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GENETICALLY MODIFIED CROP REGULATION:
THE FRAYING OF AMERICA'S PATCHWORK
FARM LANDS

I. INTRODUCTION

Proponents and critics of genetically modified (GM) crops have vigorously debated the risks and benefits of genetic modification since their creation.¹ GM crop proponents argue such crops are necessary to meet the food production demands of an ever-increasing population.² Proponents also frequently stress that no evidence exists to support the theory that GM crops are harmful.³ GM crop opponents argue that a lack of independent and long-term safety testing may provide an explanation why there is no evidence regarding the harmfulness of GM crops.⁴ Opponents also highlight environmental safety issues, such as increased reliance on pesticides and biological pollution as reasons for eliminating GM crops.⁵

These conflicting views have led to debates regarding the role government should have in regulating GM crops.⁶ The government has the difficult task of regulating GM crops to maximize their benefits and minimize their risks.⁷ If the government overregulates GM crops, frivolous costs could be imposed on GM crop developers, resulting in a disparity between food production and global population.⁸ If government regulations are inadequate, however, the world's ecosystems may suffer irreparable harm.⁹

1. See Renee Cho, *The Intensifying Debate Over Genetically Modified Foods*, STATE OF THE PLANET (July 30, 2013, 2:21 PM), <http://blogs.ei.columbia.edu/2013/07/30/the-intensifying-debate-over-genetically-modified-foods/> (discussing topics debated by GM crop proponents and critics).

2. *Id.* (providing GM crop proponents' viewpoint that GM crops higher yield will help feed growing global population).

3. *Id.* (noting GM crop proponents' assertions there is no scientific evidence of harm caused by GM crops).

4. *Id.* (stating GM crop opponents' viewpoint there are not enough independent or long-term safety studies on GM crops).

5. *Id.* (listing GM crop opponents' concerns regarding GM crop environmental safety).

6. Rebecca Bratspies, *The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops*, 10 N.Y.U. ENVTL. L.J. 297, 299 (2002) (proposing GM crop debate has created regulatory issues).

7. *Id.* (summarizing GM crop regulators' challenge in regulating).

8. *Id.* (stating potential consequence of stringent government regulation of GM crops).

9. *Id.* (stating potential consequence of lenient GM crop regulation).

This Comment discusses GM crops and how they are regulated, both domestically and internationally.¹⁰ Part II provides a background of GM crops in the United States and details their effects on the environment.¹¹ Part III explains the current legal framework surrounding GM crops in the United States at the federal and municipal levels.¹² Part IV highlights the international regulation of GM crops in Canada, Mexico, and the European Union (E.U.).¹³ Finally, Part V concludes with a comparison of domestic and international GM crop regulation and provides suggestions for improving regulation in the United States.¹⁴

II. GENETICALLY MODIFIED CROPS: A BRIEF BACKGROUND

A. The Creation of GM Crops

Scientists first commercialized GM crops in the United States in May 1994, when the company Calgene introduced FLAVR SAVR tomatoes to grocery stores nationwide.¹⁵ The GM crop industry has expanded rapidly ever since, and its supporters tout GM crops as a means to end world hunger and save the environment.¹⁶ The United States, Brazil, Argentina, Canada, and India are cumulatively responsible for over eighty-eight percent of GM crops planted worldwide.¹⁷ GM crops, however, have not lived up to their cre-

10. For a discussion of GM crops and their regulation, see *infra* notes 15-191 and accompanying text.

11. For a discussion of the background of GM crops and their environmental impacts, see *infra* notes 15-53 and accompanying text.

12. For a discussion of the current U.S. legal framework surrounding GM crops, see *infra* notes 54-128 and accompanying text.

13. For a discussion of GM crop regulation in Canada, Mexico, and the E.U., see *infra* notes 129-177 and accompanying text.

14. For a discussion of the similarities and differences between domestic and international GM crop regulation and possible improvements to U.S. regulation, see *infra* notes 178-191 and accompanying text.

15. Olivia Katrandjian, *Retro Report: The Test Tube Tomato*, HUFFINGTON POST (Aug. 24, 2013, 5:12 AM), http://www.huffingtonpost.com/olivia-katrandjian/retro-report-the-test-tube_b_3492318.html (discussing first attempt at commercialized GM crops in United States). The FLAVR SAVR tomatoes have since disappeared from grocery stores and the GM crop industry focused on engineering traits that benefit farmers instead of consumers. *Id.*

16. CLIVE JAMES & ANATOLE F. KRATTIGER, INT'L SERV. FOR ACQUISITION AGRIBIOTECH APPLICATIONS, GLOBAL REVIEW OF THE FIELD TESTING AND COMMERCIALIZATION OF TRANSGENIC PLANTS: 1986 TO 1995 26-30 (1996), available at <http://www.isaaa.org/kc/Publications/pdfs/isaaabriefs/Briefs%201.pdf> (providing perspective on potential global benefits of GM crops).

17. *GM Crops: A story in numbers*, NATURE 22-23 (last corrected May 16, 2013), http://www.nature.com/polopoly_fs/1.12893!/menu/main/topColumns/topLeftColumn/pdf/497220a.pdf (listing top five countries producing GM crops).

ators' expectations and have incited quite a bit of controversy over the last few decades.¹⁸

In the twenty years since FLAVR SAVR's commercialization, four major GM crops have emerged: soybeans, cotton, corn, and canola.¹⁹ The process of turning conventional crops into GM crops involves several steps. First, scientists must identify the trait they wish to incorporate into a crop and determine what other organisms have that trait in their genomes.²⁰ Next, scientists cut the gene out of the organism that naturally produces it and insert the gene into a "vector."²¹ Vectors are "short piece[s] of DNA capable of replicating on [their] own when inside a bacterial cell."²² Scientists then insert the modified vector into a bacterium, such as *Agrobacterium tumefaciens*, which is capable of causing disease in plants.²³ Scientists rely on the bacteria's ability to inject its own genes into the plant genome as a means of inserting the desired trait into the plant.²⁴

Scientists have engineered GM crops with a wide variety of traits, most of which attempt to enrich crop nutrients or increase crop yield.²⁵ While scientists have engineered approximately thirty different traits into commercial plants, herbicide and insect resis-

18. See Bryan Walsh, *Modifying the Endless Debate Over Genetically Modified Crops*, TIME (May 14, 2013), <http://science.time.com/2013/05/14/modifying-the-endless-genetically-modified-crop-debate/> (addressing ongoing divisive debate between advocates and opponents of GM crops).

19. See *GM Crops*, *supra* note 17, at 22-23 (highlighting GM crop industry statistics from 2012).

20. Rebecca Boyle, *How To Genetically Modify a Seed, Step By Step*, POPULAR SCI. (Jan. 24, 2011, 1:59 PM), <http://www.popsci.com/science/article/2011-01/life-cycle-genetically-modified-seed> (reporting on process Monsanto uses to create GM crops).

21. *How Are GMOs Made?*, HUDSONALPHA INST. FOR BIOTECHNOLOGY, <http://archive.hudsonalpha.org/education/kits/gmod/gmos-made> (last visited Jan. 24, 2014) (explaining process of gene transfer in GM crops).

22. *Engineer a Crop: Transgenic Manipulation*, WHY?, <http://www.pbs.org/wgbh/harvest/engineer/transgen.html> (last visited Jan. 24, 2014) (instructing how GM crops are created via interactive tutorial).

23. Boyle, *supra* note 20 (describing how genetic traits are inserted into plants using bacteria).

24. *Id.* (explaining how scientists manipulate process of bacterial infection to transfer genes to plants).

25. *GM Crop Database*, CTR. FOR ENVIR. ASSESSMENT (CERA) (last updated 2012), http://www.cera-gmc.org/?action=gm_crop_database (cataloging developed GM crops and their traits).

