Moving Beyond the WTO: A Proposal to Adjudicate GMO Disputes in an International Environmental Court

MARGUERITE A. HUTCHINSON*

TABLE OF CONTENTS

I. INTRODUCTION .................................................................................................. 230
II. GENE SHARING METHODS.................................................................................. 232
III. HEALTH AND ENVIRONMENTAL RISKS ........................................................... 234
   A. Allergens and Immunity ........................................................................... 234
   B. Biodiversity and Gene Flow ..................................................................... 235
   C. Public and Environmental Health Failures ............................................. 236
IV. ADVERSARIAL POSITIONS ON GMO ACCEPTANCE .............................................. 237
   A. America: Faith in Companies, FDA ........................................................ 237
   B. Europe: Skeptical of Regulation, Protective of Culture........................... 239
V. DIFFERENT APPROACHES TO REGULATION ........................................................ 240
   A. Process-based Approach ........................................................................ 240
   B. Product-Based Approach ....................................................................... 241
   C. Public Awakening .................................................................................... 242
      1. Voluntary Labeling ............................................................................. 242
      2. Europe’s Reporting Requirements ....................................................... 244
      3. The Cartagena Protocol .................................................................... 245
VI. DISPUTES ............................................................................................................. 246
   A. The WTO ................................................................................................... 246
   B. European Disputes ................................................................................ 247
VII. WEAKNESSES OF THE SYSTEMS ..................................................................... 252
   A. Labeling ................................................................................................... 252

* University of San Diego School of Law, J.D. 2009. The author would like to thank Professor Jorge Vargas for his help in brainstorming and the Lords of Brambleberry for inspiration.
I. INTRODUCTION

The United States has won the first significant round in the international battle over genetically modified foods. In May 2006, the World Trade Organization (WTO) ruled that a European de facto moratorium on the importation of genetically modified food was illegal. The central disagreement between the U.S. and E.U. regulators is whether to use precautionary measures when introducing genetically modified organisms (GMOs) to the food supply. The United States is unwilling to regulate scientific research by industries that bring food to market and Europe couches its concerns in terms of an environment and population susceptible to the unknown risks of those scientific developments. Europe's extreme application of the precautionary principle in its import ban to protect human health and environment was discredited by the 2006 WTO ruling, creating uncertainty about how governments can control the risks associated with “novel” foods and genetic material.

The failure of Europe and the United States to reconcile their positions on the safety of GMOs arises from diverging cultural attitudes about

4. Id. at 168.
risk, government regulation, and food. The existence of a powerful tort remedy system in the United States and widespread trust of “agribusiness” has muted domestic calls for regulation, whereas Europe remains skeptical of the efficacy of governmental regulation and tied to its heritage of local farming. International negotiators, however, have not explicitly addressed these hurdles to a consensus. In fact, a proxy issue has emerged for the United States and Europe to fight about: the scientific basis for environmental and health risks posed by GMOs.

In the face of uncertain and possibly irreversible health and environmental damage, the Rio Declaration on Environment and Development binds states to adhere to the precautionary principle. The precautionary principle, a maxim of evaluating social and economic costs, advocates restraint when consequences are unforeseeable. In the spirit of the Rio Declaration, the European Union unsuccessfully invoked the precautionary principle in justifying its GMO import moratorium. Failing to summon the approval of the WTO leaves the principle’s future application and use in determining public policy a cause of debate.

This Comment evaluates the regulation of GMOs in the American and European food supplies, and the influence of international treaties on those systems. Operating from the presumption that tort liability can be inadequate in the face of widespread and irreversible damage, this analysis will seek to propose a precautionary scheme for managing risk associated with GMOs. Specifically, this Article will advocate the development of an international environmental court with the proposed

7. Id. at 299–300.
8. Id. at 298.
11. The precautionary principle has been articulated most notably in the Rio Declaration, Principle 15: “Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.” Id. principle 15.
goals of maintaining biological diversity and ecosystem stability, and protecting humans from new allergens and toxins. Promoting these goals in the international community will require a global commitment to food product labeling, scientific testing, consumer education, and an acknowledgement that risk thresholds differ from culture to culture.

This Article begins with a brief summary of the scientific basis of creating GMOs and its historic precursors. The second section provides an overview of risks to humans and the environment. The third part of this Article analyzes the arguments put forward by both the United States and the E.U., which have defined the conflict between blocs of countries pushing GMOs abroad and those who persistently reject them. The fourth section evaluates the respective regulatory schemes imposed on GMOs by the United States and Europe, domestically and by international treaty. The success of these systems is evaluated in the fifth part through a review of the rulings in various WTO and European Court of Justice (ECJ) cases dealing with GMO trade. The weaknesses built into each system are evaluated in the sixth section. The inadequacies of tort liability systems to fully address the problems presented by GMOs are presented in the seventh section. The eighth section addresses the failings of the options for environmental adjudication within the context of the international treaty organizations. Finally, recommendations will be set forth on the use of scientific testing and labeling to ensure accountability and recourse for countries that may fall victim to the unintended consequences of GMO use. Specifically, of utmost importance is encouraging the use of an adjudicatory body that can weigh environmental and health risks alongside the policies favoring GMOs.

II. GENE SHARING METHODS

Agricultural breeding is an ancient practice, often explained as crossing the sweetest fruit tree with its most fertile neighbor. Conventionally, cross-breeding has been accomplished through the natural process of relying on bees for cross-pollenization. As scientists began work on genetic sequencing, genes carrying favorable properties, such as bright color, were isolated. New techniques were developed for introducing isolated genes from other species into organisms. These methods have allowed genes to cross species where they could not do so naturally.

The different methods of inserting the new genetic material involve penetrating the cell wall, by injection, by the creation of pores to allow

13. Id.
14. Id.
Moving Beyond the WTO
SAN DIEGO INT’L L.J.

the genetic material to pass through, or using “bioballistics,” where a
gun is used to shoot small amounts of metal covered in DNA into the
cell.\textsuperscript{16} The receiving cells often die under the impact of the mechanical
gene insertion. The goal of these methods is to force the attachment of
the genetic material in the cell. However, this happens unpredictably,
sometimes without integration, and sometimes by imprinting multiple
copies of the DNA.\textsuperscript{17} Even a successful integration of the genes that
were harvested for their desirable traits does not guarantee that the traits
will appear as intended in the receiving organism.\textsuperscript{18}

Another more organic, yet unpredictable and possibly dangerous
method of forcing gene expression, is the use of recombinant DNA.
Scientists harness the ability of plasmids and viruses to carry genetic
material from one organism to another of a different species.\textsuperscript{19} The
specific benefit of using plasmids and viruses is their similarity to bees:
they have a pre-programmed ability to invade cell nuclei and “pollenize”
by laying down new genetic material. These methods assure scientists
that the target will receive and accept the DNA, whereas the mechanical
insertion techniques amount to a game of roulette. With the danger that
the cell will be infected by the virus, the scientists must disable the disease
without disrupting its ability to penetrate the nucleus.\textsuperscript{20} However, even
when a virus successfully interferes with the nucleus, expression of the
desired traits is not guaranteed.

Viruses are also used to activate foreign genetic material by instructing
the new genes to begin producing the proteins necessary for trait expression.\textsuperscript{21}
Industry has tended toward the use of powerful viral promoters, such as
the cauliflower mosaic virus, to ensure the genes manifest themselves.\textsuperscript{22}
This can lead to disproportionate gene expression, where the foreign

\textsuperscript{16} Sophia Kolehmainen, Precaution Before Profits: An Overview of Issues in
\textsuperscript{17} Id. at 271–72. The genetic material may be imprinted multiple times in the
intended location, at many different locations, or not at all. The physical evidence of the
genetic modifications in the resulting plant is unpredictable. Id.
\textsuperscript{18} Id. at 271.
\textsuperscript{19} Id.
\textsuperscript{20} Id.
\textsuperscript{21} Id. at 279.
\textsuperscript{22} Id. Naturally occurring plants have their own viral promoters that control the
activation and manifestation of their genes. When a plant is genetically modified, the new
gene does not carry with it its normal viral promoter, so powerful foreign viral promoters
are attached to the new gene, often leading to more enhanced genetic expression than
normally occurs. Id.
DNA appears at two or three times the rate of expression of the original DNA. The promoters also are not limited to affecting the foreign DNA; they can direct the original DNA to produce proteins they normally do not. The result of using viruses and viral promoters to force gene expression is that their effects are hard to limit, producing plants with uneven characteristics, sometimes creating cancer. These viral promoters are also instrumental in pushing genetic material into other neighboring species, making it difficult for the agricultural industry to control the spread of their GMOs while they are growing in the field.

