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Genetically Modified Crops: Why Cultivation Matters

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GENETICALLY MODIFIED CROPS: WHY CULTIVATION MATTERS

With the introduction of a brighter red and slower ripening tomato, known as the "Flavr Savr tomato," the genetically modified organism ("GMO") industry exploded. The GMO industry has since left its mark on agriculture,[1] and in its wake, a shift in global biosafety regulation.[2] In the past decade, the saying, "eat your vegetables," has taken on a whole new and daunting meaning. Scientists are now linking some of the most basic crops consumed around the world to serious health complications.[3] A recent study conducted by French scientist Gilles-Eric Seralini and his colleagues revealed massive tumors, as well as liver and kidney damage, on rats that had consumed genetically modified organisms.[4]

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1. *See* S.K. Lewis, *Attack of the Killer Tomatoes? Corporate Liability for the International Propagation of Genetically Altered Agricultural Products*, 10 TRANSNAT'L LAW. 153, 158 (1997); Darren Smits & Sean Zaboroski, *GMOs: Chumps or Champs of International Trade?*, 1 ASPER REV. INT'L BUS. & TRADE. L. 111, 119 (2001).

2. *See* Lim Li Lin, *Foreword* to JUAN LÓPEZ VILLAR, GMO CONTAMINATION AROUND THE WORLD 5, 5 (2d ed. 2002).

3. *See Revealed: Monsanto GM Corn Caused Tumors in Rats*, RT NEWS (Sept. 19, 2012), http://on.rt.com/0031b0 [hereinafter *Tumors in Rats*]; *Russia Halts Imports of Monsanto Corn over Cancer Fears*, RT NEWS (Sept. 26, 2012), http://rt.com/business/russia-monsanto-corn-ban-005 [hereinafter *Russia Halts Imports of Monsanto Corn*]; *see also* Jeffrey Smith, *Spilling the Beans: Unintended GMO Health Risks*, ORGANIC CONSUMERS ASS'N, *available at* http://www.organicconsumers.org/articles/article_11361.cfm. Jeffrey Smith is the leading spokesperson on the health dangers of genetically modified organisms ("GMOs").

4. *Tumors in Rats*, *supra* note 3 (explaining the results of a study done over a two-year period). "French scientists have revealed that rats fed on GMO corn sold by American firm Monsanto, suffered tumors and other complications. . . . When testing the firm's top brand weed killer the rats showed similar symptoms." *Id. See generally* MONSANTO, http://www.monsanto.com (last visited Jan. 13, 2014). "Monsanto is the leading chemical producer for agricultural products." *Id.*; *see also* Jo Hartley, *Who and What Is Monsanto Chemical Corporation?*, NATURAL NEWS (Apr. 24, 2008), http://www.naturalnews.com/023094_Monsanto_WHO_industry.html (last visited Oct. 4, 2012); *Russia Halts Imports of Monsanto Corn*, *supra* note 3. NK603, "a seed variety made tolerant to amounts of Monsanto's Roundup weed killer," was fed to the rats and also mixed in with water at levels permitted in the United States. The results showed that these rats died earlier than those on a standard diet. Research was conducted by Gilles-Eric Seralini and his colleagues and published in the *Journal of Food and Chemical Toxi-*

A GMO is a form of life, whether plant or animal, whose genetic code (DNA) has been changed to allow characteristics to exist that would not occur naturally.[5] While the process of altering plants and animals through crossbreeding has taken place for centuries,[6] recent advancements in technology allow for GMOs to be altered in a manner that is faster and more exact.[7] Generally, this process is applied to aid in the production

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cology. "Fifty percent of male and 70 percent of female rats died prematurely, compared to only 30 percent and 20 percent in the control group." *Id.*; *Glossary*, GMO-FREE EUROPE 2012, http://gmo-free-regions.org/glossary.html (last visited Jan. 7, 2013) [hereinafter *Glossary*, GMO-FREE EUROPE]. "Genetic engineering" is defined as the "selective, deliberate alteration of genes through the introduction of new, transgenic DNA or destruction of existing DNA." It is also referred to as "gene splicing," "gene manipulation," or "recombinant DNA technology." *Glossary*, GMO-FREE EUROPE, *supra.* Also known as genetically modified, genetically altered foods, Frankenstein foods, Franken foods, genetically engineered, and transgenic species. *Id.* A genetically modified organism is "an organism, with the exception of human beings, in which genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination." *Id.*

5. GM SCIENCE REVIEW PANEL, GM SCIENCE REVIEW FIRST REPORT 90 (July 2003), *available at* http://www.bis.gov.uk/files/file15655.pdf. The process is also referred to as "transgenic" for transfer of genes. *Id.*; Samuel Blaustein, *Splitting Genes*: *The Future of Genetically Modified Organisms in the Wake of the WTO/Cartagena Standoff*, 16 PENN ST. ENVTL. L. REV. 367, 371 (2008); *see, e.g.*, GEORGE WEI, AN INTRODUCTION TO GENETIC ENGINEERING, LIFE SCIENCES AND THE LAW 32 (2002); *see also* Sophia Kolehmainen, *In Depth: Genetically Engineered Agriculture: Precaution before Profits: An Overview of Issues in Genetically Engineered Foods and Crops*, 20 VA. ENVTL. L.J. 267 (2001).

6. Ania Wieczorek & Mark Wright, *History of Agricultural Biotechnology: How Crop Development Has Evolved*, 10 NATURE EDUC. KNOWLEDGE 3 (2012), *available at* http://www.nature.com/scitable/knowledge/library/history-of-agricultural-biotechnology-how-crop-development-25885295. Selective breeding is the traditional way to modify plants, animals, and organisms. *Id.*; *see* Debra M. Strauss, *Achieving the Food Safety Mandate: Bringing the USDA to the Table*, 33 HAMLINE J. PUB. L. & POL'Y. 1, 2 (2011) [hereinafter Strauss, *Food Safety Mandate*].

7. ISAAA, AGRICULTURAL BIOTECHNOLOGY (A LOT MORE THAN JUST GM CROPS) 5 (Aug. 2010), *available at* http://www.isaaa.org/resources/publications/agricultural_biotechnology/download/agricultural_biotechnology.pdf; *see* Matthew Kuure-Kinsey & Beth McCooey, *An Introduction to Recombinant DNA* (2000), http://www.rpi.edu/dept/chem-eng/Biotech-Environ/Projects00/rdna/rdna.html. This can be done using several methods, from recombinant DNA technologies (production of new strains of organisms by combining DNA strands) to micro-injections. *Id.*

of insect or herbicide resistant crops,[8] commonly referred to as "GM crops."[9] GM foods comprised of biotech elements are regulated by the World Health Organization ("WHO"), which conducts human health risk assessments.[10] Countries such as Argentina, Australia, Canada, China, Germany, India, Indonesia, Mexico, Portugal, South Africa, Spain, the United States, and Ukraine produce GM crops.[11] However, due to genetic contamination—a phenomenon examined in Part I—GM crops are showing up around the world whether or not countries and their citizens consent to their presence.[12]

Unlike conventional pollution that breaks down over time, "genetic contamination—the flow of undesirable genes from one

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8. J.L. Gunsolus, *Herbicide Resistant Weeds*, REGENTS OF THE UNIV. OF MINN. (2008), *available at* http://www.extension.umn.edu/distribution/cropsystems/dc6077.html. Growing resistance of weeds to herbicides is an issue for many countries around the world. Weed resistance is a problem as

> many herbicide options could be quickly lost for several crops if a weed biotype is resistant to more than one herbicide . . . [Moreover, the] possibility for replacement of the herbicides lost due to resistance diminishes . . . [and it is] not easy or inexpensive to assess resistant weed biotypes.

Id. Herbicide resistance

> refers to the inherited ability of a weed or crop biotype to survive a herbicide application to which the original population was susceptible. Currently, the three known resistance mechanisms that plants employ are; an alteration of the herbicide site of action, metabolism of the herbicide, and removal of the herbicide from the target site.

Id.

9. *GMO Foods*, COMMONGROUND, http://findourcommonground.com/food-facts/gmo-foods/ (last visited Oct. 13, 2013). Methods used to create GMO plants, resulting in GMO food crops, is done via the technology known as biotechnology. *Id.*

10. *20 Questions on Genetically Modified Foods*, WORLD HEALTH ORG. (last visited Oct. 14, 2013), http://www.who.int/foodsafety/publications/biotech/20questions/en/.

11. *Countries Growing GMOs*, GMO COMPASS (Jan. 19, 2007), http://www.gmo-compass.org/eng/agri_biotechnology/gmo_planting/142.countries_growing_gmos.html.

12. *GM Contamination Register*, GENEWATCH UK & GREENPEACE INT'L, http://www.gmcontaminationregister.org/index.php?content=re&reg=0&inc=1&con=0&cof=0&year=0 (last visited Oct. 14, 2013).

plant to another—is permanent and can spread endlessly through a species."[13] GMOs have contributed to increased incidences of food and crop contamination.[14] In 2000, StarLink

13. *See* Eric Hoffman, *GM Crops*, COUNSEL FOR RESPONSIBLE GENETICS, http://www.councilforresponsiblegenetics.org/GeneWatch/GeneWatchPage.aspx?pageId=249 (last visited Jan. 8, 2014).

14. *See* Strauss, *Food Safety Mandate*, *supra* note 6, at 1-2; *see, e.g.*, Saundra Young, *Salmonella Outbreak Linked to Alfalfa Sprout*s, CNN (Dec. 24, 2010), http://www.cnn.com/2010/HEALTH/12/23/salmonella.outbreak.sprouts/index.html (last visited Jan. 8, 2014); *Salmonella Outbreak Linked to Sprouts Has Sickened Nearly 100 People*, CNN (Dec. 28, 2010), http://www.cnn.com/2010/HEALTH/12/28/salmonella.produce/index.html; *see also* P. Byrne, *Labeling of Genetically Engineered Foods*, COLO. STATE UNIV. EXTENSION (Fact Sheet No. 9.371, Sept. 20, 2010), *available at* http://www.ext.colostate.edu/pubs/foodnut/09371.html. In 2006 and 2007, the United States distributed rice exports to over thirty countries across the globe containing traces of unapproved GE rice owned by Bayer CropScience. GE and GM crops are largely considered to be the same. *Id.*; *see Bayer Settles with Farmers over Modified Rice Seeds*, N.Y. TIMES (July 1, 2011), http://www.nytimes.com/2011/07/02/business/02rice.html; GREENPEACE INT'L, BAYER CROPSCIENCE CONTAMINATES OUR RICE (2007), *available at* http://www.greenpeace.org/international/en/publications/reports/bayer-cropscience-contaminates; GREENPEACE INT'L, WHY GE FIELD TRIALS ARE A RISKY (AND EXPENSIVE) BUSINESS (2012), *available at* http://www.greenpeace.org/international/Global/international/publications/agriculture/2012/GEFactsheet-03-2012.pdf. In 2005, the discovery of illegal sales of GE rice seeds in Hubei, China led to the discovery of GE rice in baby food sold in China. GE rice eventually was discovered to be contaminating rice exports and imports in Austria, France, Germany, Cyprus, Greece, Italy, Sweden, and other countries. *Id.*; Rick Weiss, *Firm Blames Farmers, "Act of God" for Rice Contamination*, WASH. POST (Nov. 22, 2006), http://www.washingtonpost.com/wp-dyn/content/article/2006/11/21/AR2006112101265.html. In 2009, GE linseed, better known as "flax," was found in food in various countries in the European Union. Three years later, this unauthorized GE crop is still being uncovered in food sources across Europe and many believe it has been distributed to over thirty countries. *Id. See generally* SYGENTA, http://www.syngenta.com (last visited Jan. 8, 2014); *see also Don't Rely on Uncle Sam*, 434 NATURE 807 (Apr. 14, 2005), *available at* http://www.nature.com/nature/journal/v434/n7035/full/434807a.html. In 2005, the European Commission issued a statement revealing that illegal Bt10GE maize, produced exclusively by Syngenta, had entered the European food supply generating fear amongst consumers about the risks of increased antibiotic resistance in the population. Bt maize corn is

> genetically modified to provide protection against the European corn borer and the Mediterranean corn borer and/or against corn root

Corn—a GMO that is not approved for human consumption by federal regulators—was found in over 300 products and subsequently recalled, leading to massive economic losses for producers using this product.[15] The aftermath of the StarLink scandal is still plaguing countries today as this strand of corn continues to appear in their food supplies.[16]

As of January 19, 2013, there have been 366 documented instances of GMO contamination around the world.[17] Although very little testing has been done to determine the future impact of GMOs on human health and the environment,[18] GM crop contamination raises serious concerns.[19] As Seralini's study[20] illustrates, GMOs may not be as safe as some wish to think.[21] In the Netherlands, government-driven efforts to enforce compliance with both mandatory and voluntary measures have helped to cut back on instances of contamination.[22] Specifically, growers of GMOs are required to obtain authorization to grow

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> work. Bt10 contains a marker gene that codes for the widely-used antibiotic ampicillin. Under the Codex Alimentarius Guideline for Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA, antibiotic resistance genes used in food production that encode resistance to clinically used antibiotics, should not be present in foods.

