GENETICALLY MODIFIED PLANTS AND REGULATORY LOOPHOLES AND WEAKNESSES UNDER THE PLANT PROTECTION ACT

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INTRODUCTION

In July 2011, in a decision that "upturn[ed] the biotech industry and outrage[d] its opponents," the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) announced that it would not regulate a genetically modified (GM) variety of a popular lawn grass.[1] Scotts Miracle-Gro Company developed a strain of Kentucky Bluegrass that is engineered to tolerate application of the herbicide glyphosate (sold as the popular "Roundup" herbicide). In the announcement, APHIS ruled that the grass is outside the scope of federal regulation.[2] Traditionally, APHIS authority over GM plants has been based on its "plant pest" authority under the Plant Protection Act (PPA).[3] The main reason that GM plants are usually subject to the plant pest authority is that the plants have historically been engineered using material that falls squarely within the definition of a plant pest, such as a virus or bacteria.[4] For instance, the *Agrobacterium tumefaciens* bacterium and the Califlower mosaic virus—both listed specifically as plant pests by APHIS—are common tools that act as carriers or triggers for inserting foreign genes into plants.[5]

However, Scotts created the GM bluegrass without the use of any plant pest. The bluegrass was engineered using a "gene gun," which is a "common lab technique that shuttles DNA on high-velocity heavy metals."[6]

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1. Paul Voosen, *In Major Shift, USDA Clears Way for Modified Bluegrass*, N.Y. TIMES, July 6, 2011, http://www.nytimes.com/gwire/2011/07/06/06greenwire-in-major-shift-usda-clears-way-for-modified-bl-51693.html.

2. Scotts Miracle-Gro Co.; Regulatory Status of Kentucky Bluegrass Genetically Engineered for Herbicide Tolerance, 76 Fed. Reg. 39812 (July 7, 2011) [hereinafter Scotts Miracle-Gro Co.]. The letter seeking clarification of regulatory status for the grass sent by Scotts was not a new practice, and other developers had sought them in the past. *Id*.

3. 7 U.S.C. §§ 7701–7786 (2006); 7 C.F.R. § 340 (2012).

4. Emily Waltz, *GM Grass Eludes Outmoded USDA Oversight*, 29 NAT. BIOTECHNOL. 772, 772 (2011).

5. *Id*. *See also* ANIMAL & PLANT HEALTH INSPECTION SERV., U.S. DEP'T OF AGRIC., REGULATED PLANT PEST LIST, *available at* http://www.aphis.usda.gov/import_export/plants/plant_imports/downloads/RegulatedPestList.pdf (last visited Nov. 17, 2012) (listing plant pests).

6. Voosen, *supra* note 1.

Further, the genetic material inserted into the GM bluegrass to impart herbicide tolerance is sourced from thale cress, rice, and corn—none of which are plant pests.[7] APHIS determined that "Kentucky bluegrass itself is not a plant pest, no organisms used as sources of the genetic material used to create Scotts' GE Kentucky bluegrass are plant pests, and the method used to genetically engineer Scotts' GE Kentucky bluegrass did not involve plant pests"[8]—thus, plant pest oversight was not warranted.

This is the first time that a large biotech company has introduced a GM plant that contains no genetic material from plant pests and is thus considered wholly outside the scope of APHIS regulation.[9] The bluegrass decision, which confirmed that GM plants developed using non-pest methods are not subject to regulation under the PPA, sets an important precedent by exposing a large regulatory gap through which developers may avoid USDA review of GM products.[10]

In the announcement, APHIS also declined to regulate the bluegrass pursuant to its "noxious weed" authority under the PPA.[11] Under the noxious weed program, APHIS can regulate plants that it determines should be listed as noxious weeds. APHIS responded to a petition for listing and conducted a risk assessment to determine whether regulation of the bluegrass as a noxious weed was warranted.[12] Ultimately, APHIS determined that the bluegrass met the definition of a noxious weed, but declined to assert noxious weed authority because the bluegrass did not pose impacts severe enough to warrant regulation.[13] This was another area in which the bluegrass decision set an important precedent, because it shows that only those weeds with the most harmful impacts will be regulated under the noxious weed program and signals that typical weed-related concerns associated with GM plants do not meet the threshold of harm that will prompt regulation.

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7. Scotts Miracle-Gro Co., 76 Fed. Reg. at 39812.

8. *Id*.

9. Waltz, *supra* note 4, at 772–73. In the past, APHIS concluded that a GM petunia and a GM geranium were outside of its jurisdiction because the plants were not made with plant pests, but the decisions received little attention because the plants lacked broad appeal and were not developed by large companies. *Id*.; Voosen, *supra* note 1.

10. Waltz, *supra* note 4, at 772.

11. Scotts Miracle-Gro Co., 76 Fed. Reg. at 39812. *See also* 7 U.S.C. §§ 7701–7786; 7 C.F.R. § 340.2(a) (2012) (establishing noxious weed regulations).

12. ANIMAL & PLANT HEALTH INSPECTION SERV., U.S. DEP'T OF AGRIC., REVIEW OF PETITION TO ADD GENETICALLY ENGINEERED GLYPHOSATE-TOLERANT KENTUCKY BLUEGRASS TO THE FEDERAL NOXIOUS WEED REGULATIONS, 2–3 (June 30, 2011) [hereinafter APHIS, REVIEW OF PETITION], *available at* http://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/downloads/Kentucky-BG/KY-BG-FNW-PetitionReview.pdf.

13. *Id*. at 7, 11–12; Waltz, *supra* note 4, at 773.

Practically speaking, the announcement means that Scotts may now sell the GM bluegrass as if it were conventional grass—without the need for permitting for field tests, approval for commercialization, or monitoring for environmental or health impacts. The bluegrass ruling received heavy criticism for both its regulatory and environmental implications.[14] The decision has highlighted that developers can take advantage of a "huge loophole to circumvent [USDA] regulations" by using non-pest triggers.[15] The bluegrass case also shows that even where a GM plant qualifies as a noxious weed, APHIS may decide not to regulate it as such. Thus, certain GM plants can completely avoid APHIS regulation—and the environmental review that attends federal regulatory decisions. For those that are concerned about potential negative impacts of genetically modified organisms (GMOs), this signals a worrisome trend.

Indeed, public concern regarding risks associated with GMOs has begun to rise as the GM plants have become increasingly prevalent in the American agricultural landscape. GM plants have been widely adopted since their introduction to the market in 1996.[16] Today, millions of acres of United States farmland are planted with GM seeds, and most Americans consume foods containing genetically modified ingredients on a regular, if not daily, basis.[17] The biotech industry has been evolving rapidly as well,

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14. *See, e.g.*, Andrew Pollack, *U.S.D.A. Ruling on Bluegrass Stirs Cries of Lax Regulation*, N.Y. TIMES, July 6, 2011, http://www.nytimes.com/2011/07/07/business/energy-environment/cries-of-lax-regulation-after-usda-ruling-on-bluegrass.html (noting a potential "loosening in oversight" over GM crops); Tom Philpott, *Wait, Did the USDA Just Deregulate All New Genetically Modified Crops?*, MOTHER JONES (July 8, 2011), http://motherjones.com/environment /2011/07/usda-deregulate-roundup-gmo-tom-philpott (criticizing the decision as one in which "industry gets free rein to plant whatever it wants—wherever it wants."). A particular concern associated with GM grasses, as opposed to crop varieties, is the potential for more widespread effects because the grass is intended for home and commercial use, so application would not be limited to agricultural areas. *See* Voosen, *supra* note 1 ("Given its broad spread, Scotts turf could potentially be grown more broadly than any previous biotech plant."). Additionally, grasses typically have attributes such as small seed size, fast germination, and being subject to wind pollination that increase the potential of trangsene flow. *See, e.g.*, M.L. Zapiola et al., *Escape and Establishment of Transgenic Glyphosate-resistant Creeping Bentgrass* Agrostis Stolonifera *in Oregon, USA: A 4-year Study*, 45 J. APPLIED ECOL. 486–88 (2008) (finding potential for gene flow at the landscape level from GM bentgrass modified for glyphosate resistance).

15. Waltz, *supra* note 4, at 772.

16. *See* ECON. RESEARCH SERV., U.S. DEP'T OF AGRIC., ADOPTION OF GENETICALLY ENGINEERED CROPS IN THE UNITED STATES, *available at* http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.aspx (follow "Genetically engineered varieties of corn" hyperlink) (last updated July 2, 2012) (providing data obtained by the USDA's National Agricultural Statistics Service in the June Agricultural Survey for 2000–2012).