III. HEALTH AND ENVIRONMENTAL RISKS

A. Allergens and Immunity

The uncontrolled production of novel proteins in plants has potential human health implications. As genes from one organism are transferred to another, new allergenic properties can be unwittingly attached to the target. In the context of a supermarket, where food labels do not include lists of genetic modifications, people who know of their allergies will not be equipped to choose foods without the risk of becoming sick. Furthermore, the new combinations of genetic material from organisms not typically found in food make it possible for new allergens to develop. This makes it especially difficult for sufferers to identify the cause of sickness. In 1996, the risks of allergens entering the food supply without public knowledge was highlighted when a crop of soybeans modified with genes from a Brazil nut landed on the market. Despite animal testing for allergens, researchers found that these soybeans activated reactions in people who had known Brazil nut allergies.

Antibiotic resistance is another significant problem with the process of genetic modification. To test the success of an injection of foreign traits, scientists add an antibiotic resistance gene called a “marker gene” to the

23. Id.
24. Id.
25. Id. According to one study, the use of the cauliflower mosaic viral promoter led to genetic over-expression in the form of a growing cancer. Id. n.57.
26. Id. at 279.
27. Id. at 278.
28. Id.
29. Id.
30. Id.
31. Id. With Brazil nut allergies being relatively common, the soybean manufacturer, Pioneer Hi-Bred, conducted their own animal testing to test for human allergic reactions. These tests satisfied the FDA testing requirements. It was up to independent researchers at the University of Nebraska to cast a skeptical eye to these tests. Those tests, on humans, yielded positive allergy results. Id.
32. Id.
mix of genes they hope the target will accept. After the injection process, the cell is exposed to an antibiotic. If the cell survives exposure to the antibiotic, the scientists know that the foreign gene insertion was successful. Conversely, a dead cell is evidence that the cell was not successfully infected with the foreign genes. The risk to humans is that these live marker genes will be transferred to cellular bacteria and consumed with other foods, causing people to develop immunities to important antibiotics. Scientists have suggested limiting marker genes to diseases that are controlled by out-of-use antibodies.

**B. Biodiversity and Gene Flow**

The most potent risks of using GMOs come from potential damage to the environment. The emergence of new traits in food may come at the expense of the very ecological conditions that allow them to be cultivated.

The natural tendencies of wind and birds to pass seeds between fields presents a significant challenge to everyone involved in GMO production and consumption. A well-publicized consequence of planting a field with GMOs is the potential for those seeds to infect a neighboring crop that is otherwise free of genetic modification. This danger is enhanced by the use of viral promoters, with some tests showing that GMO crops are twenty times more likely to cross-pollinate to other species than their natural relatives.

Farmers facing a market of different seed options have many considerations to weigh. GMO producers, such as Monsanto, have a proprietary interest in limiting the use of their patented genetic material to the farmers with whom they enter into agreements. Farmers are required to satisfy the expectations of their buyers, who may be specifically

33. *Id.* at 277.
34. *Id.*
35. *Id.*
36. *Id.*
37. *Id.* DNA transfer could occur in humans and animals by eating genetically modified foods and exposing the bacteria in their mouths to new DNA. This DNA could latch on to the bacteria, exposing it to the resistance genes contained in the genetic marker. Such a scenario would make it difficult to control the spread of disease with antibiotics. *Id.*
38. *Id.*
39. *Id.* at 280.
40. *Id.*
41. *Id.*
buying a crop because it is not genetically modified. They might also be leery of finding patented genetic material on their property, for fear that they will become liable to a biotech company under a de facto contract. Unwarned, consumers are not able to choose what they put in their bodies. Farmers, likewise, are unable to wholly prevent gene flow. (Can you add one or two citations to these sentences? Maybe use some farmer’s anecdote and cite to it?)

C. Public and Environmental Health Failures

In 2000, questions concerning the risks of GMOs came to a head when corn products were recalled due to the presence of *Bacillus thuringiensis* (Bt). Bt is a toxin that was used in StarLink™ corn, which had been approved only for use in animal feed. The StarLink seeds eventually cross-bred with regular corn fields planted nearby, delivering Bt into the human food supply. Corn taco shells were recalled en masse due to Bt, which has the potential for causing human allergic reactions. This incident solidified the connection between GMOs and public health concerns, leading the government to take action. Some countries now regulate the side-by-side cultivation of GMO and natural crops by different farmers, and require “buffer zones” of natural crops around the perimeter of a grower’s property to mitigate seed drift.

The most popular forms of GMOs are seeds with built-in resistance to weeds or insects, such as Roundup Ready® corn, cotton, and soybeans. These GMOs integrate natural pesticides and herbicides found in other plants into the most common and profitable crops grown in the United States. In the case of Roundup Ready products, the natural weed and insect repellant are built into the seed, allowing Monsanto’s companion products, Roundup pesticides and herbicides, to attack pests without damaging the sprayed crops. Whereas farmers have traditionally been

44. *Id.* at 30–31.
45. *Id.*
47. Monsanto advertises its Roundup Ready® Corn 2 System as approved for use in the European Union, explaining that weed control is achieved through “timely applications and the appropriate rate” of its own herbicides. *See Monsanto, Input Traits*, http://www.monsanto.com/monsanto/ag_products/input_traits/products/roundup_ready_corn_2.asp. (last visited Oct. 4, 2008). Monsanto has also been developing so-called
careful to protect the plant from overexposure to chemicals, particularly to the fruit itself, the integration of these “activator” products at the genetic level has led growers to spray their crops indiscriminately and excessively. Thus, consumers face a twofold risk of food with unknowable long-term genetic effects, and a greater exposure to toxic chemicals used in the farming process.

IV. ADVERSARIAL POSITIONS ON GMO ACCEPTANCE

In international trade disputes, GMO policy brings together unresolved scientific issues that do not lend themselves to a conclusive trade policy. GMOs have been known to cross-pollinate with native species and threaten the future of valuable plant and insect diversity.48 They have been associated with the outbreak of new food allergies, and have aggravated existing allergies in consumers who were not given notice of the adjusted genetic properties of widely-used products such as soybeans.49 Experiments introducing genetically modified foods to rats show a causal relationship between consumption of GMOs and underdeveloped physiques and immune systems.50 Finally, the presence of genetically modified hormones in the meat and dairy supply is believed to raise the risk of cancer in human consumers.51 On the other hand, GMO proponents tout the benefits of vitamin-fortified foods and higher crop yields from pest-resistant plants.52 The different policies taken by the United States and the E.U. indicate a lack of consensus about how to weigh potential risks against potential benefits, and the presence of other factors that bear on government decision making.

A. America: Faith in Companies, FDA

In the United States, there has been overwhelming indifference from the public and lawmakers on the moral and ethical implications of

Traitor, or T-GURT seeds, which contain genetic properties that can only be activated by application of a proprietary chemical. See Eshan Masood, Compromise Sought on Terminator, NATURE, June 24, 1999, at 399, 721.


49. Id.

50. See Enserink, supra note 15, at 1094–95.

51. See Cummins, supra note 48, at 2.

genetically engineering food. Americans are accustomed to purchasing and eating foods pre-processed and treated with chemicals by the same large companies that are developing GMOs. This acceptance is a stark contrast to the ongoing public discussion about the consequences of using gene technology to design human babies or engage in stem cell research. These differing reactions to similar activities is consistent with a cultural predisposition to convenience and control. The willingness of the American public to consume almost anything that appears in a supermarket is the result of widespread confidence in the safety protocols of the Food and Drug Administration (FDA) and the Department of Agriculture (USDA).

