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The Great, Global Promise of Genetically Modified Organisms: Overcoming Fear, Misconceptions, and the Cartagena Protocol on Biosafety

KURT BUECHLE

INTRODUCTION

Modern biotechnology holds the key to solving many global environmental and health problems, including the need for sustainable development. Globally, the acreage of transgenic crops has increased twenty-five fold over the five-year period of 1996 to 2000. The total global acreage for 2000 is estimated to have been 109.2 million acres, nearly twice the size of Great Britain. Biotechnology has been used for twenty-five years with periodic scrutiny and risk evaluation, and there has been no evidence of harm caused by its application. Nevertheless, release and spread of any organism in a non-native environment is an important issue of global concern. Consequences that novel organisms may have on human health are also valid concerns. Unfortunately, there is no shortage of pessimists and activists who seek to severely limit or ban all genetically-modified products.
The Cartagena Protocol on Biosafety (Protocol), an agreement reached in January 2000 in Montreal and an outgrowth of the Convention on Biological Diversity (CBD), is one response to these concerns about genetically-modified organisms (GMOs). While there were already some international trade guidelines for GMOs, the Protocol is the first agreement to require consent by an importing country before transfer of certain GMOs, for the purpose of assessing risks to human health and the environment. But why is the Protocol only concerned with the products of genetic engineering, when crop geneticists have a whole array of methods available to them for use in creating new crop varieties? The Protocol fixates on a particular process and not on what should be the true focus of a biosafety agreement: the safety of the resulting product.

This paper examines some of the main structural elements of the Protocol. Specific attention will be given to how the Protocol’s narrow focus of regulating the trade of GMOs can be counterproductive and potentially quite harmful to the regions of the globe that stand to benefit the most from the use of GMOs. In part I, the goal will be to make clear precisely what the Protocol regulates. Part II will survey the potential benefits and harms associated with GMOs. In part III, the role of the precautionary principle in the Protocol will be explored, including how biotechnology fears could circumvent this role. Part IV will look at the “labeling” requirements of the Protocol and the issues surrounding labeling of GM food in general. Finally, part V will explore the potential effects of the Protocol and GMOs on developing nations.


8. Gupta, supra note 7, at 24; see Hagen & Weiner, supra note 7, at 699, 712.


10. Cf. id. (explaining that it is not wise to make a dichotomy between modern biotechnology and all other types of breeding techniques if the distinction is based only on safety concerns).
I. The Structure of the Protocol and What the Protocol Regulates

A. Living Modified Organisms (LMOs) Defined

The scope of the Protocol is laid out in article 4: “This Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.” The Protocol, therefore, regulates living-modified organisms (LMOs), but what are LMOs? The more common term in the literature is genetically-modified (GM) organism or GMO, but the Protocol chose to use the term LMO. This paper will use both terms.

Alan McHughen, a crop geneticist, has pointed out that one of the main problems of the debate over GMOs is that “[w]e lack a precise, common definition of a [GM product].” The Protocol attempts to address that problem with the term LMO, which it defines in article 3(g) as “any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.” This definition has two parts: “living organism” and “modern biotechnology.” “Living organism’ means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.” A seed, say a kernel of corn, is an example of a living organism. A plant grown from a seed would also count. “Modern biotechnology’ means the application of: a. In vitro nucleic acid techniques,
including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or b. Fusion of cells beyond the taxonomic family.”¹⁷ Corn that has been so modified would yield a kernel of corn that would be considered an LMO.

Genes are made of DNA. Genes contain the instructions for making a protein. Some bacteria known as Bacillus thurigiensis (Bt) have genes that code for proteins that act as pesticides. These genes have been placed into corn to yield “Bt-corn.”¹⁸ Bt-corn has caused much concern, because in 2000 a kind of Bt-corn called “Starlink,” which had not been approved for human consumption, accidentally ended up in some food products.¹⁹ Bt-corn will be used as an example of a GM crop and an LMO throughout this paper.

B. Protocol’s Treatment of LMOs Depends on Their Intended Use

Another problem with the GM debate identified by Alan McHughen is that “[w]e confuse and coalesce different classes of [GM products] requiring different kinds and degrees of regulatory scrutiny.”²⁰ A complete, living GMO is different than a processed GM product that contains degraded DNA and a GMO extract, e.g., vegetable oil that contains neither DNA nor protein.²¹ The Protocol does make such distinctions. The Protocol only deals with LMOs, not processed LMOs.²² As article 3(h) makes clear, a living organism is one that can replicate genetic material.²³ Once an LMO has been processed, it is no longer capable of replicating genetic information. However, one may still be able to detect genetic material and the protein products of the genetic material (see part IV C). The term “GM product” or “GM food” in this note is a general one. “GM product” or

¹⁷. Id. art. 3(i), at 1029. The terms biotechnology and genetic engineering will be used interchangeably in this paper. Recombinant DNA or rDNA technology is also a synonym, as is the term “transgenic.”


²⁰. McHUGHEN, supra note 9, at 71.

²¹. Id. at 72.

²². Cooper & Kilman, supra note 7, at A3.

²³. Protocol, supra note 6, art. 3(h), at 1028.
“GM food” may refer to an LMO or to a processed food product that would not fall under the LMO definition.

1. LMOs Intended for Introduction into the Environment

While the Protocol regulates LMOs, it treats LMOs differently depending on whether they are destined for introduction into the environment (e.g., seed to be used for planting crops), or whether they are meant for direct use as food, animal feed or for processing.24 LMOs in the former group are treated more strictly. This treatment makes sense because the Protocol arose from the CBD,25 and seeds to be planted present the greatest potential danger to the environment. These LMOs are subject to Advanced Informed Agreement (AIA), which is a type of prior informed consent.26 Articles 7 through 10 and 12 discuss the AIA procedure.27

Article 7 gives a basic overview of the process that a party to the Protocol must follow when importing, for the first time, a particular LMO “for intentional introduction into the environment.”28 A mechanism is provided for exempting certain LMOs from this standard AIA procedure, if the parties agree that they are safe.29 Article 8 requires an exporting party to notify the country that is to receive the LMO, including at least the information called for by annex I of the Protocol.30 Article 9 requires the importer, within ninety days of receiving notification, to acknowledge the exporting party’s notification.31 Article 10 explains the guidelines an importer must follow in deciding whether to accept an LMO. These guidelines require the potential importer to give its answer not just to the exporter, but also to the Biosafety Clearing-House (Clearing-House).32 Article 20 outlines the functions of the Clearing-House.33 Article 10 also allows for use of precautionary decision-making,34 which will be discussed in part III of this paper. Article 12 provides more clarification on the decision procedure

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24. See id. arts. 7, 11, at 1030, 1031-32.
25. See Gupta, supra note 7; Schweizer, supra note 7.
26. See Gupta, supra note 7, at 25.
27. Protocol, supra note 6, arts. 7-10, 12, at 1030-33.
28. Id. art. 7, at 1030.
29. See id. ¶ 4, at 1030.
30. Id. art. 8, ¶ 1, at 1030.
31. Id. art. 9, ¶ 1, at 1030.
32. Id. art. 10, ¶ 3, at 1031.
33. Id. art. 20, at 1036-37.
34. Id. art. 10, ¶ 6, at 1031.
including reference to risk assessment and risk management, which are described in articles 15 and 16 respectively.  

2. *LMOs Intended for Direct Use as Food, Feed, or for Processing*

LMOs marked for direct use as food, feed, or for processing are not subject to AIA, but other rules do apply and are outlined in article 11. These LMOs are not treated on a transactional basis. Rather, when a party decides that it will allow the importation of a particular LMO for such direct use, it must give notice within fifteen days by communicating information outlined in annex II to the Clearing-House. Article 11 also allows for precautionary decision-making and refers to risk assessment under annex III. Developing countries are allowed to treat “Article 11 LMOs” under the more strict AIA procedure. There are also “handling, transport, packaging and identification” rules for these “Article 11 LMOs,” outlined in article 18. These so-called “labeling” requirements are discussed in part IV.

II. THE PROS AND CONS OF GM CROPS

A. *Bt-Corn*

As already stated, Bt-corn will be used periodically in this note as an example of a GM crop. Bt is a soil bacterium, which during sporulation produces large quantities of toxic proteins. When ingested by an insect these toxins attach to the gut wall and prevent nutrient uptake with fatal consequences. There are different kinds of Bt toxins, some of which are specific for specific kinds of insects. The toxins only kill the larval stage of the insect and are not toxic to other kinds of organisms. Bt toxins have been used commercially as insecticides since 1958, and Bt sprays were even praised by Rachel Carson as...
an alternative to dangerous chemicals like DDT. A plant (tobacco) was first modified with a gene encoding for a Bt toxin in 1985. Pesticides, including those produced by GM crops, are regulated in the U.S. by the Environmental Protection Agency (EPA). Regulation of GMOs in the United States is controlled mainly by three agencies: the USDA, the FDA, and the EPA.

B. Benefits of GM Crops

1. Environmental Benefits

The discussion of GM crops begins with a look at their benefits; an examination of their downsides will follow. This overview of the positives and negatives of GM crops will lay the foundation for an examination of the precautionary principle’s role in the GMO debate. The promising future of Bt corn and GM crops in general appears endless. Insect-resistant crops demonstrate some of these benefits. Growers will no longer be dependent on weather conditions when deciding when to spray and will be able to reach parts of the plant traditionally difficult to reach with sprays. Farmers will realize great

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46. Id.; see also John Hodgson, GMO Roundup, 19 NAT. BIOTECH. 5 (2001) (pointing out the hypocrisy of organic food groups for criticizing the use of Bt crops when they themselves use Bt sprays). But see NOTTINGHAM, supra note 15, at 162 (explaining Bt crops may lead to insect resistance to the toxin, which could hurt the usefulness of Bt sprays).

47. NOTTINGHAM, supra note 15, at 48.


49. NOTTINGHAM, supra note 15, at 123; MCHUGHEN, supra note 9, at 150. See generally Jeffrey K. Fiance, Frankenstein Foods or Flavor Savers?: Regulating Agricultural Biotechnology in the United States and European Union, 7 VA. J. SOC. POL’Y & L. 257, 265-77 (2000); Teel, supra note 48, at 661-67. For an overview of agencies’ roles and application to Bt corn, see Carpenter, supra note 18.