Id.

15. *StarLink Scandal*, INDIA ENV'T PORTAL (Feb. 14, 2001), http://www.indiaenvironmentportal.org.in/content/29589/starlink-scandal/.

16. *See generally* Rafaat M. Elsanhoty, A.I. Al-Turki & Mohamed Fawzy Ramadan, *Prevalence of Genetically Modified Rice, Maize, and Soy in Saudi Food Products*, 171 APPLIED BIOCHEMISTRY & BIOTECHNOLOGY 883, 883–99 (2013).

17. *GM Contamination Register*, *supra* note 12.

18. WHY GE FIELD TRIALS ARE A RISKY (AND EXPENSIVE) BUSINESS, *supra* note 14.

19. *GM Contamination Register*, *supra* note 12; *see* Cheryl Hogue, *Organic Farmers, Greenpeace, Others Ask Court to Pull BT Crop Registrations*, 22 INT'L ENV'T REV. (BNA) 195, 196. (1999).

20. *See Tumors in Rats*, *supra* note 3; *Russia Halts Imports of Monsanto Corn*, *supra* note 3.

21. *Commonly Asked Questions about the Food Safety of GMOs*, MONSANTO, http://www.monsanto.com/newsviews/Pages/food-safety.aspx#q1 (last visited Jan. 8, 2014); *but see* INST. FOR RESPONSIBLE TECH., DOCTORS' HEALTH WARNING: AVOID GENETICALLY MODIFIED FOODS (2012), *available at* http://responsibletechnology.org/docs/140.pdf.

22. *See generally Netherlands: Coexistence Rules—Consensus*, GMO SAFETY (Nov. 11, 2004), *available at* http://www.gmo-safety.eu/archive/235.coexistence-rules-consensus.html.

GM crops, undergo education and management training, and sign agreements with neighbors when land will be used as buffer zones between GM and GM-free crops.[23] Such efforts to regulate the early stages of GMO cultivation help minimize instances of GMO contamination.

With the United States, Argentina, Brazil, Canada, India, and China as the leading producers of GM crops around the world,[24] the cultivation of GM crops is increasing annually at notable rates.[25] Thus, the use and consumption of the millions of hectares of land used to harvest GM crops[26] are of vital concern to the international community. Amid uncertainty as to the effects of the long-term use of GMOs, there are well-founded concerns[27] regarding GMOs' effects on human health, the environment, and the survival of organic crops.[28]

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23. J.H. Jans, Avosetta Group, GMO Regulation in the Netherlands, Contribution at Meeting 29/30 in Siena (Sept. 2006), *available at* http://www-user.uni-bremen.de/~avosetta/netherlands_06.pdf.

24. *Countries Growing GMOs*, *supra* note 11; Joana Ferreira, *GMOs, a Global Debate: Brazil, Second Largest GMO Producer in the World*, EPOCH TIMES (July 8, 2013), *available at* http://www.theepochtimes.com/n3/162906-gmos-a-global-debate-brazil-second-largest-gmo-producer-in-world/?photo=2.

25. *Countries Growing GMOs*, *supra* note 11; *see also Global GM Planting 2009*, GMO COMPASS (Mar. 29, 2010), http://www.gmo-compass.org/eng/agri_biotechnology/gmo_planting/257.global_gm_planting_2009.html. "The cultivation of genetically modified plants increased globally in 2009 as well. In comparison to 2008, field area rose by nine million hectares to a total of 134 million. This growth totalled three per cent in industrialised nations (two million hectares) and 13 per cent in developing nations (seven million hectares)." *Id.*

26. *Global GM Planting 2009*, *supra* note 25.

27. Smits & Zaboroski, *supra* note 1, at 114. Concerns include the possibility of GMOs disrupting the ecosystem by generating species that are impervious to environmental defenses such as disease or harsh weather, fear of the unknown consequences of cross-pollination or unidentified effects on insects that consume GMOs, and the introduction of GMOs into a region with the potential to diminish genetic diversity.

28. *See generally* Mary V. Gold, *Organic Production/Organic Food: Information Access Tools*, USDA (June 2007), http://www.nal.usda.gov/afsic/pubs/ofp/ofp.shtml. USDA National Organic Standards Board ("NOSB") defined organic agriculture in April 1995 as "an ecological production management system that promotes and enhances biodiversity, biological cycles and soil biological activity. It is based on minimal use of off-farm inputs and on management practices that restore, maintain and enhance ecological harmony." *Id.* The USDA Consumer Brochure defines organic food as food that "is produced by farmers who emphasize the use of

In order to minimize and prevent incidences of GM contamination, the international community must create and implement GMO-specific laws that directly regulate the cultivation of GM crops and create liability funds to redress those harmed by GMOs on a global scale. This Note argues that, in light of the current fragmented and ineffective regulatory scheme governing GM crop cultivation, the creation of a controlling multilateral treaty addressing this matter will offset the risks of GMO contamination.[29] Part I of this Note discusses the emergence of GMOs, the benefits and drawbacks of their use, and what causes GM contamination. Part II provides an overview of the existing law governing GMOs. Part III exposes existing gaps in the current regulatory scheme that result in the continued occurrence of GM contamination. Part IV proposes a solution for preventing GM contamination that specifically addresses the lack of regulation over GM cultivation. The solution calls for a multilateral treaty governing GMO cultivation that includes implementing a system—like that of the Netherlands—whereby GM crops are not rejected but rather efforts are made to respect consumer concerns over the consumption of GM crops.[30]

I. HISTORY OF GMOS AND CONTAMINATION

The contentious debate over the use of GMOs illustrates the problems that result from the convergence of "globalization, technology, and agriculture."[31] This convergence creates an unclear hierarchy of law; trade law versus environmental law, and human rights law versus intellectual property rights. The myriad, complex laws at the international, regional, and subregional levels involving the use and regulation of GMOs demonstrate a fragmented system, leading to the creation of

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renewable resources and the conservation of soil and water to enhance environmental quality for future generations . . . Organic food is produced without using most conventional pesticides; fertilizers made with synthetic ingredients or sewage sludge; bioengineering; or ionizing radiation." *Id.*

29. The purpose of this Note is not to proclaim that non-GM crops are superior to GM crops or vice versa, but rather that overseeing GM crop cultivation is essential to allow for their peaceful coexistence.

30. *See generally Coexistence in the Netherlands*, GMO COMPASS (Aug. 8, 2006), www.gmo-compass.org/eng/news/country_reports/239.coexistence_netherlands.html (last updated Dec. 12, 2013).

31. Smits & Zaboroski, *supra* note 1, at 111.

gaps in regulation that have been overlooked.[32] Despite the rapid growth of biotechnology[33] and the various benefits derived from GMOs, the international community has failed to account properly for the corresponding social and environmental risks of GMO development.[34]

A. Pre-GMO and the Green Revolution

Following World War II, there was a humanitarian surge by international crop breeding institutions[35] to aid in the reduction of world hunger by increasing crop yields.[36] These philanthropic efforts resulted in the development of new crop varieties that were more responsive to the use of "synthetic fertilizers and controlled irrigation"[37] and were considered a great success "from the standpoint of food production."[38] Norman Borlaug, an agronomist and humanitarian,[39] introduced indus-

32. *See generally* Alexander J. Stein & Emilio Rodriguez-Cerezo, *Low-Level Presence of New GM Crops: An Issue on the Rise for Countries Where They Lack Approval*, 13 J. AGROBIOTECHNOLOGY MGMT. & ECON. 173 (2010), http://www.agbioforum.org/v13n2/v13n2a08-cerezo.pdf.

33. *See* Press Release, Int'l Serv. for the Acquisition of Agri-biotech Applications, Brief 43-2011: Outlook for Biotech Crop Adoption Indicates Continued Global Growth (Feb. 7, 2012), *available at* http://www.isaaa.org/resources/publications/briefs/43/pressrelease/default.asp ; *see Glossary*, GMO-FREE EUROPE, *supra* note 4. "[M]odern biotechnology means the application of; a) in vitro nucleic acid techniques [and] b) fusion of cells beyond the taxonomic family that overcomes natural physiological reproductive or recombination barriers and that are not techniques used in traditional selection." Genetic engineering ("GE") is often used interchangeably with biotechnology. *Id.*

34. *See generally* Hartmut Meyer, S*ystemic Risks of Genetically Modified Crops: The Need for New Approaches to Risk Assessmen*t, 23 ENVTL. SCI. EUR. (Feb. 4, 2011), *available at* http://www.enveurope.com/content/23/1/7.

35. *See, e.g.*, Norman E. Borlaug, *Ending World Hunger. The Promise of Biotechnology and the Threat of Antiscience Zealotry*, 124 PLANT PHYSIOLOGY 487 (2000), *available at* http://www.plantphysiol.org/content/124/2/487.full (discussing efforts by institutes creating genetically modified foods with higher crop yields to aid hunger stricken countries).

36. Carmen Gonzalez, *Genetically Modified Organisms and Justice: The International Environmental Justice Implications of Biotechnology*, 19 GEO. INT'L ENVTL. L. REV. 583, 596–97 (2007). *See generally* GORDON CONWAY, THE DOUBLY GREEN REVOLUTION: FOOD FOR ALL IN THE 21ST CENTURY 1, 44 (Cornell Univ. Press 1998).

37. Gonzalez*, supra* note 36, at 597; CONWAY, *supra* note 36, at 52, 61.

38. *See* Gonzalez, *supra* note 36, at 597.

39. *Spotlight on GMOs*, SCITABLE, http://www.nature.com/scitable/spotlight/gmos-6978241 (last visited Oct. 13,

trial agriculture[40] to countries like Mexico, India, and Pakistan.[41] These agronomical innovations led to what is known today as the Green Revolution and earned Borlaug the Nobel Peace Prize in 1970.[42]

However, despite its name, the Green Revolution did not help the hunger crisis but rather hindered it by displacing poor farmers and damaging the land they relied upon for food production and their livelihood.[43] The Green Revolution benefited wealthy farmers who could afford expensive and innovative products,[44] causing a drop in agricultural prices and in turn hurting many small farmers.[45] Moreover, the rapid shift of farming techniques during the Green Revolution depleted and degraded many natural resources, such as soil quality.[46] Lastly, the Green Revolution concentrated market power "in a handful of agrochemical conglomerates that supplied the pesticides, fertilizers, seed and machinery needed for the capital-intensive agricultural production."[47] The proliferation of GMOs on the global market may have similar effects as the Green Revolution

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2013). Scientist Norman Borlaug developed various techniques that resulted in increased growth yields. Borlaug introduced these techniques for the "cross-breeding, harvesting, and planting [of] seeds" in countries with food-scarcity problems. "Over the next three decades, geneticists developed techniques for extending Borlaug's work by altering crops at the genetic level, resulting in what are known as GMOs." *Id.*

40. *See generally* MATTHEW SCULLY, DOMINION: THE POWER OF MAN, THE SUFFERING OF ANIMALS, AND THE CALL TO MERCY 29 (St. Martin's Griffin 2003). "Industrial agriculture" is a farming mechanism that refers to industrialized production of animals and crops. These methods include innovation in agricultural methods and technology, genetic engineering, greater economies of scale in production, new markets for consumption, and the like.