FDA’s role as a market facilitator for agribusiness complicates the integrity of its regulatory scheme. The FDA requires advance notice of the marketing of GMOs and evidence that the GMO is as safe as its conventional counterpart. In the articles in its outreach magazine, the FDA consistently bolsters an analogy between Gregor Mendel’s cross-bred peas with the current practice of splicing the genetic properties of unrelated species to enhance the performance of a plant. Under the U.S. system, agribusiness is free to develop produce with novel qualities and avoid expensive separate regulatory treatment by retaining the nutritional values of a conventional product. The resulting is essentially a smell test system for evaluating food safety, where any potentially harmful changes may go unnoticed as under-the-surface properties.

53. See Kolehmainen, supra note 16, at 269–70.
54. See generally Center for Genetics and Society, http://geneticsandsociety.org (advocating biotechnology policies that are responsive to moral concerns).
57. Raymond Formanek Jr., Proposed Rules Issued for Bioengineered Foods. FDA CONSUMER, Mar.-Apr. 2001, at 9, 11. Focus groups on labeling GM foods resulted in consumers wanting to know why foods were genetically engineered, leading the FDA to discourage labeling foods as “genetically modified.” Id. at 10.
58. See generally Linda Bren, Genetic Engineering: The Future of Foods?, FDA CONSUMER MAGAZINE, Nov.-Dec. 2003, at 28; Larry Thompson, Are Bioengineered Foods Safe?, FDA CONSUMER, Jan.-Feb. 2000, at 18. Ever since the latter part of the 19th century, when Gregor Mendel discovered that characteristics in pea plants could be inherited, scientists have been improving plants by changing their genetic makeup.” Id. at 19.
American agribusiness is heavily invested in the future of biotechnology. A pioneer in this field was Calgene, which presented a tomato with reversed ripening genes for early picking and long shelf life in 1994. Since then, the majority of soybean, corn, and cotton fields in the United States have been planted with GM seeds. Monsanto, a leader in GMO development, has marketed its Roundup Ready soybean for its increased tolerance for herbicide sprays. GMO producers argue that the importance of their enhanced products can be seen in the third world, where the seeds can have remedial effects on uneven agricultural returns and world hunger.

The flip side is that the excess yield of these GMOs tends to wind up on the market in underdeveloped countries, where the increased supply drives prices down and hurts small scale farmers.

B. Europe: Skeptical of Regulation, Protective of Culture

The E.U. has been leery of the purported benefits of GMOs. One theory has linked the cultural memory of a long struggle with European famines to an unwillingness to accept GMOs into the food supply. The visceral public reaction against GMOs in the market is also considered to be an effect of European pride in food quality and culinary heritage. Resisting the whitewashing effect of globalization and the extraordinary reach of American tastes and products, Europe has responded with efforts the United States deems protectionist.

60. See Cummins, supra note 48, at 1.
67. See Rafferty, supra note 5, at 295.
Central to the E.U.’s defense of restricting imports of GMOs is its adherence to the precautionary principle.\textsuperscript{69} In justifying restrictions on GMOs, the E.U. leans heavily on the precautionary principle’s authorization for action where scientific certainty is lacking. The principle emphasizes dangerous uncertainty over known scientific risks.\textsuperscript{70} While scientists believe that GMOs could create new allergens and toxins in human bodies, cross-breed with conventional plants, and threaten biodiversity, the short history of GMOs in the environment has failed to produce conclusive results upon which the E.U. can rely.\textsuperscript{71} The E.U. has resorted to using import moratoriums to protect its borders and raise awareness of the unknowable consequences of GMOs.

V. DIFFERENT APPROACHES TO REGULATION

A. Process-based Approach

The disparate treatment of GMOs in the United States and Europe is based on a product vs. process assessment.\textsuperscript{72} In 1990, Europe emphasized its concern with any product that contained genetic modifications with the passage of legislation that specifically required risk testing and government consent.\textsuperscript{73} This has required the member states of the E.U. to regulate laboratories where GMOs are tested, and allowed national governments to attempt to impose their own restrictions on the percentage of foreign genes in any given product.\textsuperscript{74} Currently, the European Community has imposed a maximum level of 0.9% of genetic modification in unlabeled products.\textsuperscript{75} The emphasis of Europe’s “process” system of regulation depends heavily on product testing and the traceability of genetic modifications.


\textsuperscript{70} Alexander G. Haslberger, Monitoring and Labeling for Genetically Modified Products, 287 SCIENCE 431, 432 (2000).

\textsuperscript{71} Strauss, supra note 3, at 169–170.


\textsuperscript{74} Italy to “Go it Alone” on GM Seed Thresholds, AGRA EUROPE, Oct. 10, 2003, at EP4, available at LEXIS 109086129.

B. Product-Based Approach

In contrast, the United States looks at the safety of the finished product. Having adopted a "product" method of assessment, the FDA evaluates all foods with the same safety standards, regardless of genetic modification. The standards against which GMOs are judged are their conventional counterparts for "substantial equivalence." Assuming a genetically engineered tomato has the same nutritional qualities as a conventional tomato, it will pass inspection in the United States without reference to the amount of foreign genetic material that may have been spliced to improve its shelf life, color, firmness, or hardness to pesticides. The impact these new properties have on human health will not, ordinarily, be separately considered or evaluated, nor will the environmental impact of its presence in crop fields be examined.

As there is no special emphasis in the United States on testing GMOs, the modified products enter the market undifferentiated from the standard-setting, conventional products. The result is that unwitting consumers who have no choice in what foods arrive in their communities, and who know nothing of the potential health and environmental risks of these "Frankenfoods" purchase the products. As disputes between the United States and the E.U. have garnered publicity, the American public has begun to understand that their foods are bioengineered and has expressed interest in increased regulation.

77. The Food and Drug Administration assesses the safety of GMOs according to the following: "A safety assessment is characterized by an assessment of a whole food or a component thereof relative to the appropriate conventional counterpart: A) taking into account both intended and unintended effects; B) identifying new or altered hazards; C) identifying changes, relevant to human health, in key nutrients." U.S. Food and Drug Admin., Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, CAC/GL 44-2003 (adopted 2003), http://www.cfsan.fda.gov/~lrd/biotechm.html#reg (follow "Principles for the risk Analysis of Foods Derived from Modern Biotechnology" hyperlink under "International").
78. See Strauss, supra note 3, at 174.
79. Id. at 168.
80. Id. at 189–90.
81. Memorandum from The Mellman Group and Public Opinion Strategies on Genetically Modified Food (Nov. 7, 2005), http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Public_Opinion/Food_and_Biotechnology/2005summary.pdf (showing that only 41% of Americans are aware that GMOs are sold in supermarkets, but 61% favor the government determining if such products are safe before they can be sold to the public).
As a public health matter, there have been calls for mandatory regulation and labeling of GMOs. Efforts by Representative Dennis Kucinich (D-OH) to raise lawmaker awareness of the risks posed by gaps in regulation have resulted in unpromising committee review. The five bills put forth by Representative Kucinich on the GMO issue highlight the various shortcomings of current U.S. regulations: the need for labeling, environmental risks taken on by farmers using GMO seeds and animals, the need for an analysis of the safety of GMOs, and the right of citizens to bring suit for failure to comply with safety provisions, the danger of exporting GMOs to countries without their knowledge or approval; and the need to hold biotech companies liable for environmental damage caused by the release of GMOs. Where Congress has been unwilling to take such aggressive action opposite agribusiness and life sciences industries, state legislatures have begun to lead. While many of the bills introduced at the state level are supportive of GMO technology, a more significant portion reflect public skepticism, with efforts to establish moratoria, increase regulation, or require labeling.

C. Public Awakening

1. Voluntary Labeling

The FDA has allowed agribusiness and life science companies to respond to consumer concerns through a program of voluntary labeling. Food labeling rules in the United States are not extensive, but they prohibit misleading statements. This includes omitting material facts from a food label. In terms of labeling GMOs, what constitutes a

---

82. Genetically Engineered Food Right to Know Act, H.R. 4814, 107th Cong. (2002) [hereinafter Right to Know Act].
83. See Strauss, supra note 3, at 187.
84. Right to Know Act, supra note 82.
90. Id.
93. Id.
material difference is complicated by the fact that the FDA does not perceive genetic modifications to be meaningful if the food passes the substantial equivalence test. The material facts that must be included in GMO food labels are altered nutritional values and unexpected allergens. Where a product is the substantial equivalent of its conventional relative, no notice need be given to the consumer of the alterations or the circumstances of the food’s origins.