50. NOTTINGHAM, supra note 15, at 54.
cost benefits when freed from the many costs involved with spraying. A GM crop is also less expensive to develop than a new chemical insecticide. Decreasing or totally eliminating insecticide spraying means more non-target insects will be protected. Use of GM crops also does not have to mean increased production; it can mean maintenance of current production levels while using fewer acres. More efficient use of the land means more space for nature, and consequentially a boost for biodiversity. GM crops should result in better soil conservation. Phytoremediation or the cleansing of contaminated soil using plants should be made easier. Groundwater contamination should also be less of a problem with these crops. Furthermore, new crop varieties may be designed to use water more efficiently.

2. Health Benefits of GM Crops

The positive effects of GM crops are not limited to the environment. Decreasing or eliminating the need to spray should mean less danger for spray operators, especially in developing countries. People who consume GM crops will not have to worry as much about chemical residues. Crops that are more nutritious will be available, including rice with Vitamin A to help prevent

51. Id.
52. Id.
53. Id. at 54-55.
56. See id.; see also Goklany, supra note 54, at 10; Nat’l Acad. of Sci., supra note 1, at 11. But see Nottingham, supra note 15, at 163 (explaining that transgenic crops that do well in poor soils can breed complacency that in turn can lead to further environmental degradation); Michael W. Fox, Superpigs and Wondercorn 62 (1992) (arguing that because salinization and drought are primarily man-made, it would make more sense to take care of these problems directly, instead of using genetic engineering as a crutch). A salt resistant tomato has recently been developed. See Hong-Xia Zhang & Eduardo Blumwald, Transgenic Salt-Tolerant Tomato Plants Accumulate Salt in Foliage but Not in Fruit, 19 Nat. Biotech. 765 (2001).
57. See Wolfenbarger & Phifer, supra note 55, at 2091-92; see also Goklany, supra note 54, at 12.
58. Nottingham, supra note 15, at 54.
60. See Nottingham, supra note 15, at 55.
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blindness. There will even be plant varieties containing vaccines. More will be said of these health benefits in the context of developing countries in part V.

C. Safety Concerns about GM Crops

1. Environmental Concerns about GM Crops

The use of GM crops involves many uncertainties and Bt crops are no exception. Bt toxins are proteins and as such are biodegradable. However, there remains much uncertainty about the extent of bioaccumulation for Bt toxins. Bioaccumulation is a concern because it could help promote insect resistance to Bt toxins in insects. Such resistance has already been observed in both the field and in the laboratory. However, development of such resistance may be slowed or eliminated by planting refuges of non-GM crops in GM crop fields.

A major environmental concern with GM crops is the uncertainty whether a GM crop could become a weed either by itself or by transferring its modified genes to wild relatives. Adding to this uncertainty is the large number of different ecosystems that a crop variety might end up in, and what effect it would have in each. Unplanned spread of GM crops and their genes in the environment will probably occur more through seed spillage than through pollen.
transfer to wild relatives. Seed spillage is particularly likely to occur in developing countries.

2. Health Concerns about GM Crops

a. Allergies

Complaints about the potential negative effects of GM products on health tend to be grouped into two categories: allergies and antibiotic resistance. About one to two percent of populations in Western countries have some type of food allergy. The transfer of genes to a food product may change the allergenicity of that food.

One example of a food allergen introduced into a food that was ordinarily not allergenic involves soybeans and a protein from the Brazil nut. Soybeans, as a

68. McHughen, supra note 9, at 166 (making this point and continuing on to explain that one regulator official in Great Britain would insist on keeping track of every seed!).
69. Schweizer, supra note 7, at 593 n.112.
72. Nottinghams, supra note 15, at 92 (noting only trace amounts transferred, but trace amounts are often enough to cause allergy problems). But see Andrew Pollack, Plan for Use of Bioengineered Corn in Food is Disputed, N.Y. TIMES, Nov. 29, 2000, at C4 (explaining in reference to Cry9C protein of Starlink corn, that there is so little of the protein in the corn to begin with, that after processing there unlikely to be enough to cause allergy problems). A recent report produced by Aventis for the EPA shows that the method of processing determines how much of the protein remains. Wet-milling resulted in protein levels below the level of detection and dry-milling the protein is denatured but not completely eliminated. New Starlink™ Corn Data Submitted by Aventis CropSciences, available at http://www.epa.gov/pesticides/biopesticides/otherdocs/stlink/stlinkdata.html (Apr. 23, 2001).
73. McHughen, supra note 9, at 119-21.
member of the legume family, are low in the amino acid methionine and cysteine, two of the building blocks of proteins. People whose diets are almost exclusively bean-based face a nutritional deficiency. Brazil nuts contain a protein that is rich in these particular amino acids, so researchers saw transferring the gene coding for this protein as a way of solving a nutritional problem. Unfortunately, the protein also turned out to be an allergen. The bean was never produced commercially, and researchers realized the problem of transferring such a protein before any of the beans were made. Allergenicity is certainly a concern for GMOs and the foods derived from them, but it is a relevant concern for all novel foods, regardless of whether they were modified using biotechnology. One must also appreciate that biotechnology gives us the potential to eliminate known allergens from foods.

The Starlink or Cry9C corn, the Bt corn that accidentally entered the food supply, also illustrates the issue of allergenicity. The Cry9C Bt protein is stable in stomach acid, meaning it could conceivably be an allergen. However, there are such low levels of the Bt protein in GM corn to begin with that, after processing, it is doubtful that there would be a problem even if the protein did turn out to be allergic to some people. To put things in perspective, plants have evolved a vast array of natural toxins. With Americans, by one count, consuming up to ten thousand such natural pesticides and on average 1500 mg daily, genetic

74. Id. at 120.
75. Id. at 119-20.
76. Id. at 120.
77. Id.
78. Id.; see also NOTTINGHAM, supra note 15, at 92 (stating that allergenicity of protein shown in people who knew they were allergic to Brazil nuts). Testing was performed though not required. KRISTIN DAWKINS, GENE WARS: THE POLITICS OF BIOTECHNOLOGY 33-34 (1997). But see Sarah Lueck, U.S. Notification Required to Market Gene-Altered Food, WALL ST. J., Jan. 18, 2001, at B12 (stating new FDA rules indicate that such testing will now be required). For a Canadian perspective of GM foods and alergenicity, see Angela Altass, Relax: GM Foods Won't Trigger an Allergy Epidemic, available at http://www.agcanada.com/cg/gmfoods.htm.
79. See MCHUGHEN, supra note 9, at 161.
80. For details on the Cry9C protein, see http://www.starlinkcom.com.
81. See Barnaby J. Feder, Farmers Cite Scarc e Data In Corn Mixing, N.Y. TIMES, Oct. 17, 2000, at C1.
82. Pollack, supra note 72.
modification through modern biotechnology does not appreciably change these levels.\(^{84}\)

\( b.\) **Antibiotic Resistance**

Many GM crops contain an antibiotic-resistance gene in addition to the gene for the protein that a plant breeder wants to transfer. The antibiotic gene allows the scientist to select which plants actually receive the gene of interest. The same antibiotics used in this process are also used for medical purposes. Some studies have claimed a health risk because of a concern that bacteria living in our gut could pick up these antibiotic resistance genes, thus reducing the effectiveness of these antibiotics.\(^{85}\) However, the risk of such a gene transfer in nature is exceedingly low.\(^{86}\) Over-prescription of unnecessary antibiotics and patient non-completion of prescribed antibiotic regimes are much more effective targets for regulators concerned with slowing the development of resistant bacterial strains.\(^{87}\) In addition, scientists can now remove antibiotic marker genes from crops before they are commercially developed.\(^{88}\)

III. **THE PRECAUTIONARY PRINCIPLE AND ITS IMPLICATIONS FOR GM CROPS**

\( A.\) **An Introduction to Uncertainty and the Precautionary Principle**

The complexity of ecosystems and the human body make predictions difficult and uncertain: “Ecosystems are complex, and not every risk associated with the release of new organisms, including transgenics, can be identified, much less considered. Unknown risks may surface as the frequency and scale of the introduction increases.”\(^{89}\) Uncertainties regarding novel plant breeding techniques

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\(^{84}\) J. Howard Beales III, *Modification and Consumer Information: Modern Biotechnology and the Regulation of Information*, 55 FOOD DRUG L.J. 105, 106 (2000); see also McHughen, *supra* note 9, at 167 (explaining that if we used the same modern technology and standards that we apply to gm foods that we do to conventional foods, the presence of toxins would call such foods as coffee, fruits with stones, chocolate, potatoes, etc. into question).

\(^{85}\) Nottingh, *supra* note 15, at 93-94; see id. at 95. In the context of GM food labeling, see Goldman *supra* note 83, at 736-39.

\(^{86}\) McHughen, *supra* note 9, 185-86.

\(^{87}\) Id. at 186.

\(^{88}\) Nat'l Acad. of Sci., *supra* note 1, at 16.

are nothing new. In 1906, in reference to what we now term "conventional techniques," Luther Burbank noted, "we 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 newfound knowledge." Today, people have similar concerns regarding plants and other organism engineered using modern biotechnology.

The Protocol answers these concerns by incorporating the precautionary principle, which is found in articles 10 and 11. There is no universally agreed-upon definition of the principle. Nevertheless, the Protocol defines the principle in regards to LMOs to be introduced directly into the environment as follows:

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified efficiently if US researchers would collect ecological data during large-scale trials and commercial uses of GM crops.

90. Beales, supra note 84, at 110. See generally Heppenheimer, supra note 61, at 8-16 (discussing the early days of genetic engineering and the debate over its health and safety within the scientific community, as well as on a local, state, and national level).


92. Protocol, supra note 6, arts. 10 & 11, at 1031-32.


Although there is no consensus definition of what is termed the precautionary principle, one oft-mentioned statement, from the so-called Wingspread conference in Racine, Wis., in 1998 sums it up: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."

Id.