148 VILLANOVA ENVIRONMENTAL LAW JOURNAL [Vol. XXVI: p. 145

tance are the most popular.²⁶ Other examples of commonly engineered traits include resistance to drought and delayed ripening.²⁷

B. Effects of GM Crops on the Environment

Proponents and critics have hotly debated the widespread use of GM crops since their invention over three decades ago.²⁸ GM crop proponents claim that GM crops benefit the environment through reduced use of herbicides and decreased greenhouse gas emissions.²⁹ In support of this theory, researchers have documented a significant decrease in the Environmental Impact Quotient (EIQ) associated with herbicide and pesticide use on GM crops.³⁰ Pesticide resistant GM crops' environmental profile also improved compared to conventional crops, even in countries where the average volume of pesticides increased.³¹ Researchers attributed this improvement to the "usage of more environmentally benign herbicides."³² The increasing number of farmers using pesticide-resistant GM crops also contributes to a reduction in greenhouse gas emissions in two ways.³³

First, GM crop cultivators make less pesticide "spray runs" than conventional cultivators resulting in less fuel consumption.³⁴ Many GM crop cultivators have also adopted farming methods that reduce or eliminate the need for tilling, as opposed to conventional

26. *GM Crops*, *supra* note 17, at 22-23 (noting most popular traits in commercial GM crops).

27. *GM Crop Database*, *supra* note 25 (listing possible genetic modifications in GM crops).

28. Walsh, *supra* note 18 (discussing debate surrounding GM crops).

29. Graham Brookes & Peter Barfoot, *Key environmental impacts of globally modified crop use 1996-2011*, 4 *GM CROPS & FOOD: BIOTECHNOLOGY AGRIC. & FOOD CHAIN* 109 (Apr. 2013), available at <https://www.landesbioscience.com/journals/gmcrops/2013GMC0002R.pdf> (assessing environmental impacts of GM crops).

30. *Id.* at 114 (describing research findings that GM crops reduce negative environmental effects of farming). The EIQ value is a measurement that a number of researchers are using to more accurately quantify the environmental impacts of pesticides. *Id.* at 116-17. The EIQ yields a more accurate look at the environmental impacts of pesticides than simply looking to changes in volume because the measurement examines factors such as "key toxicity and environmental exposure data related to individual products, as applicable to impacts on farm workers, consumers[,] and ecology." *Id.* at 117.

31. *Id.* at 110 (noting improved environmental profile even when average volume of pesticide increased).

32. *Id.* (noting reason for improved environmental profile).

33. *Id.* at 114 (providing study results that conclude GM crops reduce greenhouse gas emissions).

34. Brookes & Barfoot, *supra* note 29, at 114 (describing fuel savings associated with GM crops).

cultivators, which further reduces fuel consumption.³⁵ Researchers estimate that the total amount of fuel savings attributable to GM crop cultivators between 1996 and 2011 is equivalent to removing 6.5 million cars from the road for one year.³⁶ Second, with a great number of cultivators reducing or eliminating tilling from their farming practices, more carbon is being sequestered in the soil rather than entering the atmosphere.³⁷ In 2011 alone, Northern and Southern American GM crop cultivators utilizing reduced or no tilling farming practices sequestered enough soil carbon that equated to taking 9.4 million cars off the road for one year.³⁸

While some research shows that GM crops may benefit the environment, critics are concerned with the negative impact GM crops have on the environment.³⁹ The most documented environmental issue surrounding GM crops is the rise of “superweeds,” or weeds that have become resistant to herbicides.⁴⁰ Superweeds develop when GM crops transfer herbicide-resistant traits to a weed species, which produces an herbicide-resistant weed.⁴¹ GM crop cultivators typically use three farming practices that “have accelerated resistance problems.”⁴² The first of the three practices is known as monoculture and refers to “growing large swaths of the same crop in the same place year after year.”⁴³ The second practice is the tendency of GM crop cultivators to rely solely on the pesticide

35. *Id.* (comparing fuel savings of reduced tilling with GM crops over conventional crops). GM crops facilitate reduced tilling or no tilling farming practices because pesticide-resistant crop fields reduce the need for “soil cultivation and seed-bed preparation” in order to gain sufficient levels of weed control. *Id.*

36. *Id.* (estimating amount of fuel savings associated with GM crops in terms of cars).

37. *Id.* (describing how greenhouse gas emissions are reduced through reduced tilling or no tilling farming practices associated with GM crops).

38. *Id.* (estimating reduction of greenhouse gas emissions associated with GM crops in terms of cars).

39. *Genetic Engineering in Agriculture*, UNION OF CONCERNED SCIENTISTS, <http://www.ucsusa.org/our-work/food-agriculture/our-failing-food-system/genetic-engineering-agriculture#.VERrrUv4v0s> (last visited Oct. 19, 2014) (expressing concerns regarding harmful GM crop impacts).

40. *GE Food & the Environment*, CENTER FOR FOOD SAFETY, <http://www.centerforfoodsafety.org/issues/311/ge-foods/ge-food-and-the-environment> (last visited Jan. 23, 2014) (discussing role of “superweeds”).

41. *Id.* (providing information on environmental problem posed by “superweeds”).

42. *The Rise of Superweeds – and What to Do About It*, UNION OF CONCERNED SCIENTISTS, (Dec. 2013) (referring to Mortensen, et.al., 2012. *BIOSCIENCE* 6(1): 75-84.), http://www.ucsusa.org/assets/documents/food_and_agriculture/rise-of-superweeds.pdf (highlighting practices that have led to pesticide-resistant weeds).

43. *Id.* (describing monoculture and its role in creating superweeds).

150 VILLANOVA ENVIRONMENTAL LAW JOURNAL [Vol. XXVI: p. 145

glyphosate to manage weed populations.⁴⁴ Third, farmers have abandoned other conventional nonchemical means of controlling weed populations, such as crop rotation and conservation tilling, in favor of spraying glyphosate on GM crop fields.⁴⁵

There are “[a]t least [ten] weed species in [twenty-two] states” that are now resistant to glyphosate as a result of farmers planting glyphosate-resistant GM crops and spraying their fields with higher levels of glyphosate.⁴⁶ The growing prevalence of herbicide-resistant weeds has created a chemical arms race in which farmers must use more toxic combinations of herbicides to control the weed population.⁴⁷ Dow AgroSciences has created strains of corn and soy that are genetically modified to be resistant to 2,4-Dichlorophenoxyacetic acid (2,4-D), an ingredient used in Agent Orange, in response to glyphosate-resistant weeds.⁴⁸ Farmers and scientists alike are concerned about the dangers of 2,4-D, and have petitioned the Environmental Protection Agency (EPA) and the United States Department of Agriculture (USDA) to seriously consider the significant risks.⁴⁹

44. *Id.* (discussing GM crop farmers’ reliance on glyphosate for weed control and its creation of superweeds). Conventional farming techniques typically include applying multiple pesticides to control weed populations because it is significantly more difficult for weeds to become resistant to several chemicals. *Id.* See also Natasha Gilbert, *Case studies: A hard look at GM crops*, NATURE 24-25 (May 1, 2013), <http://www.nature.com/news/case-studies-a-hard-look-at-gm-crops-1.12907> (describing change in farming practices and shift to using only one herbicide). Many crop varieties are genetically modified to be glyphosate-resistant so farmers have the option of spraying glyphosate directly onto crops without being concerned about killing them, which has led many farmers to rely solely on glyphosate as a means of quick and easy weed control. *The Rise of Superweeds*, *supra* note 42, at 3.

45. *The Rise of Superweeds*, *supra* note 42, at 3 (discussing trend of moving away from traditional, nonchemical means of controlling weeds).