41. Jill Richardson, *Norman Borlaug's Unsustainable Green Revolution*, COMMON DREAMS (Oct. 5, 2009), http://www.commondreams.org/view/2009/10/05-9.

42. *See id.*; *see also Norman Borlaug—Biographical*, NOBELPRIZE.ORG, http://www.nobelprize.org/nobel_prizes/peace/laureates/1970/borlaug-bio.html (last visited Oct. 13, 2013).

43. Andrew McKillop, *Green Revolution Food Crisis, a Deeper Shade of Brown*, MARKET ORACLE (Nov. 15, 2011), http://www.marketoracle.co.uk/Article31561.html.

44. *See* Gonzalez, *supra* note 36, at 597.

45. *See id.*

46. *See* Richardson, *supra* note 41; Gonzalez, *supra* note 36, at 597–98.

47. Gonzalez, *supra* note 36, at 598; *see* Mohsen Al Attar Ahmed, *Monocultures of the Law: Legal Sameness in the Restructuring of Global Agriculture*, 11 DRAKE J. AGRIC. L. 139, 145 (2006).

in their production, cultivation, and distribution, as GM-crop availability from only a few controlling agrochemical companies will further displace farmers who cannot afford GMO seed and products.

B. Proponents of GMOs

GMOs are capable of providing tremendous benefits, such as increased food production and heightened resilience in crops, making them a valuable tool to combat problems associated with malnutrition.[48] Proponents of GMOs argue that biotechnology, and specifically genetically modified foods, could solve various social and environmental issues through amplified crop yields and a reduction in the use of chemical pesticides and herbicides.[49] Because GMOs have faster reproduction rates and

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48. DEBORAH B. WHITMAN, GENETICALLY MODIFIED FOODS: HARMFUL OR HELPFUL? (Apr. 2000), *available at* http://www.csa.com/discoveryguides/gmfood/review.pdf.

49. *See id.*; *see also Healing, Fueling, Feeding: How Biotechnology Is Enriching Your Life*, BIOTECHNOLOGY INDUS. ORG. (May 1, 2001), http://www.bio.org/articles/healing-fueling-feeding-how-biotechnology-enriching-your-life.

> Biotech is helping to heal the world [through] reducing rates of infectious disease; saving millions of children's lives; changing the odds of serious, life-threatening conditions affecting millions around the world; tailoring treatments to individuals to minimize health risks and side effects; creating more precise tools for disease detection; and combating serious illnesses and everyday threats confronting the developing world. In addition, "biotech is helping to fuel the world by . . . reducing use of and reliance on petrochemicals; using biofuels to help cut greenhouse gas emissions by 52% or more; decreasing water usage and waste generation; and tapping into the full potential of traditional biomass waste products." Lastly, it has been argued that biotech improves crop insect resistance, enhances crop herbicide tolerance and facilitates the use of more environmentally sustainable farming practices. Biotech is helping to feed the world by: Generating higher crop yields with fewer inputs; lowering volumes of agricultural chemicals required by crops-limiting the run-off of these products in the environment; using biotech crops that need fewer applications of pesticides and that allow farmers to reduce tilling farmland; developing crops with enhanced nutrition profiles that solve vitamin and nutrient deficiencies; producing foods free of allergens and toxins such as mycotoxin; and improving food and crop oil content to help improve cardiovascular health.

Id.

heightened resistance to disease and weather fluctuations, they have the capacity to replenish plant populations that have been devastated or depleted.[50] Moreover, because GM crops do not require the use of pesticides, they in turn reduce the likelihood of pesticides contaminating the atmosphere, soil, water, and any resulting food.[51] There are also economic incentives to producing GMOs as they provide for higher crop yields that thrive in inhospitable conditions and require less maintenance.[52] Furthermore, proponents argue that GMOs could solve world hunger by producing higher caloric species.[53]

C. What Is So Bad About GMOs?

Because GMO science is in its "infancy,"[54] consumers worry about the long-term outcomes that may be revealed down the road.[55] Opponents of GMOs—like GMO-Free Europe—"advocate for the immediate cessation of GMO use and research"[56] and argue that GMOs pose various health hazards and environmental risks.[57] Aside from the moral conundrum of altering the natural state of organisms,[58] GMOs and the use of

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50. *See* Lewis, *supra* note 1; *see* Smits & Zaboroski, *supra* note 1, at 113.

51. *Id*.

52. *See* Smits & Zaboroski, *supra* note 1, at 113.

53. *See* Lewis, *supra* note 1, at 156; *see* Smits & Zaboroski, *supra* note 1, at 113.

54. Smits & Zaboroski, *supra* note 1, at 115.

55. *See* Kynda R. Curtis, Jill J. McCluskey & Thomas I. Wahl, *Consumer Acceptance of Genetically Modified Food Products in the Developing World*, 7 J. AGROBIOTECHNOLOGY MGMT. & ECON. 70 (2004), http://www.agbioforum.org/v7n12/v7n12a13-mccluskey.htm.

56. *See* Blaustein, *supra* note 5, at 367, 374. *See generally* GMO-FREE EUROPE, *supra* note 4.

57. *See* Smits & Zaboroski, *supra* note 1.

58. *Assessing Socio-Economic Impacts of GMOs*, BIOSAFETY INFO. CTR. (Dec. 13, 2010) [hereinafter *Assessing Socio-Economic Impacts of GMOs*], http://www.biosafety-info.net/article.php?aid=751. Many feel that aspects of "biotechnology tamper with 'God's plan,' while others are fearful of unknown potential consequences of biotechnology." Furthermore,

> certain aspects of biotechnology are against the teachings of the Catholic Church. Because Catholics believe that life begins at fertilization, they are against the harvesting of human embryonic stem cells, because this technique results in the destruction of the embryo. On the other hand, the Vatican has come out in favor of GMO food as a way to help feed the poor. Much of the discussion also centers around human cloning, which can be used in two different ways:

biotechnology may actually contribute to world hunger by making farmers dependent on private corporations for seed or other agricultural necessities, leaving important matters—like what we eat—in the hands of a few individuals.[59] Opponents of GMOs argue that regardless of GMOs ability to produce more abundant crops, hunger is a result of "poverty and poor governance not lack of food."[60] There are concerns that GMOs may increase poverty and income inequality by reducing the necessity of manual labor and disadvantaging farmers who do not have the means to make the expensive shift to GMO use.[61]

> there is reproductive cloning and therapeutic cloning. Reproductive cloning is used to make a clone of another person while therapeutic cloning is the basis for regenerating damaged or lost tissues through the use of embryonic stem cells. Some in one group, say US Senate conservatives, have come out against the former, but for the latter.

Id.; *see* HENRY I. MILLER & GREGORY CONKO, THE FRANKENFOOD MYTH: HOW PROTEST AND POLITICS THREATEN THE BIOTECH REVOLUTION 1, 29 (2004); *see* Blaustein, *supra* note 5, at 367, 371; *see also What About the Ethical Issues?* SCI. & SOC'Y, http://www.scienceandsociety.emory.edu/GMO/-ReligionGMO.htm (last visited Jan. 10, 2014).

59. *See* Elizabeth Denlinger, *Problems and Questions: What Is All the Controversy About*?, GENETICALLY MODIFIED ORGANISMS, http://iml.jou.ufl.edu/projects/spring01/denlinger/problems.html (last visited Jan. 9, 2014) (citing Deborah Toler, *Biotechnology Not the Solution*, TORONTO STAR, July 25, 2000, first ed.; J. vanWijk, *Biotechnology and Hunger: Challenges for the Biotech Industry*, 41 BIOTECHNOLOGY DEV. MONITOR 2, 2–7 (2000)).

60. David M. Kaplan, *What's Wrong with Genetically Modified Food?*, at 1, 7, *available at* http://www.csid.unt.edu/files/What's%20Wrong%20With%20Genetically%20Modified%20Food.pdf, *originally printed in* ETHICAL ISSUES OF THE 21ST CENTURY (Frederick Adams ed., Charlottesville: Phil. Documentation Ctr. Press 2004).

61. *See* Gonzalez, *supra* note 36, at 610–11; Denlinger, *supra* note 59 (quoting Toler, *supra* note 59).

> The World Bank states that the world food supply in 1994 could have fed 6.4 billion people so hunger stems not necessarily from lack of food, but also from economic and political reasons. The world produces enough grain to feed every person at least 3,500 calories a day yet 800 million people in the world are hungry (Toler 2000) . . . Many opponents argue that biotech companies are using world hunger as a form of "moral blackmail" to sell GMOs. Consumers feel they have to accept biotechnology or else they feel guilty about standing in the way of progress to help stop world hunger (Knee, 2000). The companies make themselves out to be the saviors of hungry people

Moreover, GMO use could disrupt the environment through the introduction of transgenic species, or species with a transplanted genome.[62] Because transgenic species[63] are more resistant to natural defenses, like weather change, they have the potential to alter the natural vegetative composition of specific geographic regions and threaten existing biodiversity.[64] Moreover, GMOs threaten biodiversity as their cheaper production costs and higher crop yields increase the likelihood that food producers will grow fewer strains of crop.[65] Reliance on a few strands of crop additionally heightens the risk of food-related calamities. For example, the Irish potato famine resulted in

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> throughout the world, but to not actually use their own expertise to help developing nations because they have no profit incentive.

Denlinger, *supra* note 59.

62. *Pros and Cons of Transgenic Crops: Environmental Considerations*, THE MAIZE FULL LENGTH CDNA PROJECT, http://www.maizecdna.org/outreach/e1.html. "The introduction of a new variable could be significant enough to affect non-target organisms living in the same environment as transgenic crop." *Id.*; *Biodiversity: Threatened by Genetically Modified Plants?*, GMO COMPASS (Dec. 11, 2006), http://www.gmo-compass.org/eng/safety/environmental_safety/166.biodiversity_threatened_genetically_modified_plants.html. This alteration of the natural composition of specific geographic regions threatens existing biodiversity. *Id.*

63. *Transgenic Organisms*, GENETICS HOME REFERENCE (Jan. 13, 2014), http://ghr.nlm.nih.gov/glossary=transgenicorganisms. "Transgenic means that one or more DNA sequences from another species have been introduced by artificial means . . . Transgenic plants can be made by introducing foreign DNA into a variety of different tissues." *Id.*

64. *See* Smits & Zaboroski, *supra* note 1, at 114; *see also* Vassili V. Velkov, Alexander B. Medvinsky, Mikhail S. Sokolov & Anatoly I. Marchenko, *Will Transgenic Plants Adversely Affect the Environment?*, 30 J. BIOSCI. 515, 527 (2005), *available at* http://www.ias.ac.in/jbiosci/sep2005/515.

> Among the potential direct effects of transgenic crops and their management are changes in soil microbial activity due to differences in the amount and composition of root exudates, changes in microbial functions resulting from gene transfer from the transgenic crops, such as pesticide applications, tillage, and application of inorganic and organic fertilizer sources. Possible indirect effects of TPs [Transgenic Products], including changes in the fate of TPs residues and alterations in land use and rates of soil erosion, deserve further study.

Id.

65. *See* Smits & Zaboroski, *supra* note 1. *Agricultural Biotechnology*, PEW CHARITABLE TRUSTS (2007), http://www.pewtrusts.org/our_work_detail.aspx?id=442.

part from Ireland's reliance upon a few strains of genetically uniform potato plants.[66]

GMOs not only pose ecological concerns, but economic ones as well.[67] Biotech companies have developed "terminator technology" designed to create edible but infertile GM seeds.[68] The "terminator technology" harms farmers who employ traditional methods of reusing seeds from one year's crop for the following year's harvest by forcing them to buy new seeds annually.[69] Additionally, because GM crops can be grown in first world environments previously unable to produce such crops, the export markets of developing nations are hindered.[70] Furthermore, small farms are confronted with the burdensome task of competing with "big business farms" that can more easily assume production costs and other expenses that accompany the use of GMO crop production.[71]

D. Contamination: How GMOs Pose a Threat to Non-GMOs

GMO contamination threatens consumer health, the environment, and the farming industry.[72] GMOs have repeatedly contaminated organic or non-GM crops across the world.[73] The

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66. Sara M. Dunn, *From Flavor Sav'r to Environmental Saver? Biotechnology and the Future of Agriculture*, *International Trade, and the Environment*, 9 COLO. J. INT'L ENVTL. L. & POL'Y 145 (1998).