17. *See* Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167, 2177 (2004) (estimating that 70% of food on grocery store shelves contains GM products); Mary Clare Jalonick, *Shoppers Wary of GM Foods Find They're Everywhere*, WASH. POST, Feb. 25, 2011, http://www.washingtonpost.com/wp-dyn/content/article/2011/02/25/AR2011022500643.html (discussing prevalence of genetically engineered foods).

with new products hitting the market, such as crops engineered for complex traits like drought tolerance,[18] an apple that does not brown when sliced or bruised, and the first GM animal designed for human consumption.[19] Increased awareness of the ubiquity of GMOs, examples of apparent regulatory shortcomings like the bluegrass case, and development of novel GMOs have all led to heightened concern regarding the risks that GMOs may pose to human health and the environment and calls for improved regulatory oversight.[20]

Over the relatively short history of GM plants in the United States, several major problems associated with the regulatory structure have emerged: no environmental review for field testing of new plants; weak environmental review under the National Environmental Policy Act (NEPA) for deregulation decisions; narrow consideration of harm under the PPA in deregulation decisions, which excludes most risks posed by GM plants; a lack of authority for continued monitoring or oversight for plants

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18. In late 2011, APHIS announced a determination of nonregulated status for a corn variety that is modified for drought tolerance. Monsanto Co.; Determination of Nonregulated Status of Corn Genetically Engineered for Drought Tolerance, 76 Fed. Reg. 80869 (Dec. 27, 2011). Historically, most GM crops used in the United States have been modified for a single trait—usually tolerance for herbicides or resistance to insects or viruses—but drought tolerance involves manipulation of multiple genes. The commercialization of crops with modification for complex traits could be worrisome from an ecological perspective because, unlike most simple trait modifications, the introduction of complex traits could confer a competitive advantage that could lead to invasiveness or weediness outside of agricultural areas. *See, e.g.*, Phillip Dale et al., *Potential for the Environmental Impact of Transgenic Crops*, 20 NAT. BIOTECHNOL. 567, 569 (2002) (explaining that while single trait modifications like herbicide tolerance are unlikely to cause a weed problem, other biological changes such as "tolerance to extremes of . . . water . . . could potentially have significant effects on persistence and invasiveness."). However, this was not seen as a threat in the case of Monsanto's corn. *See* ANIMAL & PLANT HEALTH INSPECTION SERV., U.S. DEP'T OF AGRIC., MONSANTO COMPANY PETITION FOR DETERMINATION OF NON-REGULATED STATUS, FINAL ENVIRONMENTAL ASSESSMENT 47–51 (Nov. 2011), http://www.aphis.usda.gov/brs/aphisdocs/09_05501p_fea.pdf (determining that Monsanto's corn posed no risk of hybridization and that it is unlikely to survive absent human intervention). It appears that more complex trait GM plants could be on the path towards commercialization, as APHIS is currently reviewing field tests for a genetically engineered clone of a Eucalyptus hybrid that has been modified to possess traits for cold tolerance. ArborGen, LLC; Availability of an Environmental Assessment for Controlled Release of a Genetically Engineered Eucalyptus Hybrid, 77 Fed. Reg. 7123 (Feb. 10, 2012).

19. Andrew Pollack, *That Fresh Look, Genetically Buffed*, N.Y. TIMES, July 12, 2012, http://www.nytimes.com/2012/07/13/business/growers-fret-over-a-new-apple-that-wont-turn-brown.html (discussing federal review of the "Arctic Apple"); Emma Marris, *Transgenic Fish Go Large*, 467 NATURE 259 (2010) (discussing AquAdvantage Salmon).

20. For instance, several states including Vermont, Connecticut, and California have attempted to pass bills requiring labeling of GMOs based on consumer "right to know" concerns. Carl Etnier, *Vermont Not Alone in Pushing for GMO Labeling of Foods*, VT DIGGER (Apr. 3, 2012, 10:47 PM), http://vtdigger.org/2012/04/03/vermont-not-alone-in-pushing-for-gmo-labeling-of-foods/. Many consumer advocacy groups also launched anti-GMO or GMO labeling campaigns, citing health and environmental concerns. Julia Moskin, *Modified Crops Tap a Wellspring of Protest*, N.Y. TIMES, Feb. 7, 2012, http://www.nytimes.com/2012/02/08/dining/a-suit-airs-debate-on-organic-vs-modified-crops.html?_r=2.

once they are approved for commercialization; and the total lack of authority to review plants that utilize the loophole exposed in the bluegrass case. Essentially, GM plants are being put on the market without sufficient or appropriate pre-market review, and then APHIS does not watch for, or respond to, any unanticipated issues that may arise.

This paper evaluates the key gaps and weaknesses in the regulatory structure governing GM plants and advocates for changes that would help address some of the identified risks that attend GM plant use. Part I begins with background information on GM plants and a discussion of the main risks and concerns associated with GM plants. Part II discusses the regulatory structure for GMOs generally, and then more specifically by APHIS under the PPA. The regulatory gaps and weaknesses, and their effects, will also be identified. Part III offers a variety of recommendations for changes in regulatory policy and structure that would help close gaps and improve oversight. Part IV concludes that many transgenic plant risks and impacts could be addressed effectively in the short term with smaller changes under the PPA, but ultimately an overhaul of the broader regulatory framework that is applied to GMOs is warranted. In the short term, the most important change that could be made would be to enable APHIS to retain at least some authority to monitor for and respond to any unanticipated adverse impacts posed by GM plants after the plants have been put on the market.

I. BACKGROUND

Genetically modified plants (also referred to as "bioengineered," "transgenic," or "genetically engineered" organisms) are plants that have been modified through the application of recombinant DNA technology (rDNA).[21] The process of rDNA genetic modification is described in law as "biotechnology."[22] Scientists take genetic material from an organism and insert that material into a different organism in order to introduce a desirable trait.[23] Unlike traditional selective breeding, which is limited to reproductively compatible species, biotechnology allows scientists to transfer genes between entirely unrelated species to create "transgenic" organisms.[24]

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21. Mandel, *supra* note 17, at 2175.

22. *See Biotechnology*, ANIMAL & PLANT HEALTH INSPECTION SERV., U.S. DEP'T OF AGRIC., http://www.aphis.usda.gov/biotechnology/index.shtml (last modified Mar. 20, 2012) ("APHIS uses the term biotechnology to mean the use of recombinant DNA technology, or genetic engineering (GE) to modify living organisms."). For purposes of this paper, rDNA genetic modification is referred to as "genetic modification" (GM) or "biotechnology."

23. Mandel, *supra* note 17, at 2175.

24. *Id*.

GM plants have been widely adopted, especially in the case of crops. Over 90 varieties of GM plants have been approved for commercialization in the United States.[25] In 2012, 94% of all cotton, 93% of all soybean, and 88% of all corn planted in the United States by acreage was a GM variety.[26] By far, the most commonly introduced traits are to impart tolerance to herbicides (such as the popular glyphosate "Roundup Ready") or resistance to insects.[27] Despite its prevalence, GM plant commercialization remains controversial, and many members of the public remain concerned about potential health and environmental impacts.[28]

Concerns associated with GM plants are numerous. In terms of non-environmental risks, most concerns center on economic and health impacts. The economic concerns relate mainly to cross-pollination and subsequent contamination of conventional crops by GM varieties.[29] When contamination occurs, growers are unable to market their crops as "GM-free," export value is lost to countries that do not embrace biotech crops, and organic growers can lose organic certification for contaminated crops—resulting in lost sales, decreased revenue, and the possible loss of conventional (or heritage and heirloom) seed lines.[30] An example of this concern come to life is the LibertyLink rice case, where an experimental strain of GM rice "cross-bred with and 'contaminated' over 30 percent of U.S. ricelands," causing futures prices of U.S. rice to fall significantly in

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25. *See Petitions of Nonregulated Status Granted or Pending by APHIS as of September 27, 2012*, ANIMAL & PLANT HEALTH INSPECTION SERV., U.S. DEP'T OF AGRIC., http://www.aphis.usda.gov/biotechnology/not_reg.html (last visited Nov. 17, 2012) [hereinafter *Petitions of Nonregulated Status*] (listing approved nonregulation status and pending petitions).

26. *Adoption of Genetically Engineered Crops in the U.S.: Extent of Adoption*, ECON. RESEARCH SERV., U.S. DEP'T OF AGRIC., http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx (last visited Nov. 17, 2012).

27. The herbicide-tolerant plants are typically designed to withstand post-emergence application of a broad-spectrum herbicide. Insect resistant plants are inserted with genes (usually the Bacillus thuringiensis (Bt) soil bacterium) that promote production of proteins which are toxic to insects. *See id.* (discussing adoption of herbicide-tolerant and insect-resistant GM crops).

28. *Adoption of Genetically Engineered Crops in the U.S.: Documentation,* ECON. RESEARCH SERV., U.S. DEP'T OF AGRIC., http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/documentation.aspx (last visited Nov. 17, 2012) ("U.S. farmers have adopted genetically engineered (GE) crops widely since their commercial introduction in 1996, notwithstanding uncertainty about consumer acceptance and economic and environmental impacts.").

29. *See* Mary Jane Angelo, *Regulating Evolution for Sale: An Evolutionary Biology Model for Regulating Unnatural Selection of Genetically Modified Organisms*, 42 WAKE FOREST L. REV. 93, 108–10 (2007) (distinguishing cross-contamination and pesticide resistance in organic crops as economic risks created by GM plants).

30. *See id*. at 109 (noting that farmers lose revenue when they are unable to sell their crops as "organic" due to GM cross-contamination).

2006.[31] Litigation ensued, and the developer paid out $750 million to settle claims with about 11,000 farmers for crop contamination.[32]

Human health risks relate mainly to food safety. The main food safety concerns identified relate to the potential toxicity and allergenicity of GM foods.[33] For allergenicity, there is a worry that inserting novel genes into a plant could trigger allergic reactions.[34] This could occur either by use of genetic material from a source that is unknown to the human diet or by use of genetic material from a known allergen to produce a crop that consumers would have no reason to suspect would contain a known allergen (for instance, using a nut to modify corn).[35] Another risk is that consumption of GM crops could lead to consumption of new toxins or increased levels of naturally occurring toxins.[36] Some also worry that GM crops could contain fewer nutrients than non-GM counterparts.[37] Most consumers eat GM foods on a daily basis, and the biotech industry claims that 15 years of widespread consumption with no widely reported health problems suggests that the risks are "overhyped."[38] There is no confirmed case of human disease or illness caused by GM food.[39] Still, consumers remain worried, and some long-term health effects may be unknown given that the explosion of GM food products on grocery store shelves has been a relatively recent phenomenon.[40]

Another category of risk centers on environmental concerns. In general, the most prominent environmental concerns relate to: (1) weeds and the ability for GM crops to become weeds or for wild weeds to become "superweeds"; (2) insect resistance to crops that contain biological pesticides and the creation of "superbugs"; and (3) reduced biodiversity and effects on nontarget organisms.