For various definitions of the precautionary principle, see KNEEN, supra note 15, at 140 ("The precautionary principle, as defined by the 1990 Bergen Ministerial Declaration, says 'Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation.' In other words, err on the side of caution."). See also MCHUGHEN, supra note 9, at 139.
organism in question . . . , in order to avoid or minimize such potential adverse effects.\textsuperscript{94}

In the context of the Protocol, the "trigger"\textsuperscript{95} for the precautionary principle is the proposed importation of an LMO. An importing country has the choice of either allowing an LMO in or holding off until such time that it has enough scientific data so as to be more certain that importation would be safe. Having the default position at no importation gives a country a great deal of flexibility, whether this is too much flexibility is a matter of debate.

\section*{B. Possible Conflicts of the Protocol with the WTO}

Differences in precautionary approaches amongst treaties, especially the differences between the Protocol’s approach and that taken by the WTO’s Agreement on the Application of Sanitary and Phytosanitary Measures (SPS),\textsuperscript{96} may be grounds for future trade wars.\textsuperscript{97} While the Protocol probably will not take precedence over the WTO,\textsuperscript{98} conflicting statements in the Protocol’s preamble and ambiguous language elsewhere create significant confusion regarding priority issues.\textsuperscript{99} For example, the preamble reads: “Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements,”\textsuperscript{100} which is immediately followed by “Understanding that the above recital is not intended to subordinate this Protocol to other international agreements.”\textsuperscript{101}

Notwithstanding the above concerns, the precautionary approaches of the Protocol and the WTO are not very different. The SPS requires that countries

\begin{footnotesize}
\textsuperscript{94} Protocol, supra note 6, art. 10, at 1031; see also id. art. 11, at 1031-32 (giving a similar definition for "article 11 LMOs").
\textsuperscript{95} See Applegate, supra note 91, at 416.
\textsuperscript{97} See DAWKINS, supra note 78, at 35-39; see also NOTTINGHAM, supra note 15, at 136 (“The USA is likely to use its powers under the WTO if it feels any of its transgenic crops exports are being unfairly treated in Europe.”); Gupta, supra note 7, at 31. For similar reasoning in regards to potential trade wars over labeling of GM foods, see Lara Beth Winn, Special Labeling Requirements for Genetically Engineered Food: How Sound Are the Analytical Frameworks Used by FDA and Food Producers?, 54 FOOD DRUG L.J. 667, 687 (1999). See also Fredland, supra note 70.
\textsuperscript{98} See Teel, supra note 48, at 701.
\textsuperscript{99} See Gupta, supra note 7, at 30-31; see also Hagen & Weiner, supra note 7, at 706-08.
\textsuperscript{100} Protocol, supra note 6, pmbl., at 1027.
\textsuperscript{101} Id.
\end{footnotesize}
use sound science in designing their regulations pertaining to human, animal, and plant health and safety. Precautionary decision-making is permitted, but only temporarily until more scientific evidence is gathered. Under article 15, the Protocol also calls for “sound science” as part of a risk assessment procedure laid out in annex III.

C. A Pessimistic Protocol?

The chief failure of the Protocol’s use of the precautionary principle and risk assessment of LMOs may be its fixation on potential harms, while ignoring potential benefits. Indur Goklany has explained that this kind of selective application of the precautionary principle has already been used to justify a ban of GM crops. He believes that this misapplication happens because the precautionary principle alone does not provide any guidance on how it should be applied in areas where regulatory decisions could result in both “uncertain benefits and uncertain costs to public health and the environment.” His application of the precautionary principle to GM crops shows that a ban on GM crops “would increase overall risks to public health and to the environment. Thus it would be more prudent to research, develop, and commercialize [GM crops] than to ban such crops, provided reasonable caution is exercised.”

A recent report issued by the Royal Society of Canada suggests that the Protocol’s version of the principle is relatively lenient:

The most permissive (minimally precautionary) interpretations of the principle, on the other hand, place most of the burden of proof upon those who allege potential risks, while perhaps relaxing the standards of proof (this is the only “precautionary”

102. See SPS Agreement, supra note 96; Gupta, supra note 7, at 25.
103. See SPS Agreement, supra note 96; Gupta, supra note 7, at 25.
104. Protocol, supra note 6, annex III, at 1045-46.
105. See Henry I. Miller & Gregory Conko, The Protocol’s Illusionary Principle, 18 NAT. BIOTECH. 360, 360 (2000) [hereinafter Miller & Conko, Protocol’s Illusionary Principle]; cf. Heppenheimer, supra note 61, at 8 (“As in so many areas of life, relative costs and benefits always need to be balanced in deciding how to regulate a new technology. A classic example of this give-and-take occurred in the 1970s, as molecular biologists” were developing the fundamentals of biotechnology.). For a general criticism of the precautionary principle and its role in the Protocol, see Henry I. Miller & Gregory Conko, The Science of Biotechnology Meets the Politics of Global Regulation, ISSUES SCI. & TECH., Fall 2000, at 47, 48 [hereinafter Miller & Conko, Science of Biotechnology]
106. GOKLANY, supra note 54, at I.
107. Id.; see also ROYAL SOC’Y OF CAN., supra note 71, at 196 (arguing precautionary principle could lead to over regulation that could prevent realization of GMO benefits).
108. GOKLANY, supra note 54, at 2; see NAT’L. ACAD. OF SCI., supra note 1, at 19.
aspect), but they insist that the social and economic costs of exercising restraint be balanced against the potential risks. They “open the door to cost-benefit analysis and discretionary judgement.” The formulations of the Precautionary Principle in the Rio Declaration and the Cartagena Biosafety Protocol are both examples of this kind of cost-effectiveness approach.109

The basis for this classification of the Protocol’s version of the principle is not immediately obvious. Beyond the use of “sound science,” the Protocol does not appear to put many limitations on importers in deciding whether to allow the import of an LMO.

GM crops do have the potential to harm biodiversity via “genetic erosion.”110 Genetic erosion is defined as a decrease in biodiversity. Biotechnology, together with modern agricultural practices, has the potential to increase the rate of genetic erosion.111 The introduction of exotic species is another major threat to biodiversity, especially endangered species.112 Kudzu is one of the more infamous exotic plant species that became a serious weed,113 and it is not a GMO. The Protocol made a serious error when it singled out GMOs as possible weeds, since there is little basis to assume that GMOs pose any unique threat to an ecosystem.114 Jonathan Adler has remarked: “The sad irony of the Biosafety Protocol is that it may well retard, rather than advance, the protection of biodiversity. Under the guise of adopting ‘precautionary’ measures to protect the environment, the Protocol could restrict one of the most important tools for biodiversity conservation-agricultural biotechnology.”115 As has already been discussed, GM crops can mean increased productivity with less clearing of

109. ROYAL SOC’Y OF CAN., supra note 71, at 197 (citation omitted).
110. Saigo, supra note 7, at 793-96.
111. Id. at 793.
112. Adler, supra note 54, at 767.
114. See Adler, supra note 54, at 774; see also Carol Kaesuk Yoon, Some Biotech Upstarts Fizzle Against Native Plants, N.Y. TIMES, Feb. 20, 2001, at F2 (“Just being genetically engineered does not make a plant any more likely to become an invasive or persistent weed, according to a huge new decade-long study published this month in Nature.”).
115. Adler, supra note 54, at 763-64. But see MICHAEL W. FOX, BEYOND EVOLUTION 56 (1999) (“It is far and reasonable to conclude that biotechnology is being applied as a band-aid remedy for the diseases and other production-related problems of both crops and factory-farmed animals whose environments are stressful and disease inducing.”).
The drafters of the Protocol may have had good intentions. However, good intentions do not necessarily lead to good law. Furthermore, efforts to stop a particular danger, as history has demonstrated, can end up having the opposite effect.

D. The Fear Factor: When Emotions Cloud the Facts

The precautionary principle’s position that a GMO should be excluded from commerce until a country believes that there is sufficient certainty that it will not harm people or the environment is a valid approach. However, the precautionary principle can be abused. People can fear the process of genetic engineering and use the principle as a shield or as an excuse. For example, a country could refuse to allow the import of a GM crop because it just does not like the process of genetic engineering. This country claims that they are refusing the GMO because of valid concerns. In reality, they are being disingenuous.

A country may make an honest decision based on the existing scientific information. The problem is that, because of the power of public opinion, a country may cave into fear and make it a practice not to allow any GMOs. This problem is demonstrated in part by the sentiment surrounding the EU’s recent (February 2001) passage of new rules regulating GMOs and movement toward lifting a moratorium on approval of GM crops. The strict nature of the new rules is a response to the fear Europeans have of GM foods. It also reflects a desire on the part of some EU members for even stricter rules. "Even if a product is approved at the EU level, countries such as Austria and France might refuse to allow the use of genetically modified products on their territory."
Uncertainty or rational concerns about the safety of GM foods, and fear of everything genetically-modified are not the same thing. Fear arises not from uncertainty but from misunderstanding. However, people can understand something and still decide they do not like it. The right-to-know argument says that people have a right to know whether their food has been genetically modified. While right-to-know seems on the surface to be a reasonable enough position, it turns out to be wrought with difficulties. These labeling difficulties will be explored in depth in Part IV. For now, it is important to point out some of the connections between fear and labeling. Consumer fear has been given as the chief reason why consumers want labeling of GM foods. Additionally, labeling requirements for GM foods in the EU seem to have been passed because of fear amongst consumers. Consumer fear together with the labeling requirement of the Protocol will also likely encourage the failure of GMOs in the marketplace.

1. Regional Differences in Sentiments Toward GM Food

The contrast in sentiment between the U.S. and Europe is remarkable. The bovine spongiform encephalopathy (BSE) or mad cow disease crisis that has gripped Europe, and particularly the UK, is probably one of the factors responsible for this difference. Some activists have even suggested, quite

125. See Ambuj Sagar et al., The Tragedy of the Commoners: Biotechnology and Its Publics, 18 NAT. BIOTECH. 2, 3 (2000) (asserting that this linkage of fear and misunderstanding is likely related to the issue of risk perception). See generally Paul A. Slovic, Perception of Risk, 236 SCIENCE 280 (1987) (offering background on the topic of risk perception); Clayton P. Gillette & James E. Krier, Risk, Courts and Agencies, 138 U.PA.L REV. 1027 (1990) (discussing selective aversion to new technologies); Richard Pildes & Cass R. Sunstein, Reinventing the Regulatory State, 62 U. CHI. L. REV. 1, 29-33 (1995) (looking at public's perception of risk in the context of the regulatory state). However, this idea of fear and misunderstanding is a distinct concept. With fear there is an absolute or general dislike of a particular technology or item. With risk perception there is primarily just a misunderstanding of the relative danger of a technology or item, there is not necessarily a dislike of the same.