The FDA has provided guidance on the voluntary labels producers may opt for when there are no material facts to disclose. There is a consistent theme running through the examples the agency provides: a voluntary label should highlight the positive purpose of the genetic modification. The FDA also encourages producers to use the consumer-friendly word “biotechnology” over “genetic modification” or “genetic engineering,” citing focus group responses to the terms. Additionally, the FDA prohibits simplistic statements on labels, such as “GMO free” on several grounds. First, the FDA asserts that consumers do not understand the terms GMO or GM, but they do understand the word “biotechnology.” Second, the Agency argues that labels advertising a lack of bioengineering have a chance of being misleading. It also points out that most foods have undergone crop cultivation, which constitutes genetic modification.

The FDA relies on its own lack of threshold designations and testing requirements to explain that it cannot ensure that conventional products are “GMO free.” Its suggestions for labels disclaiming GMOs are straightforward and prohibit any connotation of better safety, vis-à-vis a

---

94. See GUIDANCE FOR INDUSTRY, supra note 91.
95. Id.
96. Id.
97. Id. (using “[t]his product contains high oleic acid soybean oil from soybeans developed using biotechnology to decrease the amount of saturated fat” as an example of an acceptable voluntary label).
98. Id.
99. Id.
100. Id.
101. Id.

A statement that a food is “free” of bioengineered material may be difficult to substantiate without testing. Because appropriately validated testing methods are not currently available for many foods, it is likely that it would be easier to document handling practices and procedures to substantiate a claim about how the food was processed than to substantiate a “free” claim.
foods’ GMO counterpart. Curiously, a definition of the term that consumers are so comfortable with—biotechnology—is undefined in the FDA’s materials on labeling. These guidelines also fail to educate the public about the process by which biotechnology alters the food supply, and its potential effects on the environment. By disallowing food producers’ conclusive statements on the safety of foods, the FDA has retained power in the public eye and, in fact, over the determination of food safety.

2. Europe’s Reporting Requirements

European attention has been focused on the issue of GMO safety even prior to the marketing of the first genetically modified food. Since then, the E.U. has passed legislation aimed at aggressively informing the public of GMOs’ presence and environmental impact. Specifically, Council Directive 2001/18 authorizes a series of actions when a GMO is poised to enter the market: a notification procedure, a period of public comment, an assessment report, and the promulgation of principles for determining environmental risk. The directive also sets forth a uniform labeling requirement for products with GMOs to read: “This product contains genetically modified organisms.” Directive 2001/18 distinguishes its goals and constituencies from those of the FDA by explicitly referring to the sensitivity of the environment in accepting and spreading new species.

The most novel, and controversial, provisions of Council Directive 2001/18 allow for evidence of human health or environmental risks to impose a moratorium on GMOs. The failure of the United States to differentiate its GMO exports from its conventional products was ill-received in Europe, where mandatory labeling and GMO trace testing was already in place. The result was a temporary ban in Europe, under

102. Id. (using “[o]ur tomato growers do not plant seeds developed using biotechnology” as an example of an acceptable voluntary label).
103. See Council Directive 90/220, supra note 73 (enacted four years prior to the appearance of the FLAVR SAVR tomato, a product of Calgene).
105. Id. art. 13.
106. Id. art. 13 § 2.
107. Id. cl. (4).
108. Id. art. 20, § 2, reads:
If new information has become available, from the users or other sources, with regard to the risks of the GMO(s) to human health or the environment after the written consent has been given, the notifier shall immediately take the measures necessary to protect human health and the environment, and inform the competent authority thereof.
Moving Beyond the WTO
SAN DIEGO INT’L L.J.

Council Directive 2001/18, of GMO imports from 2003 to 2004.\(^{110}\) A host of countries that follow the U.S.’s lead on GMO policy responded to the ban with a successful World Trade Organization (WTO) complaint on the grounds that the ban constituted a barrier to trade.\(^{111}\) Prior to the 2006 ruling of the WTO, the E.U. recognized that its position was untenable by passing Regulation 641/2004, which established rules for the authorization of new GMOs in the market.\(^{112}\)

3. The Cartagena Protocol

In the background of these state regulations is the recent adoption of the Cartagena Protocol on Biosafety.\(^{113}\) The focus of the Cartagena Protocol is the regulation of living modified organisms, such as plants and animals, and their effects on biodiversity.\(^{114}\) The protocol also highlights the disorganization of information about GMOs by establishing a Biosafety Clearing-House to “[f]acilitate the exchange of scientific, technical, environmental, and legal information on, and experience with, living modified organisms . . .”\(^{115}\) The Cartagena Protocol is explicitly limited to the regulation of live modified organisms, which it defines as having the capacity to transmit genetic material\(^{116}\) thus specifically excluding from its purview the conflicts over GMOs in food.\(^{117}\) However, the adoption of


\(^{111}\) Id. The United States, Australia, Argentina, Brazil, Canada, India, Mexico, and New Zealand challenged the fairness of the E.U. temporary moratorium as an invalid barrier to trade. Id.


\(^{114}\) Id.

\(^{115}\) Id. art. 20.

\(^{116}\) Id. art. 3(g), (h).

this protocol by over 130 countries signals an international consensus on
the potential environmental perils of unregulated genetic modification.\(^{118}\)

VI. DISPUTES

A. The WTO

The central contention in the trade disputes over GMOs has been whether states have a valid scientific basis for their restrictive actions.\(^ {119}\)

This emphasis is drawn from the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).\(^ {150}\) The SPS Agreement is relevant to GMO trade disputes because it governs the protective measures states can employ in protecting human and plant life.\(^ {121}\)

The response to Europe’s 2003 moratorium on GMO imports was severe. Three complaints were filed in the WTO Dispute Settlement Body, to adjudicate the merits of the E.U. position.\(^ {122}\) The result, predictably, was to favor the GMO exporters’ argument that the E.U. had failed to satisfy the SPS Agreement requirement for a scientific basis for its moratorium.\(^ {123}\)

Critics have derided the decision for failing to consider the unknowable consequences of a new technology.\(^ {124}\)

Another significant criticism is that the WTO is the wrong body to be handling disputes on sensitive environmental topics.\(^ {125}\) The adoption of

---

119. This theme is articulated in both the GUIDANCE FOR INDUSTRY from the FDA, supra note 91, and Council Directive 2001/18, supra note 104, which require evidence of unforeseeable consequences before restrictive action can be taken.
120. Marrakesh Agreement Establishing the World Trade Organization, Agreement on the Application of Sanitary and Phytosanitary Measures, art. 2 §2, Apr. 15, 1994, 1867 U.N.T.S. 493, states: “Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.” Art. 5, § 7 provides for provisional measures when sufficient scientific information is unavailable. Id.
121. Id.
124. See Greenpeace European Unit, Say No to Genetic Engineering, http://www.greenpeace.org/eu-unit/campaigns/say-no-to-genetic-engineering (last visited Sept. 19, 2008) (arguing that the environmental impacts will be discovered after remediation is possible).
125. See EURACTIV.COM, supra note 110.
the Cartagena Protocol lends support to this argument. The creation of
the Biosafety Clearing-House under the protocol clearly announces the
need for greater scientific and legal understanding of GMOs, which, by
implication, is lacking in other international bodies. In contrast, the
WTO, lacking any scientific expertise, regularly determines the sufficiency
of scientific data in adjudicating disputes. The WTO does not specialize
in interpreting the SPS Agreement, a treaty that was adopted to fortify
national efforts to protect the environment. The concept of creating
environmental safeguards through the apparatus of trade is ill-founded.

B. European Disputes

Disputes within the European Union have predictably been settled in
favor of a precautionary approach in distributing GMOs. Member states
are responsible for implementing controls consistent with E.U. directives,
such as Council Directive 2001/18. However, uniform systems are not
required and each state can exercise a veto over the importation of E.U.
approved GMOs. France was instrumental in using these vetoes to
implement the de facto moratorium on GMOs that led to the WTO
disputes. This behavior is particularly controversial where a GMO has
successfully passed the E.U. environmental and safety tests required
to enter the market relies on an argument couched in state sovereignty,
and acts as an explicit challenge to the validity of E.U. laws. The
European Court of Justice has ruled, in previous cases between states,
that a member state is free to independently restrict GMOs on a
temporary basis when it provides substantial scientific support of health
or environmental risk. This focus on scientific evidence is consistent
with the WTO’s interpretation of the SPS Agreement, but it has proven
to be more permissive in allowing member states to invoke the
precautionary principle in presenting their scientific evidence.