67. *Pros and Cons of Transgenic Crops*, *supra* note 62.

68. *Id.*

69. *Id.*; *see, e.g.*, DAVID KRUFT, IMPACTS OF GENETICALLY-MODIFIED CROPS AND SEEDS ON FARMERS (2001), *available at* http://law.psu.edu/_file/aglaw/Impacts_of_Genetically_Modified.pdf; Colin Todhunter, *Genetically Engineered "Terminator Seeds:" Death and Destruction of Agriculture*, GLOBAL RESEARCH (Jan. 21, 2013), *available at* http://www.globalresearch.ca/genetically-engineered-terminator-seeds-death-and-destruction-of-agriculture/5319797.

70. *See* Lewis, *supra* note 1, at 156; Smits & Zaboroski, *supra* note 1, at 114–15. Providing wealthy nations with the means to produce crops not naturally occurring in their environment creates disparity between developing and developed nations, as poorer countries lack the resources to successfully engage in agricultural export competition. *Id.*

71. *See* K.S. Beaudoin, *On Tonight's Menu: Toasted Cornbread with Firefly Genes? Adapting Food Labeling Law to Consumer Protection Needs in the Biotech Century*, 8 MARQUETTE L. REV. 237, 238 (1999); *see* Smits & Zaboroski, *supra* note 1, at 115.

72. WHY GE FIELD TRIALS ARE A RISKY (AND EXPENSIVE) BUSINESS, *supra* note 14.

73. Ben Lilliston, *Farmers Fight to Save Organic Crops*, PROGRESSIVE (Sept. 2011), http://www.progressive.org/0901/lil0901.html; *see* Ronnie Cum-

United States Department of Agriculture ("USDA") purports to take organic farmers' concern for contamination to heart, noting the compounding challenges they face, however, no resolutions that protect these farmers' interests have been reached to date.[74] Wariness toward GMO consumption has taken a partic-

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mins, *The Organic Elite Surrenders to Monstanto: What Now?*, ORGANIC CONSUMERS ASS'N (Jan. 27, 2011), www.organicconsumers.org/articles/article_22449.cfm. "There can be no such thing as 'coexistence' with a reckless industry that undermines public health, destroys biodiversity, damages the environment, tortures and poisons animals, destabilizes the climate, and economically devastates the world's 1.5 billion seed-saving small farmers." *Id.*

74. *See* Jason Mick, *Monsanto Defeats Small Farmers in Critical Bioethics Class Action Suit*, DAILY TECH (Mar. 1, 2012), www.dailytech.com/Monsanto+Defeats+Small+farmers+in+critical+bioethics+class+action+-suit/article24118.htm; *see also Organic Farmers Sue Monsanto to Protect Against Contamination*, ALLGOV (Apr. 21, 2011), http://www.allgov.com/news/controversies/organic-farmers-sue-monsanto-to-protect-against-contamination?news=842543; *see also Organic Farmers Sue Monsanto*, RT NEWS (July 28, 2011), http://rt.com/usa/organic-monsanto-lawsuit-seed. In 2011, organic farmers in America united to put an end to unfair litigation sparked by incidences of Monsanto GM Crop Contamination.

> 270,000 organic farmers filed a lawsuit in March in an attempt to keep a portion of the world's food supply organic . . . crops of theirs have been contaminated by Monsanto's seed, and even though the contamination has been largely natural and unintended, Monsanto has been suing hundreds of farmers for infringing on their patent for incidentally using their product.

Id.; *see also* Susan Decker & Jack Kaskey, *Monsanto Sued by Organic Farmers over Modified-Seed Patents*, BLOOMBERG NEWS (May 29, 2011), http://www.bloomberg.com/news/3011-03-29/monsanto-sued-by-organic-farmers-over-modified-seed-patents-1-.html.

> In an effort to maintain a portion of the world's food supply as organic, farmers sued for the contamination of their corn, cotton, sugar beets and other crops by Monsanto seed. The lawsuit is preemptive to protect against patent-infringement claims should the farmers' land and plants be found to have traces of Monsanto's modified seed . . . A patent infringement case stemming from unauthorized saving of GM seeds was . . . tried in the Canadian courts. In this case, Monsanto Company sued Percy Schmeiser, a local farmer, for saving and planting GM seeds produced from pollen that had blown onto his field from a neighboring farm. Schmeiser himself had no contract with Monsanto. The court found that the defendant planted seeds saved from a field onto which pollen from GM canola

ular toll on organic or conventional farmers who risk economic loss and injury from contamination of non-GM crops, making their products unmarketable.[75] In addition, concerns regarding the unknown effects associated with long-term exposure to GMOs have been evident in consumers' attitudes toward food.

Although the future of GMO use influences and affects various fields of interest, the organic farmer is "on the front lines of the GMO battlefield."[76] Apart from the usual problems farmers face—foreign subsidies, low commodity prices, and nature itself[77]—they must now tackle a new set of issues elicited by GMOs. The production, cultivation, and use of GMOs presents a unique challenge different from the challenges with other internationally traded goods, as they can inadvertently pervade various political spheres through the undetected contamination of seeds and harvests.[78] As the European Commission noted, "[o]nce a GMO is released into the environment, it could be impossible to recall it or prevent its spread and therefore adverse effects must be avoided as they might be irreversible."[79]

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had blown. The court found further that Schmeiser had engaged in those activities knowingly. This violated the patent Monsanto held on the Roundup tolerant seed. Mr. Schmeiser was required to deliver to Monsanto any remaining saved seed and to pay Monsanto the profits earned from the crops, plus interest.

Id.; *see also* Maria Godoy, *Did Congress Just Give GMOs a Free Pass in the Courts?*, NPR (Mar. 21, 2013), http://www.npr.org/blogs/thesalt/2013/03/21/174973235/did-congress-just-give-gmos-a-free-pass-in-the-courts.

75. *See* Debra M. Strauss, *The Role of Courts, Agencies, and Congress in GMOs: A Multilateral Approach to Ensuring the Safety of the Food Supply*, 48 IDAHO L. REV. 267, 309 (2012) [hereinafter Strauss, *Role of Courts*]; *see also GM Crops*, SOC'Y OF BIOLOGY, https://www.societyofbiology.org/policy/policy-issues/environmental-sciences/plant-science/gm-crops (last visited Jan. 10, 2014).

76. Smits & Zaboroski, *supra* note 1, at 114.

77. *See id.*

78. *See* Alison Peck, *The New Imperialism: Towards an Advocacy Strategy for GMO Accountability*, 21 GEO. INT'L ENVTL. L. REV. 37, 38 (2008).

79. VILLAR, *supra* note 2, at 8 (quoting EUROPEAN COMM'N, THE EUROPEAN COMMUNITY AND THE DELIBERATE RELEASE OF GENETICALLY MODIFIED ORGANISMS TO THE ENVIRONMENT (Occasional Paper 1990)).

1. What Does it Mean to be Contaminated?

Unintended contamination of non-GM crops by GM materials can occur at four stages of the commercial chain: seed production, on-farm commercial grain production, grain handling and transport, and food manufacturing and processing.[80] Contamination results from unwanted strands of seed comingling with the intended seed.[81] Pollen-drift, a naturally occurring process, is a key contributor to the problem of contamination.[82] In order for cross-pollination to occur, pollen from a GM plant must be carried, either by wind or insects, to a non-GM plant.[83] Factors such as rainfall, tree barriers, topography, wind speed and direction, the season, and fertility of the GM pollen all affect the transport of GMOs and the likelihood of contamination.[84]

Additionally, human action or inaction at the production, cultivation, and distribution levels contributes to the likelihood of contamination.[85] The range of the buffer zone[86] between GM and non-GM crops, the mixing of crops in storage spaces, and the failure to properly clean storage spaces and transportation devices all exacerbate the likelihood of contamination.[87] Likewise, at the manufacturing and processing stages, failure to adequately monitor ingredients in a given product promotes instances of contamination.[88]

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80. *See generally* PIONEER, BEST MANAGEMENT PRACTICES FOR IDENTITY PRESERVATION IN CORN, http://www.pioneer.com/CMRoot/Pioneer/US/products/stewardship/management.pdf (last visited Feb. 25, 2014).

81. *See* Peck, *supra* note 78, at 38.

82. *See* MICHAEL R. TAYLOR & JODY S. TICK, PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY & RES. FOR THE FUTURE, POST-MARKET OVERSIGHT OF BIOTECH FOODS: IS THE SYSTEM PREPARED? 49 (2003), http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/hhs_biotech_corn_0403.pdf.

83. *See* Peck, *supra* note 78, at 38.

84. *Id.*

85. *See* TAYLOR & TICK, *supra* note 82, at 49.

86. A buffer zone is "a neutral area separating conflicting forces." *Buffer Zone*, MARRIAM-WEBSTER.COM, http://www.merriam-webster.com/dictionary/buffer%20zone (last visited Jan. 17, 2014).

87. Lilliston, *supra* note 73.

88. TAYLOR & TICK, *supra* note 82, at 49–50. Inability to guarantee 100% varietal purity is "due to the inevitable comingling that occurs during farming and other commodity operations, such as from equipment and on-farm storage; transportation systems involving trucks, rail cars, and barges; and elevator storage, including local, river, terminal, and plant elevators." *Id.*

Contamination of seeds and harvests presents unique concerns as GM materials invade the sovereign realms of other nations by unintentionally introducing foreign substances into the other nations' food sources when they have not yet "been fully researched, debated, or regulated through [other countries'] . . . political processes."[89] Notable cases of GMO contamination are the 2000 StarLink Scandal[90] and the recent high mortality rate amongst monarch butterflies.[91] These examples illustrate how quickly GMOs can pervade a nation's food source and how they have the ability to alter and damage existing biodiversity.

(quoting Leah L. Porter, *To Split or Not to Split: Why It's Not the Only Question, in* STARLINK: LESSONS LEARNED (2001)).

89. *See* Peck, *supra* note 78, at 38.

90. VILLAR, *supra* note 2, at 10–13; *see* Kaplan, *supra* note 60, at 2, 9, 15, 33; *see* Gregory N. Mandel, *Confidence-Building Measures for Genetically Modified Products: Stakeholder Teamwork on Regulatory Proposals*, 44 JURIMETRICS J. 41, 52–54 (2003). "The USDA's failure to adequately monitor the introduction of GMOs into the food chain resulted in one of the most reported cases of contamination that affected human consumption." *Id.*; Jennifer Clapp, *Illegal GMO Releases and Corporate Responsibility: Questioning the Effectiveness of Voluntary Measures*, 66 ECOLOGICAL ECON. 348, 364 (2008). "Traces of StarLink corn were found in imported corn and corn products in Japan, Korea, Nicaragua, and Mexico. Five years later, Cry9C still turned up in the corn supply in the US and in other countries." *Id.*

91. *See* WHITMAN, *supra* note 48. Although monarch caterpillars do not eat corn, the pollen from Bt corn blows onto milkweed plants that caterpillars consume, killing them. Because humans can take up to at least thirty years to reveal medical complications developed by low-grade exposure—unlike butterflies, which possess a short life span and can show results from toxic exposures in just a few weeks—humans may be subject to similar effects. *Id.*; John E. Losey, Linda S. Rayor & Maureen E. Carter, *Transgenic Pollen Harms Monarch Larvae*, 399 NATURE 214, 214 (1999), *available at* http://www.nature.com/scitable/content/Transgenic-pollen-harms-monarch-larvae-97961; *see also* Patrick Dixon, *Monarch Butterfly Deaths from GM Pollen*, GLOBALCHANGE, http://www.globalchange.com/monarch.htm (last visited Jan. 15, 2014); IZA KRUSZEWSKA, N. ALLIANCE FOR SUSTAINABILITY (ANPED), ROMANIA: THE DUMPING GROUND FOR GENETICALLY ENGINEERED CROPS—A THREAT TO ROMANIA'S AGRICULTURE, BIODIVERSITY AND EU ACCESSION (2003). Beginning in August 2000, after the discovery of StarLink's maize in the human food chain, companies began to recall products. The USDA eventually issued a formal recall of StarLink maize grown on 350,000 acres in the United States. *Id.*; *see* JANE RISSLER & MARGARET MELLON, UNION OF CONCERNED SCIENTISTS, GONE TO SEED: TRANSGENIC CONTAMINANTS IN THE TRADITIONAL SEED SUPPLY 9, 45–46 (2004), http://www.ucsusa.org/assets/documents/food_and_agriculture/seedreport_fullreport.pdf.