126. See NOTTINGHAM, supra note 15, at 147-48; see also discussion infra Part IV.D.

127. See Winn, supra note 97, at 677-78.

128. See Fredland, supra note 70, at 212.

129. See Weston, supra note 66, at 406.

130. See McHughen, note 9, at 1, 105; Francer, supra note 49, at 294-300; Fredland, supra note 70, at 189; see also Patrice Laget & Mark Cantley, European Responses to Biotechnology: Research, Regulation, and Dialogue, ISSUES IN SCI. & TECH., Summer 2001, at 37, 40 ("Although differences in opinion between EC and U.S. experts were not great, public attitudes in Europe took a separate path."); Philipp Aemi, Public Attitudes Towards Agricultural Biotechnology in Developing Countries: A Comparison between Mexico and the Philippines, at http://www2.cid.harvard.edu/cidbiotech/dp/discussion_aemi.pdf (offering a look at opinions about biotechnology in developing countries).

131. See Sagar et al., supra note 125, at 2; Fredland, supra note 70, at 188; see also Julia A. Moore, More Than a Food Fight, ISSUES IN SCI. & TECH., Summer 2001, at 31, 32-33.
erroneously, that BSE was caused by genetic engineering. Another factor has been a recent problem with doxin-tainted food. Another theory for the differences in public sentiment is that the regulatory process is much more open in the U.S. than Europe, where decision-making is often elite and closed-door. Nevertheless, anti-biotech sentiment may be rising even in the U.S.

2. Myths and Poor Reporting

Myths and the urban legends of biotechnology are additional culprits of GM food fears. Poor journalism is partly responsible for the spread of these myths. "Journalists have always been shameless purveyors of the well-told anecdote as a means of conveying a large trend or idea." That type of statement is an over-generalization, and is not a fair characterization of most journalists. However, there have been some significant weaknesses in reporting on biotechnology. These weaknesses are partly due to those journalists who do not have a good grasp of the underlying science. There is also a general tendency to emphasize bad news over good news. Whereas the media gave unbelievable amounts of attention to stories suggesting that the Bt Cry9C protein, found in Starlink corn, might be an allergen and that Bt might be a serious risk to butterflies, they paid relatively little attention when researchers later announced that these risks were insignificant.

The Monarch Butterfly/Bt-corn controversy is an excellent example of how issues can get confused by the media and the public. Butterflies belong to the same biological grouping as the corn pests that plant geneticists were targeting. So while the harm to butterflies caused by pollen from Bt corn may have been

132. McHughen, supra note 9, at 175. *But see id.* at 175 ("Both BSE ("mad cow disease") and GMOs seem to result from or in the intensification of agriculture. Industry drives the fastest, most efficient possible route to generate food, for example, feeding cattle with whatever is readily available or cheap.").
133. Sagar et al., *supra* note 125, at 2; *see also* Francer, *supra* note 49, at 311.
134. Sagar, et al. *supra* note 125, at 2; *see also* Francer, *supra* note 49, at 311.
136. *See generally* McHughen, *supra* note 9, at 114-21 (explaining the truth behind a number of infamous stories about GM products).
137. *See id.* at 177-78.
139. For example, many good news sources have been cited in this note.
141. *See McHughen, supra* note 9, at 177.
143. *See generally McHughen, supra* note 9, at 178.
144. *Id.*
unintended, it was not unexpected. In addition, the Bt toxin is toxic whether it is expressed by a plant or is sprayed by an organic farmer. Subsequent research has shown that the risk of Bt corn to Monarchs to be far less than originally believed. A more serious threat to Monarchs appears to be the destruction of their wintering grounds in Mexico. Additionally, new varieties will be developed that do not express the Bt toxin in their pollen.

Sometimes the underlying science is flawed, and that can help breed fear and confusion. The findings of Arpad Pusztai, a researcher in Scotland, have caused some of the greatest controversy regarding the health effects of GM crops. Dr. Pusztai fed GM potatoes containing an insecticide gene (from snowdrops) to rats and claimed it poisoned them. Despite Pusztai’s claims that the public was being treated as human guinea pigs, the potatoes were never meant for human consumption. Additionally, the Royal Society criticized the rat studies as “flawed in design, execution and analysis,” and lack[ing] detailed controls. Nevertheless, even if such studies show that GMOs do not pose health problems, some scientists are concerned that there is no proof of their long-term consequences.

3. Anti-Biotechnology Activism

Some anti-biotechnology activists are also adding to public confusion about GM goods. Jeremy Rifkin, one of the more prominent activists, has a long history as a militant foe of technology—organizing protests, writing books, and

145. Id at 189.
146. Id at 190.
147. Mark Henderson, Threat That Never Was, TIMES OF LONDON, Dec. 14, 2000, http://www.thetimes.co.uk/article/0,74-50894-00.html; Milloy, supra note 83; see also Dick Ahlstrom, Butterflies Fox Scientists Out in the Field of Corn, THE IRISH TIMES ON THE WEB, May 24, 2001, at http://scripts.ireland.com/search/highlight.plx?TextRes=&Path=/newspaper/science/2001/0524/sci4.htm (describing a Canadian study that showed minimal effects of the toxin on butterflies); Gene-altered Corn Seen as Slight Risk, SAN DIEGO UNION & TRIBUNE, July 25, 2001, at A9, available at 2001 WL 6474553 (“Though there is a small chance that one in 100,000 monarch caterpillars could be affected by toxic corn pollen, research suggests even those larvae will mature into healthy butterflies, the agency reported.”).
One campaign involved trying to get America's top chefs to boycott GM vegetables. This anti-biotechnology activism is truly a global phenomenon. France's Jose Bové is perhaps the leading figure in Europe. In India, Vandana Shiva is a particularly vocal critic of GM food, expressing outrage that some badly needed food aid delivered to the storm-devastated Indian state of Orissa in 1999 was genetically-modified. Activists declare that no science can guarantee the safety of GM products, but this reasoning is unproductive because one can never prove a negative. Many activists are also adept at manipulating the media and attracting the media's attention using all kinds of stunts. Activists have been quite successful at linking the name "Frankenstein" with GM foods, and it has been a great way to generate fear. Books have been written that appear solely aimed at discouraging the use of GM foods, and generating

156. Id.
157. McNeil, supra note 121 ("Critics like Jose Bové have become popular heroes for tearing up greenhouses full of test plants. Last week, a prosecutor asked for a 3-month sentence for Mr. Bové for raiding an agronomy center in Montpellier.").
158. Bailey, supra note 5.
159. Adler, supra note 54, at 777; see also MCHUGHEN, supra note 9, at 129 ("Opponents of GM technology point out, correctly, that 'No developer of GMOs has assured us the GMO is risk-free!' They neglect to indicate that developers of conventional products similarly decline to provide the same assurance for their non-GM products."); id. at 167 (explaining science cannot prove a negative); Weston, supra note 66, at 405 ("Having to present evidence of absolute safety is an insurmountable burden."); Gary Taubes, The Cell-Phone Scare: When Fear is the Opponent, Science Doesn't Stand a Chance, TECH. REV., Nov./Dec. 2000, at 117, 118 (In the context of cellular phones: "This proving-a-negative problem comes with an important corollary: Experimental science is also inherently incapable of achieving perfection. The experiment does not exist, nor will it ever, that can unambiguously throw up zeros across the board simply because the phenomenon it has set out to study is nonexistent.").
160. MCHUGHEN, supra note 9, at 173; see also Bailey, supra note 5, (explaining that such stunts have at time involved considerable property damage); Kunich, supra note 48, at 814-15 (discussing "eco-terrorism").
161. The name "Frankenstein" and other variations on the theme have become almost synonymous with GMOs and GM food. See KNEEN, supra note 15, at 172, 174, 175; Fredland, supra note 70, at 185, 187; John Hodgson, GMO Roundup, 18 NAT. BIOTECH. 911 (2000) (commenting on Greenpeace's U.S. presidential candidate "frankentony"); Marian Burros, Labeling Foods with Designer Genes, N.Y. TIMES, Jan. 3, 2001, at F2; Heppenheimer, supra note 61, at 12.
For a Quick Recipe for "Frankenfood Frenzy": Combine lots of emotionally-charged doomsday rhetoric with a good amount of anti-capitalist sentiment. Add just a pinch of scientific uncertainty about safety and you've created enough "Frankenfood" Frenzy to serve the world. Caution: This dish can be ruined if contaminated by facts about the health or environmental benefits of genetically modified foods. "Frankenfood" Frenzy, REASONONLINE, at http://reason.com/bi/bi-gmf.shtml.
For an example of a highly-developed use of the Frankenstein metaphor in the context of GMOs, see generally John S. Applegate, The Prometheus Principle: Using the Precautionary Principle to Harmonize the Regulation of Genetically Modified Organisms, 9 IND. J. GLOBAL LEGAL STUD. 207 (2001).
public alarm. People have every right to express their opinions and to abhor anything genetically-modified, but they do have alternatives to GM food. Organic food is one of the most prominent alternatives. However, organic food production has significant health and environmental risks of its own.

4. Spreading Knowledge, Understanding, and Acceptance

What needs to be done to improve public understanding? Better educating the public about the science of GM crops and risk perception is the obvious answer, but how one accomplishes this is not so clear. One can explain the basics of the science in a way that most people will be able to understand. The greater acceptance of GM products in the U.S. has been stated to be positively correlated with greater education and exposure of Americans to biotechnology. However, a survey in the UK actually showed greater opposition to biotechnology after those surveyed had a training course on the subject. Of course, how one asks the question in a survey can bias the results. People arguably have a right not to like biotechnology. Still, one's fears or dislike of GM foods are likely to be much more complicated than a mere difference of opinion.

