scientists, *Risks of Genetic Engineering*, at http://www.ucsusa.org/food_and_environment/biotechnology/page.cfm?pageID=346 (last modified Oct. 30, 2002).

¹⁴² GATT, *supra* note 104, at art. XX(b), ¶ I(b).

¹⁴³ TBT Agreement, *supra* note 106, at Preamble.

¹⁴⁴ *Id.* at art. 2, ¶ 2.

¹⁴⁵ *Id.*

¹⁴⁶ *See id.*

¹⁴⁷ Fredland, *supra* note 3, at 189.

¹⁴⁸ *Id.* at 189-90 (quoting Council Regulation 1139/98, *supra* note 82, at art. 1.1, ¶ 4).

a skeptical European public is less likely to knowingly buy products labeled as containing GMOs. However, a skeptical European public is just as likely to skip over a product whose contents are unknown; if agricultural producers do not have to label their products, and consequently choose not to label their goods, European consumers may assume the producer has something to hide—namely GMOs.

Also, labeling requirements may cause the production of GM foods to be more costly.¹⁴⁹ First, farmers will be forced to develop more effective separation techniques in order to ensure that GM crops and *natural* crops are adequately separated.¹⁵⁰ Second, scientifically determining which products do or do not contain miniscule amounts of GMOs could also be very costly.¹⁵¹ Nonetheless, these surges in cost will be equally passed on to all producers of GM agriculture, including those members of the Community.¹⁵² The United States may be disproportionately affected, but the regulations and any obstacle-like effects they produce apply equally to all GM agricultural producers.¹⁵³

Ultimately, EC regulations may have actually made it much easier for some GMOs to enter the European market—GMOs that never would have entered the market if individual European countries were allowed to legislate the matter.¹⁵⁴ More importantly however, GMOs do get traded in the European market. For example, four types of GM maize are traded in the European Union including Novartis' genetically modified maize, which has been circulating throughout Europe despite serious objections.¹⁵⁵ Considering this, the obstacle does not appear to be insurmountable.

VI. EC REGULATIONS DO NOT AMOUNT TO NTBS

In light of current international trade law (the GATT, SPS, and TBT Agreements), EC measures against GMOs do not equate to NTBs. As concluded above, the EC's legislation over GMOs has not violated Article III of the GATT because the European Community has a valid Article XX defense—its Directive and Regulations are “necessary to protect human, animal or plant life or health.”¹⁵⁶ Of course, the SPS and TBT Agreements restrict Art. XX defenses. Nonetheless, the European Community's GMO legislation does not violate these Agreements either.

¹⁴⁹ Fredland, *supra* note 3, at 191.

¹⁵⁰ *Id.*

¹⁵¹ *See id.*

¹⁵² *See id.*

¹⁵³ *See id.*

¹⁵⁴ *See Williams, supra* note 128.

¹⁵⁵ *See Stewart & Johanson, supra* note 83, at 284-85; *see also* Francer, *supra* note 54, at 277-78 (discussing Novartis' maize).

¹⁵⁶ GATT, *supra* note 104, at art. XX, ¶ 1(b).

A. EC GMO Legislation in Light of the SPS Agreement

First, the scientifically supported requirement of the SPS Agreement essentially states that a protective measure must be “based on” a risk assessment and “not maintained without sufficient scientific evidence.”¹⁵⁷ In light of the scientific uncertainty surrounding GM food and products, the European Community has based its GMO legislation on an appropriate risk assessment considering the real and potentially dangerous health and environmental risks posed by GMOs. Again, the potential for these risks to manifest has been confirmed through scientific experimentation.¹⁵⁸ Thus, EC measures have not been maintained without scientific evidence. Proponents of GMOs cannot negate the risk potential of GM products; they can only say with equal uncertainty that they do not think the potential risks will manifest themselves in a significant way.

Also, because GM engineering is in its infant stages, it is possible that the European Community’s restrictions on GMO trade are *necessary* to protect human health and the environment.¹⁵⁹ At this juncture, scientific evidence has not provided us with the ability to know what is, or what is not necessary. Moreover, the European Community’s GMO legislation may have “minimized collateral effects on international trade” by creating a single European market for GM products.¹⁶⁰ The EC measures are at least less harmful to international trade than individual restrictions proposed by individual states would have been—especially considering the fact that some states attempted to ban GM crops and their products altogether.¹⁶¹

Second, EC restrictions on GMO trade do not “arbitrarily or unjustifiably discriminate” between U.S. GM products and other GM products. All GM foods must undergo the same scrutiny before being introduced into free circulation in the European market. More importantly, European GM agriculture must also undergo the same restrictions.¹⁶² Therefore, EC measures against GM agriculture do not seem to “arbitrarily or unjustifiably discriminate” against international trade.¹⁶³

Lastly, if we apply current international standards to GMOs, we find that the Codex recommends special treatment for those products in which genetic modification has created a material difference from the original, *natural* product.¹⁶⁴ Essentially, the presence of foreign genes within a plant creates an entirely new entity, making the GM plant materially different

¹⁵⁷ SPS Agreement, *supra* note 105, at art. 2, ¶ 2.

¹⁵⁸ See Kolehmainen, *supra* note 12, at 276-77; see also Martin Enserink, *supra* note 120.

¹⁵⁹ See SPS Agreement, *supra* note 105, at art. 2, ¶ 1.

¹⁶⁰ See Walker, *supra* note 115, at 271.