II. EXISTING REGULATION OF GMOS

The evolution and expansion of biotechnology is not a scientific activity that exists in a vacuum; instead, it is entrenched in economic, social, and political conditions. The Precautionary Principle ("PP") is one framework that has emerged as a means to address socioeconomic concerns regarding GMOs.[92] Intended to encourage policymakers to take action in situations where there is the potential for harm but no existing concrete scientific proof,[93] the PP applies where there is insufficient, inconclusive, or uncertain scientific data, or where a preliminary evaluation shows potential dangers to the environment, or human, plant, or animal populations.[94] The PP allows countries to assess the various socioeconomic effects of GMOs, how GMOs can be categorized according to specific strands, possible modes of GMO distribution, and the impact of GMOs on the marketplace.[95]

The Convention on Biological Diversity ("CBD" or "Convention") and the Cartagena Protocol on Biosafety ("CPB" or "Protocol") are the primary multilateral environmental agreements ("MEAs") that govern GMOs and incorporate the PP.[96] These agreements account for human health and biological diversity.[97] Nevertheless, the PP is largely used as a means to justify measures taken to bar GMOs from entering the food chain[98] and is not used as an effective tool to maximize coexistence. The following is an overview of the main bodies of law that address and govern GMOs with respect to their trade, use, and production.

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92. Julian Kinderlerer, *The Cartagena Protocol on Biosafety*, 4 COLLECTION OF BIOSAFETY REVS. 12, 12 (2008), http://www.icgeb.org/~bsafesrv/pdffiles/Kinderlerer.pdf.

93. *See* Gerhard Adam, *GMO Foods and the Precautionary Principle*, SCIENCE 2.0 (Feb. 21, 2012, 7:52 PM), http://www.science20.com/gerhard_adam/gmo_foods_and_precautionary_principle-87151.

94. *Glossary: Precautionary Principle*, EUROPA, http://europa.eu/legislation_summaries/glossary/precautionary_principle_en.htm (last visited Oct. 1, 2013).

95. *Assessing Socio-Economic Impacts of GMOs*, *supra* note 58.

96. *See* Kinderlerer, *supra* note 92, at 34.

97. *See id.* at 32.

98. *See* Michael Pollan, *The Importance of the Precautionary Principle*, N.Y. TIMES (Dec. 9, 2001), http://www.nytimes.com/2001/12/09/magazine/09PRINCIPLE.html.

A. The Protocol to the Convention on Biological Diversity

Negotiated under the United Nations Environment Programme ("UNEP"), the CBD was signed at the Earth Summit in Rio de Janeiro in June 1992 and entered into force on December 29, 1993.[99] The CBD's main objectives are spelled out in Article 1 as follows:

> [T]he conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.[100]

While primarily focused on the conservation and sustainability of ecosystems, the CBD also addresses environmental impacts of GMOs by looking at factors associated with GMOs and alien species.[101] The parties to the Convention set out that contracting parties are obligated to prevent the introduction of alien species[102] and to regulate or eliminate species that threaten the environment.[103]

The CBD establishes the groundwork for GMO regulation via the creation of a protocol that enforces the safe transfer of GMOs and recognizes that the majority of genetic resources are cultivated in developing nations.[104] Lastly, this protocol establishes a state's right to genetic and biodiversity resources in its

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99. *Glossary*, GMO-FREE EUROPE, *supra* note 4.

100. Convention on Biological Diversity art. 1, *opened for signature* June 5, 1992, 1760 U.N.T.S. 79; *see also* Laurence Boisson de Chazournes, *Convention on Biological Diversity and Its Protocol on Biosafety*, UN AUDOIVISUAL LIBRARY OF INT'L LAW, http://legal.un.org/avl/pdf/ha/cpbcbd/cpbcbd_e.pdf (last visited Jan. 17, 2014).

101. *See Genetically Modified Crops: 7. Are GMOs Regulated by International Agreements?*, GREENFACTS, http://www.greenfacts.org/en/gmo/2-genetically-modified-crops/7-gmo-regulation.htm#2 (last visited Jan. 17, 2014) [hereinafter *Are GMOs Regulated*]; *Glossary*, GMO-FREE EUROPE, *supra* note 4.

102. *Background*, CONVENTION ON BIOLOGICAL DIVERSITY, http://www.cbd.int/invasive/background.shtml (last visited Jan. 17, 2014).

103. Boisson de Chazournes, *supra* note 100.

104. *See About the Nagoya Protocol*, CONVENTION ON BIOLOGICAL DIVERSITY, http://www.cbd.int/abs/about/ (last visited Feb. 5, 2014).

sovereign territory.[105] In accordance with the CBD, states must implement domestic strategies to ensure the protection of biodiversity, including, but not limited to, monitoring and identifying processes and activities that may adversely impact biodiversity.[106]

B. Cartagena Protocol on Biosafety

The CPB arose out of the CBD[107]and was agreed to by over 130 countries.[108] The CPB marks the first international regulatory scheme to directly govern genetic engineering[109] and represents an important progression in both international and environmental law.[110] Established as a supplementary agreement to the CBD and negotiated under UNEP, the CPB entered into force in December 1993.[111] The Protocol is aimed at protecting biodiversity by ensuring that living modified organisms ("LMOs")[112] are handled, transported, and used in a safe manner and requires documentation when LMOs are to be transported.[113] Under the Protocol, a country may ban LMO imports, such as crops, if it feels that the introduction of the products would jeopardize the environment.[114]

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105. *See* Juan Antonio Herrera Izaguirre, *International Law and GMOs: Can the Precautionary Principle Protect Biological Diversity?*, 118 BOLETIN MEXICANO DE DERECHO COMPARADO 97 (2007), *translation available at* http://www.ejournal.unam.mx/bmd/bolmex118/BMD000011804.pdf.

106. *See* Boisson de Chazournes, *supra* note 100.

107. Kinderlerer, *supra* note 92, at 36.

108. Lin, *supra* note 2. The CPB has 100 countries as signatories and many more are in the process of ratification.

109. *Id.*

110. *See generally* Kinderlerer, *supra* note 92.

111. *See* Cartagena Protocol on Biosafety to the Convention on Biological Diversity, *opened for signature* May 15, 2000, 2226 U.N.T.S. 208 [hereinafter Cartagena Protocol].

112. *Id.*; *About the Protocol*, CONVENTION ON BIOLOGICAL DIVERSITY, http://bch.cbd.int/protocol/background/ (last updated May 29, 2012); *Glossary*, GMO-FREE EUROPE, *supra* note 4. "Living Modified Organism (LMO) is defined in the . . . CPB as 'living modified organism' that possesses a novel combination of genetic material obtained through the use of modern biotechnology." The CPB uses the term LMO to distinguish living GMOs from non-living GMOs or GM products, such as flour from GM maize, because the scope of the CPB is the protection of biodiversity. *Id.*

113. Cartagena Protocol, *supra* note 111, art. 1; *see Are GMOs Regulated*, *supra* note 102.

114. Cartagena Protocol, *supra* note 111, art. 24.

The Protocol sets out various means for notifying and receiving notification of the movement of LMOs around the world.[115] Article 18 of the CPB addresses compliance with international rules and standards for the safe handling, packaging, and transportation of LMOs.[116] Under the CPB, Articles 7, 10, and 12 require notice of transboundary movement of LMOs through the Advance Informed Agreement Procedure ("AIA").[117] Exporting parties must give notice to the importing country, enabling the receiving country to consent or reject to the transfer of LMOs after a risk assessment has transpired.[118] Additionally, the CPB requires full disclosure of GMO imports via Article 20, which establishes the Biosafety Clearing-House.[119] The Biosafety Clearing-House provides a mechanism to access information on "scientific, technical, environmental, legal and capacity building information"[120] regarding the movement of GMOs. Lastly, the adoption of the PP in Article 26,[121] as a central component of the Protocol, provides nations with the ability to account for a plethora of non-scientific risks.[122]

Despite the CPB's incorporation of the PP as a central precept during the negotiation of the Protocol, it was emphasized that the CPB was not to take precedence over other existing regulatory schemes—such as those established by the World Trade Organization ("WTO").[123] Thus, the Protocol limits the application of the PP in its mandate that parties' considera-

115. *About the Protocol*, *supra* note 112.

116. Cartagena Protocol, *supra* note 111, art. 18.

117. *Id.*; *see* Blaustein, *supra* note 5, at 367, 380.

118. *Background to the Cartagena Protocol on Biosafety*, AFR. BIOSAFETY NETWORK OF EXPERTISE, http://www.nepadbiosafety.net/subjects/legal-and-policy/cartagena-protocol (follow "Advance Informed Agreement" hyperlink) (last visited Jan. 17, 2014).

119. *Id.* The Biosafety Clearing House ("BCH") is a mechanism established under Article 18(3) of the CBD to "promote and facilitate technical and scientific cooperation between the parties to the CBD." In particular, the BCH is to take into account the special needs of developing countries and countries that are centers of origin and diversity. The BCH serves as a repository of information for the implementation of the Protocol and provides for a means for the exchange of information. *Id.*

120. *Biosafety Clearing-House*, CONVENTION ON BIOLOGICAL DIVERSITY, http://bch.cbd.int/ (last visited Oct. 9, 2013); Cartagena Protocol, *supra* note 112, art. 20.

121. *Assessing Socio-Economic Impacts of GMOs*, *supra* note 58.

122. *See* Lin, *supra* note 2.

123. *See* Kinderlerer, *supra* note 92, at 36, 37.

tions of certain socioeconomic issues comply with other international agreements.[124] Although the preamble to the CPB states that it is "not intended to subordinate this Protocol to other international agreements,"[125] it also states that the Protocol will not conflict with or override "the rights and obligations of a Party under any existing international agreements."[126]

C. International Plant Protection Convention

A third convention that regulates GMOs is the International Plant Protection Convention ("IPPC"). The IPPC aims to prevent the spread of pests that negatively affect plants, conserve plant diversity, and protect national resources through international cooperation.[127] Recognized by the Agreement on the Application of Sanitary and Photosanitary Measures ("SPS Agreement"), the WTO encourages strict adherence to IPPC standards.[128] With 161 contracting parties as of 2007, the IPPC "provides a framework and a forum for international cooperation, harmonization and technical exchange."[129] The IPPC extends not only to cultivated plants but also to direct and indirect damage by pests.[130] It acknowledges risks regarding GMOs that should be accounted for, including:

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124. *Assessing Socio-Economic Impacts of GMOs*, *supra* note 58.

125. *See* Kinderlerer, *supra* note 92, at 37.

126. Chee Yoke Ling & Lim Li Ching, *The WTO Agreements: An Introduction to the Obligations and Opportunities for Biosafety*, *in* BIOSAFETY FIRST: HOLISTIC APPROACHES TO RISK AND UNCERTAINTY IN GENETIC ENGINEERING AND GENETICALLY MODIFIED ORGANISMS 427, 439 (Terje Traavik & Lim Li Ching eds., 2007).

127. *See Are GMOs Regulated*, *supra* note 101; R. Griffin, *Introduction to the International Plant Protection Convention (IPPC)*, *in* FOOD & AGRIC. ORG. OF THE UNITED NATIONS, 3 MULTILATERAL TRADE NEGOTIATIONS ON AGRICULTURE (2000), *available at* http://www.fao.org/docrep/003/x7354e/x7354e05.htm.

128. KOFI HUMADO, U.S. AGENCY FOR INT'L DEV., TECHNICAL REPORT NO. 6, SANITARY & PHYTO-SANITARY CAPACITY EVALUATION OF THE GAMBIA, GHANA AND NIGERIA 6, 11 (2005), *available at* http://www.hubrural.org/IMG/pdf/wath_sps_evaluation_eng.pdf.

129. *Convention, Model Instruments and Related Information*, INT'L PLANT PROTECTION CONVENTION (last visited Sept. 29, 2013), https://www.ippc.int/about/convention-text.