E. Perils and Promises of the Precautionary Principle in Light of GMO Fears

Even though the Protocol adopted “a risk assessment rather than the much feared nonscientific criteria for decisionmaking,” its version of the

163. See generally McHughen, supra note 9, at 232-37 (discussing the viability of organic food as an alternative to GMOs).
164. Id. at 233-36.
165. See id. at 3; Francer, supra note 49, at 305-08. See generally Sagar et al., supra note 125 (looking not just at matters of risk perception, but also how to address and respect the concerns of “stakeholders”).
166. McHughen, supra note 9, at 3; see also Francer, supra note 49, at 306 (containing a challenge to scientists to explain their findings in ways that the public can understand).
168. McHughen, supra note 9, at 106.
169. Francer, supra note 49, at 299; see also Jane E. Brody, Gene Altered Foods: A Case Against Panic, N.Y. TIMES, Dec. 5, 2000, at F8 (“Ask American consumers whether they support the use of biotechnology in food and agriculture and nearly 70 percent say they do. But ask the question another way, ‘Do you approve of genetically engineered (or genetically modified) foods?’ and two-thirds say they do not.”).
precautionary principle may still allow for nonscientific decisionmaking. Some people have already used the precautionary principle as grounds to ask governments to ban all GM crops. Critics at a recent conference felt that the principle's nature left its exact application dependent on whoever the regulators happen to be in any given situation. A country would need to find, conceivably, only a single scientist to issue a report claiming an environmental or health risk to stop the importation of an LMO. Additionally, views can vary widely amongst scientists, especially along disciplinary lines, with molecular biologists predicting less risk and ecologists being more conservative (cautious).

Despite the potential for abuse, one should not dismiss the utility of the precautionary principle in the context of GMOs. The value of the principle is that it allows countries to deal with uncertainty, and to make decisions in the absence of sufficient safety data on novel compounds and organisms. There is still a great deal we do not know about genetic engineering and the new crop varieties and other organisms that have been made using the technology. However, there are critical differences between a process and the product that process creates. Unfortunately mixing "process apples" with "product oranges" has lead to a great deal of fear and confusion. For the precautionary principle to be truly effective, it needs to be applied to all novel organisms, and not just to those developed using modern biotechnology. The principle should be used even-handedly, or not be used at all. To do otherwise would be to allow fear and possibly alternative protectionist trade motives to paralyze the introduction of GMOs and their potential benefits.

172. See Miller & Conko, Science of Biotechnology, supra note 105, at 53; see also Hagen & Weiner, supra note 7, at 711 (arguing that the Protocol's precautionary language would lead countries to restrict LMO imports even "when the weight of scientific information suggests that the LMOs in question are safe").

173. Appell, supra note 93, at 18; see also Miller & Conko, Protocol's Illusionary Principle, supra note 105, at 360 ("The precautionary approach and precautionary principle are neologisms coined by opponents of technology who wish to rationalize banning things they don't like, such as gene splicing, cellular phones, oil exploration, and carbon dioxide emissions.").

174. Appell, supra note 93, at 18.

175. Fredland, supra note 70, at 205; see also Adler, supra note 54, at 768-69 (arguing that the Protocol's language "is sufficiently broad and tentative to justify almost any level of GMO regulation by individual countries").


177. ROYAL SOC'Y OF CAN., supra note 71, at 196.
IV. THE PROTOCOL'S "MAY CONTAIN" LANGUAGE AND THE PROBLEMS ASSOCIATED WITH LABELING GMOs

Beyond the Protocol's precautionary language, the other main provision that raises serious scientific policy issues is its labeling requirement. Article 18.2(a) of the Protocol reads:

Each Party shall take measures to require that documentation accompanying, . . . Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol.178

This "may contain" language is the result of a compromise between countries who wanted no labeling and those that wanted documentation describing the identity and unique attributes of all LMOs contained in a given shipment of LMOs.179

While the Protocol does not cover LMOs once they are processed into various food products, and so does not require the United States to label such products for export,180 the "may contain" requirement still poses significant problems. Additionally, while there is no present requirement for labeling of food products that do not constitute LMOs, that could change in the near future.181 Recent events suggest a turn toward more labeling. The EU-U.S. Biotechnology Consultative Forum released a report calling for mandatory labeling of GM food at the end of 2000.182 In early 2001, the FDA issued voluntary labeling

178. Protocol, supra note 6, art. 18, at 1035.
179. Gupta, supra note 7, at 29.
180. Cooper & Kilman, supra note 7.
181. Gupta, supra note 7, at 29.
Europe’s extensive labeling requirements are another harbinger of the future of labeling elsewhere. The first step in examining the GM labeling issue will be to look at the perils of drawing lines between genetic engineering and all other techniques.

1. Scapegoating the Rookie

One of the problems with drawing a line between biotechnology and "conventional" breeding technologies is the sheer number of such technologies. If people are going to regulate GMOs, they should be regulating other processes as well. A sound biosafety mechanism should focus on risks from any source and not just new sources.

GM crops are subject to a high degree of safety scrutiny compared to these other techniques, even though some of these techniques potentially involve much greater risks. The technologies include mutation breeding. Unlike genetic engineering, with mutational breeding scientists do not know what genetic changes have been made and have little or no knowledge at the molecular level of the apparent novel characteristics of a novel variety. Even so, extrapolating...
from knowledge at the molecular level to the ecological level is difficult. Nevertheless, if crops derived using the potentially risky technique of mutational breeding are assumed safe, then why not crops derived using the much more precise science of biotechnology?

In some sense, one could say that all modern foods are "genetically modified," albeit not always using modern biotechnology. The corn of today, genetically modified or not, is so removed from its "natural" ancestor that its origins were disputed until modern genetic analyses became available. One can also describe the products of modern biotechnology as not fundamentally different from conventional methods, because conventional methods have been used to move genes across species and even genera to produce crops that have been on the market for decades.

Others believe that modern biotechnology really is different, and there are some strong arguments in their favor. These arguments hinge on both quantitative and qualitative differences between genetic engineering and other techniques. First, there are quantitative issues. Biotechnology makes possible a large number of organisms, potentially much more than using traditional techniques. The collective impact of these numbers combined with the difficulty of predicting their effects presents problems for risk assessment. The quantitative aspects are not limited to the number of possible organisms; they are also related to the enhanced speed with which they can be developed. Second, there are qualitative issues in that not only are there a large number of possible varieties, but also a large number of kinds of varieties. That is, genetic engineering allows genes to be added to an organism not just from its relatives, but also from almost any other organism. Another qualitative concern is that a gene inserted through genetic engineering tends to be inserted randomly into the

192. See Schweizer, supra note 7, at 583-84.
193. McHughen, supra note 9, at 71. See Frederick H. Degnan, The Food Label and the Right-to-Know, 52 FOOD & DRUG L.J. 49 (1997); see, e.g., Saigo, supra note 7, at 784; see also NAT'L ACAD. OF SCI., supra note 1, at 15 (for support of the “precision” argument).
195. Id. at 107-08.
196. Id. at 105-06; see also Degnan, supra note 193, at 49 (revealing that the FDA shares this view); ROYAL SOC'Y OF CAN., supra note 71, at 221 (revealing that Canada shares the view as well).
197. Winn, supra note 97, at 671; Wolfenbarger & Phifer, supra note 55, at 2092.
198. Wolfenbarger & Phifer, supra note 55, at 2092.
199. See id.
200. See Winn, supra note 97, at 671.
201. See id.; Wolfenbarger & Phifer, supra note 55, at 2092.
202. See Winn, supra note 97, at 671; Wolfenbarger & Phifer, supra note 55, at 2092.
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recipient organism’s genome. There is also a related uncertainty of how the introduced gene will interact with other genes in the organism.

There are then clearly problems that are unique to genetic engineering. Even so, any process has unique risks as well as benefits. Genetic engineering can be thought of as a set of tools, which allows one to move DNA with a level of precision and control never before possible. Whether genetic engineering does harm or not depends on how one uses it. Looking at genetic engineering as a set of tools, a hammer can provide a useful analogy. One can use a hammer as a bludgeon, but one can use the same hammer to build a house. Do we ban or regulate hammers because of the former? Of course not. Similarly, singling out crops produced using genetic engineering is largely counterproductive. This kind of discrimination can be quite costly to consumers (in respect to labeling see infra), especially in the Third World, as will be discussed in part V.

2. Rational Labeling: The FDA’s Approach

The FDA has never considered the method of crop development to be the type of information that should be listed on a product. "[A]n implicit component of the policy [of the FDA] is the fact that foods developed through biotechnology are not inherently dangerous and should be regulated like ordinary foods unless a new plant variety differs from its traditional counterpart to such an extent that the common or usual name no longer applies, or unless it presents a safety issue about which consumers must be informed." This idea is also known as "substantial equivalence." While the transfer of a gene could cause

203. See Winn, supra note 97, at 671.
204. Id.
205. This type of analogy admittedly has its limitations. What about fire? Nuclear power? These technologies can be used for good and evil, we certainly do regulate them, and in some situations ban them. However, the key is "in some situations." That is, we should be focused on applications. We should be wary in making rash generalizations about technologies. For an example of a source comparing biotechnology to a set a tools, see Heppenheimer, supra note 61, at 10 ("Between 1967 and 1971, investigators developed a biochemical tool kit to accomplish [the production of GMOs], with the tools taking the form of specialized enzymes."). See also MCHUGHEN, supra note 9, at 46 (using "tools" to describe new genetic techniques); Id. at 70 (using word "toolbox").
206. Degnan, supra note 193, at 55; Fred H. Degnan, Biotechnology and the Food Label: A Legal Perspective, 55 FOOD & DRUG L.J. 301 (2000). The FDA does consider conventional methods of genetic engineering techniques to be proper subject matter for labeling. Id. Since the agency views genetic engineering techniques as simply extensions of traditional methods at the molecular level, it sees no need to label GM foods. Id at 307. But see Winn, supra note 97, at 685 (arguing "that genetic engineering is situated uniquely, relative to processes such as canning, freezing, pasteurization, traditional plant breeding, and others").
207. Degnan, supra note 193, at 55.
208. See ROYAL SOC’Y OF CAN., supra note 71, at 177-91.
such problems, the FDA will only require labeling when a particular transfer is shown to present such a problem.\textsuperscript{209} The agency also stresses that the scientific community recognizes that the use of genetic engineering in food products does not give rise to unique risks or hazards.\textsuperscript{210}

The FDA's policy toward labeling is a voluntary policy, but there have now been proposed standards for those who wish to label GM food.\textsuperscript{211} In 1992, the Agency had announced that foods derived from GMOs would not be treated differently from products derived from "traditional" organisms.\textsuperscript{212} However, in early 2001, the Agency stated that what had previously been voluntary notification prior to putting a new GM food on the market would now become mandatory.\textsuperscript{213} The Protocol's position on notification may have been partly responsible for this trend.