46. Greg Jaffe, *What You Need to Know About Genetically Engineered Food*, THE ATLANTIC (Feb. 7, 2013, 8:36 AM), <http://www.theatlantic.com/health/archive/2013/02/what-you-need-to-know-about-genetically-engineered-food/272931/> (explaining prevalence of herbicide-resistant weeds in U.S.).

47. *GE Food & the Environment*, *supra* note 40 (discussing consequences of “superweeds”).

48. *USDA IGNORES HARMS FROM GENETICALLY ENGINEERED CROPS*, EARTHJUSTICE (Jan. 3, 2014), <http://earthjustice.org/news/press/2013/usda-ignores-harms-from-genetically-engineered-crops> (reporting on new “agent orange” crops).

49. Lucia Graves, *‘Agent Orange Corn’ Debate Rages As Dow Seeks Approval Of New Genetically Modified Seed*, HUFFINGTON POST (last updated Oct. 29, 2012, 12:09 AM), http://www.huffingtonpost.com/2012/04/26/enlist-dow-agent-orange-corn_n_1456129.html (discussing critics concerns with “agent orange” corn).

Another environmental concern about GM crops is the possibility of biological pollution.⁵⁰ If proper precautions are not taken, genes from GM crops can find their way into the genomes of wild species, conventional crops, and organic crops.⁵¹ Within the last year, the United States saw two documented cases of crops that were contaminated with genes from GM crop varieties.⁵² While the long-term environmental effects of biological pollution from GM crops remain to be seen, it is clear that genes can easily move from population to population and should be treated with care.⁵³

III. CURRENT LEGAL FRAMEWORK SURROUNDING GM CROPS IN THE UNITED STATES

A. Federal Legal Framework

Lawmakers created the current regulatory framework for biotechnology in the United States with the objective of maintaining the country's competitive edge in a global market while placing little emphasis on environmental safety.⁵⁴ The Office of Science and Technology Policy finalized the Coordinated Framework for Regulation of Biotechnology (Coordinated Framework) in 1986, and it continues to govern the manner in which biotechnology is regu-

50. *GE Food & the Environment*, *supra* note 40 (listing environmental concerns associated with GM crops). It is worth noting that there are natural forms of biological pollution, including Dutch elm disease, chestnut blight, and kudzu vine invasion, that are completely unrelated to biotechnology and GM crops. *Id.* The form of biological pollution this Comment will explore is also known as "gene flow," a process in which genes from one population enter the gene pool of another population. *Gene Flow Definition*, SCITABLE, <http://www.nature.com/scitable/definition/gene-flow-227> (last visited Jan. 23, 2014) (defining gene flow).

51. *GE Food & the Environment*, *supra* note 40 (listing concerns related to GM crops and biological pollution).

52. See *Genetically modified wheat found in Oregon field raises trade concerns*, THE GUARDIAN (May 29, 2013, 5:35 PM), <http://www.theguardian.com/environment/2013/may/29/oregon-genetically-modified-wheat-monsanto> (reporting on evidence of unapproved genetically modified wheat in Oregon farmer's field); see also Suzanne Goldenberg, *Washington state alfalfa crop may be contaminated with genetic modification*, THE GUARDIAN (Sept. 12, 2013, 5:34 PM), <http://www.theguardian.com/environment/2013/sep/12/gm-crop-contamination-alfalfa-monsanto> (reporting on evidence of genetically modified alfalfa in Washington farmer's field).

53. See *Genetic Engineering in Agriculture*, *supra* note 39 (discussing potential risks of GM crops and how little is known about long-term effects).

54. See Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856, 50,856-57 (proposed Dec. 31, 1984) (describing United States' interest in allowing biotechnology to thrive). The government expressed its desire to "minimize the uncertainties and inefficiencies that can stifle innovation and impair the competitiveness of U.S. industry." *Id.* at 50,857.

152 VILLANOVA ENVIRONMENTAL LAW JOURNAL [Vol. XXVI: p. 145

lated today.⁵⁵ The Coordinated Framework divides the task of regulation at the federal level among three agencies: the Food and Drug Administration (FDA), the EPA, and the USDA through Animal and Plant Health Inspection Service (APHIS).⁵⁶

1. *The FDA*

The Federal Food, Drug, and Cosmetic Act (FFDCA) grants the FDA the power to regulate food safety and, more specifically, remove “adulterated or misbranded” food from the market.⁵⁷ The FDA regulates GM plants pursuant to the FFDCA, though, notably, no provisions of the FFDCA specifically address GM plants.⁵⁸ Under the FFDCA, the FDA labels substances in food as either “generally recognized as safe” (GRAS), or a “food additive,” which requires review and approval by the FDA before being added to foods.⁵⁹ The FFDCA defines a food additive as “any substance . . . [that] may reasonably be expected to . . . becom[e] a component or otherwise affect[] the characteristic of any food.”⁶⁰ While GM crops could have fallen under the definition of food additives and, therefore, received a higher-level of scrutiny, the FDA determined that GM crops are GRAS.⁶¹ Upon a determination that a substance is GRAS, the FDA no longer requires approval that the substance is “safe,” and exempts the substance from food safety regulations.⁶²

The FDA provides voluntary consultations to new GM crop developers to assure their companies that the crops are safe for consumption.⁶³ The developers select which data the FDA analyzes,

55. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,302 (June 26, 1986) (announcing biotechnology’s regulatory framework).

56. *Id.* at 23,303 (describing role each agency will play in regulating biotechnology).

57. 21 U.S.C. § 331(a) (2012) (enumerating FDA’s powers under FFDCA).

58. *Center for Food Safety v. Vilsack (Vilsack II)*, 718 F.3d 829, 833 (9th Cir. 2013) (discussing where FDA derives its authority to regulate biotechnology).

59. 21 U.S.C. § 321(s) (2012) (categorizing substances as either “food additive” or GRAS); *see also* 21 C.F.R. § 170.30 (2013) (outlining various requirements for classifying substances as GRAS).

60. § 321(s) (defining “food additive”).

61. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,990 (May 29, 1992) (stating genetic material used to create GM crops is presumed to be GRAS); Rebecca Bratspies, *Is Anyone Regulating? The Curious State of GMO Governance in the United States*, 37 VT. L. REV. 923, 938 (Summer 2013) (discussing opportunity for FDA to regulate GM crops under food additive standard).

62. *See* Bratspies, *supra* note 61, at 937-38 (providing background on limited review of GRAS substances).

63. *Id.* at 938 (discussing voluntary consultation provision in FDA regulations).

and may choose not to share “negative or inconclusive results.”⁶⁴ Additionally, there is no requirement that developers follow the FDA’s recommendations after reviewing their data.⁶⁵

2. *The EPA*

The EPA, much like the FDA, has limited authority to regulate GM crops.⁶⁶ The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) grants the EPA authority over GM crops through its herbicide regulations.⁶⁷ Domestic producers of herbicides must register their herbicides with the EPA before they sell and distribute their products.⁶⁸ Herbicide manufacturers must provide the EPA with information regarding the herbicide, and then the EPA determines the herbicide’s effectiveness and potential adverse effects associated with its use.⁶⁹

After evaluating each herbicide, the EPA sets conditions for the herbicide’s use and puts those conditions in the labeling instructions that every user is required to comply.⁷⁰ These conditions include limits on how much herbicide can safely be applied on specific plants.⁷¹ The EPA reevaluates herbicides every fifteen years to determine if the products remain suitable for use.⁷² Given FIFRA’s limited scope, the EPA can only regulate GM crops that are altered to produce pesticides.⁷³ Even in these situations, FIFRA limits its authority to the pesticide the crop produces and not the plant itself.⁷⁴

64. *Id.* (highlighting possible biases present in FDA voluntary consultation provision).