130. *Countries Overview*, INT'L PLANT PROTECTION CONVENTION, *available at* https://www.ippc.int/nppos (last visited Jan. 17, 2014). Pest is "any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products." *Id.*

1. New genetic characteristics that may cause invasiveness (drought resistance, herbicide tolerance, pest resistance),
2. Gene flow (transfer of genes to wild relatives or other compatible species), and
3. Effects of non-target organisms (beneficial insects or birds).[131]

The goal of the IPPC contributes to biosecurity by reducing the risks connected with the presentation of plant pests into a given environment.[132]

D. The Codex Alimentarius

Established with the primary goal of protecting consumer health and setting guidelines for food safety standards, the Codex Alimentarius ("Codex") also promotes cooperation between various international trade practices.[133] Although the Codex guidelines are voluntary and thus do not have a binding effect on national legislation,[134] they have some legal significance.[135] In 1995, the WTO announced that the Codex would serve as a tool for evaluating food regulations challenged as restrictions on trade.[136] Some of the risk management tools that the Codex promotes are safety assessments of all GM food prior to their approval for commercial sale, traceability, and food labeling.[137]

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131. GREENFACTS, SCIENTIFIC FACTS ON GENETICALLY MODIFIED CROPS 14 (2004), http://www.greenfacts.org/en/gmo/gmo-greenfacts-level2.pdf.

132. *Biosecurity in Food and Agriculture*, INT'L PLANT PROTECTION CONVENTION, https://www.ippc.int/about/why_it_matters/ippc_and_biosecurity (last visited Sept. 29, 2013).

133. Mauro Vigani, Valentina Raimondi & Alessandro Olper, *GMO Regulations, International Trade and the Imperialism of Standards* 11–12 (LICOS Ctr. for Insts. & Econ. Performance, Discussion Paper No. 255/2009, 2010).

134. *20 Questions on Genetically Modified Foods*, *supra* note 10.

135. Phil Bereano, *A Primer on GMOs and International Law*, GENEWATCH, *available at* http://www.councilforresponsiblegenetics.org/genewatch/GeneWatchPage.aspx?pageId=422 (last visited Jan. 17, 2014). Phil Bereano is on the roster of experts for the Cartagena Protocol, co-founder of the Council for Responsible Genetics, and currently represents the Washington Biotechnology Action Council and the 49th Parallel Biotechnology Consortium at international meetings. *Id.*

136. *Id.*

137. PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, U.S. VS. E.U.: AN EXAMINATION OF THE TRADE ISSUES SURROUNDING GENETICALLY MODIFIED

Furthermore, unlike the CPB and CBD, all of the primary countries producing and cultivating GMOs—"the [United States], Canada, Argentina, and Australia—are Codex members and agreed to these risk assessment guidelines" adopted by the WTO.[138]

The Codex promotes safety assessments of GM foods prior to their approval for commercial sale, provides traceability mechanisms, and encourages food labeling.[139] In addition to the Codex risk assessment requiring an "evaluation of actual hazards presented by the new [GM] foods," the guidelines expand the scope of what constitutes a valid basis for food regulation by accounting for "Other Legitimate Factors."[140] Moreover, the Codex Agreement creates guidelines for conditions that organic foods should meet at the international level and provides assistance to governments who aim to create national legislation and regulation.[141]

E. The World Trade Organization and the SPS Agreement

The WTO was in part established with the objective of

> [r]aising standards of living . . . effective demand and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment.[142]

While WTO legislation does not automatically exclude socioeconomic concerns, it applies a high threshold as the socioeconomic factors must be confirmable, transparent, and without favoritism.[143] In particular, socioeconomic concerns that arise under the WTO must meet the key requirements of "a legitimate objective, based on scientific or other evidence, not more

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FOOD 19 (2005) [hereinafter U.S. VS. E.U.], *available at* http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/Biotech_USEU1205.pdf.

138. Bereano, *supra* note 135.

139. U.S. VS. E.U., *supra* note 137, at 19.

140. Bereano, *supra* note 135.

141. FOOD & AGRIC. ORG. OF THE UNITED NATIONS & WORLD HEALTH ORG., CODEX ALIMENTARIUS: ORGANICALLY PRODUCED FOODS at iii (1st rev. 2001) [hereinafter CODEX ALIMENTARIUS], *available at* ftp://ftp.fao.org/docrep/fao/005/Y2772E/Y2772e.pdf.

142. *See* Kinderlerer, *supra* note 92, at 32.

143. *Assessing Socio-Economic Impacts of GMOs*, *supra* note 58.

trade-restrictive than necessary, and non-discriminat[ory]."[144] Thus, as a prerequisite, socioeconomic risks must be related to health or trade related risks to be covered by the WTO agreements. This therefore limits protections addressing farmer welfare and non-GM crops from regulation by the WTO.[145]

The SPS agreement—assumed by the WTO in 1994 and put into effect in 1995—[146] establishes that countries are allowed to ensure the safety of food, animal, or plant products that they import and that countries should not impose unnecessarily inflexible requirements as a means to thwart trade.[147] Cases concerning GMOs have primarily been considered in the context of the SPS Agreement.[148] The SPS Agreement focuses on containing the spread of pests, diseases, and organisms that carry or cause disease; on protecting humans and animals from risks arising out of additives, contaminants, toxins, and diseases carried by animals; and on the prevention of damage from the entry, creation, or spread of organisms.[149] The SPS Agreement incorporates standard-setting bodies—"the Codex Alimentarius Commission for food safety, the International Office of Epizootics (OIW) for animal health and the IPPC for plant health"—to ensure that countries adhere to such internationally agreed upon standards.[150]

F. The United States

The U.S. government's oversight of biotech foods and of enforcement systems to ensure compliance with such regulatory schemes is unproductive.[151] Failing to sign either the CBD or the CPB, there is minimal binding law in the United States when it comes to resolution mechanisms for alleged instances

144. *Id.*
145. *Id.*
146. SCIENTIFIC FACTS ON GENETICALLY MODIFIED CROPS, *supra* note 131, at 13.
147. *Id.*
148. *Assessing Socio-Economic Impacts of GMOs*, *supra* note 58.
149. SCIENTIFIC FACTS ON GENETICALLY MODIFIED CROPS, *supra* note 131, at 13.
150. *Food Import & Export Standards: WTO-SPS Co-ordination*, DEP'T OF AGRIC., FORESTRY & FISHERIES (DAFF), http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Food-Import-Export-Standards/WTO-SPS-Co-ordination (last visited Feb. 25, 2014) (S. Afr.).
151. *See generally* TAYLOR & TICK, *supra* note 82.

of contamination in either domestic or international judicial forums.[152] Despite efforts made by local, state, and federal authorities to pass GM-restrictive legislation,[153] the overwhelming majority of bills that have been passed at the federal level have been in support of biotechnology companies.[154] In May 2002, Representative Dennis Kucinich proposed five bills seeking to strengthen the existing regulation of agricultural biotechnology.[155] H.R. 5579 sought to provide additional protections to farmers and ranchers harmed by GM products and establish a "'Farmer's Bill of Rights' to ensure fairness for farmers and ranchers in their dealings with biotech companies that sell genetically engineered seeds, plants, or animals."[156]

Additionally, H.R. 4816 aimed to hold biotech companies liable for injuries resulting from the release of genetically engineered organisms into the environment.[157] These injuries included "crop failures suffered by farmers, cross pollination of

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152. *See* Peck, *supra* note 78, at 37.

153. *See* Strauss, *Role of Courts*, *supra* note 75, at 302; *see also* Will Allen, *Farmer Debunks Corporate Propaganda Against Proposed Law to Label Genetically Modified Food*, ORGANIC CONSUMERS ASS'N (Aug. 27, 2012), *available at* http://www.organicconsumers.org/articles/article_26160.cfm. Farmers

> have tried to pass farmer protection laws against spillage and drift of GMO seed and pollen. These laws were designed to respond to the fact that biotech companies could sue farmers for patent infringement if GMO crops inadvertently sprout up as "weeds" on their farms . . . Monsanto alone has brought 136 cases against more than 400 farmers.

Id.

154. *See* Strauss, *Role of Courts*, *supra* note 75, at 301.

155. *See id.* at 302.

156. Debra M. Strauss, *We Reap What We Sow*: *The Legal Liability Risks of Genetically Modified Food*, 16 J. LEGAL STUD. BUS. 149, 171 (2010) [hereinafter Strauss, *We Reap What We Sow*]. The bill sought to hold biotech companies liable to any party injured by the release of GMOs into the environment if the injury resulted from the genetically engineered product and sought to prevent biotech companies from waiving liability or avoiding it by contract. *Id.*; Genetically Engineered Technology Farmer Protection Act, H.R. 5579, 111 Cong. (2010). The bill would also require biotech companies to disclose "legal and environmental risks" that GMOs may pose to the consumer, prevent "non-competitive practices involving technology fees," preclude biotech companies from limiting liability for harm, and prohibit sale of "certain nonfertile plant seeds." *Id.*

157. Genetically Engineered Organism Liability Act of 2002, H.R. 4816, 107th Cong. (2002).

neighboring farms, and increased insect resistance, as well as health and environmental impacts on consumers."[158] Unfortunately, these bills were just proposals and fizzled out in subcommittees.[159] Likewise, in 2010, Representative Kucinich tried to introduce similarly restrictive biotech regulation under the Genetically Engineered Organism Liability Act.[160] The 108th Congress has taken no further steps on the bill since 2010 when it was submitted to the appropriate house committees.[161] Such enforcement and liability proposals would help to place a greater burden of responsibility on GM-crop cultivators, in turn reducing instances of GMO contamination.

In January 2011, Congress and the president enacted the Food and Drug Administration ("FDA") Food Safety Modernization Act ("FSMA").[162] This new legislation was a direct response to increasing incidents and lawsuits regarding GMO contamination.[163] The FSMA bolsters existing food regulations and creates proactive legislation by enlarging the scope of the FDA's ability to inspect plants and order recalls domestically and abroad.[164] The FSMA also allows the FDA to require food producers to develop food safety plans.[165] Nevertheless, the FSMA does not specifically address GMOs, but rather "gives the FDA the power to mandate recalls of such contaminated foods,"[166] thus lacking any preventative guidelines.

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158. Introduction of Genetically Engineered Regulatory Framework, 152 CONG. REC. E687 (daily ed. May 2, 2006); Genetically Engineered Organism Liability Act of 2002, H.R. 4816, 107th Cong. (2002); *see* Strauss, *Role of Courts*, *supra* note 75, at 302.

159. Strauss, *Role of Courts*, *supra* note 75, at 302; Strauss, *We Reap What We Sow*, *supra* note 158.

160. Genetically Engineered Organism Liability Act of 2010, H.R. 5579, 111th Cong. (2010).

161. *See* Strauss, *We Reap What We Sow, supra* note 157, at 177; Genetically Engineered Organism Liability Act of 2010, H.R. 5579, 111th Cong. (2010); TADLOCK COWAN, CONG. RESEARCH SERV., RL32809, AGRICULTURAL BIOTECHNOLOGY: BACKGROUND AND RECENT ISSUES (2010).

162. *See* Strauss, *Food Safety Mandate*, *supra* note 6, at 2.

163. *Id*. at 18.

164. *Id*.

165. *Id*. at 18–19.

166. Lisa Sorg, *Why You Should Care about the Food Safety Modernization Act*, INDY WEEK (Jan. 12, 2011), www.indyweek.com/indyweek/why-you-should-care-about-food-safety-modernization-act/Content?oid=1950088; Kimberly Hartke, *FSMA: Will "Food Safety" Undermine Food Security?*, FARM-TO-

III. GAPS IN EXISTING LAWS GOVERNING GMOS

The ability of nations to effectively monitor and enforce compliance with biosafety laws and regulations is essential to the efficacy of international agreements and regulations governing GMOs.[167] GMOs threaten a nation's sovereignty and safety, as they are able to infiltrate food and crop production chains.[168] Because these agreements were crafted at different times—by delegations from varying governments—they possess diverse goals pertaining to trade, environment, food, agriculture, health, and politics.[169] Insufficient regulation of GM cultivation threatens existing biodiversity as it presents the potential for increased instances of contamination of non-GM crops.[170]

A. Enforcement Issues

Existing bodies of law that regulate GMOs lack the ability to effectively enforce safety measures. While issues such as "coexistence, labeling, identity preservation and traceability" are recognized and regulated under the CBD,[171] GM cultivation has largely been left unregulated despite its ability to heavily contribute to instances of contamination. The CBD sets out commitments of the contracting parties; yet, these parties are free to determine their own mechanisms of enforcement and legislation.[172]

CONSUMER LEGAL DEF. FUND (Aug. 27, 2013), http://www.farmtoconsumer.org/news_wp/?p=12288.