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31. Andrew Harris & David Beasley, *Bayer to Pay $750 Million to End Lawsuits over Genetically Modified Rice*, BLOOMBERG (July 1, 2011), http://www.bloomberg.com/news/2011-07-01/bayer-to-pay-750-million-to-end-lawsuits-over-genetically-modified-rice.html.

32. *Id.* Some claims went to trial and resulted in jury awards in the millions in favor of farmers. *Id.*

33. Angelo, *supra* note 29, at 103–04; A.M. Shelton et al., *Economic, Ecological, Food Safety, and Social Consequences of the Deployment of Bt Transgenic Plants*, 47 ANN. REV. ENTOMOLOGY 845, 867–69 (2002).

34. Mandel, *supra* note 17, at 2190.

35. *Id*. at 2191; Angelo, *supra* note 29, at 104–05.

36. Mandel, *supra* note 17, at 2192.

37. *Id*.

38. *See* Jalonick, *supra* note 17 (discussing prevalence of genetically engineered foods).

39. Mandel, *supra* note 17, at 2190.

40. *Id*. at 2190–94 (discussing human health concerns). *See also* Amy Dean & Jennifer Armstrong, *Genetically Modified Foods Position Paper*, AM. ACAD. OF ENVTL. MED. (May 8, 2009), http://www.aaemonline.org/gmopost.html (asserting that "GM foods pose a serious health risk in the areas of toxicology, allergy and immune function, reproductive health, and metabolic, physiologic and genetic health and are without benefit" and citing studies finding health effects of GM plants on mice and rats).

First, there are several potential weed-related risks that GM plants pose. The most prominent is that GM crops could out-cross to related species or otherwise contribute to the creation of new weeds or "superweeds": weeds that have developed biological advantages (typically herbicide tolerance) that make them particularly difficult to control.[41] GM plants themselves may also become weeds.[42] Even without any genetic out-crossing, plantings of GM plants that are tolerant of a particular herbicide can have the effect of creating superweeds where widespread application of that herbicide causes weeds to develop their own tolerance and makes the herbicide ineffective against those weeds.[43]

Some of these weed-related concerns have already become real problems in agricultural settings. Widespread adoption of glyphosate-tolerant GM crops (usually marketed as "Roundup Ready") has led to an increase in glyphosate application—which, in turn, has led to a rapid development of glyphosate-resistant weeds.[44] There are now 11 weed species that have developed resistance to glyphosate in 26 states, and millions of acres of crops have been infested with the weeds—reducing yields and costing farmers money in added labor and chemical costs to combat the weeds.[45] The glyphosate-resistant weeds are especially hardy and have led to the use of herbicides that are more toxic and environmentally damaging than glyphosate.[46] Biotech companies have begun developing seeds for GM crops that can withstand application of stronger chemicals, such as a corn by Dow Chemical that can tolerate a reformulated version of 2,4-D, which is one of the major components of Agent Orange.[47] Companies have also been

41. Miguel A. Altieri, *The Ecological Impacts of Transgenic Crops on Ecosystem Health*, 6 ECOSYSTEM HEALTH 13, 16–17 (2000); Angelo, *supra* note 29, at 107. *See*, *e.g.*, Phillip Dale et al., *supra* note 18, at 569 (discussing potential weed impacts of GM plants); NAT'L RESEARCH COUNCIL, THE IMPACT OF GENETICALLY ENGINEERED CROPS ON FARM SUSTAINABILITY IN THE UNITED STATES 110 (2010), *available at* http://www.nap.edu/catalog.php?record_id=12804 (discussing potential weed impacts of GM plants).

42. Altieri, *supra* note 41, at 16 (noting that some transgenes may confer or enhance weediness in some crops and enhance their capacity to persist in agricultural fields); Angelo, *supra* note 29, at 107 (noting that GM plants may become weeds).

43. Altieri, *supra* note 41, at 16.

44. William Neuman & Andrew Pollack, *Farmers Cope With Roundup-Resistant Weeds*, N.Y. TIMES, May 3, 2010, http://www.nytimes.com/2010/05/04/business/energy-environment/04weed.html?pagewanted=1&_r=1; Jack Kaskey, *Attack of the Superweed*, BLOOMBERG BUSINESSWEEK (Sept. 8, 2011), http://www.businessweek.com/magazine/attack-of-the-superweed-09082011.html. *See also* Andrew Pollack, *Study Says Overuse Threatens Gains from Modified Crops*, N.Y. TIMES (Apr. 13, 2010), http://www.nytimes.com/2010/04/14/business/energy-environment/14crop.html (discussing study by National Research Council which found that some management practices such as over-reliance on glyphosate were reducing utility of GM crops and leading to weed problems).

45. Kaskey, *supra* note 44.

46. *Id.*

47. *Id.*

developing "stacked" hybrids, which are plants with several GM and conventional traits that impart resistance to multiple herbicides (thus allowing application of *both* glyphosate and 2,4-D to one plant).[48] The potential deregulation of the Dow "Agent Orange" corn has led to criticism—with opponents concerned about the potential for increased herbicide use overall, effects of herbicide drift to fruits and vegetables that cannot withstand strong chemicals, application of the 2,4-D herbicide to food crops and possible health risks, and worry that weeds will develop resistance to 2,4-D and in turn create bigger superweed problems.[49]

Next, there is a potential for insects to develop resistance to toxins produced in GM plants that are modified for insect resistance. This can lead to a "superbug" phenomenon similar to superweeds. Insect-resistant plants continually produce toxins, and pest species are continually exposed to these toxins. This can lead to rapid development of resistance by the insect to the introduced toxin.[50] Some pest species have already developed resistance to the commonly introduced *Bacillus thuringiensis* (Bt) toxin.[51] Plants are now being developed to produce multiple toxins instead of only Bt in order to help "delay" the development of resistance by insects to GM crops.[52] This trend may also lead to increased pesticide applications and the use of stronger chemicals to combat pests that have developed resistance.[53]

There are also concerns related to biodiversity and effects on nontarget organisms. Biodiversity may be diminished through the widespread monoculture planting of GM plants and genetic contamination of non-GM plants.[54] Contamination of wild and conventional relatives due to

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48. Tom Philpott, *Dow and Monsanto Team Up on the Mother of All Herbicide Marketing Plans*, MOTHER JONES (Jan. 25, 2012), http://motherjones.com/tom-philpott/2012/01/dows-new-gmo-seed-puts-us-agriculture-crossroads.

49. *See, e.g.*, Andrew Pollack, *Dow Weed Killer, Nearing Approval, Runs Into Opposition*, N.Y. TIMES (Apr. 25, 2012), http://www.nytimes.com/2012/04/26/business/energy-environment/dow-weed-killer-runs-into-opposition.html?_r=1&hpw&gwh=DABD9D32748D82E6B94CB7A09564DFDA (discussing concerns raised by consumer and environmental groups to Dow's 2,4-D-resistant corn); Andrew Kimbrell, *"Agent Orange" Corn: Biotech Only Winner in Chemical Arms Race as Herbicide Resistant Crops Fail*, HUFFPOST FOOD (Feb. 22, 2012, 11:25 AM) http://www.huffingtonpost.com/andrew-kimbrell/agent-orange-corn-biotech_b_1291295.html (outlining concerns associated with Dow's corn).

50. Angelo, *supra* note 29, at 110.

51. NAT'L RESEARCH COUNCIL, *supra* note 41, at 111. *See also* Scott Kilman, *Monsanto Corn Under Attack by Superbug*, WALL ST. J., Aug. 29, 2011, http://online.wsj.com/article/SB10001424053111904009304576532742267732046.html (discussing a study tracking a rootworm's recent development of resistance to Monsanto's Bt SmartStax corn in Iowa); Bruce Tabashnik et al., *Insect Resistance to* Bt *Crops: Evidence Versus Theory,* 26 NAT. BIOTECHNOL. 199 (2008) (discussing development of insect resistance to *Bt* crops).

52. NAT'L RESEARCH COUNCIL, *supra* note 41, at 112.

53. *Id.*

54. Altieri, *supra* note 41, at 15.

outcrossing could change the makeup of plant communities and reduce overall genetic diversity.[55] Introduction of GM herbicide-resistant crops may reduce weed species diversity and ecosystem complexity on GM fields and neighboring areas.[56] Finally, although there is uncertainty regarding this issue, GM plants have the potential to adversely affect non-target species due to toxicity or secondary effects.[57]

Much of the general concern associated with GM plant use stems from a lack of information regarding the long-term health and environmental impacts of GM plants. There is a fairly large degree of scientific uncertainty in a number of areas, notwithstanding the widespread use of GM plants.[58] When GM crops were first planted commercially in the mid-1990s, the potential environmental benefits and risks of the crops went largely unstudied, and the state of information has not improved significantly in recent years.[59] Current research primarily relates to the few GM plants that have been widely adopted (such as Bt and herbicide-resistant types of well-understood crops such as corn), but even those have only been studied over a short time frame. Little is known about minor crops and the "many GM products in the research and development stage that may pose much more significant risks."[60] GM plants have had a fairly brief presence in the agricultural landscape, so there could be long-term health or environmental impacts that we simply do not know about yet.