65. *Id.* at 938-39 (noting lack of enforcement of agency recommendations).

66. *Id.* at 935 (commenting on EPA’s limited regulatory authority concerning GM crops).

67. 7 U.S.C. § 136-136y (2012) (establishing EPA’s power to regulate herbicides).

68. *Id.* at § 136a(a), 136j(a)(2)(F) (2012) (stating it is illegal to sell, distribute, or use pesticides without registration under FIFRA).

69. *Id.* at § 136a(c)(1)(C), (F), 136a(c)(5) (defining EPA registration process for herbicides).

70. *Id.* at § 136a(c)(5), 136j(a)(2)(G) (listing requirements for EPA registration and labeling compliance).

71. *Id.* at § 136a(c)(5), 136j(a)(2)(G) (stating requirements for EPA registration and labeling compliance).

72. 7 U.S.C. § 136a(g)(1)(A)(iv) (setting forth subsequent registration review requirements regarding registered herbicides).

73. 40 C.F.R. § 174.1 (2013) (stating pesticide regulations apply to plant-incorporated protectants).

74. *See* Bratspies, *supra* note 61, at 937 (noting lack of authority and enforcement power over GM crops).

3. APHIS

APHIS is a branch within the USDA created “[t]o protect the health and value of American agriculture and natural resources.”⁷⁵ APHIS works to ensure that animals and plants within the United States are free from “agricultural pests and diseases.”⁷⁶ One of APHIS’s specific duties is regulating genetically modified organisms, including GM crops.⁷⁷

APHIS is able to regulate GM plants under the authority of the Plant Protection Act (PPA).⁷⁸ APHIS “may prohibit or restrict . . . movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, article, or other means of conveyance . . . to prevent the introduction . . . or the dissemination of a plant pest or noxious weed.”⁷⁹ The PPA defines a plant pest as:

[A]ny living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product:

- (A) A protozoan.
- (B) A nonhuman animal.
- (C) A parasitic plant.
- (D) A bacterium.
- (E) A fungus.
- (F) A virus or viroid.
- (G) An infectious agent or other pathogen.
- (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs.⁸⁰

Scientists typically create GM plants using bacteria or viruses that APHIS classifies as plant pests.⁸¹ In fact, APHIS’s regulations provide a list of presumed plant pest organisms and state that “[a]ny genetically engineered organism composed of DNA . . . from

75. *About APHIS*, USDA http://www.aphis.usda.gov/about_aphis/ (last visited Jan. 30, 2014) (stating APHIS’s mission).

76. *Id.* (stating broadly APHIS’s duties).

77. *Id.* (listing APHIS’s roles and efforts in accomplishing its specific mission).

78. Plant Protection Act, 7 U.S.C. §§ 7701-86 (2012) (codifying APHIS’s authority to regulate GM plants).

79. *Id.* at § 7712(a) (providing intent of PPA).

80. *Id.* at § 7702(14) (defining plant pest).

81. *Vilsack II*, *supra* note 58, at 835 (describing how GM plants fall under PPA). For example, in *Vilsack II*, Monsanto and Forage Genetics transferred the glyphosate-resistant gene from an Agrobacterium to a conventional alfalfa plant to create RRA. *Id.* at 835.

any of the groups of organisms listed below shall be deemed a regulated article.”⁸²

Any party may petition APHIS to deregulate a GM plant in accordance with the procedures specified by the regulations.⁸³ The petitioning party must provide evidence that suggests the GM plant does not “pose a greater plant pest risk” than the conventional plant.⁸⁴ Upon finding no risk of plant pest harm, the PPA requires APHIS to deregulate a presumptive plant pest because such a finding indicates the agency no longer has the necessary regulatory authority to make that determination.⁸⁵

APHIS also has the regulatory authority to control noxious weeds, which the PPA defines as weeds that are “likely to be aggressively invasive, have significant negative impacts, and are extremely difficult to manage or control once established.”⁸⁶ While the PPA considers certain GM plants as presumptive plant pests, it does not presume that they are noxious weeds.⁸⁷ APHIS may determine whether a GM plant is a noxious weed *sua sponte*.⁸⁸ Additionally, a third party may petition APHIS to assess whether other GM plants not yet evaluated by APHIS should be classified as noxious weeds.⁸⁹

B. State Legal Framework

Presently, no state has enacted a statute prohibiting the “manufacture or sale” of GM crops.⁹⁰ Fifteen states, however, have enacted legislation that restricts the ability to plant GM crops.⁹¹ Of

82. 7 C.F.R. § 340.2 (2013) (providing list of presumed plant pests). For example, since *Agrobacterium* is on the list of presumed plant pests, APHIS deemed RRA a presumptive plant pest because it contained DNA from an *Agrobacterium*. 70 Fed. Reg. 36,917, 36,918 (June 27, 2005) (stating RRA was presumed plant pest until petition for deregulation was approved).

83. 7 C.F.R. § 340.6 (2013) (formalizing petition for deregulation procedure of GM plants).

84. *Id.* at § 340.6(c) (listing required data and information for petition).

85. *Id.* at § 340.6(e)(1) (stating outcome when APHIS determines no plant pest risk).

86. 7 U.S.C. § 7712(f)(1) (2012) (granting APHIS authority to regulate noxious weeds); *see also* Noxious Weed Status of Kentucky Bluegrass Genetically Engineered for Herbicide Tolerance, 76 Fed. Reg. 39,811, 39,811 (July 7, 2011) (defining noxious weed).

87. *Vilsack II*, *supra* note 58, at 836 (contrasting status of GM plants under regulations for plant pests and noxious weeds).

88. *Id.* (discussing APHIS’s discretion to classify noxious weeds).

89. 7 C.F.R. § 360.500 (2013) (formalizing petition process to list plant as noxious weed).

90. *Genetically Modified Food*, 50 State Surveys, THOMSON REUTERS, Aug. 2013 (summarizing data on state statutes regarding GM food).

91. *See id.* (providing detailed information about each state’s statutes).

156 VILLANOVA ENVIRONMENTAL LAW JOURNAL [Vol. XXVI: p. 145

these states, most require GM crop cultivators to obtain a special permit from the appropriate state government entity prior to planting.⁹² Additionally, thirteen states have enacted legislation, known as state preemption laws, which prevent local community governments within those states from regulating seeds, including GM seeds.⁹³ In states without preemption laws, some municipalities have decided to ban GM crop cultivation within their borders.⁹⁴ For example, municipalities in California, Hawaii, and Oregon have recently enacted or proposed bans on GM crop cultivation.⁹⁵

1. California

In March 2004, Mendocino County, California became the first county in the United States to ban GM crops within its borders.⁹⁶ Marin County and the City of Arcata followed suit by enacting their own ordinances banning GM organisms.⁹⁷ Similarly, the City of Los Angeles (L.A.) is currently seeking to enact a local ordinance banning GM crops.⁹⁸ If the ordinance takes effect, L.A. would be the

92. See, e.g., FLA. STAT. ANN. § 581.083 (West 2012) (prohibiting introduction or release of any genetically engineered plant that may harm state plant life without permit); see also, MISS. CODE ANN. § 69-25-10 (West 2012) (prohibiting cultivation of genetically engineered plants for any purpose besides agriculture without permit).

93. *Genetically Modified Food*, *supra* note 90 (listing state statutes related to state preemption). See e.g., ARIZ. REV. STAT. ANN. § 3-243 (West 2005) (stating counties, cities, towns, or other political subdivisions in Arizona do not have authority to regulate seeds).

94. For a discussion of the current U.S. municipalities that have banned GM crops, see *infra* notes 96-128 and accompanying text.