\textit{B. The Product vs. Process Debate}

Our "line-drawing" discussion started out as of one of biotechnology versus all other technologies, but it now appears that the issue might be better characterized as one of process versus product. Unacceptable risks characterize certain GM products. However, those risks are dependent upon the nature of the product—not the process used to develop that product.\textsuperscript{214} In other words, if the product had been generated using conventional technologies, it would still carry the same risks.\textsuperscript{215} All of this ties back into the discussion of the precautionary principle. The lack of any significant unexpected or unusual results from the process of genetic engineering over the last quarter century suggests that the

\begin{itemize}
\item 209. Degnan, \textit{supra} note 193, at 55.
\item 210. \textit{Id.}; see also Miller & Conko, \textit{Science of Biotechnology}, \textit{supra} note 105, at 48 ("But none of the risks that may be associated with gene-spliced organisms is inherent in the method of production, and certainly none is unique to recombinant DNA manipulation.").
\item 211. See Lueck, \textit{supra} note 78. \textit{But see} Kilman, \textit{supra} note 183 (It remains unclear what language food companies are permitted to use to say that they have avoided the use of biotechnology in their products.).
\item 212. \textit{NOTTINGHAM, supra} note 15, at 125.
\item 214. \textit{MCHUGHEN, supra} note 9, at 159. \textit{But cf} KNEEN, \textit{supra} note 15, at 121 (explaining that in the context of meat processing, the safety of the product is assumed from the safety of the process).
\item 215. \textit{MCHUGHEN, supra} note 9, at 159; see also \textit{NOTTINGHAM, supra} note 15, at 145 ("In many cases there is no scientific evidence to suggest that the methods of production using genetic engineering per se alter food composition in a meaningful or uniform manner. The food industry understandably wants labeling to be on a strictly logical and scientific basis.").
\end{itemize}
process of genetic engineering survives the precautionary principle, but the same cannot necessarily be said of all GM products.\textsuperscript{216}

The language of annex III suggests that the Protocol may take a product approach: "Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment."\textsuperscript{217} However, this case-by-case approach only applies to LMOs. Why exclude organisms that were created using conventional methods, and that can pose environmental and health risks?

The Bt-corn of earlier discussion can be more precisely described as an "input" crop.\textsuperscript{218} Input crops are those designed for insect or herbicide tolerance.\textsuperscript{219} They represent a benefit for farmers, but do not result in a product that is significantly different for the consumer.\textsuperscript{220} A label in such a case is not very helpful. In the case of a "quality" crop, the GM crop results in an end product with different characteristics, e.g., altered nutritional value.\textsuperscript{221} Consequently, when a crop has been modified in ways that would affect its use, a label is much more valuable.\textsuperscript{222} However, the important information is the "fact of the difference, not the method used to produce the difference."\textsuperscript{223} Still, the Codex Committee on Food Labelling (CCFL) of the Codex Alimentarius

\footnotesize
\begin{itemize}
\item \textsuperscript{216} McHughen, supra note 9, at 140; see also Heppenheimer, supra note 61, at 14 (Even in the early days of biotechnology: "Despite extensive efforts to detect some evidence of actual or potential hazard, none has been found.").
\item \textsuperscript{217} Protocol, supra note 6, annex. III, at 1045; see also Miller & Conko, Protocol’s Illusionary Principle, supra note 105 ("Annex II contains a guide to what the protocol considers adequate risk assessment. It properly focuses on the biological characteristics of the individual products, but leaves much discretion to regulators about the framework for risk analysis.").
\item \textsuperscript{218} Beales, supra note 84, at 107.
\item \textsuperscript{219} Id.
\item \textsuperscript{220} Id.
\item \textsuperscript{221} Id.
\item \textsuperscript{222} See id. (The author discusses "input" crops where the genetic differences are essentially only of interest to farmers. In the case of "quality" crops that limitation does not hold true because the differences should be of interest to consumers as well as farmers.).
\item \textsuperscript{223} Id. at 111. The U.S. Supreme Court agreed in a 1924 case regarding apple vinegar. See Goldman, supra note 83, at 724 ("The misrepresentation was in respect of the vinegar itself, and did not relate to the method of production merely. When considered independently of the product, the method of manufacture is not material. The [Food and Drugs Act of June 30, 1906] requires no disclosure concerning it." (quoting United States v. Ninety-six Barrels (More or Less) Alleged Apple Cider Vinegar, 265 U.S. 438, 445 (1924)); see also Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 35 n.10 (D. D.C. 2000) (citing the same 1924 case to show that the manufacturing method is irrelevant.).
\end{itemize}
Commission, the principal international body overseeing food labeling, is split on whether to label based on product or process. The one instance where the FDA has required a process to appear on a label is food irradiation. This exception does in some sense prove the rule, as irradiation can materially affect flavor, shelf-life, and other qualities that consumers expect from their food. On the other hand, biotechnology or genetic engineering is a neutral process. If one could point to one, albeit theoretical, common danger of GM products, it would be the use of antibiotic marker genes. As already mentioned, scientists can now remove antibiotic marker genes from crops before they are commercially developed, and even if they are not, the odds of such a gene being transferred in nature are infinitesimal.

C. The Segregation Nightmare

The Protocol requires that products “intended for direct use as food or feed, or for processing” be “clearly” labeled that they “may contain” LMOs. Saying a product may contain something is hardly clear, and can actually be deceptive. The main reason the “may contain” language appears is that GM crops and non-GM crops are routinely mixed during the storage and shipment,
and separating them is all but impossible. In fact, crop varieties, regardless of whether modern biotechnology or traditional techniques were used in their development, are almost always mixed together during shipment, because grain is sorted based on physical, not genetic characteristics.

While testing for the presence of GMOs is possible, segregation is impractical largely due to cost. If segregation were required, the cost of segregation could exceed the value of the product itself. Such segregation would effectively prevent farmers from growing the same insect-resistant GM crops that allowed them to grow food more economically in the first place.

The "may contain" label seems like one way to avoid all these segregation costs, because crops would not have to be completely segregated. Unfortunately, the patent uncertainty of a "may contain" label ends up making the label practically meaningless. Especially in the U.S., such labeling would be ubiquitous, as all products containing corn or soy would end up being labeled. Additionally, as the FDA's policy reflects, statements that are "not technically false or which may be literally true" can still cause deception. Some jurisdictions, including the UK, impose fines for failing to label a GM product as such. However, there is no penalty for putting a "may contain" label on

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232. McHughen, supra note 9, at 78-79; see Nottingham, supra note 15, at 146; see also Beales, supra note 84, at 114-15; see also Fredland, supra note 70, at 191. But see Kneen, supra note 15, at 145 ("The very same companies that say biotech crops cannot be segregated are also engaged in developing genetically engineered specialty crops whose value lies in the fact that their identity is preserved from seed through to delivery to the processor. . .").

233. See McHughen, supra note 9, at 78-79; see also Beales, supra note 84, at 114.


235. See McHughen, supra note 9, at 79; see also Beales, supra note 84, at 112-13 (arguing that the costs of segregation should be born by those who care about having GM food; therefore, any labeling of GMOs should be voluntary); see also Goldman, supra note 83, at 722 (giving more examples for the higher costs that would be involved with separation); see also Feder, supra note 81, at C1 (giving some information on the subject in the context of the Starlink controversy).

236. Nottingham, supra note 15, at 146.

237. Id.

238. McHughen, supra note 9, at 223-24.

239. Beales, supra note 84, at 116; see also Heppenheimer, supra note 61, at 16 ("Today one-fourth of the nation's corn is genetically altered, while 70 percent of the processed food contains ingredients from transgenic corn, soybeans, and other plants.").

240. Degnan, supra note 193, at 59 (quoting Ninety-five Barrels, 265 U.S. at 442-43).

241. Alan McHughen, Uninformation and the Choice Paradox, 18 Nature Biotech. 1018, 1019 (2000); see also Emma Dorey, EU Plans to Label and Trace GMOs, 19 Nature Biotech. 795 (2001) (While not discussing the use of fines, the author explains a labeling system for GMOs adopted by the European Commission in July 2001.).
products that are not genetically modified.\textsuperscript{242} Since players in the food market do not want to risk having to pay fines, they will just label everything as "may contain" GM products, even if it costs them some sales.\textsuperscript{243}

People may interpret the "may contain" label as meaning that food companies do not care enough to find out, but because a product can be derived from a large number of different sources, finding out may be a near impossible task.\textsuperscript{244} The "may contain" label also has the power to inconvenience the consumer if one wants to avoid GM foods; one will likely steer clear of foods that may not actually contain any products of GMOs at all.\textsuperscript{245} In a more general sense, over-labeling or special labeling of GM food may give the uninformed consumer the impression that a genetically-engineered product is inherently unsafe.\textsuperscript{246} Such labeling can even be in itself unsafe, if really important information, such as the presence of an allergenic food substance, becomes overshadowed.\textsuperscript{247} Negative labeling, i.e., ["contains no GM product,"] is equally problematic, largely because of the inability to prove a negative.\textsuperscript{248}