127. see id.
128. Press Release, ECJ, Judgment of the Court of Justice in Case C-6/99, Association
Greenpeace France and Others v. Ministere de l’Agriculture et de la Peche and Others
129. See id.
130. CHEMISTRY & INDUSTRY, supra note 126.
131. The Italian government was successful at the ECJ in forcing Monsanto to label
food containing GMOs. See Case C-236/01 Monsanto Agricoltura Italo v. Presidenza
In 2000, the European Court of Justice first gave member states the leeway to regulate GMOs independently in *Greenpeace v. Ministere de l’Agriculture et de la Peche and Others* declaring that national governments have the first decision in whether a GMO can enter the market.132 A member state receives an application to distribute a GMO from a food developer and can either approve or disapprove the application unilaterally. The Court validated this process by affirming that national authorities are qualified to assess the health and environmental risks posed by a particular GMO.133 If it foregoes a veto at this stage, the application is passed on to the European Community, where the precautionary principle is the official standard for evaluating the application.134 Relying on the due diligence of the initial accepting state in assessing risks, the European Community will broadly accept the GMO unless another state, having done its own risk assessment, protests.135 Member states can reject a GMO after Community authorization, and effectively force another review of it if there is new information about its health and environmental effects at the Community level.136

The underlying facts of the *Greenpeace* case centered on whether an initial authorization by a member state, which was then forwarded to the European Community at large, could be annulled after Community approval.137 France had been approached with an application for a genetically modified strain of maize, which it approved and forwarded to the European Community.138 After the E.C. gave authorization to distribute the maize throughout Europe, Greenpeace lobbied to have the French authorization annulled.139 The French court agreed with Greenpeace, but submitted the matter to the E.C.J. on the question of whether it had the discretion to act counter to a European Community order.140 The Court responded that approving a GMO application and sending it up for Community approval binds the initial country to permit the goods to be distributed.141 Thus, France could not act to ban the maize it had

133. *Id.*
134. *Id.*
136. *Id.*
137. *Id.*
138. *Id.* France requested that the E.C.J. determine what liberties a Member State could take with regards to asserting its veto after the fact, and what effects that would have on the GMO application process. *Id.*
139. *Id.*
140. *Id.*
141. *Id.*
Moving Beyond the WTO
SAN DIEGO INT’L L.J.

recommended after receiving Community approval without presenting new scientific information about risk factors.\textsuperscript{142}

The \textit{Greenpeace} decision is significant in that it limits the opportunity to apply the precautionary principle to a GMO. Each state has an absolute right to initially reject an application for any reason. Once a GMO passes through the requirements of one member country then, it is evaluated by the European Community at large for precautionary principle concerns. If the organism is approved for wide distribution, that decision can only be challenged in the E.C.J. by a showing of new information that would significantly affect a precautionary principle analysis of the health and environmental risks posed by the GMO. This higher evidentiary threshold for post-approval challenges reflects the presumptions inherent in the precautionary principle that: unknown risks can be avoided by failure to invite them, and heightened scientific certainty about risks diminishes the attractiveness of inaction.\textsuperscript{143} The policy is significantly deferential to the concerns of the member states in that it assumes each country is capable of evaluating those risks, and demands a new evaluation of the GMO by the European Community upon any new information provided to it by a state.\textsuperscript{144}

An E.C.J. decision settling a dispute between Italy and Monsanto now permits deference to a member state in deciding to temporarily ban an approved GMO in light of new information.\textsuperscript{145} This decision, however, implements the “substantial equivalence” test used in the United States for approving GMO food.\textsuperscript{146} The dispute arose when traces of GMO corn were found in processed foods previously approved as substantially equivalent to conventional corn products.\textsuperscript{147} A designation of substantial equivalence signals that a substance has no health risk, allowing it to enter the market without wading through the GMO application process at issue in \textit{Greenpeace}.\textsuperscript{148} After a strain of Monsanto Bt-corn entered the market, Italian scientists detected traces of GMOs and questioned

\textsuperscript{142.} \textit{Id.}
\textsuperscript{143.} \textit{See Cartagena Protocol, supra note 113, arts. 15, 16.}
\textsuperscript{144.} \textit{Press Release, ECJ, Judgment of the Court of Justice in Case C-6/99, supra note 128.}
\textsuperscript{146.} \textit{Id.}
\textsuperscript{147.} \textit{Id.}
\textsuperscript{148.} \textit{Id.}
whether the modified corn was safe, leading to a “precautionary suspension” of its distribution in Italy.\textsuperscript{149} Monsanto challenged the independent ban by Italy as counter to E.C. law.\textsuperscript{150} The Italian court turned to the E.C.J. to rule on the question of whether a substance with traceable amounts of transgenic properties properly fit within the category of substantially equivalent foods, and whether it was appropriate that organisms with trace elements should be allowed to enter the market through the simplified process accorded such foods.\textsuperscript{151} The E.C.J. resolved this issue by ruling that differences between a conventional product and a GM product would not destroy a GMO’s substantial equivalence to its conventional counterpart. However, a member state could determine the substantial equivalence of a given organism by evaluating its risk to public health.\textsuperscript{152} The Court also ruled that the substantial equivalence method of bypassing the GMO approval process did not represent a lower safety standard for such foods.\textsuperscript{153} It suggested that foods with traces of GMOs ought to be properly labeled as required under the law.\textsuperscript{154} The Court again emphasized that information causing a state to question the purported safety of a GMO on the market could be used as grounds to institute a temporary ban on the product, and force a secondary review of that product by the E.C.\textsuperscript{155}

By preserving the rights of member states to act independently, the Court in \textit{Monsanto} effectively dampened the ability of food companies to slip GMOs into Europe in sheep’s clothing. The cover of “substantial equivalence,” which works in the United States for introducing GMOs that are presumed to be innocuous, is not guaranteed in Europe. The goal of wider consumption may not, in fact, be the guaranteed outcome: a label on each unit alerts reluctant European consumers of the content of the item, and prompts scientists, such as the ones in Italy, to question its safety. The E.C.’s refusal to step in on behalf of the GMO distributor in defending “substantial equivalence” serves as a nod toward state sovereignty within the E.C., and to the precautionary principle. Without allowing member states to weigh in on the designation of “substantial equivalence”

\textsuperscript{149} Id.
\textsuperscript{150} Id.
\textsuperscript{151} Id.
\textsuperscript{152} Id.
\textsuperscript{153} Id. The E.C.J. noted that the GMO regulations have two objections: “to ensure the functioning of the internal market in novel foods, and to [] protect public health.” \textit{Id.}
\textsuperscript{154} Id.
\textsuperscript{155} Id.
labels to certain GMOs might raise the presumption that these items have not had the benefit of a skeptical eye.

The regulatory regimes at the international level and within the European Union differ substantially on how to sufficiently support a GMO ban. The WTO starts from the premise that a GMO is safe, and only "detailed scientific evidence" can warrant a temporary ban. It draws the requirement of scientific evidence from the SPS Agreement, a high threshold for evaluating health and environmental impact. Such a requirement is analogous to a canary in a coal mine: states are expected to go down an uncertain and possibly dangerous path without information, and retreat is permitted only when there is demonstrable evidence of danger—the equivalent of a dead canary. The WTO has resisted the precautionary measures by countries unwilling to take the health and environmental risks that more cavalier states greet with permissive regulations.

The E.C.J. has been clear that the focus of the inquiry never strays far from observance of the precautionary principle. Permitting a GMO to enter the market is a question, not the default rule. The significance of allowing individual states to pass upon applications prior to E.C. review signals respect for the unique values of the member states, while providing a guaranty that the applications reaching committee review are relatively benign. Subsequent objections by other member states reflect the concern that precautionary needs differ from region to region. New information raised to challenge a GMO need not rise to the level of detailed scientific evidence; it need only be sufficient to change the outcome of a precautionary evaluation of the GMO. The effect of such an open-door policy for evaluating the safety of these organisms is that potential side effects can be discussed and hypothecated before research and experience develop a full story.