Indeed, research and knowledge regarding GM plant impacts has not kept pace with the adoption of the technology, leading to heightened public concern regarding risk. Some of this concern is probably overstated. However, not all of these concerns are merely hypothetical risks, and some worries associated with GM plants have materialized into recognized harms. It is now clear that GM crops can cross-breed with and contaminate related non-GM crops, resulting in financial losses for organic and

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55. *Id.* at 17. Some scientists think that outcrossing is unlikely due to a lack of wild relatives that grow in proximity to GM crops in the U.S., Angelo, *supra* note 29, at 107–08, and differences in chromosome number, phenology, and habitat between GM crops and wild relatives. Shelton et al., *supra* note 33, at 857. However, most research on the issue has been conducted on major crops, like corn, for which there are not wild relatives. There is a stronger risk of outcrossing for less-studied species such as alfalfa and wheat. NAT'L RESEARCH COUNCIL, *supra* note 41, at 107.

56. Dale et al., *supra* note 18, at 571.

57. *See id.* at 568 (discussing effects of GM plants on non-target species); Altieri, *supra* note 41, at 18–19 (discussing effects of Bt crops).

58. Angelo, *supra* note 29, at 110–11 (discussing the "substantial scientific uncertainty regarding the potential risks" associated with GM crops and their release in the environment and introduction to the human diet).

59. *See id.* at 110 (noting that our experience with new GM technologies is "extremely limited").

60. *Id.* at 110–11. *See also* NAT'L RESEARCH COUNCIL, *supra* note 41, at 217–18 (discussing research and informational gaps).

conventional farmers.[61] "Gene flow between [GM] and non-[GM] crops is almost impossible to prevent completely with current technology."[62] Out-crossing can occur between some GM plants with wild and weedy relatives.[63] This means that GM plants can spread to non-agricultural areas, which heightens biodiversity and weed-related concerns.[64] It is also certain that some GM plants can have cascade effects by creating resilient pests (like glyphosate-resistant superweeds), which require stronger chemicals to control, and the development of new GM plants that can withstand or produce those powerful chemicals.[65] Thus, while some things about GM plants remain unknown—especially long-term effects and whether there are any human health impacts—we now know that there are some real consequences associated with GM plant use that can have serious economic and environmental impacts.

II. REGULATORY STRUCTURE AND WEAKNESS IN GM PLANT OVERSIGHT

A. Regulation of Genetically Modified Organisms Under the Coordinated Framework

Regulatory oversight for genetically modified organisms in the United States is shared among three different agencies that in turn rely on various sources of authority. The governing policy for GM regulation is laid out in the Coordinated Framework for the Regulation of Biotechnology. The White House Office of Science and Technology Policy adopted the Framework in

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61. For instance, the LibertyLink rice case involved contamination of approximately 30% of rice grown in the United States stemming from experimental GM rice plantings and resulting in millions of dollars of losses for rice growers. *See* Harris & Beasley, *supra* note 31 (discussing LibertyLink case).

62. NAT'L RESEARCH COUNCIL, *supra* note 41, at 112.

63. *Id.* (noting that some crops where gene flow with wild and weedy relatives is possible include "canola, alfalfa, sunflower, creeping bentgrass, wheat, and rice").

64. *See* Daniel J. Schoen, Jay R. Reichman & Norman C. Ellstand, *Transgene Escape Monitoring, Population Genetics, and the Law*, 58 BIOSCIENCE 71 (2008) (noting that "reports of transgene migration from agricultural to wild populations have begun to emerge"; citing transgene escape of creeping bentgrass from field trials and hybridization of transgenic canola with a weedy relative as examples; and identifying hard to control weeds, decline of wild plant populations, and nontarget species effects as problems associated with this trend).

65. *See* NAT'L RESEARCH COUNCIL, *supra* note 41, at 112 (describing escalation of chemical controls as pests become resistant). Dow's 2,4-D corn is not the only plant being developed to withstand non-glyphosate herbicides. Dow is also working on soybeans and cotton that can withstand 2,4-D, and Monsanto is developing soybeans, cotton, and corn that can withstand dicamba (a related chemical). Other companies are developing plants to resist other herbicides. Pollack, *supra* note 49. "Of the 20 genetically engineered crops awaiting approval, 13 are intended to be resistant to one or more herbicides." *Id.* Other methods to combat superweeds include heavy plowing, which can cause soil erosion. Neuman & Pollack, *supra* note 44.

1986 to address the budding biotechnology industry in the U.S.[66] The Framework announced that existing laws would govern GM products, and that no new laws were needed.[67] The Framework divided GM oversight between three federal agencies: the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the U.S. Department of Agriculture (USDA).[68] Thus, no single agency or law governs GM organisms. This decision required some creative interpretation of existing statutes in order to extend coverage to new GM products, which resulted in a patchwork system of regulation that has been widely criticized as ineffective.[69]

The USDA has primary authority over all GM plants under the PPA.[70] "The PPA gives the Secretary of Agriculture, and through delegated authority, USDA's Animal and Plant Health Inspection Service (APHIS), the ability to prohibit or restrict the importation, exportation, and the interstate movement of plants, plant products, certain biological control organisms, noxious weeds, and plant pests."[71]

The EPA also plays a role in overseeing GM plants, but regulates only those plants that have been modified to contain or produce pesticides. In order to register, an applicant needs to show a lack of unreasonable adverse risk to humans or the environment.[72] The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) has been interpreted to cover GM plants that are "pest-protected," meaning plants that contain inserted genetic material to express pesticidal traits.[73] Practically speaking, this means that anyone who wants to introduce or commercialize a GM plant with pesticidal traits must first obtain registration approval from the EPA.

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66. Margaret Rosso Grossman, *Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort*, *in* THE REGULATION OF GENETICALLY MODIFIED ORGANISMS: COMPARATIVE APPROACHES 299, 300 (Luc Bodiguel & Michael Cardwell, eds., 2010).

67. *Id.*; Mandel, *supra* note 17, at 2216.

68. Angelo, *supra* note 29, at 114.

69. *See, e.g.*, *id.* at 95 (noting the "regulatory gaps, overlaps, and inconsistencies" associated with the Framework); Mandel, *supra* note 17, at 2228–46 (criticizing the "piecemeal, haphazard" regulatory system developed under the Framework).

70. Mandel, *supra* note 17, at 2224.

71. ANIMAL & PLANT HEALTH INSPECTION SERV., U.S. DEP'T OF AGRIC., PLANT PROTECTION ACT FACTSHEET (June 2002), [hereinafter *Plant Protection Act Factsheet*] http://www.aphis.usda.gov/publications/plant_health/content/printable_version/fs_phproact.pdf.

72. Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136a(c)(8) (2006). FIFRA defines "unreasonable adverse effects on the environment" as an unreasonable risk "taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." *Id.* § 136(bb).

73. Mandel, *supra* note 17, at 2222.

Lastly, the FDA oversees genetically modified animals. As compared with GM plants, GM animals are a relatively new development.[74] The FDA regulates GM animals under the Federal Food, Drug, and Cosmetic Act (FFDCA) by treating GM animals as a "new animal drug."[75] The FFDCA defines a new animal drug as "articles . . . intended to affect the structure or any function of the body of . . . animals."[76] The process for commercializing GM animals involves a New Animal Drug Application (NADA), and requires a determination by the FDA as to whether a product is "safe."[77] Under the NADA process, the FDA mainly considers whether a GM animal is safe to eat, nutritionally equivalent to conventional products, and safe for the environment.[78]

Under the Framework, there is "no clearly identifiable overriding guiding principle for regulating the risks of GMOs . . . . [and] no clear standards to guide [agency] decisions on whether a GMO should be permitted to be released into the environment."[79] The three agencies often incorporate health and environmental protection into GMO decisionmaking. However, full consideration of those concerns is lacking because none of the laws that the agencies operate under directly address GMOs and there is no governing policy to guide this area of regulation.

B. The Plant Protection Act

The PPA was enacted in 2000 to consolidate all or parts of 10 previously existing plant laws, such as the Plant Quarantine Act, the Federal Plant Pest Act, and the Federal Noxious Weed Act.[80] The PPA provides broad authority to the USDA Secretary "to prevent the introduction . . . or the dissemination of a plant pest or noxious weed within the United

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74. The FDA is currently considering an application by AquaBounty Technologies for approval to commercialize the "AquAdvantage salmon," which is a fast-growing fish that contains an inserted growth hormone from the Chinook salmon and a genetic on-switch from the ocean pout. These modifications result in faster growth by triggering a continuous growth cycle in the salmon (instead of the normal seasonal growth cycle). If approved, the AquAdvantage fish would be the first GM animal to be commercialized for human consumption. The approval process has been highly contentious, with critics citing environmental and labeling concerns. *See* Marris, *supra* note 19 (discussing the AquAdvantage Salmon); Andrew Pollack, *Genetically Altered Salmon Get Closer to the Table*, N.Y. TIMES, June 25, 2010, http://www.nytimes.com/2010/06/26/business/26salmon.html (outlining viewpoints for and against approval of the AquAdvantage salmon).

75. FOOD AND DRUG ADMIN., GUIDANCE FOR INDUSTRY REGULATION OF GENETICALLY ENGINEERED ANIMALS CONTAINING HERITABLE RECOMBINANT DNA CONSTRUCTS 12–13 (2009).

76. 21 U.S.C. § 321(g)(1)(C) (2006).