167. *See* Lin, *supra* note 2.

168. *Id.*

169. *See generally* Bereano, *supra* note 135.

170. Laura Moore Smith, *Divided We Fall: The Shortcomings of the European Union's Proposal for Independent Member States to Regulate the Cultivation of Genetically Modified Organisms*, 33. U. PA. J. INT'L. 841, 842, 848 (2012); *see also* Comm. on the Env't, Pub. Health & Food Safety, *Report on the Proposal for a Regulation of the European Parliament and of the Council Amending Directive 2001/18/EC as Regards the Possibility for the Member States to Restrict or Prohibit the Cultivation of GMOs in Their Territory*, at 16, COM (2010) 0375 (Apr. 20, 2011), *available at* http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&reference=A7-2011-0170&language=EN&mode+XML#_part1_def2. (Apr. 20, 2011) (by Corinne LePage).

171. *See* SUMAN SAHAI, CAN GM AND NON-GM CROPS BE SEGREGATED IN INDIA—IS COEXISTENCE POSSIBLE? 2, *available at* http://www.cbd.int/doc/external/cop-09/gc-coexist-en.pdf (last visited Feb. 25, 2014).

172. Boisson de Chazournes, *supra* note 100.

The CBD takes strides toward establishing more stringent GM regulation by committing members to identify activities that may negatively affect conservation and sustainability and to regulate or manage such activities.[173] However, these provisions are not binding and are thus unenforceable, except by the sovereign contracting party.[174] Furthermore, by focusing on process-oriented measures and by relying on the willingness of parties to comply and cooperate with the underlying objectives, the CBD lacks specific remedies for redressability.[175]

Similarly, the Codex guidelines are voluntary—and thus do not have a binding effect on national legislation.[176] While major GMO-producing countries are members to the Codex Agreement, the existing recommendations have minimal influence over enforcement and compliance measures.[177] Except for defining the term "organic," the Codex Agreement fails to adequately regulate the cultivation of GMOs except for noting that GMOs are "not compatible with the principles of organic production (either the growing, manufacturing, or processing) . . ."[178]

Under the IPPC, nations are required to implement regulatory schemes to oversee and control biosecurity for food and agriculture and adhere to international frameworks and guidelines.[179] This legally binding international agreement has been recognized by the WTO, which "identifies the IPPC as the reference organization developing international standards for plant health (phytosanitary) measures."[180] Nevertheless, the WTO does not directly govern GMOs and does not seek to regu-

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173. *Id.*
174. *Id.*
175. *Id.*
176. *See 20 Questions on Genetically Modified Foods*, *supra* note 10.
177. *See id.*
178. Codex Alimentarius Comm'n, *Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods*, GL 32-1999 (as amended 2013*)*, *available at* http://www.ncarboretum.org/assets/File/PDFs/Research/cxg_032e.pdf.
179. *See* Opi Outhwaite, *The International Legal Framework for Biosecurity and the Challenges Ahead*, 19 REV. EUROPEAN COMMUNITY & INT'L ENVTL. L. 207, 215 (2010).
180. *The WTO and the International Plant Protection Convention (IPPC)*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/coher_e/wto_ippc_e.htm (last visited Oct. 13, 2013).

late cultivation mechanisms. Although the preamble to the Agreement that establishes the WTO asserts a commitment to the social and environmental goals of states,[181] the WTO has been criticized as being environmentally insensitive and solely reliant on principles of the free market.[182]

B. Compliance Issues

One major challenge to the global success of GMO regulation is the compliance issues raised by domestic and international trends of a given country. Neither the CBD, IPPC, nor the Protocol provide for dispute resolution mechanisms regarding GMOs.[183] Moreover, the existing bodies of law that govern GMOs have been largely ineffective as states are unwilling to prosecute such offenses, and even if lawsuits are brought, courts are likely to be moderate in their sentencing policies.[184] Likewise, countries that have built up infrastructure to support GMO production and technology will be less willing to comply with laws that impose burdensome regulations and costly penalties for violations of such laws.

As other international environmental regulatory schemes demonstrate, there has been greater success in the implementation of environmental laws when a managerial approach has been adopted[185]that facilitates a focus on the "effectiveness in altering environmentally unsustainable behavior."[186] The failure of major GMO distributors and growers—such as the Unit-

181. Marrakesh Agreement Establishing the World Trade Organization pmbl., Apr. 15, 1994, 1868 U.N.T.S. 201.

182. *See* Blaustein, *supra* note 5, at 367, 377; *see* also Paulette L. Stenzel, *Why and How the World Trade Organization Must Promote Environmental Protection*, 13 DUKE ENVTL. L. & POL'Y F. 1 (2002).

183. *See* Blaustein, *supra* note 5, at 367, 381.

184. *See generally* CRYILLE DE KLEMM & CLAIRE SHINE, IUCN—WORLD CONSERVATION UNION, BIOLOGICAL DIVERSITY CONSERVATION AND THE LAW: LEGAL MECHANISMS FOR CONSERVING SPECIES AND ECOSYSTEMS (1993), *available at* http://data.iucn.org/dbtw-wpd/edocs/EPLP-029.pdf.

185. *See* DONALD M. GOLDBERG, GLENN WISER, STEPHEN J. PORTER & NUNO LACASTA, CIEL & EURONATURA, BUILDING A COMPLIANCE REGIME UNDER THE KYOTO PROTOCOL 2, *available at* http://ciel.org/Publications/buildingacomplianceregimeunderKP.pdf (last visited Jan. 17, 2014). The managerial approach has been a key point of the success of many international agreements such as the Montreal Protocol. Montreal Protocol on Substances That Deplete the Ozone Layer, 16 Sept. 1987, 1522 U.N.T.S. 3, 27 I.L.M. 1550.

186. GOLDBERG ET AL., *supra* note 185.

ed States and Australia—to comply with international standards of GMO regulation thwarts efforts by all countries to diminish instances of contamination and protect non-organic crops.

Various regulatory schemes govern GMOs, yet their effectiveness is frustrated by the lack of participation by some of the largest producers and cultivators of GM products.[187] Although the CPB is legally binding on member states,[188] its success is questionable because the United States, Canada, and Australia—major players in the GM market[189]—have not signed or ratified the CPB.[190] The United States takes issue specifically with the Protocol's relation to the WTO rules and the Protocol's application of the PP, as it allows for decisions that ban imports and require labeling. Because the major GMO-producing nations refuse to adhere to the Protocol, the CPB does not create an operative monitoring system,[191] which hinders its overall objective.

Just as the global regulation of GMOs is fragmented and futile, there is no single statute or federal agency in the United States that governs the regulation of biotechnology.[192] The weakness of monitoring and enforcement systems in the United States makes it difficult to detect health and environmental dangers, hindering both compliance with and the development of a global approach to addressing GMOs.[193] As demonstrated by the StarLink scandal, the regulation of GMOs in the United States falls short of acceptable standards.[194] The United States is one of the largest promoters of biotechnology in the world, yet it has been unable to successfully control GMOs domestically while aggressively promoting their use worldwide.[195] Just

187. *See generally* WHITMAN, *supra* note 48.

188. *20 Questions on Genetically Modified Foods*, *supra* note 10.

189. *See* Gonzalez, *supra* note 36, at 603–04; *Glossary*, GMO-FREE EUROPE, *supra* note 4.

190. *Glossary*, GMO-FREE EUROPE, *supra* note 4.

191. *See* Gonzalez, *supra* note 36, at 601.

192. ANDREW C. FISH & LARISA RUDENKO, PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, GUIDE TO U.S. REGULATION OF GENETICALLY MODIFIED FOOD AND AGRICULTURAL BIOTECHNOLOGY PRODUCTS 2 (Feb. 2007), *available at* http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/hhs_biotech_0901.pdf.

193. TAYLOR & TICK, *supra* note 82, at 7.

194. *See* VILLAR, *supra* note 2, at 11.

195. *Id.* at 9.

five companies—notably Monsanto, Novartis, and Pioneer Hybrid International—grow GM-maize alone on roughly ten to twenty million acres of land across the United States.[196]

In the United States, three separate government agencies regulate GM foods: the Environmental Protection Agency ("EPA"), which assesses GM plant safety in relation to the environment; the USDA, which focuses on whether a plant is safe to produce; and the FDA, which evaluates the safety of a plant for human consumption.[197] The decentralized and fragmented regulatory framework between the USDA, EPA, and FDA results in oversight of GMOs "from the issuance of permits through regulating what products ultimately reach store shelves."[198]

IV. A MULTILATERAL TREATY REGULATING GMO CULTIVATION

Over the years, there has been a push by many nations for the implementation of a comprehensive regulatory system to govern the advent of biotechnology.[199] As individuals began to express concern over the risks associated with GMOs, countries began to contemplate the political and socioeconomic repercussions involved with genetic engineering.[200] As the previously discussed Seralini study and the StarLink case illustrate, one nation's ability to regulate and enforce compliance with GMO biosafety laws is fundamental to the security and sovereignty of all nations.[201]

Despite numerous laws, rules, and procedures governing and monitoring GMOs, countries are still falling short of successfully controlling the spread of GMOs.[202] As Juan Villar, consultant

196. Dixon, *supra* note 91; *see* Kaplan, *supra* note 60, at 5, 15.

197. *See* WHITMAN, *supra* note 48.

198. *See* Strauss, *Food Safety Mandate*, *supra* note 6, at 3; Blake Denton, Comment, *Regulating and Regulators: The Increased Role for the Federal Judiciary in Monitoring the Debate over Genetically Modified Crops*, 25 U.C.L.A. J. ENVTL. L. & POL'Y 333, 355 (2007); *cf.* Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61, 65 (2000) (quoting a National Academy of Sciences committee recommendation that "Congress should establish a unified and central framework for managing federal food safety programs headed by a single organization").

199. *Id.*

200. *Id.*

201. *Id.*

202. *See* VILLAR, *supra* note 2, at 9.

and negotiator for various national and international environmental treaties and organizations, notes:

> Legal frameworks were supposed to be adequate to ensure that GMOs wouldn't endanger the environment or human health. Biotech companies were supposed to comply with those frameworks. Regulatory bodies were supposed to monitor and oversee GMO releases to ensure they were complying with the legal frameworks. But the reality shows a completely different picture.[203]

When a GMO is released, it causes unpredictable effects on the environment, existing biodiversity, and human health.[204] The common occurrence of non-GM crop contamination and the presence of unauthorized GMOs in other nations illustrate the shortcomings of the current regulatory frameworks.[205]

The legal debate surrounding the use and trade of GMOs is unique as GMOs "are part of complex social, political, and scientific networks that connect the biotech industry with national and international laws, markets, and dietary practices."[206] The multifaceted nature of both the regulation of GMOs and private and public compliance with such laws has proved to be burdensome and costly.[207] Furthermore, decision making at the international level is often subject to "power asymmetries, resource imbalances, collective action problems, and general citizen disinterest" affecting the level of member participation and support.[208] The difficulty of decision making at the international level contributes to the hesitation surrounding implementing regulations. For example, "if governments pay too much attention to food safety to the point of overkill, GMO-dependent economies will suffer."[209] Alternatively, "if governments are too

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203. *Id.*

204. *Id.* at 19.

205. *Id.*

206. *See* Kaplan, *supra* note 60, at 7.

207. Jessica Bayer, George Norton & Jose Falck-Zepeda, *Cost of Compliance with Biotechnology Regulation in the Philippines: Implications for Developing Countries*, 13 J. AGROBIOTECHNOLOGY MGMT. & ECON. 53, 53–62 (2010).