The difference between the WTO and E.C.J. systems illustrates the fundamental dispute over whether to adjudicate GMOs as a trade or an environmental issue. The presence of multinational food companies promoting their newest creations in every possible market, and the lack of an international body dedicated to settling environmental problems between countries, has placed cases dealing with resistance in the lap of the WTO, whose mission is to promote free trade. The problem is that trade issues are not the gravamen of the complaints that arrive at the WTO: states are not asking for decisions regarding dumping or other anti-competitive practices. The basis for GMO bans have been aimed at
protecting delicate environmental and public health systems, yet the SPS Agreement binds the WTO to make blunt rulings requiring scientific certainty. Without the power to act cautiously and discriminately, biological diversity and human resistance to allergens may suffer at the hand of capitalism and free trade, powered by an international system that values market access for corporations more than it values market integrity.

VII. WEAKNESSES OF THE SYSTEMS

A. Labeling

The crux of the argument between Europe and the United States amounts to a trade issue for the United States, and a health and environmental issue for Europe. The United States has resisted labeling because conscious European consumers would be able to make educated decisions about the American goods on sale, particularly about the profitable processed foods that are loaded with GMOs. In contrast, Europe has become highly sensitive to food origins and treatment. Their demands for information have grown out of public crises involving Mad Cow disease and invasive species decimating traditional environmental balance and crops.

Regulating consumer products became mandatory in the United States in the early twentieth century in order to protect the consuming public from dangerous foods and drugs. \(^{156}\) Oversight was necessary to mitigate the health risks posed by drug companies and traveling medicine men advertising and pawning their concoctions to a trustful public. \(^{157}\) The availability of drugs was unmonitored, leading consumers to be unwittingly exposed to substances such as opium, heroin, and cocaine. \(^{158}\) The FDA notes that information about drugs was limited to that obtained through bitter experience. \(^{159}\)

Ironically, labeling in the United States came about through the action of women’s groups adopting a “pure food” campaign. \(^{160}\) Under pressure from a public convinced by the efforts of the pure food ladies, the FDA adopted regulations limiting the use of preservatives and chemicals only as necessary, and requiring that the producer prove a product’s


\(^{157}\) Id.

\(^{158}\) Id. at 35. Labeling of drugs was often limited to names such as “Kick-a-poo Indian Sagwa” without indicating the presence of intoxicating substances. This “reflected both the limited medical capability of the period and public acceptance of the doctrine that the buyer could and should look out for himself.” Id.

\(^{159}\) Id.

\(^{160}\) Id.
safety. Interestingly, this is exactly the opposite approach taken by the FDA in regulating GMOs. Genetic modifications are assumed to be safe, unless proven otherwise by consumer reaction or the patent presence of toxins, such as in Starlink\textsuperscript{TM} corn. The premise of this policy is that, by and large, naturally occurring substances are safe for human consumption and do not require vetting on a case-by-case basis. This, again, creates a de facto regulatory vacuum, where consumers operate in a state of caveat emptor, and only learn that certain genetic material is toxic to them by an unexpected allergic reaction.

The weakness of the American position in resisting labeling requirements by European markets is its inconsistency with its closely-held values. Consumer education, transparency, and guarding public health have long been embraced in the United States, often with more urgency and effectiveness than within Europe. Failure to label GM foods serves none of these public interests, and aligns the FDA with the drug companies that design, patent, and market the foods with less oversight, especially when compared to their pharmaceutical counterparts.

\textbf{B. Regulations}

Europe has adopted a regulation system that seems to address American concerns about barriers to trade with its own health and environmental concerns. As the E.U. has been slowly changing its regulatory framework to mirror the substantial equivalence test in the United States, new products, such as corn, have been introduced for marketing in the E.U. without resistance.\textsuperscript{162} In fact, reports have emerged indicating that farmers in France, the most vocal critics and staunch resisters of GM foods, have been clamoring for GM seed varieties because of their superior quality and yield.\textsuperscript{163} Europe’s system allows for the use of seeds evaluated for substantial equivalence with conventional goods, including their environmental effects, while still requiring informative labels that address consumer rights.

\textsuperscript{161} Id. The standoff between agricultural and health interests on one side, and proponents of laissez faire government on the other, was tipped with the support of women’s organizations and the publication of Upton Sinclair’s \textit{The Jungle}.


The European GMO approval process is, compared to the American system, cautious to the point where every participant has significant power to exert its will. The Greenpeace and Monsanto cases reiterate that every member state is deemed capable of scientifically evaluating the effects of a GMO, and contribute to the application of the precautionary principle. The lack of a unified process or a consolidated agency to evaluate proposed GMOs creates the risk that every state receiving a GMO application will act independently to disproportionately influence the entire European community. It is certain that each state’s actions will be based on their unique prejudices and predispositions toward issues of the environment, trade, and health. While this gives the E.U. the advantage of having more diverse minds evaluate GMOs and their probable effects, the process is also susceptible to hijacking by interest groups or countries that do not provide objective analysis. In contrast with the American FDA, manufacturers of GMOs have limited opportunities to work in tandem with European regulators. The strength of public opinion opposing GMOs in Europe further pits the goals of regulators and facilitators of new products against those of the developers of GMOs. In cases where industry genuinely has better, safer products to offer, the process of introducing them to the European market would be hindered by the need to lobby every government and respond to criticisms and research of varying seriousness and relevance.

VIII. TORT LAW OPTIONS

The process-based approach of regulating GMOs in Europe lends itself toward developing expectations about the organism, and about liability arising from its use, at the time it enters the market. The manifestations of this front-end understanding are requirements that the derivation process be disclosed and labeled, and the willingness and ability of European countries to pull questionable items off the market. By contrast, the United States does not make specific inquiries into a GMO product when it is first introduced. Its use of the “substantial equivalence” test equates, for all purposes, a GMO with the conventional food item.

A. Consumer Expectations

In American tort cases, foods are subject to liability under the consumer expectations test because they are relatively simple products that consumers understand and know about. The Restatement (Third)
of Torts takes the position that a seller is liable when a food contains a harmful ingredient that a "reasonable consumer" would not expect to find in food. Liability attaches to a product when it poses an "unreasonable danger," meaning that the risk of consuming the product would not be anticipated by an ordinary purchaser. Dangerous products typically contain a manufacturing or design defect that the seller was in a better position to know of, and provide warning to the consumer. When a consumer is injured by a product defect, the seller can be held strictly liable for injuries.

The problems with using this test for GMO foods are manifold. First, injuries resulting from the genetic modifications in food may not be readily detected or linked to the substance that caused them. Second, the personal injuries considered most likely to arise from GMOs—allergies—will not necessarily win under a strict consumer expectations test. Many consumers are aware that foods trigger allergic reactions, and that some allergies develop over time in response to consumption patterns. That expectation does not change merely because a product was developed in a laboratory rather than naturally.

Last, the significant damage feared by introducing GM crops into the environment could not be addressed using the consumer expectations test. While individuals have standing in the United States to sue for environmental damage, this is typically done through showing non-compliance with a governmental regulation. With genetically modified crops, environmental impacts on conventional crops, biodiversity, soil, and wildlife will be difficult to trace and take years to surface. By the time any plaintiff is able to prove these effects, the damage will be done and possibly irreversible. In the meantime, potential plaintiffs can be effective only by influencing legislation and regulatory activities, and monitoring growers for compliance with existing laws.