¹⁶¹ See, e.g., Walsh, *supra* note 28, at 38.

¹⁶² See Fredland, *supra* note 3, at 215.

¹⁶³ SPS Agreement, *supra* note 105, at art. 2, ¶ 3.

¹⁶⁴ Fredland, *supra* note 3, at 215.

from the original.¹⁶⁵ Thus, EC restrictions on GMO trade comply with internationally accepted standards.

B. EC GMO Regulations in Light of the TBT Agreement

First, the EC labeling regulations appear to have satisfied the legitimate objective requirement¹⁶⁶ as the TBT Agreement may consider the desire for uniform regulation legitimate.¹⁶⁷ Many individual European states had implemented anti-GMO policies ranging from Norway's complete ban on all products containing antibiotic-resistant marker genes, to France's "go-slow" approval of new GMO varieties.¹⁶⁸ The European Community developed GMO regulations in order to combat these individual state actions that had the potential to "impede the free movement of [GMOs] and thereby adversely affect the functioning of the internal market."¹⁶⁹ Essentially, then, the European Community's attempt to legislate against these wide-ranging policies and to create uniformity of treatment in the Community has satisfied the "legitimate objective requirement" of the TBT Agreement.

Second, it is not clear that EC labeling requirements are unnecessary obstacles to trade. There is no doubt that a skeptical European public is less likely to knowingly buy products labeled as "containing GMOs." However, a skeptical European public is just as likely to skip over a product whose contents are unknown. More importantly, labeling requirements may cause the production of GM foods to be more costly.¹⁷⁰ Yet, any surge in cost will be equally passed on to all producers of GM agriculture, including those producing members of the European Community.¹⁷¹ The United States may be disproportionately affected, but the Regulations and their effects apply equally to all GM agricultural producers.¹⁷² Certainly, while EC Regulations are not perfectly conducive to the complete free-flow of international trade, it is not clear that we can call them "unnecessary obstacles." EC regulations may actually have made it much easier for some GMOs to enter the European market.¹⁷³ More importantly, GMOs do get traded in Europe. For example, four types of GM maize have been widely circulated in the Community despite objections made by member states.¹⁷⁴

¹⁶⁵ See generally Kolehmainen, *supra* note 12, at 273.

¹⁶⁶ TBT Agreement, *supra* note 106, at art. 2, ¶ 2.

¹⁶⁷ See generally *id.*

¹⁶⁸ Williams, *supra* note 128, at 768.

¹⁶⁹ Fredland, *supra* note 3, at 189-90 (quoting Council Regulation 1139/98, *supra* note 82, at Art. 1.1, ¶ 4).

¹⁷⁰ See *id.* at 191.

¹⁷¹ See *id.*

¹⁷² See *id.*

¹⁷³ See Williams, *supra* note 128, at 768.

¹⁷⁴ See Stewart & Johanson, *supra* note 83, at 284-85.

In view of all this, it does not seem that the EC Regulations pose too much of a threat to international trade, especially when one considers the scientific uncertainty and potential risks surrounding GM products; it is quite likely that the EC's Regulations are "necessary" to protect human health and the environment. Thus, it is not clear, at least at this juncture, that EC regulations are unnecessary obstacles.

VII. CONCLUSION

There is no doubt that States can only go as far as the WTO, the SPS and TBT Agreements allow considering international law reigns supreme. Nonetheless, the line drawn by each of the above Agreements becomes somewhat "fuzzy" when human and environmental health is potentially threatened. Yet, it is clear that EC restrictions on GMO trade: (1) are based on a proper risk assessment considering all available scientific evidence, (2) have minimized collateral effects on international trade, (3) are not arbitrary or unjustifiable, (4) conform to international standards, (5) satisfy a legitimate objective, and (6) are ultimately necessary considering all that is unknown about GMOs. Therefore, the Community's Directive and Regulations do not overshoot the boundaries of current international law and Europe's Precautionary Principle approach obeys the rules of international trade.

States and their agencies "need time to understand GMO technology and comprehend its full range of possible effects before knowing how to regulate it most effectively."¹⁷⁵ At this stage, the world just does not know enough about GMOs to create the "perfect" regulatory system. The current relevant question is how much risk is too much risk, and where do States draw the line? The Europeans have made that decision, and for now, with a world of information left to gather on the benefits and risks of GMOs, their decision is acceptable.

For certain, a delicate balance must be struck in terms of regulating the trade of GMOs. Over-regulation of GM products has the potential to wreak havoc on our established free-trade regime and could diminish any potential benefits GMOs may have on food production. Under-regulation, on the other hand, may spell disaster for human health and the environment. The truth is, "[o]nce the technology escapes, we cannot take it back."¹⁷⁶ Thus, we must take the time to ensure that GMOs are safe.

When it comes to biotechnology and GMOs, we currently live in a world of "potentials," and neither the GATT, SPS, or TBT Agreements provide clear-cut rules for these "would be" situations. The world could certainly use all the benefits GMOs have to offer, but can we handle the

¹⁷⁵ Kolehmainen, *supra* note 12, at 288.

¹⁷⁶ Stone, *supra* note 2, at 705.

risks? EC GMO legislation has offered Europe a way to keep on moving forward, albeit slowly. The European precautionary approach may allow the world to eventually take hold of all the potential positives of biotechnology while confronting the risks before they potentially get out of control. Thus, it seems that, for now, EC restrictions on GMO trade are acceptable.