95. For a discussion of the current GM crop legislation in California, Hawaii, and Oregon, see *infra* notes 96-128 and accompanying text.

96. Robin Meadows, *California Voters Assess Anti-GMO Initiative*, 58 CAL. AGRIC. 182, 182 (2004), available at <http://californiaagriculture.ucanr.org/landingpage.cfm?i=i&article=ca.v058n04p182> (discussing Mendocino County's impact as first county in country to ban GM crops); see also, 10A MENDOCINO CNTY. CODE § 10A.15.020 (2013), available at <http://www.co.mendocino.ca.us/agriculture/agriculturedivision.htm> (prohibiting private citizens, groups, or corporations from growing GM organisms in Mendocino County).

97. 6 MARIN CNTY. CAL. CODE OF ORDINANCES § 6.92.020 (2013), available at http://library.municode.com/HTML/16476/level2/TIT6PUPESAMO_CH6.92PRGRGEMOOR.html#TIT6PUPESAMO_CH6.92PRGRGEMOOR_6.92.010FIPU (prohibiting GM organism cultivation in Marin County, California); 5 ARCATA MUNICIPAL CODE § 5935 (2013), available at <http://www.codepublishing.com/ca/arcata/> (prohibiting GM organism cultivation in City of Arcata, California).

98. Kathleen Miles, *Los Angeles Proposes Banning GMOs*, HUFFINGTON POST (Oct. 21, 2013, 10:21 PM), http://www.huffingtonpost.com/2013/10/21/los-angeles-ban-gmo_n_4137166.html (summarizing Los Angeles city council motion to ban GM organisms); see also Los Angeles City Council Motion 13-1374 (Oct. 18, 2013), available at http://clkrep.lacity.org/onlinedocs/2013/13-1374_Mot_12-3-13.pdf (proposing motion to ban GM organisms in Los Angeles).

largest geographical area in the United States to ban GM crops.⁹⁹ David King, head of Learning Garden and Seed Library of L.A., helped draft the motion for ordinance.¹⁰⁰ King stated that the ordinance “would be symbolic more than anything else,” since there are few, if any, GM seed cultivators in the city.¹⁰¹ The ban would send the message that the second-largest city in the United States is opposed to GM crops.¹⁰²

2. *Hawaii*

Individual counties within the Hawaiian Islands are also pushing for stricter regulation of GM crops.¹⁰³ In November 2013, Kauai County Council overrode Mayor Bernard Carvalho’s veto to enact Bill 2491 (Kauai Bill).¹⁰⁴ The Kauai Bill requires large agricultural companies to disclose where they have sprayed pesticides, what quantities of pesticide they applied, and whether they planted GM crops.¹⁰⁵ Furthermore, the Kauai Bill also mandates the creation of five hundred foot “buffer zones” around day cares, nursing homes, and schools where agricultural companies cannot apply pesticide.¹⁰⁶

Hawaii County Mayor William Kenoi signed Bill 113 (Hawaii Bill) into law on December 5, 2013.¹⁰⁷ The Hawaii Bill prohibits “open air cultivation, propagation, development, or testing of ge-

99. Miles, *supra* note 98 (noting importance of possible Los Angeles GM crop ban).

100. *Id.* (discussing David King’s role in drafting Los Angeles ordinance).

101. *Id.* (quoting David King’s thoughts on GM organism ban).

102. *Id.* (summarizing purpose of enacting Los Angeles GM organism ban).

103. Christopher D’Angelo, *Hawaiian islands take more steps to limit spread of GMO crops*, REUTERS (Dec. 6, 2013), <http://www.reuters.com/article/2013/12/07/usa-gmos-hawaii-idUSL2N0JL1RL20131207> (summarizing Hawaiian Islands’ efforts to limit GM crop cultivation). There are four counties in the state of Hawaii: Honolulu County, Hawaii County, Maui County, and Kauai County. *County Governments*, HAWAII.GOV, <https://portal.ehawaii.gov/government/county-governments/> (last visited Feb. 13, 2014).

104. *Kauai County Council Override Frees Way For GMO Bill*, HUFFINGTON POST (Nov. 16, 2013), http://www.huffingtonpost.com/2013/11/16/kauai-county-council-override_n_4289302.html (reporting on Kauai County Council’s vote to override Mayor’s veto of GM organism bill).

105. B. 2491 § 22-22.4, 2013 Kauai Cnty. Council (Haw. 2013) (amending Chapter 22 of Kauai County Code 1987 to require commercial agricultural companies to disclose information regarding pesticide use and GM crop cultivation).

106. *Id.* at §§ 22-23.5 (forbidding commercial agricultural companies from applying pesticides within buffer zones).

107. Sophie Cocks, *Big Island Mayor Signs Biotech, GMO Ban Into Law*, HUFFINGTON POST (Dec. 5, 2013, 10:21 PM), http://www.huffingtonpost.com/2013/12/05/big-island-biotech-ban_n_4395521.html (discussing Hawaii County’s enactment of bill banning GM crops).

158 VILLANOVA ENVIRONMENTAL LAW JOURNAL [Vol. XXVI: p. 145

netically engineered crops or plants” on the largest Hawaiian island.¹⁰⁸ There are two exemptions to the widespread ban on GM crops: a grandfather clause for existing cultivators of GM crops, and an exception for cultivators of GM papaya.¹⁰⁹ The Hawaii Bill also requires GM crop cultivators to register the locations of their fields each year with Hawaii County.¹¹⁰ GM crop cultivators who violate the ban are subject to a one thousand dollar fine for each day they are in noncompliance.¹¹¹

Maui County Councilmember Elle Cochran introduced a GM crop bill to the Maui County Council on December 6, 2013.¹¹² The Council forwarded the bill to the Policy and Intergovernmental Affairs Committee for its first round of readings on January 28, 2014.¹¹³ The language in the Maui County bill parallels the language of the Kauai Bill; it requires large agricultural companies to disclose information about pesticides and GM crops in addition to creating pesticide buffer zones.¹¹⁴

In response to the GM crop ordinances in Hawaii, agricultural companies Syngenta, Pioneer Hi-Bred International, and Agrigenetics filed suit against the County of Kauai in U.S. District Court in Honolulu on January 10, 2014.¹¹⁵ The companies collectively produce GM corn, soybean, canola, and rice seeds on approximately 11,500 acres on the island of Kauai.¹¹⁶ The companies

108. B. 113 § 14, 2012-2014 Hawaii Cnty. Council (Haw. 2013), *available at* <http://records.co.hawaii.hi.us/Weblink8/0/doc/798046/Page1.aspx> (prohibiting farmers from cultivating GM crops on island of Hawaii).

109. *Id.* (exempting existing GM crop farmers and GM papaya farmers).

110. *Id.* (requiring GM crop farmers to register with county government annually).

111. *Id.* (stating penalty for violating Hawaii County GM crop ban).

112. *Agenda*, COUNCIL OF THE CNTY. OF MAUI (Dec. 6, 2013), *available at* <http://www.mauicounty.gov/ArchiveCenter/ViewFile/Item/18552> (announcing Council member Cochran transmitted proposed bill on pesticides and GM crops).

113. *Meeting Agenda*, POLICY & INTERGOVERNMENTAL AFFAIRS COMM. (Jan. 28, 2014), *available at* <http://www.mauicounty.gov/ArchiveCenter/ViewFile/Item/18691> (announcing Council member Cochran introduced proposed bill to Maui Policy and Intergovernmental Affairs Committee).

114. PAF 13-300, 2013 Maui Cnty. Council (Haw. 2013), *available at* <http://www.mauicounty.gov/ArchiveCenter/ViewFile/Item/18581> (amending Title 20 of Maui County Code to require agricultural companies to disclose pesticide use and GM crop cultivation and mandating pesticide buffer zones).