167. Id. § 402A cmt. c.
168. Id. § 402A.
B. Alternatives: Risk-Utility and Design Defect Tests

Some scholars have suggested that food be evaluated using the traditional risk-utility test. ¹⁷⁰ This test is commonly used by courts seeking to evaluate whether a product contains such a dangerous defect that it should not be marketed. ¹⁷¹ A risk-utility analysis requires a showing that the cost of correcting a product defect would have been less than assuming the risk of the defective product. ¹⁷² Imposing this test in food-related tort litigation could sufficiently motivate GMO developers to fully research alternative designs and the risks of injury to the consuming public. As critics of the test point out, however, this pressure could result in consumers suing food companies for their failure to engineer foods to replace a conventional product carrying a normal risk of allergens and other toxins. ¹⁷³

The results of using the risk-utility test for food would be perverse. Large companies, facing liability for not engineering their food, could effectively put an end to wide distribution of natural foods. Smaller farmers might be tempted to fill that gap in supply, but they would be at the peril of defending expensive lawsuits for their use of natural seeds. From a regulatory standpoint, the cost of switching to a risk-utility test in the courtroom may eventually lead to calls for greater ex ante regulation of food production. As risk-utility would tend to encourage greater transparency in food research, development, and content, it would also lead to the marketing of even more highly-processed substances. Giving consumers an outlet to challenge the safety of natural foods and the presence of naturally-occurring risks inherent to them may lead to demand for “risk-free” foods. Such a menu would require extensive research and engineering to eliminate side-effects and risk factors. The resulting products would run counter to the interests of anti-GMO constituencies: new, fully-evaluated and processed foods and plants would enter the food supply and environment en masse, without any information on their long-term effects.

The risk-utility test might also require a plaintiff to show that another design of the product would be a reasonable and safer alternative to the “defective” one that allegedly caused the plaintiff’s injury. ¹⁷⁴ The implication is that any GMO food could be challenged with the evidence that a safe

¹⁷³ See Noah, supra note 43, at 56.
¹⁷⁴ Dancy v. Hyster Co., 127 F.3d 649, 654 (8th Cir. 1997).
conventional product exists, and any natural product could be challenged with the existence of a food better engineered for safety. Any engineer or grower of food would be disincentivized, under this regime, from experimenting with new cross-breeds or other genetic modifications. New products would be guaranteed sources of litigation, with merciless plaintiffs hauling in similar products that withstood the risk-utility test in prior lawsuits as examples of "reasonable alternative designs." Worse, the presence of a safe alternative to the defective product makes the new design look like negligence by the manufacturer. Some jurisdictions have dealt with this problem by shifting the burden of proof that a product is not defective to the defendant, but many courts require that the plaintiff prove that the defective condition posed an "unreasonable danger" to the consumer. As discussed above, a plaintiff may have difficulty proving that an allergen or toxin is unreasonably dangerous when found in a GMO food product, as they appear in the conventional, or "safe," foods that a GMO would be compared to in such a case.

C. Failure to Warn in Labeling

Labeling GMOs is the most commonly called-for measure in the debate over allowing these products into the supermarket. The idea of giving consumers a choice over what food to consume—genetically modified or not—is based on the idea that there are inherent risks in consuming GM products. Labels and warnings are typically used by manufacturers and sellers to communicate directions for safe use of a product. In the context of GMOs, labels would function to warn consumers of possible allergens and other qualities that fail to conform to consumer expectations.

The Restatement (Second) of Torts discusses the obligation to label products made "under secret formula." When the properties of a product

175. See Barker v. Lull Engineering Co., 20 Cal.3d 413, 433 (1978) (lightening the plaintiff's burden of proving negligence by a manufacturer in defect-design cases, by moving the burden of proof to defendant in showing that the product is not defective).

176. RESTATEMENT (SECOND), supra note 166, at cmt. g. Generally, the plaintiff must offer a safer alternative design in proving the unreasonable danger of the product. Nunnally v. R.J. Reynolds Tobacco Co., 869 So.3d 373, (Miss. 2004) (requiring plaintiff to submit evidence proving the unreasonable danger posed by cigarettes). But see Cronin v. J.B.E. Olson Corp., 8 Cal. 3d 121 (1972) (shifting the burden of proof to the defendant on the risk-benefit test when the plaintiff is injured).

177. Id. § 397 cmt. b.

178. Id. § 397.
are not manifested in its appearance or on its label, the user is deemed to have relied on the seller’s expertise in making the product safe for its intended use.\textsuperscript{179} The obligations underlying this liability are that the seller use reasonable care in designing a safe product, and communicating directions for safe use.\textsuperscript{180} The Restatement sets the standard for comprehending warning statements and knowledge of risks at that of the ordinary user of a product, who is not expected to have in-depth understanding of the properties of that product.\textsuperscript{181}

A manufacturer may be liable to an injured plaintiff if the ingredients listed on a label do not provide an ordinary consumer with enough information to understand the properties of the product.\textsuperscript{182} Under the current regulatory framework in the United States, GMOs do not need to be labeled and are not differentiated in the market from conventional products. Manufacturers may voluntarily label GMOs, but these labels are limited to simplified statements notifying the consumer of the presence of genetic modifications, not lists of formulas used to derive the product. If anti-GMO activists succeed in pressuring the government to require more stringent food labels, lists of exotic genes may not adequately inform consumers of the foreign content they are consuming.

Inadequate GMO labeling has caused allergic reactions in the public on two well-known occasions. As discussed above, genetically modified soybeans entered the food supply without notice to consumers that they were GMOs, and that they had been altered using genes from Brazil nuts, a food commonly known to cause allergic reactions.\textsuperscript{183} Secondly, StarLink\textsuperscript{TM} corn intended for use in animal feed entered processed food intended for humans through a sequence of farmers, grain elevator operators, and purchasers failing to label the corn as directed by the federal government.\textsuperscript{184} Even after the grain community was informed by the federal government that StarLink\textsuperscript{TM} contained a toxin known to cause violent allergic reactions and needed to be quarantined, reasonable care was not exercised to identify the corn as a potential hazard, and some allergic reactions did ensue.\textsuperscript{185}

Assuming that StarLink\textsuperscript{TM} corn had contained a detailed, formulaic label, identifying the Bt strain that carried the toxin at issue, it is still unlikely that allergic consumers would have avoided the product. Ordinary consumers

\begin{itemize}
  \item \textsuperscript{179} \textit{Id.} § 397 cmt. b.
  \item \textsuperscript{180} \textit{Id.}
  \item \textsuperscript{181} \textit{Id.} § 397 cmt. c.
  \item \textsuperscript{182} \textit{Id.} § 397.
  \item \textsuperscript{183} Kolehmainen, \textit{supra} note 16, at 278. Institute for Food Research, \textit{Brazil Nut Allergy}, http://www.ifr.ac.uk/public/foodinfosheets/edpbrazil.html (stating that Brazil nuts are the most common trigger of nut-related allergic reactions in the United Kingdom).
  \item \textsuperscript{184} Brian O'Reilly, \textit{Reaping a Biotech Blunder}, FORTUNE, Feb. 19, 2001, at 156.
  \item \textsuperscript{185} \textit{Id.}
\end{itemize}
will not be able to read ingredient lists with understanding unless the genetic contents are listed with their origins or possible effects. This would require a soybean label identifying Brazil nuts as an ingredient, or a corn label listing Bt as known to cause allergic reactions. The effect would be to wipe out the benefits to industry of the substantial equivalence test, because everything would require a label. Although this labeling promises to be burdensome to manufacturers, consumers have the more difficult task of sorting through food that looks equivalent, but may have added dangers.

IX. INTERNATIONAL ADJUDICATION

The traditional institutions for resolving international disputes have been roundly criticized for their insensitivity to environmental claims. After a series of conventions on the need for an environmental court in the late 1980s and early 1990s, an Italian Supreme Court judge introduced a draft convention for the Establishment of an International Court for the Environment that addressed the shortcomings of the international legal system. Shortly after this development, the International Court of Justice (ICJ) announced that a permanent panel of its judges would be available, at the consent of the parties in a dispute, to adjudicate as a Chamber of the Court for Environmental Matters (CEM). This panel, however, does not resolve the inadequacies of the ICJ. The justices are drawn from the ICJ and possess no special expertise in scientific or environmental matters. Moreover, the panel cannot assert compulsory jurisdiction over any dispute. States might also point to a general anti-


187. See Kalas, supra note 187, at 233 (quoting the 1992 Draft Statute of the International Environmental Agency and the International Court of the Environment). Under the Draft Statute, states would be held legally accountable to the international community for domestic and extraterritorial environmental damage. Standing in such lawsuits would not be limited to other states, but could be invoked by individuals and NGOs as well. Id.