208. *See* Gregory Shaffer, *A Structural Theory of WTO Dispute Settlement: Why Institutional Choice Lies at the Center of the GMO Case*, 41 N.Y.U. J. INT'L L. & POL. 1, 56 (2008).

209. Smits & Zaboroski, *supra* note 1, at 116.

lax, potential damage may be significant or even irreversible."[210]

The coexistence of GMO and GMO-free products is not an issue that can be left to consumer interests and the market alone. Rather, it requires some form of organization, if not government regulation.[211] While current protocols and conventions regulate GMOs on an expansive plane—including, but not limited to, labeling requirements, purity thresholds, and trade authorizations—the existing regulations fail to address the actual cultivation of GM crops.[212] Regulating the initial and final stages of the GMO process is not enough to prevent cases of GMO contamination, as the process of cultivation itself has been left largely unregulated.[213] Therefore, the implementation of more stringent requirements for the cultivation of GM crops will allow for a better chance of coexistence by instilling in consumers and farmers alike the autonomy to choose what to consume and grow.[214]

The system of GMO regulation as it currently exists responds to issues as they arise.[215] While it has become an accepted assumption that the presence of GMOs to some extent is unavoidable in certain crops, international frameworks have set the bar low for enforcing policies that cut down on instances of contamination.[216] One country that has been successful in implementing a system of GM regulation that can serve as a model for other countries is the Netherlands.[217] Coexistence "refers to the choice of consumers and farmers between conventional, organic and GM crop production."[218] As the first country in the European Union to develop coexistence standards with

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210. *See id.*

211. *See generally* Maria Lee, *The Governance of Coexistence Between GMOs and Other Forms of Agriculture: A Purely Economic Issue?*, 20 J. ENVTL. L. 193 (2008).

212. John Davidson, *GM Plants: Science, Politics, and EC Regulations*, 178 PLANT SCI. 94, 94–98 (2010).

213. *Id.*

214. Vigani, Raimondi & Olper, *supra* note 133, at 12.

215. *See* TAYLOR & TICK, *supra* note 82, at 49.

216. *Id.*

217. *See generally Coexistence in the Netherlands*, *supra* note 30.

218. *Coexistence of Genetically Modified Crops with Conventional and Organic Agriculture*, AGRIC. & RURAL DEV., EUROPEAN COMM'N, http://ec.europa.eu/agriculture/gmo/coexistence/index_en.htm (last visited Sept. 13, 2013); Jans, *supra* note 23.

"consensus from all stakeholders," powerful agricultural organizations[219] were able to reach an agreement on practical measures for enabling coexistence "between farmers—both conventional and organic—seed producers, and chain organizations involved in Dutch agriculture."[220] It is vital to implement regulations that incorporate biotechnological advancements, yet also focus on environmentally friendly laws.[221] Unlike other countries, the Netherlands does not reject the use of GMOs but rather seeks to uphold consumer interests regarding consumption of GM crops.[222]

The Netherlands government's regulation of GMOs imposes guidelines on growers and users and is designed to "keep adventitious mixing of GM and conventional agricultural products to an absolute minimum," reducing instances of contamination from the outset and promoting coexistence.[223] The regulatory approach of GMOs in the Netherlands focuses on notifi-

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219. *The Netherlands: Coexistence with Consensus*, GMO COMPASS (Dec. 21, 2006), http://www.gmo-compass.org/eng/regulation/coexistence/135.netherlands_coexistence_consensus.html.

> The LTO, a Dutch agricultural organization, as well as Biologica, the umbrella organisation for organic agriculture, came together to establish an agreement on coexistence. The group was joined by the Platnum NL association of plant breeders and (ABC) Platform Earth Farmer Consumer, making what became known as the "VanDijk Committee," named after the chairperson of the group. The Committee presented a report called "Coexistance in Primary Production" to the Dutch minister of agriculture.

Id.

220. Jans, *supra* note 23.

221. *See, e.g.*, George Kidd, *Juggling GMOs: Balancing Benefits, Risks, & Unknowns*, MINN. J.L. SCI. & TECH. LAWSCI BLOG (Oct. 26, 2012, 12:31 PM), http://blog.lib.umn.edu/mjlst/mjlst/2012/10/juggling-gmos-how-to-balance-a-natural-sensation-with-an-inevitable-catastrophe.html (discussing the balancing act between competition of GMO production and the need to make effective and safe food for human consumption); PEACEFUL COEXISTENCE AMONG GROWERS OF: GENETICALLY ENGINEERED, CONVENTIONAL, AND ORGANIC CROPS, PEW INITIATIVE ON FOOD & BIOTECHNOLOGY (2006) [hereinafter PEACEFUL COEXISTENCE].

222. PEACEFUL COEXISTENCE, *supra* note 221.

223. SUSANNE SLEENHOFF & PATRICIA OSSEWEIJER, THE NETHERLANDS 11–3, https://www.kcl.ac.uk/medicine/research/divisions/dns/projects/consumerchoice/downloadfiles/Chapter11.pdf (last visited Feb. 25, 2014).

cation procedures, compliance with prescribed guidelines, minimum separation distances between GM and non-GM crops, and a liability fund for economic losses resulting from contamination.[224]

A grower must obtain authorization prior to the government permitting it to grow GM crops.[225] Additionally, growers must report to a centralized national register so that neighboring farmers "can be made aware in advance" of the presence of GM crops.[226] The requirement to receive authorization to grow GM crops and to subsequently notify neighboring landowners of one's intent to cultivate GMOs promotes coexistence and creates a centralized body to handle the approval of the release of GMOs.[227]

The Netherlands' regulation of GMOs also requires compliance with prescribed codes of practice designed to avoid the mixing of GM and GM-free crops.[228] Humans play a major role in GMO cultivation, chiefly through their role in seed production, which exacerbates instances of contamination by the inadvertent mixing of GM and non-GM seeds when crops are planted, harvested, and traded.[229] At both large- and small-scale levels of production and grain distribution, human actions—such as the commingling of crops in storage spaces, grain elevators, and trucks, and the growing practices themselves—are a focal point for factors that contribute to contamination.[230] Requiring farmers to take steps to minimize contamination by "thoroughly cleaning machinery, maintaining separation distances, and implementing segregated storage and transport"[231] establishes preventative measures.

Precautionary efforts to separate GM crops from non-GM crops and create barriers between them would reduce instances of contamination, particularly when dealing with high-volume bulk handling systems. Regulation in the Netherlands has set minimum separation distances for different crops such as pota-

224. *Coexistence in the Netherlands*, *supra* note 30.
225. *Id.*
226. *The Netherlands: Coexistence with Consensus*, *supra* note 60.
227. *See id.*
228. *Id.*
229. *See id.*
230. *Id.*
231. *Id.*

toes, sugar beet, and maize.[232] Naturally, the cost of segregating GM grain is a source of concern, as it would likely require expensive equipment and facilities to ensure that comingling is prevented.[233] Nevertheless, such costs to maintain organic crops are vital in the face of the uncertainties that GMO consumption poses, and by preventing comingling of crops at the outset of production, instances of contamination will be more effectively reduced.[234]

Violating coexistence measures can expose an individual to liability under Dutch civil law as failure to adhere to such requirements is a criminal offense that can subject a grower to a maximum penalty of imprisonment and fines of up to €45,000.[235] The Netherlands defines economic loss to farmers as "any loss in the value of product compared to what it would have brought in if it had not contained GM material."[236] While redressability does not directly thwart instances of contamination, it provides incentives for farmers who use GM crops to ensure that their crops do not contaminate organic crops. Furthermore, organic growers are able to protect themselves from lost earnings and tarnished reputations.[237] Likewise, conventional farmers may also seek damages if the crops they are trying to market breach the threshold level of GM presence set in the country and consequently require the product to be labeled as containing GM ingredients.[238]

The system in the Netherlands goes further than most other countries by providing farmers with civil liability claims for the contamination of crops, such as economic damage, tarnished

232. *Id.* "For GM fields adjacent to conventional fields, the separation distances are 3 metres for potatoes, 1.5 metres for sugar beet, and 25 metres for maize. If the GM field is adjacent to a field with a certified GM-free crop . . . the minimum separation distances increase." *Id.*

233. *Id.*

234. *See* Strauss, *Food Safety Mandate*, *supra* note 6, at 2; Lilliston, *supra* note 73. Costs associated with maintaining organic crops include buffer zones, cleaning equipment, inspections of crops and processing facilities, and frequent testing. Seed testing alone can cost on average around ten dollars a bag, which can add up for the total crop yield. *Id.*

235. Jans, *supra* note 23.

236. PEACEFUL COEXISTENCE, *supra* note 221.

237. *See* Jans, *supra* note 23.

238. *Id.*

reputation, and anxiety.[239] Additionally, the government created a fund of money for contamination claims, as well as an independent arbitration body to settle disputes and oversee the fund.[240] Damages are limited to economic loss resulting from contamination that is above legal threshold limits.[241] This acknowledges the fact that small traces of GMOs in crops are expected, while also protecting those farmers whose crops have been contaminated by GM crops. In addition, a farmer who adheres to GMO regulations, yet is still faced with liability due to inadvertent contamination of GMO seed with organic crop, is covered by a public fund created to compensate the injured party for the loss in situations where compliance with the guidelines is shown.[242] The Netherlands's requirement that those who use or market GMOs or biotechnology must provide funding for the public pool that covers liability caused by GMO contamination places the burden of costs where it should be.

Higher standards of liability for farmers and manufacturers for instances of contamination will create accountability and ensure cooperation amongst parties involved with GMO use.[243] Companies that cultivate and trade GMO products on the global market should be held responsible for damages arising out of GMO contamination. In addition, individual countries should establish a liability fund similar to that of the Netherlands, whereby domestic growers of GMOs contribute to a liability fund from which reparation can be paid for financial losses caused by contamination.[244]

It is important that the international community address particular enforcement concerns, such as oversight of the inspection of facilities that handle GM crops, and the import and

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239. *See* Melissa Concada Castillo & Willem H. van Boom, *Netherlands*, *in* EUROPEAN CTR. OF TORT & INS. LAW, LIABILITY AND COMPENSATION SCHEMES FOR DAMAGE RESULTING FROM THE PRESENCE OF GENETICALLY MODIFIED ORGANISMS IN NON-GM CROPS annex I, 306, at 311–12 (Bernhard A. Koch ed., 2007).

240. *Id.*

241. PEACEFUL COEXISTENCE, *supra* note 221.

242. *Coexistence in the Netherlands*, *supra* note 30.

243. *See* JIM RIDDLE, SW. RESEARCH & OUTREACH CTR., UNIV. OF MINN., GMO CONTAMINATION PREVENTION: WHAT DOES IT TAKE? (2012), *available at* swroc.cfans.umn.edu/prod/groups/cfans/@pub/@cfans/@swroc/documents/article/cfans_article_390283.pdf.

244. *Netherlands: Coexistence Rules—Consensus*, *supra* note 22.

export of GM materials.[245] It is highly unlikely that the human eye could detect genetically modified organisms, therefore, it is important that permit holders must have a certain skill level in order to facilitate proper inspections of GMOs.[246] Moreover, each country faces unique risks associated with GMOs and their threat to the environment and human health, making legislative enforceability complex.[247] Therefore, it would be pertinent to require individuals with extensive skill and experience to handle and oversee GMO use and cultivation.[248]

CONCLUSION

The future state of the environment and our health is to some extent unpredictable. However, there are measures that can be taken to mitigate certain risks, such as the hazards that GMOs present. This Note contends that creating a multilateral treaty to address and regulate cultivation of GM crops will aid in the prevention of contamination. The current regulatory scheme governing GM crop cultivation is fragmented and ineffective, leading to increased instances of contamination with few means available to seek an adequate remedy. Cultivation is a crucial step of the GM crop production process, and the international community's failure to properly oversee and regulate this method has left many nations powerless in determining the admissibility of GMOs in their territories. A GMO-specific body of law, which embraces biotechnological advancements but focuses on the safety of the environment, will best serve the international community by setting guidelines for cultivation methods of GM crops and offering a form of relief from instances of contamination.

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245. *See generally* CODEX ALIMENTARIUS, *supra* note 141, at iii–iv.
246. *Id.* at 9.
247. *See generally id* at 5.
248. *See generally id*.

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