115. Jacob Bunge, *Ag Firms Sue to Block Anti-GMO Law*, WALL ST. J. (Jan. 13, 2014, 4:07 PM), <http://online.wsj.com/news/articles/SB10001424052702303819704579316993737808588> (reporting on agricultural companies' lawsuit to declare Kauai's law invalid).

116. Complaint at 8-11, *Syngenta Seeds, Inc. v. Cnty. of Kaua'i*, (filed Jan. 10, 2014) (No. 1:14-cv-00014) (describing plaintiffs' business operations and development of GM crops in Kauai).

requested that the court declare the Kauai Bill invalid and enter an injunction preventing Kauai County from enforcing the Kauai Bill.¹¹⁷

The agricultural companies argued that the Kauai Bill was invalid for a number of reasons.¹¹⁸ First, the ordinance “attempts to regulate in an area already occupied by state and federal law . . . or conflicts with such existing laws and regulations.”¹¹⁹ Second, the ordinance “violates [the companies’] . . . constitutional rights to equal protection and due process by arbitrarily targeting [the companies] and exempting virtually all other users of pesticides.”¹²⁰ Third, the ordinance further violates the companies’ right to equal protection and due process by “imposing burdensome operational restrictions and civil and criminal penalties that have no legal or factual justification.”¹²¹ Fourth, the ordinance’s buffer zones constitute an uncompensated taking because the companies are forbidden from planting inside the zones.¹²²

3. Oregon

In Oregon, Benton and Lane Counties sought to ban GM crops within their borders.¹²³ Although each county proposed a ban through an initiative petition process, Oregon Governor John Kitzhaber signed Senate Bill 863 on October 8, 2013, preempting local efforts to legislate on seeds, including GM seeds.¹²⁴ Bill 863

117. *Id.* at 67 (providing details of plaintiffs’ requested relief including how Kauai Bill violates plaintiffs’ rights and interests protected by United States and Hawaii law).

118. *Id.* at 4 (setting forth plaintiffs’ reasons why they believe Bill 2491 is invalid).

119. *Id.* (stating plaintiffs’ first reason Bill 2491 is invalid).

120. *Id.* (stating why Bill 2491 violates plaintiffs’ constitutional rights of equal protection and due process).

121. Compl. at 5 (stating another reason ordinance violates plaintiffs’ equal protection and due process rights).

122. *Id.* (providing plaintiffs’ explanation for why buffer zones constitute uncompensated takings). The plaintiffs also stated that the ordinance “violates the Kaua’i County Charter,” and was inappropriately adopted over a veto by Mayor Carvalho “by a supermajority . . . that included a member who was selected in a manner that violated the Hawai’i Open Meeting Law.” *Id.*

123. Cassandra Profita, *Three Oregon Counties See Petitions To Ban Genetically Modified Crops*, OR. PUBLIC BROADCASTING (July 11, 2013, 2:39 PM), <http://www.opb.org/news/blog/ecotrope/three-oregon-counties-see-petitions-to-ban-genetically-modified-crops/> (discussing Oregon county petitions to ban GM crops).

124. Yuxing Zheng, *John Kitzhaber signs 5 special session bills on PERS, taxes, GMO (2013 special session)*, OREGONIAN (Oct. 8, 2013, 10:58 AM), http://www.oregonlive.com/politics/index.ssf/2013/10/john_kitzhaber_signs_5_special.html (summarizing Oregon Senate Bill 863’s effect on Benton and Lane counties’ efforts to ban GM crops).

160 VILLANOVA ENVIRONMENTAL LAW JOURNAL [Vol. XXVI: p. 145

took effect immediately upon its passage.¹²⁵ Only a ballot initiative in Jackson County was exempted from Bill 863 because it was “[p]roposed by initiative petition and, on or before January 31, 2013, qualified for placement on the ballot in a county”¹²⁶ Jackson County’s ban forbids farmers from cultivating GM crops within its borders.¹²⁷ The ban exempts “certain health, educational, scientific and medical research institutions if activities are conducted under secure, indoor laboratory conditions.”¹²⁸

IV. LAWS REGULATING GM CROPS IN OTHER COUNTRIES

A. Canadian GM Crop Approval Process

Health Canada is the Canadian counterpart to the FDA, and is responsible for overseeing the pre-market evaluation process of “novel foods” in Canada.¹²⁹ Health Canada’s definition of “novel foods” includes GM crops.¹³⁰ Health Canada has an eight-step regulatory process that GM crops must pass before manufacturers can market or sell the crops in Canada.¹³¹ This regulatory process can take between seven and ten years to complete.¹³²

The first step in the regulatory approval process involves GM crop creators consulting the Novel Foods Section of the Food Directorate prior to beginning the safety assessment.¹³³ The purpose of this consultation is to help GM crop creators understand the reg-

125. Or. S. B. 863, 2013 Spec. Sess. (Or. 2013), available at <https://olis.leg.state.or.us/liz/2013S1/Measures/Text/SB863/Enrolled> (declaring emergency and taking effect on its passage).

126. *Id.* (limiting application of Bill 863); see Zheng, *supra* note 124 (stating Jackson County’s ban is exempt from Bill 863); see also, Amelia Templeton, *Southern Oregon County Will Consider GM Crop Ban In 2014*, OR. PUBLIC BROADCASTING (Jan. 10, 2013), <http://earthfix.opb.org/communities/article/southern-oregon-county-will-consider-gmo-ban-in-20/> (stating Jackson County’s ban qualified for 2014 ballot).

127. Jackson County, Or., The Genetically Engineered Plant Ordinance (Aug. 8, 2012), available at <http://www.naturalnews.com/files/The-Genetically-Engineered-Plant-Ordinance-JACK-15-1-Full-Ordinance.pdf> (prohibiting farmers from cultivating GM crops).

128. *Family Farms Measure*, OUR FAMILY FARMS COALITION http://www.ourfamilyfarmscoalition.org/family_farms_measure (last visited Oct. 19, 2014) (stating Jackson County’s ban exemptions).

129. *The Regulation of Genetically Modified Food*, HEALTH CAN. (last updated Dec. 12, 2012), http://www.hc-sc.gc.ca/sr-sr/pubs/biotech/reg_gen_mod-eng.php (discussing Health Canada’s responsibility to assess safety and nutrition of foods derived from biotechnology).

130. C.R.C. c. 870 B.28.001 (Can.) (defining novel food).

131. *The Regulation of Genetically Modified Food*, *supra* note 129 (outlining regulatory process for approval of GM crops).

132. *Id.* (providing estimated duration of regulatory process).

133. *Id.* (specifying first step in regulatory process for GM crop approval).

ulatory process requirements and provides a forum for raising any specific safety concerns they may have.¹³⁴ Second, a GM crop creator must submit a pre-market notification to the Novel Foods Section, which will test the GM crop product for safety.¹³⁵ In the third step of the process, expert biotechnology and food safety scientists evaluate the GM crop product for safety.¹³⁶ The scientists assess the various GM crop characteristics, such as:

Development of the modified organism, including the molecular biological data that characterizes the genetic change; composition of and nutritional information about the GM food compared to a non-modified counterpart food; the potential for production of new toxins in the food; the potential for causing allergic reactions; microbiological and chemical safety of the food; the potential for any unintended or secondary effects; key nutrients and toxicants; and, major constituents (for example, fats, proteins, carbohydrates) and minor constituents (for example, minerals and vitamins).¹³⁷ In the fourth step, Health Canada safety evaluators request “further documentation” from a GM crop creator if “any of the information provided . . . is insufficient. . . .”¹³⁸

Fifth, after the safety evaluations are complete, Health Canada safety evaluators summarize the evaluation results and the evaluators’ recommendations in a report.¹³⁹ In the sixth step, Health Canada prepares a Food Rulings Proposal that is “reviewed by senior staff (Directors and Director General) in the Food Directorate to ensure that all issues have been addressed.”¹⁴⁰ After the senior staff reviews the Food Rulings Proposal, the Food Directorate decides whether the GM crop product has been approved.¹⁴¹ The seventh step in the approval process requires Health Canada to send a Letter of No Objection to the GM crop creator.¹⁴² The Letter of

134. *Id.* (stating purpose of pre-submission consultation).