77. Martin Smith et al., *Genetically Modified Salmon and Full Impact Assessment*, 330 SCIENCE 1052, 1052–53 (2010) (quoting 21 U.S.C. §§ 321(u), 360b(d)(1)(B) (2006)).

78. Pollack, *supra* note 74.

79. Angelo, *supra* note 29, at 141–42.

80. *Plant Protection Act Factsheet*, *supra* note 71.

States."[81] The Secretary has delegated authority under the PPA to APHIS.[82] The Act's overall purpose is to control or prevent the spread of plant pests and noxious weeds "necessary for the protection of the agriculture, environment, and economy of the United States."[83] In general, the PPA and pre-existing plant health laws address concerns related to the introduction of foreign invasive and harmful plant pests and pathogens, and the need to control the effects of such introductions.[84] The PPA expanded upon prior authority by enhancing civil penalties for violations and by significantly expanding regulatory authority over noxious weeds.[85]

There are two main operative regulatory mechanisms under the PPA and APHIS's implementing regulations. First, APHIS regulates the release and spread of "plant pests."[86] Plant pests are defined to include certain organisms (for instance, snails or bacteria) that can injure or cause disease or damage to plants.[87] Under the regulations, organisms that are or contain plant pests are "regulated articles" subject to APHIS authority.[88] Traditionally, GM plants have been considered regulated articles because the plants were modified using material from a known plant pest.[89]

Any person may petition APHIS for a determination that a "regulated article" does not present a plant pest risk and is therefore not subject to plant pest restrictions.[90] APHIS may respond to a petition by granting it in whole or in part, or by denying it after a period of public notice and

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81. 7 U.S.C. § 7712(a) (2006). The actions that APHIS may take upon a determination of necessity include prohibition or restriction of "importation, entry, exportation, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, article, or means of conveyance." *Id.*

82. 7 C.F.R. §§ 2.22(a)(2)(xxxi), 2.80(a)(36) (2010).

83. 7 U.S.C. § 7701(1) (2006).

84. *See The Plant Protection Act: Hearing on H.R. 3766 Before the Subcomm. on Dep't Operations, Nutrition, and Foreign Agric.*, 105th Cong. 4–5 (1998) (statements of Hon. Bob Goodlatte & Hon. Charles T. Canady), *available at* http://commdocs.house.gov/committees/ag/hagplant.000/hagplant_0f.htm.

85. *Plant Protection Act Factsheet*, *supra* note 71.

86. 7 C.F.R. § 340 (2012).

87. 7 U.S.C. § 7702(14) (2006). Under the regulations, plant pests include:

> any living stage . . . of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any other organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants.

7 C.F.R. § 340.1 (2012).

88. 7 C.F.R. § 340.1 (2012).

89. *Id.* § 340.1.

90. *Id.* § 340.6(a).

comment.[91] If such a determination is granted, the product may move freely in commerce with no further APHIS oversight. In the case of GM plants, this action effectively ends APHIS regulatory authority and forecloses the possibility of continued monitoring or intervention where there are unforeseen impacts.[92]

Second, APHIS regulates noxious weeds. Under the noxious weed regulations, a "noxious weed" is considered any plant or plant product that can injure or cause damage to agricultural interests (such as crops, livestock, poultry, and irrigation), navigation, or the natural resources of the United States, public health, or the environment.[93] This broad definition could bring many plants or plant products within the reach of noxious weed regulation. Under its noxious weed authority, APHIS may ban or restrict the import or interstate transport of plants that it lists by regulation as noxious weeds.[94] Any person may petition to add or remove plants from the list. Once a petition is submitted, APHIS must make a decision whether to list or delist a plant that is "based on sound science" and within a reasonable time.[95] After a plant is listed as a noxious weed, it cannot be imported or disseminated within the United States unless APHIS grants a permit allowing that action.[96] The Administrator can deny a permit application based on specified factors and may place conditions upon the grant of a permit.[97]

The ultimate decision whether to list a plant as a noxious weed or not is discretionary.[98] APHIS uses a two-part decisionmaking framework for noxious weeds: "(1) Does the species proposed for listing meet the PPA definition of a noxious weed? (2) If the answer to question 1 is yes, then should the species be listed as a noxious weed and regulated by the Secretary?"[99] APHIS conducts a "weed risk assessment" to determine whether a plant meets the definition of a noxious weed and to inform listing

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91. *Id*. § 340.6(d)(2)–(3). The denial of a petition may be appealed within 10 days of the denial decision. *Id*. § 340.6(f)(1).

92. Mandel, *supra* note 17, at 2234.

93. 7 C.F.R. § 360.100 (2012).

94. 7 U.S.C. § 7712(f)(1) (2006). *See also* 7 C.F.R. § 360.200 (2012) (listing plants that are currently considered noxious weeds).

95. 7 U.S.C. § 7712(f) (2006); 7 C.F.R. §§ 360.500, 360.501 (2012).

96. 7 C.F.R. § 360.300 (2012).

97. *Id*. §§ 360.303, 360.304(a).

98. 7 U.S.C. § 7712(f)(1) (2006) ("In the case of noxious weeds, the Secretary *may* publish, by regulation, a list of noxious weeds . . . .") (emphasis added); *id.* § 7712(a) ("The Secretary *may* prohibit or restrict the importation . . . of any . . . noxious weed . . . .") (emphasis added).

99. APHIS, REVIEW OF PETITION, *supra* note 12, at 5.

decisions.[100] Even where a plant meets the statutory definition of a noxious weed, APHIS may decide on policy grounds not to add the plant to the list of regulated weeds.[101] APHIS currently lists about 100 plant taxa as noxious weeds.[102] As of spring 2012, no GM plants have been listed.

C. Regulatory Gaps and Weaknesses

A look at the regulatory regime applied to GM plants reveals several shortcomings that result in a failure to fully address the risks and concerns associated with the release of GM plants into the environment. Most importantly, the review of health and environmental impacts of GM plants leaves significant gaps under the PPA.

First, most new GM plants reach the field-testing stage through the notification process.[103] "Several thousand" such notification decisions have now been made.[104] Under that process, APHIS assumes the environmental safety of GM plants based on the plants meeting certain criteria and efforts to minimize releases outside of test fields.[105] Thus, APHIS conducts no environmental assessment during the notification process.[106] There is no limit to the volume or acreage of GM plants planted through the notification

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100. *See, e.g.*, ANIMAL & PLANT HEALTH INSPECTION SERV., U.S. DEP'T OF AGRIC., WEED RISK ASSESSMENT FOR NON-HERBICIDE TOLERANT AND HERBICIDE TOLERANT TYPES OF *POA PRATENSIS* L., KENTUCKY BLUEGRASS (2011), *available at* http://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/downloads/Kentucky-BG/WRA-Poa-pratensisTypes.pdf (assessing weed risks for GM and non-GM Kentucky bluegrass and finding that while weed risk was high, damage potential was low).

101. Int'l Ctr. for Tech. Assessment v. Johanns, 473 F. Supp. 2d 9, 26 (D.D.C. 2007) ("While [APHIS's] decisions must be 'based on sound science' and must meaningfully assess the weed's capability to cause harm to the interests enumerated in the statute, [APHIS] need not add to the list every plant that fits the statutory definition of a 'noxious weed.' . . . Decisions as to which noxious weeds present the greatest prospective threats, and therefore should be subject to restriction, are left to the Secretary's discretion."). In literature related to the Scotts bluegrass decision, APHIS emphasized that the decision whether to list weeds is policy-based. ANIMAL & PLANT HEALTH INSPECTION SERV., U.S. DEP'T OF AGRIC., QUESTIONS AND ANSWERS: KENTUCKY BLUEGRASS FACTSHEET (July 2011) [hereinafter APHIS, QUESTIONS AND ANSWERS], *available at* http://www.aphis.usda.gov/newsroom/2011/07/pdf/KY_bluegrass_Q&A2011.pdf ("It is important to note that while the weed risk assessment identifies whether a plant is a weed, it does not set policy for the agency. The decision on whether to add any new plant species to the Federal noxious weed list is based on the findings of a risk assessment and also a policy determination of whether the plant should be regulated at the Federal level.").

102. ANIMAL & PLANT HEALTH INSPECTION SERV., U.S. DEP'T OF AGRIC., FEDERAL NOXIOUS WEED LIST (Dec. 10, 2010), http://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/downloads/weedlist.pdf (last updated Feb. 1, 2012).

103. Mandel, *supra* note 17, at 2231-32.

104. *See* BD. ON AGRIC. AND NAT. RES., NAT'L RESEARCH COUNCIL, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS: THE SCOPE AND ADEQUACY OF REGULATION 178 (2002) [hereinafter BD. ON AGRIC. AND NAT. RES.] (analyzing the notification process).

105. *Id*. at 123.

106. *Id*.

process.[107] The same is true for the related permitting process, which is a "relatively rare" process that requires submitting a more detailed analysis of GM plants to APHIS before planting is allowed.[108] APHIS has been criticized for its notification and permitting procedures and has been cited for having poor information regarding sites and plantings, weak investigation and enforcement, and failure to provide adequate guidance to growers on how to contain GM plants and seeds.[109] That APHIS conducts no—or very little—environmental review for experimental plantings of new GM plants and sets no clear acreage or volume limits is troubling, considering that most new products are initially introduced into the environment through APHIS procedures and the behavior of the plants in the natural environment is largely speculative at that point. For instance, a few well-known examples of GM plants have escaped from field-testing sites and established in surrounding areas, including a GM lawn grass that spread to natural settings[110] and a GM rice variety that contaminated conventional crops and caused significant economic damage.[111]

Second, the deregulation process does not typically include rigorous environmental or health review. Petitions for deregulation are brought pursuant to APHIS's plant pest authority in 7 C.F.R. part 340. In general, APHIS is not obliged to identify or quantify the level of risk it considers unacceptable under the PPA,[112] and APHIS does "not violate the PPA by failing to elevate environmental concerns over other legitimate factors" when taking action or formulating rules pursuant to its PPA authority.[113] Review under the plant pest authority is very narrow and limited to whether a plant poses a plant pest risk. APHIS's task in performing a plant pest risk assessment is "to determine whether [a GM plant] itself pose[s] a plant pest risk because of its genetic modification."[114] The PPA does not require

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107. *Id*. at 179.