188. The CEM was formed pursuant to Article 26 of the ICJ Statute, which allows the Court to “form one or more chambers, composed of three or more judges as the Court may determine, for dealing with particular categories of cases ....” Statute of the International Court of Justice, art. 26.1, Oct. 24, 1945, 59 Stat. 1031. The jurisdiction of the court and the CEM is limited to states. Id. art. 34.

environmental bias in the ICJ, which would be unlikely to produce favorable results to a party seeking to protect the environment in a trade dispute. So it is not surprising that after nearly fifteen years of existence, the Chamber has never been called upon to settle a dispute.

The problems of standing and compulsory jurisdiction are central to the problem of creating any new adjudicatory forum for environmental issues. The current international system rests on state sovereignty, which denies NGOs and individuals access to the institutions that have been ruling on the environmental policies that affect them. In the United States, the Alien Tort Claims Act has mediated the challenge of obtaining jurisdiction over states or transnational companies involved in environmental destruction, but the judiciary remains hesitant to adjudicate disputes that have another available and appropriate forum. With most criticism of the current international forums being directed at the standing issue, and with a general consensus that environmental progress will be made only with the initiation and cooperation of environmental NGOs, a new acceptance of non-state actors as the mouthpieces of transnational values must be recognized in any new dispute settlement body.

A. Alternative Forums

Two other entities have emerged as front-runners in the search for an alternative to the WTO. The Permanent Court of Arbitration (PCA) sits in The Hague under the auspices of the United Nations, and the International Court of Environmental Arbitration and Conciliation (ICEAC) works


190. See Wu, supra note 190 (describing ICJ precedent that explicitly rejects using “potential environmental harm” as a defense to avoiding a treaty).

191. See Wu, supra note 190 (describing ICJ precedent that explicitly rejects using “potential environmental harm” as a defense to avoiding a treaty).


193. See Kalas, supra note 187, at 191–92 (citing the difficulty for individual plaintiffs to bring claims in national courts under theories of international environmental law).

194. Conference, The George Washington University Law School Conference on International Environmental Dispute Resolutions, 32 GEO. WASH. J. INT’L L. & ECON. 325, 327 (2000). The unwillingness of states to initiate environmental claims in the ICJ or the CEM may be due to their unwillingness to have their own environmental regulations and practices examined and exposed. Id.
out of offices in Mexico and Spain at the request of consenting parties.\textsuperscript{195} What is distinct about these forums as opposed to the ICJ and the WTO is their emphasis on mediation and conciliation, their lack of compulsory jurisdiction, and the extent to which the parties can be involved in choosing the adjudicators and experts.\textsuperscript{196}

The different characteristics of these forums demonstrate why neither of them fills the gaps that make the WTO and ICJ so imperfect. Where the WTO and ICJ maintain an eminence associated with compulsory jurisdiction and command traditional binding decisions overseen by an inflexible panel of adjudicators, they are both unable to accommodate the non-state actors who are crucial environmental advocates. These compulsory forums are also more intimidating to the states that are brought before them, who fear public disclosure and want to exercise more control over the adjudicatory process and panelists. The PCA, while voluntary for the parties, has the power to issue binding decisions, but it provides little of the transparency that parties hope to achieve when bypassing the WTO and ICJ. Its jurisdiction is limited to cases with one state as a party, meaning that this forum is not conducive to individuals or NGOs pursuing corporate polluters.\textsuperscript{197}

The ICEAC, on the other hand, has been called a precursor to a World Court for the Environment.\textsuperscript{198} Its structure provides the flexible options sought by states, individuals, and NGOs, except that it cannot compel jurisdiction over the parties.\textsuperscript{199} It is available at the request of any person, NGO, corporation, or state, and can facilitate multilateral disputes.\textsuperscript{200} It offers dispute resolution by conciliation and arbitration, and offers advisory opinions on the use of different environmental protection solutions.\textsuperscript{201}

\textsuperscript{195} Kalas, \textit{supra} note 187, at 212–13.
\textsuperscript{196} \textit{Id.}; see also Wu, \textit{supra} note 190, at 264–65. The PCA provides parties with lists of arbitrators and experts who have previous experience with environmental disputes. The parties are free to employ these recommended experts or find their own. \textit{Id.} at 265.
\textsuperscript{197} Kalas, \textit{supra} note 187, at 213. The culpability of transnational corporations in environmental pollution is widely understood, but impossible to stop on a global level. \textit{See id.} at 193. As GMOs have been systematically promoted abroad on a “testing grounds” basis, claims that companies are taking advantage of the lack of regulation in the third world will continue to arise.
\textsuperscript{198} \textit{Id.} at 214.
\textsuperscript{199} \textit{Id.}
\textsuperscript{200} \textit{Id.} The necessity of including many actors in facilitating environmental solutions has led to calls for more inclusive dispute resolution methods over the traditional two-party, adversarial system. \textit{See Wu, supra} note 190, at 264.
\textsuperscript{201} Kalas, \textit{supra} note 187, at 214.
Additionally, the members of its large panel of judges specialize in environmental law, giving the ICEAC decisions the credibility of impartial experts, over whom the parties have had no special input.\textsuperscript{202} The fact that this forum was created by lawyers and judges on a voluntary basis to forge a new approach to settling environmental problems is an explicit reproach to the traditional mechanisms offered through the system of state sovereignty underlying the WTO and the United Nations.\textsuperscript{203}

X. RECOMMENDATIONS

A. Scientific Adjudication

Input from scientists is conspicuously lacking from the development of international trade law regarding GMOs. The WTO follows the SPS Agreement in requiring detailed scientific evidence to support a restriction on GMOs, but what qualifies as sufficiently detailed or scientific is not well established through case law.\textsuperscript{204} This obligation to show scientific evidence also serves to disqualify well-researched theories from consideration. As scientists become more adept at studying environmental and biological systems, the inferences they can draw from the genetic properties of newly designed foods will likely be more instructive of long-term effects than any hard data derived in limited studies.

The most disturbing element of how the interests of GMO producers and the environment are resolved is the context of the adjudication. Starting from the premise that this is a trade issue, and working within the framework of the WTO, does not give adequate attention to the scientific issues that constitute half the disagreements. It is not surprising that the WTO regularly rules in favor of countries advancing trade interests, and against those advocating for environmental protection. The international community needs a body, savvy to scientific methods and arguments, to evaluate the claims of environmentalists and industry, and to investigate the risks posed by new substances. As the consequences of environmental degradation become better publicized and addressed internationally, it is appropriate that an adjudicating body, learned in and committed to environmental and health matters, be used to address disputes that arise primarily because of those concerns. The ICEAC provides

\textsuperscript{202} Id.
\textsuperscript{203} Id. It has been proposed that corporations agree to jurisdiction in the ICEAC or other voluntary bodies when they contract with states for investment opportunities. Wu, \textit{supra} note 190, at 267.
\textsuperscript{204} See Case C-236/01 Monsanto Agricultura Italiio, 2003 E.C.R. 1-810S. Conflicting scientific evidence and theories regarding safety persuaded the court to allow temporary restrictions on GMOs. \textit{Id}.
a good model of such a system, but a multinational treaty underlying it would be required to compel jurisdiction.

**B. Adherence to the Precautionary Principle**

A significant cognitive barrier to resolving the approaches taken by the American and European regulatory agencies is a disagreement over application of the precautionary principle. Whereas Europe incorporates it at every level of evaluation that a GMO undergoes before being marketed, the United States fails to apply it at many levels. First, the United States does not give end consumers the right to exercise the precautionary principle independently, which could be achieved through product labeling and user choice. Second, the substantial equivalence test allows products onto the market when they are not fully understood, which violates the call of the precautionary principle to reserve action for circumstances where risks are known.

The risk of leaving GM foods to be regulated through a process of injury and litigation is that new standards of proving product defect could arise, damaging both an important industry and consumers. The United States should seek to implement a new process resembling the European system for evaluating GMOs. The hallmarks of such a system would be calculating GM content, limiting the GM content of marketed goods, labeling GM content for consumer protection, and close monitoring of the substances. Creating a process that addresses the concerns of industry and environmentalists would effectively create a middle ground for Europe and America to work from. Resolving that central dispute between those constituencies is essential to moving forward with an international regime that regulates from the perspective of environmental protection, not trade problems.