135. *Id.* (specifying second step in regulatory process for GM crop approval).

136. *The Regulation of Genetically Modified Food, supra* note 129 (stating third step in regulatory process for GM crop approval).

137. *Id.* (specifying GM crop characteristics scientists will evaluate for safety).

138. *Id.* (stating fourth step in regulatory process for GM crop approval).

139. *Id.* (stating fifth step in regulatory process for GM crop approval).

140. *Id.* (stating sixth step in regulatory process for GM crop approval).

141. *The Regulation of Genetically Modified Food, supra* note 129 (marking point at which Food Directorate decides whether GM crop product should be approved).

142. *Id.* (stating seventh step in regulatory process for GM crop approval).

162 VILLANOVA ENVIRONMENTAL LAW JOURNAL [Vol. XXVI: p. 145

No Objection “indicates that the product can be sold in Canada for the intended uses, as listed in the submission, and whether there are any restrictions or requirements associated with the Health Canada decision.”¹⁴³ Health Canada concludes the approval process by posting a decision document on their Novel Foods and Ingredients webpage.¹⁴⁴ The decision document “describ[es] the novel food and summariz[es] the safety information used to determine its safety as a food.”¹⁴⁵ A list of approved novel foods, including GM crops, is then made available on Health Canada’s website with links to relevant safety assessments.¹⁴⁶

B. Mexico’s Debate Over GM Corn

Mexico grew approximately 100,000 hectares of GM cotton and soybean in 2013.¹⁴⁷ Mexico, nevertheless, since 1998 has banned farmers from planting GM corn for consumption on Mexican soil.¹⁴⁸ One reason the Mexican government has treated GM corn differently than other products is that corn is sacred to many native Mexicans.¹⁴⁹ Corn originated in Mexico, and, for many, this “fact is deeply bound up in the nation’s sense of itself.”¹⁵⁰ Even though so many Mexican citizens are strongly opposed to GM corn, some small farmers still plant GM corn seeds smuggled across the United States-Mexico border.¹⁵¹

President Felipe Calderón changed Mexican law in 2009 to allow large agricultural companies to complete field tests of GM corn

143. *Id.* (providing information contained in Letter of No Objection).

144. *Id.* (stating final step in regulatory process for GM crop approval).

145. *Id.* (describing information included in decision document posted to Health Canada’s website).

146. *Novel Food Decisions*, HEALTH CAN. (last updated Oct. 15, 2014), <http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/index-eng.php> (listing approved novel foods and providing links to safety assessments).

147. *ISAAA Brief 46-2013: Executive Summary*, INT’L SERV. FOR THE ACQUISITION AGRIBIOTECH OF APPLICATIONS, <http://www.isaaa.org/resources/publications/briefs/46/executivesummary/default.asp> (last visited Feb. 11, 2014) (listing area of GM crops planted by country).

148. Drake Bennett, *Brazil Says ‘Yes’ to Genetically Modified Foods. Mexico Says ‘No’*, BLOOMBERG BUSINESSWEEK (Oct. 30, 2013), <http://www.businessweek.com/articles/2013-10-30/brazil-says-yes-to-genetically-modified-foods-dot-mexico-says-no> (discussing Mexico’s ongoing debate on GM corn).

149. *Id.* (stating reason why Mexico is reluctant to permit GM corn cultivation).

150. *Id.* (providing explanation of Mexican patriotism associated with corn).

151. Mica Rosenberg, *Mexico farmers quietly plant banned GM corn*, REUTERS (Mar. 7, 2008, 1:18 PM), <http://www.reuters.com/article/2008/03/07/us-biotech-crops-mexico-idUSN0732845620080307> (noting that some small Mexican farmers are planting GM corn illegally).

in approved regions of the country.¹⁵² President Calderón did not approve any commercial-scale GM corn cultivation before he left office in 2012.¹⁵³ Since then, agricultural companies Monsanto, Pioneer Hi-Bred International, and Dow AgroSciences de Mexico's applications to cultivate GM corn have been in limbo.¹⁵⁴ In October 2013, a federal judge in Mexico City ordered an injunction suspending all GM corn cultivation in Mexico.¹⁵⁵ While many GM corn opponents suspect the judicial injunction is a step in the right direction, Mexican government officials feel the injunction may only be temporary.¹⁵⁶

C. The European Union's Stance on GM Crops

There are five E.U. countries that planted GM crops in 2013: Spain, Portugal, Romania, the Czech Republic, and Slovakia.¹⁵⁷ Spain accounts for a majority of the GM crops planted in the E.U., including approximately 137,000 hectares of the 148,000 hectares planted in 2013.¹⁵⁸ Although these five countries choose to plant GM crops, many E.U. countries are against GM crop cultivation.¹⁵⁹

GM crop cultivators may only begin growing in E.U. countries after the European Food Safety Authority (EFSA) has authorized the GM crop.¹⁶⁰ The approval process begins with an agricultural company submitting an application for authorization to cultivate a GM crop to the appropriate authority within a particular E.U. Mem-

152. David Alire Garcia, *Past and future collide as Mexico fights over GMO corn*, REUTERS (Nov. 12, 2013, 3:26 PM), <http://www.reuters.com/article/2013/11/12/us-mexico-corn-idUSBRE9AB11Q20131112> (discussing recent changes to Mexico's legal framework surrounding GM corn).

153. *Id.* (providing timeline of political events related to GM corn in Mexico).

154. *Id.* (explaining reasons why no agricultural company has started commercial-scale GM corn cultivation in Mexico).

155. *Id.* (noting judicial decision to halt GM corn cultivation in Mexico).

156. *Id.* (discussing permanence of judicial injunction on GM corn cultivation).

157. *ISAAA Brief 46-2013: Executive Summary*, *supra* note 147 (summarizing GM crop cultivation practices by country).

158. *Id.* (noting Spain's dominance in E.U. GM crop market).

159. Alicia Bayer, *What countries have banned GMO crops?*, EXAMINER.COM (June 18, 2011, 2:33 PM), <http://www.examiner.com/article/what-countries-have-banned-gmo-crops> (noting E.U. countries that have banned sale or cultivation of GM crops).

160. Regulation (EC) No. 1829/2003 of the European Parliament and of the Council, Article 4, sub-paragraph 2 (requiring European Food Safety Authority authorization before GM crop can be marketed).