108. *Id*. at 183. However, even though more information is required, APHIS only conducts environmental assessments for a small percentage of permit applications. *Id.*

109. OFFICE OF THE INSPECTOR GEN., AUDIT REPORT: ANIMAL AND PLANT HEALTH INSPECTION SERVICE CONTROLS OVER ISSUANCE OF GENETICALLY ENGINEERED ORGANISM RELEASE PERMITS, i–iv (Dec. 2005) [hereinafter OFFICE OF THE INSPECTOR GEN., AUDIT REPORT], *available at* http://www.usda.gov/oig/webdocs/50601-08-TE.pdf.

110. Andrew Pollack, *Grass Created in Lab is Found in Wild*, N.Y. TIMES (Aug. 16, 2006), http://www.nytimes.com/2006/08/16/science/16grass.html.

111. *See* Harris & Beasley, *supra* note 31 (discussing LibertyLink rice).

112. Cactus Corner v. USDA, 450 F.3d 428, 433 (9th Cir. 2006).

113. Natural Res. Def. Council (NRDC) v. USDA, 613 F.3d 76, 86–87 (2d Cir. 2010) (citing NRDC v. USDA, Nos. 05 Civ. 8005(LLM) & 05 Civ. 8008(LLM), 2008 WL 1610420, at *4–5 (S.D.N.Y. June 4, 2007)). The *NRDC* court also noted the Secretary's "dual responsibility to protect plants by reducing plant pest risk and to facilitate commerce by avoiding unduly burdensome trade restrictions." *Id.* at 87.

114. Ctr. for Food Safety v. Vilsack, 844 F. Supp. 2d 1006, 1015 (N.D. Cal. 2012).

APHIS to consider major concerns associated with GM plant use, such as the effects of transgenic contamination, potential to interbreed, effect of increased herbicide use, or development of herbicide resistant weeds in conducting a plant pest risk assessment.[115] Because the noxious weed provisions operate independently of petitions for deregulation under the plant pest authority, typical deregulation decisions do not analyze potential noxious weed risks.[116] Plant pest risk analysis similarly excludes consideration of human health or economic impacts.

Third, under the current interpretation of the PPA, APHIS has no ability to issue partial or limited deregulations. "If APHIS approves a petition for deregulated status, deregulation is absolute. APHIS generally indicates that it cannot 'conditionally,' 'temporarily,' or 'partially' deregulate. For example, APHIS cannot deregulate an article but require monitoring of it."[117] Although it has been argued that APHIS can, in fact, issue partial deregulations to limit the impacts of GM plants such as transgenic contamination,[118] courts may grant *Chevron* deference to APHIS's determination that "[u]nder both the PPA and agency regulations, APHIS's authority to regulate organisms . . . is predicated upon the existence of a plant pest risk."[119] Thus, where APHIS concludes that there is no plant pest risk, APHIS has determined that it lacks the ability to regulate the plant any further. This leads to a major weakness in GM plant regulation. Once a plant is deregulated, the PPA no longer provides authority for any continued monitoring of GM plants to watch for, or respond to, unanticipated environmental impacts or to limit the volume or location of plantings where there may be environmental risk. Consequently, unforeseen problems could develop and go unnoticed or unaddressed until serious damage occurs.

Fourth, "the sufficiency of the environmental testing that APHIS does engage in is questionable."[120] Most environmental review of GM plant decisions is conducted pursuant to NEPA. Despite having made about 90

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115. *Id.* at 1015–16.

116. *Id.* at 1014–15.

117. BD. ON AGRIC. AND NAT. RES., *supra* note 104, at 183.

118. George A Kimbrell, *Regulating Transgenic Crops Pursuant to the Plant Protection Act*, *in* FOOD, AGRICULTURE POLICY, AND THE ENVIRONMENT (forthcoming 2012).

119. *Ctr. for Food Safety*, 844 F. Supp. 2d at 1017. The court in *Ctr. for Food Safety* deferred to APHIS following the Supreme Court's decision in *Monsanto v. Geertson Seed Farms*, 130 S.Ct. 2743 (2010), and noted that the *Monsanto* Court discussed partial deregulation as a regulatory alternative pending or following the completion of an EIS under NEPA but did not directly address the authority to partially deregulate alfalfa under the PPA, and neither court that considered the issue "suggest[ed] that APHIS could continue to regulate RRA after the agency had determined that the crop did not pose a plant pest risk." *Id*. at 10.

120. Mandel, *supra* note 17, at 2232.

nonregulated status determinations for GM plants,[121] APHIS has conducted only two full Environmental Impact Statements (EIS)—both of which were court-ordered.[122] APHIS categorically excludes NEPA review for plants submitted through the notification process for field trials.[123] The vast majority of deregulation decisions utilize only an Environmental Assessment—rather than the more thorough EIS. APHIS's environmental review of GM plants has been criticized as "questionable"; "lacking scientific rigor, balance, and transparency"; and having "weak and inconsistent" analysis of risks.[124] Courts and commentators alike have asserted that APHIS does not take the environmental review process seriously enough with respect to GM plants.[125]

Fifth, as the bluegrass case illustrates, there is a major loophole through which GM crops can avoid federal regulation altogether. Where a GM plant is made using a non-traditional technique without a plant pest in the modification process, the plant is never considered a "regulated article" and thus never within USDA's purview. This offers a strong incentive to developers to utilize non-pest techniques, since substantial compliance costs (such as environmental testing, litigation, and field studies) and lost profits (due to the time that it takes to get APHIS approval) could be avoided altogether.[126] Compounding this issue, the loophole could mean that NEPA review is not triggered for GM plants that are "nonregulated" (as opposed to deregulated), possibly resulting in no federal environmental review whatsoever for plants that get through the loophole.[127] Although some argue the exploitation of this loophole will be minimal because seed producers would incur costs in developing non-pest modification techniques and

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121. *See Petitions of Nonregulated Status*, *supra* note 25 (listing approved nonregulation status and pending petitions).

122. *Id.*; Kimbrell, *supra* note 118.

123. *Petitions of Nonregulated Status*, *supra* note 25; Mandel, *supra* note 17, at 2231–32.

124. Mandel, *supra* note 17, at 2232 (quoting BD. ON AGRIC. AND NAT. RES., *supra* note 104, at 148–49) (internal quotations omitted).

125. *See, e.g.*, Kimbrell, *supra* note 118 (outlining criticisms to APHIS's environmental review process).

126. Waltz, *supra* note 4, at 773 ("On a semantic technicality, regulatory costs go from $50 million to zero.") (internal quotations omitted).

127. Where GM plants employ a non-pest modification such that APHIS regulation is never triggered under the PPA's plant pest hook, APHIS may have no obligation to conduct environmental review. In other words, where a plant is nonregulated—that is, never subject to APHIS's regulatory authority—there is no "major federal action" for which APHIS is required to comply with NEPA, and there is no "final agency action" for a plaintiff to challenge sufficiency of environmental review. Whether or not APHIS should conduct NEPA review where it does not assert regulatory authority over a GM plant is likely to be an issue that will be fought out in court, but based on the bluegrass case it appears that APHIS believes no environmental review is necessary in these circumstances. One issue to consider is whether a denial of a petition to list a plant as a noxious weed under 7 C.F.R. part 360 would qualify as an agency action that would be challenged under NEPA.

APHIS approval is seen as a way to gain consumer acceptance of GM products,[128] the fact remains that the bluegrass decision has unquestionably exposed a major regulatory gap and paved the way for developers that want to avoid USDA regulation under the PPA. For instance, Scotts has several GM grasses currently in development that utilize non-pest techniques, and the bluegrass case was "largely an exercise . . . to set a precedent" for those other grasses to avoid regulation.[129] The exploitation of this loophole will likely be most prevalent in the case of non-food crops, for which public concern regarding health risks is lower.[130] Ultimately, it is too soon to predict how large of an effect the exposure of the loophole will have, but the plant pest authority—APHIS's main regulatory hook in the GM context—could become a nullity if major biotech companies decide to utilize the loophole.

III. METHODS TO IMPROVE REGULATORY OVERSIGHT OF GM PLANTS

A look at APHIS action with respect to GM plants over the past few years illustrates a growing trend: As an agency whose overall purpose is to promote domestic agriculture, the USDA's approach with respect to GM plants is geared towards deregulation.[131] Recent developments have presented dramatic changes—successful introduction of complex traits, development of crops able to withstand stronger chemical applications, and exposure of gaps and a major loophole in oversight—but the regulatory landscape has remains geared toward getting new GM crops to market as soon as possible.[132] Although the USDA has attempted to revise its regulations with respect to GM crops under the PPA for years, there is little predictability as to when or whether revisions will be enacted or what form

128. Waltz, *supra* note 4, at 773.

129. *Id*. at 772–73.