\section*{D. The "Right-to-Know" Nothing}

One of the main arguments for mandatory labeling of GM products is the consumer's "right-to-know."	extsuperscript{249} This right-to-know concept and the existence of mandatory labeling in Europe\textsuperscript{250} and elsewhere\textsuperscript{251} may be the principal reason for

\begin{itemize}
\item \textsuperscript{242} McHughen, supra note 241, at 1019.
\item \textsuperscript{243} Id.
\item \textsuperscript{244} McHughen, supra note 9, at 224.
\item \textsuperscript{245} See id. at 223-24.
\item \textsuperscript{246} See Nottingham, supra note 15, at 146; see also Degnan, supra note 193, at 59. The FDA is concerned that claims by food companies that their products are free of GMOs will be interpreted by consumers to mean that such products are healthier. Kilman, supra note 183. FDA officials are also concerned that certain marketers may be attempting to exploit "the public's worries about an unfamiliar technology. . . ." Id.
\item \textsuperscript{247} Beales, supra note 84, at 116.
\item \textsuperscript{248} McHughen, supra note 9, at 224-25. A recent study sponsored by the Wall Street Journal showed that many products claiming to contain no GM ingredients, actually do. Patricia Callahan & Scott Kilman, Seeds of Doubt: Some Ingredients Are Genetically Modified, Despite Labels' Claims, WALL ST. J., Apr. 5, 2001, at A1; see also Kilman, supra note 183 ("The FDA also doubts that food companies can make a non-GMO claim with absolute certainty.").
\item \textsuperscript{249} See Nottingham, supra note 15, at 147-54; Goldman, supra note 83, at 720; Teel, supra note 48, at 659; see also Francer, supra note 49, at 297 ("The Greenpeace World Wide Web site declares, 'We want natural food! Consumers want real food and the right to know and to choose.'"). For general background on the issue of right-to-know, see Degnan, supra note 206. See also Degnan, supra note 193; Eli Kintish, Sticker Shock, NEW REPUBLIC, Jan. 22, 2001, at 11, 12. "[R]epeated surveys show that the majority of U.S. consumers want to know about the presence of genetically-modified ingredients, apparently so that they can choose whether to avoid them." Kilman, supra note 183.
\item \textsuperscript{250} See Degnan, supra note 193, at 56-57.
\end{itemize}
the "may contain" provision in the Protocol. But if "may contain" labels are problematic in themselves, then labeling of products made from food commodities labeled "may contain" LMOs is even more flawed. Yet, this kind of labeling is what happens in countries mandating labeling of GM foods.252

The Protocol's approach toward labeling is troubling because the Protocol is presumably designed for the safety of human health and the environment, not for consumer preferences. Frederick Degnan's summary of the FDA food labeling law is instructive here:

Congress, over decades of regulation of the food label, has concluded consistently that the central purpose of the food label—i.e., to meaningfully inform, warn, and instruct—must be accomplishable. . . . Simply put, although consumer interest in receiving information is important, consumer interest alone is not enough to justify requiring that such information be included in food labels.253

The FDA's position has been upheld in court.254

In September of 2000, the D.C. district court dismissed a case filed by the Alliance for Bio-Integrity, other public interest groups, and religious groups against the FDA over its 1992 policy statement on GM foods, discussed above (Part IV A2).255 The D.C. district court, among other holdings, accepted the FDA's position that it was not required to label GM foods as a class solely on the grounds of consumer demand or the process used.256 The plaintiffs included religious leaders who claimed their religious freedoms were being violated, because a lack of GM food labeling made it almost impossible for them to adhere

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251. See Aaron J. Bouchie, Australia/NZ label GM foods, 18 NAT. BIOTECH. 911 (2000) (giving information on Australia and New Zealand's labeling standard, as well as those of other entities); see also Denise M. Lietz, A Precautionary Tale: The International Trade Implications of Regulating Genetically Modified Foods in Australia and New Zealand, 10 PAC. RIM L. & POL.'Y J. 411 (2001) (providing background on labeling laws and policy in Australia and New Zealand).

252. See, e.g., McHughen, supra note 241, at 1019.

253. Degnan, supra note 193, at 60.


256. Id.; see also Shalala, 116 F. Supp. 2d at 178 n.8 ("Thus, without a determination that, as a class, rDNA derived food pose inherent risks or safety consequences to consumers, or differ in some material way from their traditional counterparts, the FDA is without authority to mandate labeling."); id. at 179 ("[T]he FDA lacks a basis upon which it can legally mandate labeling, regardless of the level of consumer demand.").
to their strict dietary laws.\textsuperscript{257} The District Court found no violation of their right to free exercise of religion.\textsuperscript{258} The FDA also had not violated the Religious Freedom Restoration Act.\textsuperscript{259} People have the right to oppose GM foods on the basis of religion, but they should have the burden of determining the source and sanctity of their food.\textsuperscript{260} Religious preferences are a form of consumer preference. Having the government label foods based on religious preferences could lead to similar demands from different groups having their own personal preferences.\textsuperscript{261} When one extrapolates such demands to a global level, on which the Protocol operates, trade in foodstuffs would arguably become debilitated.

Mandatory labeling of GM products not only fails to inform, it can actually reduce consumer choices.\textsuperscript{262} And, tying in the process versus product debate, the right to know argument is in no way limited to genetic engineering. If consumers have a right-to-know about one process, genetic engineering, why not others?\textsuperscript{263} Still, if people do not understand what is on the label, it is hard to justify putting that information on the label, absent some reason other than simply personal preference.\textsuperscript{264} Alan McHughen has proposed a public database of all food products and their processes as an alternative to labeling.\textsuperscript{265} Much information on GMOs is already available to the public in Europe, the U.S. and Canada.\textsuperscript{266} The Protocol's Clearing-House\textsuperscript{267} also responds in part to this call.

If GM labeling is going to be allowed at all, both internationally and domestically, then it ought to be done on a voluntary rather than a mandatory basis.\textsuperscript{268} Voluntary labeling makes sense from an economic perspective, because those who are interested in the information will pay for the added costs involved with labeling, and those who do not value the information will not have to pay for

\begin{itemize}
\item \textsuperscript{257} Teel, supra note 48, at 660-61.
\item \textsuperscript{258} Shalala, 116 F. Supp. 2d at 179-80.
\item \textsuperscript{259} Id. at 181.
\item \textsuperscript{260} MCHUGHEN, supra note 9, at 220.
\item \textsuperscript{261} Id.
\item \textsuperscript{262} McHughen, supra note 241, at 1018. See generally Goldman, supra note 83.
\item \textsuperscript{263} See Beales, supra note 84, at 109.
\item \textsuperscript{264} See MCHUGHEN, supra note 9, at 209-11 (using sodium benzoate as an example of an ingredient listing that most people do not know anything about, so this information does not help the consumer. Sodium benzoate harms rats in relatively low amounts, but is still considered to be one of the safer food preservatives.).
\item \textsuperscript{265} Id. at 241-42; see also NAT'L. ACAD. OF SCI., supra note 1, at 15 (arguing for a public database containing information on allergens and natural toxins).
\item \textsuperscript{266} MCHUGHEN, supra note 9, at 242.
\item \textsuperscript{267} Protocol, supra note 6, at 1036-37.
\item \textsuperscript{268} See Goldman, supra note 83, at 723; see also ROYAL SOC'Y OF CAN., supra note 71, at 226-27 (reaching this same conclusion). See generally Degnan, supra note 193, at 59-60.
\end{itemize}
THE GREAT, GLOBAL PROMISE OF GMOs

269 In connection with the earlier discussion about GM products with “quality” attributes, manufacturers may eventually want to label their GM goods as “value added products.”

While the Protocol by itself may hasten domestic labeling laws in the West, consumer demand will be more of an impetus in developing countries, because of the difficulty of implementing a labeling regime and the increased cost of food products. Nevertheless, the Protocol and GMOs in general stand to have a substantial impact on the Third World.

V. THE IMPACT OF GMOs AND THE PROTOCOL ON DEVELOPING COUNTRIES AND SUSTAINABLE DEVELOPMENT

Developing countries were actually the group that originally called for the Protocol’s creation, but it is as yet unclear whether it really serves their best interests. The potential environmental and health benefits of GM crops in general have already been discussed, and these benefits will arguably have the greatest impact in developing countries. A recent National Academy of Sciences report stresses the importance of GM crops in realizing sustainable development:

We conclude that steps must be taken to meet the urgent need for sustainable practices in world agriculture if the demands of an expanding world population are to be met without destroying the environment or natural resource base. In particular, GM technology, coupled with important developments in other areas, should be used to increase the production of main food staples, improve the efficiency of production, reduce the environmental impact of agriculture, and provide access to food for small-scale farmers.

269. See Beales, supra note 84, at 112-13; Kintish, supra note 249, at 12.
270. McHUGHEN, supra note 9, at 229; see also Beales, supra note 84, at 113 (arguing that voluntary labeling provides an ongoing market test to determine if consumers actually care about a given food characteristic).
272. Id. at 24.
273. See infra Part II.B; see also GOKLANY, supra note 54, at 15 (showing a table of health benefits-problems especially affecting the third world).
274. NAT’L ACAD. OF SCI., supra note 1, at 6; see also Kinderlerer, supra note 4, at 563 (arguing that biotechnology will likely be needed to obtain sustainability); Borlaug, supra note 5 (arguing that we will be able to feed world in 2025 without a significant impact on the environment, only if we use biotechnology).
Despite the promises of GM crops for achieving goals of sustainability in developing countries, there are also negatives, and GM crops may, in some respects, make things worse. Transgenic crops can be more expensive for Third World countries when all costs are considered. People go hungry not necessarily because of a lack of food, but because of a lack of access to food. In their July 2000 report, the National Academy of Sciences estimated that there are about 800 million people or eighteen percent of the developing world who do not have access to sufficient food. Nevertheless, GM crops are not necessarily antithetical to improving access to food.

A. A New Imperialism?

To some developing countries, the wave of GM crops may seem like a new tide of imperialism. One critic of GM crops has remarked:

We should not be fooled into believing that the intent of engineering the seed and occupying the land is to feed the world or save the environment; it is to gain control and create dependency. Like all imperial and colonial endeavors, its purpose is to gain the ability to exploit the resources of the colonized area and people for the benefit of the imperial powers. The new twist is that the imperial powers are now corporations, not states.

However, developing countries can also view restrictions on GM foods by developed countries, and especially by the EU, as imperialistic and harmful, considering the promise these foods have in alleviating hunger in developing countries.