164 VILLANOVA ENVIRONMENTAL LAW JOURNAL [Vol. XXVI: p. 145

ber State.¹⁶¹ The GM crop approval application requires a number of supporting documents such as:

- Studies showing that the GM food is not dangerous to health or the environment
- Analyses showing that the GM food is substantially equivalent to conventional counterparts (e.g. by analysis of particular constituents / nutrients)
 - Suggestions for product labeling
 - Methods and sample material for detecting GM content
 - An application may include a proposal for post-market monitoring[]
 - Summary of the application dossier.¹⁶²

Following inclusion of these documents, the E.U. Member State then sends the application to the EFSA, “Notif[ying] all of the Member States and allow[ing] them to access the application.”¹⁶³

The EFSA has six months after receiving all required application documents to issue an opinion on the safety of a GM crop.¹⁶⁴ The EFSA bases its opinion on “a scientific evaluation from a panel of experts on genetic engineering,” that determines whether “a GM product remains within the range variability naturally found within its conventional counterparts.”¹⁶⁵ The agricultural company submitting the GM crop approval application must “show[] that all measures have been taken to prevent negative effects on human and animal health and environment.”¹⁶⁶ EFSA submits an opinion to the European Commission and Member States containing: (1) a scientific safety assessment; (2) suggestions for labeling the product; (3) any restrictions or conditions, such as post-market monitoring, on approval; (4) E.U. reference laboratory’s confirmation of detection methods; and (5) a post-marketing plan for environmental monitoring.¹⁶⁷ The EFSA publicizes its opinion, omitting any

161. See *The Long Road to Authorisation*, GMO COMPASS (Jan. 10, 2006), http://www.gmo-compass.org/eng/regulation/regulatory_process/157.eu_gmo_authorisation_procedures.html (summarizing first step of GM crop approval process within European Union).

162. *Id.* (listing requisite supporting documents for GM crop approval application).

163. See *id.* (describing E.U. Member State actions upon receiving GM crop approval application).

164. See *id.* (summarizing phase two of E.U. GM crop approval process).

165. *Id.* (describing basis of EFSA’s safety assessment).

166. *The Long Road to Authorisation*, *supra* note 161 (noting the safety standard GM crops must meet to be approved).

167. *Id.* (describing contents of EFSA’s opinion regarding GM crop approval).

confidential or sensitive business information pertaining to the agricultural company that submitted the application.¹⁶⁸

Phase three of the approval process requires that the European Commission draft a decision within three months of receiving the EFSA's opinion.¹⁶⁹ If the Commission's decision differs from the EFSA's public opinion, the Commission must provide a written justification.¹⁷⁰ The draft is then submitted to the Standing Committee on the Food Chain and Animal Health, consisting of representatives from all E.U. Member States.¹⁷¹ The Standing Committee "approve[s] or reject[s] the Commission's draft with a qualified majority."¹⁷²

If the Standing Committee does not agree with the draft or cannot reach the qualified majority, the Standing Committee refers the draft to the European Council of Ministers and informs the European Parliament.¹⁷³ The Council of Ministers then has ninety days to approve or reject the draft by a qualified majority.¹⁷⁴ If the Council of Ministers rejects the draft, the Commission revises the draft.¹⁷⁵ If the Council of Ministers approves the draft, or the Standing Committee cannot reach a qualified majority, the draft is authorized and becomes effective.¹⁷⁶ Authorized drafts are effective for ten years and approved GM crops are recorded in the public register.¹⁷⁷

168. *See id.* (stating EFSA's opinion is available to public).

169. *See id.* (describing final phase of approval process).

170. *See id.* (stating Commission's requirement when its decision differs from EFSA's opinion).

171. *See The Long Road to Authorisation, supra* note 161 (describing next step in legislative decision making process).

172. *Id.* (stating Standing Committee must approve or reject Commission's decision by majority). The qualified majority is defined in the Treaty of Nice and consists of 232 out of 321 votes. *Id.* At least sixty-two percent of the E.U. population must be represented in the qualified majority. *Id.*

173. *See id.* (providing next steps when Standing Committee does not approve or reject Commission's draft by qualified majority).

174. *See id.* (stating legislative process if Standing Committee refers draft to European Council of Ministers).

175. *See id.* (stating legislative process if Council of Ministers rejects draft).

176. *See The Long Road to Authorisation, supra* note 161 (stating how draft becomes effective).

177. *See id.* (providing requirements for approved GM crops).

166 VILLANOVA ENVIRONMENTAL LAW JOURNAL [Vol. XXVI: p. 145

V. ANALYSIS OF U.S. FRAMEWORK COMPARED TO INTERNATIONAL LAWS AND SUGGESTIONS FOR FUTURE REGULATION

GM crop regulation varies from country to country in a number of important ways.¹⁷⁸ The most striking way the United States differs from other countries discussed in this Comment is the lack of “independent, accurate, and credible risk assessment” prior to GM crop approval.¹⁷⁹ Agencies in Canada and the E.U. both set out criteria for the type of data and evaluations that should be submitted in an application for GM crop approval.¹⁸⁰ The U.S. should adopt similar criteria in statutory or regulatory authority in order to avoid perpetuating a system where GM crop manufacturers submitting the approval applications are also judging the quality and completeness of the data.¹⁸¹

Additionally, while the U.S. is not unique in its choice to regulate GM crops under a pre-existing statutory scheme, the patchwork system currently in place is failing.¹⁸² The Coordinated Framework has “fragment[ed] the regulatory evaluation of [GM] crops into illogical zones of authority that inhibit intelligent priority setting.”¹⁸³ This problem could potentially be solved in two ways: (1) assigning GM crop regulation to a single agency; or (2) creating a leadership position to oversee the individual agencies’ approval processes.¹⁸⁴

The U.S. could model a new GM crop regulatory system similar to Canada and the E.U., and designate the FDA as the single agency to oversee GM crop regulation.¹⁸⁵ Since it was established in 1906, the FDA has been the ultimate authority on food safety in the U.S.¹⁸⁶ Similar to the Canadian and E.U. regulatory schemes, the

178. See Maria Gariela Balboa, *Legal Framework to Secure the Benefits While Controlling the Risks of Genetically Modified Foods: A Comparison of the Cartagena Protocol and Three National Approaches*, 31 TEMP. J. SCI. TECH. & ENVTL. L. 255, 256 (2012) (introducing various national approaches to GM crop regulation).

179. *Id.* at 283 (discussing controversy due to lack of independent risk assessments for GM crop approval in U.S.).

180. See *supra* notes 132-46 and 157-77 and accompanying text for further discussion of Canadian and European agency requirements for the type of data and evaluations that accompany GM crop approval applications.

181. Bratspies, *supra* note 6, at 349 (discussing need for more research prior to application process).

182. See *id.* at 348 (discussing U.S.’s lack of central decision-making authority).

183. *Id.* at 347 (noting shortcomings of U.S. Coordinated Framework regulation of GM crops).

184. *Id.* at 348 (providing suggestions for improved regulatory framework).

185. See *supra* notes 129-30 and 160 and accompanying text.

186. See John P. Swann, *FDA’s Origin*, U.S. FOOD AND DRUG ADMINISTRATION (last updated June 23, 2014), available at <http://www.fda.gov/AboutFDA/>

FDA could conduct a safety review of all existing and new GM traits before crops containing such traits are introduced into commerce.¹⁸⁷ If the U.S. were to adopt such a regulatory scheme, the environmental, social, and economic impacts of GM crops could be evaluated and addressed on a more consistent basis.¹⁸⁸

While assigning GM crop regulation to a single agency would create a more consistent regulatory scheme, the FDA may not be equipped to regulate the environmental, social, and economic impacts of GM crops.¹⁸⁹ A more practical solution may be for our federal government to create a leadership initiative to “coordinate the diverse activities of various federal departments and agencies.”¹⁹⁰ A Coordinated Framework with efficient had inter-agency communication could make comprehensive and informed decisions about regulation of GM crops.¹⁹¹

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WhatWeDo/History/Origin/ucm124403.htm (detailing history and origins of FDA’s authority over food safety in U.S.).

187. *See supra* notes 131-46 and 161-77 and accompanying text.

188. *See supra* notes 131-46 and 161-77 and accompanying text.

189. *See supra* notes 57-65 and accompanying text.

190. Bratspies, *supra* note 6, at 348 (discussing need for a central decision making authority in GM crop regulation).

191. *See id.* (advocating benefits of coordinating activities of all federal agencies involved in GM crop regulation).

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