130. Pollack, *supra* note 14.

131. Angelo, *supra* note 29, at 142 ("USDA's approach is focused on deregulating GMOs.").

132. *Id.* Indeed, in November 2011 APHIS announced rule changes designed to streamline the deregulation petition process and cut the time needed to review petitions by half. Press Release, Animal & Plant Health Inspection Serv., USDA Announces Improvements to Genetically Engineered Petition Process (Nov. 14, 2011) *available at* http://www.aphis.usda.gov/newsroom/2011/11/ge_petition_process.shtml; *see also* Jack Kaskey, *Genetically Modified Crops to Get Faster Approval, USDA Says*, BLOOMBERG BUSINESSWEEK (Feb. 24, 2012), http://www.businessweek.com/news/2012-02-24/genetically-modified-crops-to-get-faster-approval-usda-says.html (detailing rule changes and noting criticism that the revisions are meant to limit public input and the review is a "rubber stamp" process). Under the new rules, new versions of existing technologies go through an expedited process of approximately 13 months, while novel technologies would undergo two rounds of public comment and a review period of approximately 16 months. The average review time under existing procedures is about three years. *Id*.

revisions would take.[133] Unless and until those changes occur, oversight will continue under the *status quo* laid out by existing regulations. This Part explores ways that GM plant oversight could be improved. It begins by discussing a proposal to regulate GM plants under noxious weed authority of the PPA. It then discusses other methods that could help to close regulatory gaps and address some of the concerns associated with GM plant use.

A. Noxious Weed Authority

One solution suggested to help close regulatory gaps within the existing regulatory framework is to apply noxious weed authority under 7 C.F.R. part 360 to transgenic plants. Due to the newly exposed loophole in plant pest authority and concerns associated with the weediness of recently approved GM crops such as bluegrass, alfalfa, and complex-trait varieties, the noxious weed provisions could be an attractive way to remedy these issues. For instance, the Center for Food Safety's George Kimbrell argues that noxious weed authority under the PPA can and should be applied to regulate transgenic impacts such as contamination and resistant weeds.[134] Kimbrell asserts that full use of PPA authority would help to improve GM plant oversight in the short-term before legislative changes occur.[135] While Kimbrell argues convincingly that noxious weed authority could be applied to address some transgenic impacts, the bluegrass decision and other indications from APHIS suggest that APHIS is not prepared or required to apply its noxious weed authority to assert jurisdiction over GM crops.

The noxious weed authority is a discretionary power. As in the case of Kentucky bluegrass, a plant may meet the statutory definition of a noxious weed, but not be listed for regulation on policy grounds. So long as APHIS meets procedural requirements such as basing its decision on sound science, APHIS retains "considerable discretion" in deciding whether a plant that meets the statutory definition of a noxious weed should be added to the federal listings and regulated.[136]

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133. Waltz, *supra* note 4, at 773 (noting that the USDA has considered widely varying proposals for rule revisions but in the meantime there may be "more bluegrass-like decisions from APHIS"); Ctr. for Food Safety v. Vilsack, 844 F. Supp. 2d 1006, 1040 (N.D. Cal. 2012) (outlining and accepting APHIS's argument that while a proposed rule would amend regulations to expand scope of authority, APHIS is bound by current rules prior to any formal amendment).

134. Kimbrell, *supra* note 118.

135. *Id.*

136. Int'l Ctr. for Tech. Assessment v. Johanns, 473 F. Supp. 2d 9, 26 (D.D.C. 2007) ("While its decisions must be 'based on sound science' and must meaningfully assess the weed's capability to cause harm to the interests enumerated in the statute, it need not add to the list every plant that fits the statutory definition of a 'noxious weed.'"). In literature related to the Scotts bluegrass decision, APHIS

GM plants are unlikely to come within the reach of noxious weed authority because APHIS has so far applied a narrow interpretation of the types of plants that should be regulated under the noxious weed authority. In the Kentucky bluegrass decision, APHIS offered guidance on when a noxious weed will be regulated. APHIS emphasized that few weeds would rise to a level warranting regulation: "Only a fraction of these problematic weeds are considered to be so invasive, so harmful, and so difficult to control that Federal regulatory intervention to prevent their introduction or dissemination is justified."[137] The take-home point is that a GM plant may carry an acknowledged noxious weed risk, but APHIS may decline to regulate it based on a decision that the weed's impacts are not severe enough. "Decisions as to which noxious weeds present the greatest prospective threats, and therefore should be subject to restriction, are left to the Secretary's discretion."[138]

Indeed, APHIS should not be expected to regulate all GM plants that meet the statutory definition of a noxious weed. Some GM plants, like bluegrass or alfalfa, may carry a weed risk but are not traditionally viewed as "weeds"—to be sure, many such crops are valued by society. Even if APHIS wanted to generally regulate GM plants as noxious weeds, practical realities would prevent it from doing so. APHIS has made a clear policy choice to direct its noxious weed funds to deal with certain weeds that have significant negative impacts.[139] In addition to funding problems, APHIS may also lack the personnel necessary to deal with such an expansion of noxious weed jurisdiction. APHIS voiced these concerns in the Scotts bluegrass decision, noting that "[f]unding for federal regulatory response for Kentucky bluegrass is unlikely to be available at a time when our noxious weed program is facing funding limitations, and the required response would be beyond the combined federal and state regulatory capacity."[140] Thus, it is reasonable to assume that absent an increase in

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emphasized that the decision whether to list weeds is policy-based. APHIS, QUESTIONS AND ANSWERS, *supra* note 101 ("It is important to note that while the weed risk assessment identifies whether a plant is a weed, it does not set policy for the agency. The decision on whether to add any new plant species to the Federal noxious weed list is based on the findings of a risk assessment and also a policy determination of whether the plant should be regulated at the Federal level.").

137. APHIS, REVIEW OF PETITION, *supra* note 12, at 8. Examples of impacts that APHIS identified that it looks for in listing decisions include: lost productivity of crop fields, parasitic damage to crops, reduced productivity of pasture, injury to humans or livestock (toxicity), unchecked growth, physical obstructions, disruption of water flow, and habitat alteration. *Id.* at 8–10.

138. *Int'l Ctr. for Tech. Assessment*, 473 F.Supp.2d at 26.

139. *See* APHIS, REVIEW OF PETITION, *supra* note 12, at 3–4 (noting that the "vast majority of program funding is dedicated to addressing a small number of targeted Federal noxious weed priorities").

140. *Id.* at 12.

funding and capacity for the noxious weed program (or development of serious negative weed impacts), APHIS is unlikely to exercise its discretionary authority to assert jurisdiction over GM plants given the program's limited resources.

Further, APHIS has adopted a policy of regulating noxious weeds at the species level.[141] Where genetic engineering does not create a new species of a plant, the GM plant will be considered for listing along with its conventional counterpart.[142] Where there is little evidence of serious noxious weed impacts associated with the conventional counterpart, APHIS will probably not list the species as a noxious weed absent compelling evidence of weed risk from the GM variety. APHIS's ability to respond to weed problems may also be limited where a GM variety's conventional counterpart is already established in the United States, making it less likely that a plant will be listed where APHIS would be unable to undertake a meaningful regulatory response.[143]

Lastly, APHIS has signaled that it will not take regulatory action under the noxious weed authority to prevent the "superweed" problem associated with crops engineered to be resistant to glyphosate. In the Scotts bluegrass decision, APHIS stated that it has "little authority" to prevent the evolution of herbicide-tolerant weeds and noted that APHIS has never regulated a weed as noxious because of resistance to an herbicide alone, nor taken action to "prevent the *evolution* of noxious weeds."[144] Whether or not APHIS is correct that it possesses little authority to prevent the evolution of noxious weeds,[145] it seems clear that APHIS is not eager to apply the noxious weed authority to address GM plant impacts like "superweeds."

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141. *See, e.g.*, APHIS, REVIEW OF PETITION, *supra* note 12, at 5 ("Thus, consistent with the provisions of the PPA which provide APHIS authority to regulate noxious weeds, it has been the Agency's policy to regulate at the species level.").

142. For instance, the single gene insertion to create glyphosate tolerance in Scotts bluegrass did not create a new species of Kentucky bluegrass. APHIS, QUESTIONS AND ANSWERS, *supra* note 101.

143. Under the PPA, APHIS has broad general authority over any plant meeting the definition of a noxious weed, but specific authority to take remedial action "to prevent the dissemination of a . . . noxious weed that is *new to or not known to be widely prevalent*" in the United States. 7 U.S.C. § 7714(a) (2002) (emphasis added). APHIS has interpreted the PPA to mean that where a species is *not* new or not widely prevalent, APHIS lacks the authority to take remedial measures. APHIS, REVIEW OF PETITION, *supra* note 12, at 12. This could preclude application of remedial measures to many GM plants, because though the GM variety is "new," the conventional counterpart is probably not new and could be widely prevalent, as was the case for bluegrass. *See id.* (stating that Kentucky Bluegrass is not new, and is widely prevalent).