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275. NOTTINGHAM, supra note 15, at 164.
276. Id. at 157; see also KNEEN, supra note 15, at 25 (pointing to a World Bank report that stated that if the world's food had been evenly distributed in 1994, there would have been more than enough food for everybody to have had an adequate daily diet).
277. NAT’L ACAD. OF SCI., supra note 1, at 3.
278. Id. at 4.
279. KNEEN, supra note 15, at 180; see also Sean D. Murphy, Biotechnology and International Law, 42 HARV. INT’L L.J. 47, 66 (2001) (discussing “bio-colonialism” and the exploitation of developing countries through licensing fees).
1. Big Agriculture in the Third World

Large international agriculture and biotechnology companies want to grow transgenic crops in the Third World that are often not geared to the domestic needs of these countries' peoples. Transgenic plants in industrialized countries can be engineered to yield products that were once derived from products made and crops produced in developing countries, leading to a loss of jobs. Some believe that GM crops share the same philosophy as that of the Green Revolution—high-input and high-yield, which necessitates the use of great quantities of fertilizer causing further environmental problems. Norman Borlaug, "father of the Green Revolution" of the 1960s and 1970s, has been criticized for his strong support of the new revolution of biotechnology. Nevertheless, he is not alone in his support for this "new green revolution." Nor should he be alone, considering the numerous benefits of GMOs.

Just to survive, biotechnology companies may need to start with lucrative crops designed for the developed world. Eventually they should be able to turn more attention to developing countries, and there are already products in the pipeline that could help these countries. GM crops are being developed that produce vaccines that ordinarily would be difficult to transport in developing...
countries. "Golden rice" has been developed that is engineered to produce Vitamin A, which will help prevent blindness in areas where this nutrient has traditionally been deficient in peoples’ diets.

2. Intellectual Property Issues for the Third World

Intellectual property rights are one way that developed countries and their companies exert control over the Third World. Industrialized nations own ninety-seven percent of all the world’s patents, and people or corporations based in these nations own more than eighty percent of the patents granted in developing countries. "Terminator technology" and related "genetic use restriction technologies" (GURT) are one of the more controversial aspects of intellectual property rights relating to GM crops. This technology would allow biotech companies to produce sterile seeds, i.e., seeds that would allow farmers to grow one generation of crops, but the resulting plants would be sterile. Variations on this technology would allow farmers to grow seeds or have the plants express particular traits only if they paid the company who developed the seed to trigger these events.

Terminator technology is a special concern because some 1.4 billion people rely on farm-saved seed. These people may not be able to afford to buy seeds and the triggering chemicals needed to gain their full benefits. Such seeds would prevent farmers from doing their own hybrid breeding, and unintentional hybridization with their existing crop varieties could render those crops sterile. However, these problems are inconsequential if farmers do not buy the seeds to begin with, and they will have no incentive to do so if the biotech companies fail to market them correctly. Most importantly, Monsanto, the company who

288. See Langridge, supra note 1; NAT’L. ACAD. OF SCI., supra note 1, at 12-13.
289. See GOKLANY, supra note 54, at 14; Press Release, supra note 61.
290. See generally NAT’L. ACAD. OF SCI., supra note 1, at 29-34.
292. See MCHughEN, supra note 9, at 192-93; NAT’L. ACAD. OF SCI., supra note 1, at 32-34; Saigo, supra note 7, at 789; Barnaby J. Feder, Monsanto to Bar a Class of Seeds, N.Y. TIMES, Oct. 5, 1999, at A1.
293. See Feder, supra note 292, at A1.
294. See MCHughEN, supra note 9, at 192-93.
295. Saigo, supra note 7, at 789.
296. Id.
297. Id.
298. See MCHughEN, supra note 9, at 192.
owns the technology, has announced that it will neither use technology itself nor license it to others. 299

Some critics are concerned that a handful of companies control or will control ownership of crops globally. 300 While this is a legitimate concern, there are and will be alternative sources for GM products instead of directly from private companies. 301 One example is the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), a joint public-private venture that seeks to make biotechnology applications available to the developing world. 302 Additionally, both Farmer’s Rights under the UN’s Food and Agriculture Organization (FAO) 303 and the Plant Breeder’s Rights based on the Union for Protection of New Varieties (UPOV) 304 represent intellectual property protection regimes that are favorable to farmers, including those in developing countries.

B. The Protocol’s Socio-economic Initiatives

While the Protocol does not specifically address intellectual property concerns, it does help developing countries in other ways. As already mentioned, developing countries are allowed to treat both LMOs destined for introduction into the environment and those meant for direct use as food, feed, and processing under the AIA. 305 Additionally, the Protocol specifically allows socio-economic considerations to be taken into account in deciding whether to allow the importation of a particular crop:

1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations,

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299. See Feder, supra note 292.
300. See KNEEN, supra note 15, at 180; Saigo, supra note 7, at 796-97; see also Antonio Regaldo, Syngenta Sequences the Genome of Rice, But Access to the Data Will Be Restricted, WALL ST. J., Jan. 26, 2001, at B6. See generally John H. Barton & Peter Berger, Patenting Agriculture, ISSUES IN SCI. & TECH., Summer 2001, at 43 (providing an overview of the global patent system on plants with suggestions on what to do with the oligopoly in this area).
301. See MCHUGHEN, supra note 9, at 197; see also MANNING, supra note 285, at 33 (describing a collaboration between Texas Tech and Ethiopia); Press Release, supra note 61 (reporting that “Golden Rice” will be available from the International Rice Research Institute (IRRI), though the technology was a gift from industry. The IRRI is a member of Consultative Group on International Agricultural Research (CGIAR)).
303. See DAWKINS, supra note 78, at 52.
304. See MCHUGHEN, supra note 9, at 244.
305. See infra Part I.B.
socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.306

This allowance for socioeconomic considerations is potentially beneficial, since indigenous and subsistence farmers can help to preserve biodiversity and prevent genetic erosion.307 Other arguments include those already discussed, most notably the replacement of goods derived from developing countries by GM crops grown in developed countries.308 Unfortunately, while article 26 may be well intentioned, it has the potential to cause more mischief even than the precautionary principle.309 The socio-economic provision effectively allows countries to ban GM crops absent any scientific basis.310 As Alan McHughen puts it, “Socio-economic aspects may well be important in the global debate, and ought to be discussed in a suitable forum. But they negate the credibility of any claim of ‘science-based’ procedures when they are inserted into the ‘scientific’ risk assessment.”311

The uncertainty regarding the Protocol’s relationship to other treaties, including the WTO, means that it is not clear whether actions taken under article 26 would be consistent with other international obligations.312 What would actually count as “socio-economic” is also unclear.313 It might mean being able to deny import of GM crops that would hurt the viability of domestic farmers, but not the ability to turn away imports based purely on consumer sentiment.314 In

306. Protocol, supra note 6, art. 26, at 1039.
307. See Saigo, supra note 7, at 815.
308. See infra Part V.A.
309. Cf. Lott, supra note 117.
310. Adler, supra note 54, at 771.
311. McHughen, supra note 9, at 144.
312. See Hagen & Weiner, supra note 7, at 708.
313. Id.
314. Id.
order to prevent exclusionary trade policies, the execution of article 26 will have to be done cautiously.\textsuperscript{315}

\textbf{C. Regulatory Weaknesses of Developing Countries}

Another possible route for Third World exploitation is that these countries often do not have the resources to establish effective regulations for policing GM products.\textsuperscript{316} This deficiency could be used by multinational companies to sell GM crops that would be prohibited elsewhere.\textsuperscript{317} These countries often rely on the exporting, developed country for regulatory review with the belief that if the food is safe for their citizens, then it is good enough for theirs.\textsuperscript{318} The Protocol seems to be a relative success in responding to these problems by giving developing countries a voice and some protection, instead of being at the mercy of the exporter. The agreement may also help these countries to develop their own regulatory frameworks and capacity.\textsuperscript{319} Article 22 expressly mandates capacity-building for biosafety and financial assistance for implementation for those countries that need such help.\textsuperscript{320} However, one must also address a “brain drain” of scientists from developing to developed countries.\textsuperscript{321}

\textbf{VI. Conclusion: Don’t Shoot the Messenger!}

GMOs are having and will have a dramatic, positive impact on world agriculture. The Protocol, if properly implemented, has the potential to help countries deal with the uncertainties and valid scientific concerns about GMOs with regard to both human health and the environment. However, if abused, the Protocol’s precautionary provisions will likely short-circuit attempts to deliver the benefits of GMOs to those who especially need them in developing countries.

\textsuperscript{315} Saigo, supra note 7, at 815.
\textsuperscript{316} See NOTTINGHAM, supra note 15, at 122-23; see also MCHUGHEN, supra note 9, at 156-57 (explaining that since developing countries often lack the ability to establish appropriate regulations, they rely upon the regulations of the exporter).
\textsuperscript{317} See NOTTINGHAM, supra note 15, at 123; see also Kinderlerer, supra note 4, at 564 (reporting that developing countries are concerned as to whether companies are “dumping” GMOs on them because they cannot be produced in Europe).
\textsuperscript{318} See MCHUGHEN, supra note 9, at 156-57.
\textsuperscript{319} See Gupta, supra note 7, at 31.
\textsuperscript{320} Protocol, supra note 6, art. 22, at 1038; cf. NAT’L. ACAD. OF SCI., supra note 1, at 2 (“Public health regulatory systems need to be put in place in every country to identify and monitor any potential adverse human health effects of transgenic plants, as for any other new variety.”).
\textsuperscript{321} See MANNING, supra note 285, at 125.
Genetic engineering is like a messenger; it allows scientists to transfer genes from one organism to another. The message or gene being sent may occasionally result in a dangerous, novel organism. This danger derives not from the messenger but from the particular message being sent. To have an effective biosafety program, we must be concerned with individual products and not the process used to generate them. Genetic engineering is but one process available for generating novel organisms. The ultimate effect of the Protocol’s narrow focus on the process of genetic engineering remains to be determined. However, ignoring novel organisms generated using other means leaves the door wide open for potential harm to both human health and the environment. This myopia begs the question: Does the Protocol really rest on biosafety, or is it a capitulation to unwarranted fears of biotechnology?