144. APHIS, REVIEW OF PETITION, *supra* note 12, at 12. APHIS also pointed out that the development of herbicide resistant weeds has occurred "long before the advent of [herbicide tolerant] crops," and is not an issue uniquely related to GM crops modified for herbicide resistance. *Id.*

145. It seems that APHIS would indeed have the ability to address future harms (like evolution of superweeds) associated with GM plant adoption based on the definition of noxious weed and the

B. Changes Under the Existing PPA Framework

APHIS could improve oversight by altering its internal interpretation of the PPA or by advocating for legislative adjustments in a few key areas. For a number of reasons already discussed, it is unlikely that APHIS will voluntarily assert authority over GM plants under its noxious weed authority given current regulatory conditions.[146] However, a few tweaks could make the noxious weed authority a more viable way to address GM plants. For example, APHIS could amend its "species-level" regulatory policy under its noxious weed authority.[147] The species-level policy effectively excludes GM plants from regulation under the noxious weed program because it dilutes consideration of weed impacts that may be specific to the GM variety.[148] Abandoning this policy in the transgenic context makes sense because a GM variety is distinguishable from, and could pose different risks than, conventional varieties (even if it is the same species). Further, the policy is a disincentive for oversight because it imposes a tremendous prospective regulatory burden on APHIS, which would need to regulate both the GM variety and conventional counterparts under its current interpretation. Creating a carve-out from the species-level policy for GM plants would be beneficial because it would allow APHIS to focus solely on the noxious weed concerns, if any, that are uniquely associated with the GM variety of a given species and would make it more likely that APHIS could implement a targeted regulatory response to those concerns. Though a carve-out would be helpful to both APHIS and public proponents of GM regulation, APHIS is ultimately unlikely to exercise its discretionary noxious weed authority over GM plants unless there is significantly increased funding and support for the noxious weed program. Thus, increased funds should be dedicated to this program if it is chosen as a method for dealing with GM plants. APHIS could reallocate general funds or request an increase of directed funding from Congress.

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grant of general regulatory authority over noxious weeds contained in the PPA. The noxious weed definition embraces any plant that can injure or cause damage to "crops . . . other interests of agriculture . . . the natural resources of the United States . . . or the environment," and harms such as evolution of herbicide-resistant weeds could easily be considered injury or damage to one of those categories. 7 U.S.C. § 7702(10) (2006). Further, the language includes any plant that "*can* directly or indirectly injure or cause damage," rather than "*does*" injure or damage, so evolution of superweeds and other prospective harms could be included within the scope of authority. *Id.* (emphasis added). *See also* Kimbrell, *supra* note 118 (arguing that "one of the most important uses" APHIS could make of the noxious weed authority would be to address development of herbicide-resistant weeds).

146. Section III.B, *supra*.

147. *See* Section III.A, *supra* at 26–27 (discussing the species-level policy).

148. *Id.*

Also, some regulatory changes could be made to the PPA's implementing regulations that would greatly improve oversight. APHIS has already proposed most of these changes in a draft programmatic EIS released in 2007 regarding rule amendments that would increase oversight of GM plants.[149] First, APHIS could introduce rules that would allow for post-market monitoring of GM plants. Under current rules, once a GM plant is deregulated, there is no continued oversight of that plant.[150] This means that potential issues that could arise after commercialization may be unknown to APHIS, or APHIS could lack the ability to respond to problems. Thus, a rule that would allow for at least some post-market monitoring (for instance, in the case of GM plants with novel traits or made using less studied gene insertions) would improve oversight because APHIS could watch for—and potentially respond to—unexpected impacts.[151] This could take the form of issuing partial or conditional deregulations that require ongoing reporting or testing for transgenic impacts for those GM plants that APHIS considers to be risky or novel.[152] Where there is suspicion or evidence of adverse impacts such as contamination, APHIS could step in to require remedial action. Ultimately, post-market oversight is one of the most important areas in which regulation could be improved. It would ensure that APHIS could "detect and correct any unanticipated problems," thereby helping to avoid serious environmental harms and improving consumer confidence.[153] Some issues for policymakers to consider are who would bear the costs for testing and monitoring, what the scope of such programs should look like, and whether APHIS itself would implement oversight programs. If APHIS were to fund or implement the programs, there would likely need to be a significant increase in APHIS personnel and financial resources. Additionally, it is possible that post-market oversight could require a legislative change since courts have upheld APHIS's interpretation that it lacks regulatory authority under the PPA over a GM plant for which there is a finding of no plant pest risk.

The notification and permitting procedures, under which GM plants are first released into the environment, should include at least some initial

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149. Introduction of Organisms and Products Altered or Produced Through Genetic Engineering, 72 Fed. Reg. 39021 (July 17, 2007) (codified at 7 C.F.R.§ 340).

150. *Id*. at 39023.

151. *See id.* ("APHIS is exploring the concept of a system that could give increased flexibility for handling special cases involving less familiar traits by creating provisions that allow for imposition of conditions for unconfined release. This could facilitate commercialization, while requiring appropriate restrictions or monitoring."); BD. ON AGRIC. AND NAT. RES, *supra* note 104, at 192–216 (discussing need for post-market monitoring).

152. *See* Introduction of Organisms and Products Altered or Produced Through Genetic Engineering, 72 Fed. Reg. at 39024 (discussing options for limited deregulation where some oversight is retained by APHIS).

153. Mandel, *supra* note 17, at 2248.

evaluation to determine whether plants pose environmental risks. The notification process should be replaced by a permit-only system to allow for greater involvement by APHIS, and to allow for APHIS to better evaluate the risks of a given plant and whether conditions should attach to a permit.[154] A permit system should allow for exemptions to permitting requirements in cases where: GM plants have very low risks, APHIS is familiar with the behavior of that class of plant in the environment, adequate measures are taken to avoid escape, and exemptions are established through notice and comment rulemaking.[155] Regardless of any changes to the existing notification and permitting process, however, APHIS could greatly improve oversight by ensuring that it gathers sufficient information and keeps records on field trials, inspecting fields regularly and enforcing against violations, and providing adequate information to growers on best practices to avoid adverse impacts.[156]

APHIS could also improve GM plant oversight by closing the loophole in plant pest coverage that was exposed by the Scotts bluegrass case. Under the current rules, the "trigger" for coverage under the plant pest provisions is based solely on taxonomic considerations.[157] Where a GM plant is made without the use of an organism listed in the definition of a plant pest, it can escape APHIS risk analysis altogether. To avoid this situation, the taxonomic trigger should be expanded such that genetic modification itself is considered a trigger for plant pest review.[158] This modification would close the loophole in plant pest oversight so that new GM plants that use non-pest modification techniques would still be subject to the PPA. The

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154. APHIS previously considered a "tiered" permit system that would categorize plants based on environmental risk and agency familiarity. Introduction of Organisms and Products Altered or Produced Through Genetic Engineering, 72 Fed. Reg. at 39023. Under this system, the lowest-risk plants would be subject to a permitting process similar to the current notification process. *Id.*

155. UNION OF CONCERNED SCIENTISTS, COMMENTS RE: USDA APHIS PROPOSED RULE REGULATING GENETICALLY ENGINEERED ORGANISMS, Comment No. APHIS-2008-0023-0433, at 9 (2008) *available at* http://www.ucsusa.org/assets/documents/food_and_agriculture/UCS-comments-GE-rule.pdf (discussing reasonableness of exemptions to permit requirements).

156. *See generally* OFFICE OF THE INSPECTOR GEN., AUDIT REPORT, *supra* note 109, at i–iv (citing poor implementation of notification and permitting procedures by APHIS).

157. Plant pests are currently defined as:

> [a]ny living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants.

7 C.F.R. § 340.1 (2012).

158. *See* BD. ON AGRIC. AND NAT. RES., *supra* note 104, at 79–83 (recommending use of the process of genetic engineering as a trigger for regulation).

National Research Council has recommended that all GM plants be reviewed for risk, stating:

> It is not possible for a regulatory agency to judge ex ante whether a transgenic crop is similar to a conventional crop variety and therefore has acceptable risks, . . . [so] all transgenic crops should be reviewed through regulatory oversight. . . . [m]ost genetic changes would be expected to have low environmental risk, so all transgenic crops should be reviewed quickly to identify the smaller fraction that will need closer scrutiny.[159]

Indeed, a workable system could feature a brief initial evaluation for all new GM plants to determine whether the genetic changes pose a significant risk. If the risk is low (for instance, the GM plant is a new variety of an already widely used modification), the GM plant could move forward without more detailed review. Higher risk plants would accordingly go through more thorough analysis and could be subject to the partial or conditional deregulation discussed earlier. This scenario would avoid a situation where risk analysis would be unworkably burdensome for regulators, but all new GM plants would at least pass through an initial risk analysis through the process-based trigger for review.

Additionally, consideration of transgenic impacts would be greatly enhanced if APHIS amended its implementing regulations so that noxious weed effects were incorporated into deregulation decisions under the plant pest provisions. As it stands now, the plant pest and noxious weed regulations are distinct and operate independently such that deregulation decisions (brought under the plant pest regulations in 7 C.F.R. part 340) require no consideration of noxious weed impacts—or any other potential harm aside from the narrow plant pest risk.[160] Synthesizing these regulations would ensure that more of the concerns associated with GM plant use would be considered in APHIS regulatory decision making. A system should be devised in which any petition to commercialize GM plants could trigger a risk analysis that includes consideration of *both* plant

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159. *Id*. at 83.

160. Ctr. for Food Safety v. Vilsack, 844 F. Supp. 2d 1006, 1014 (N.D. Cal. 2012). There, the plaintiff environmental group argued that despite the fact that 7 C.F.R. part 340 requires no analysis of noxious weed effects in a deregulation decision, APHIS nonetheless should have considered those risks pursuant to PPA's "expansive noxious weed mandate" when it deregulated RoundUp Ready Alfalfa. *Id.* The court rejected the environmental group's claim, finding that "APHIS was under no obligation to assess whether [the alfalfa] posed a noxious weed risk when it made its deregulation determination." *Id*. at 1015. The court noted that "Congress provided distinct mechanisms for regulating plant pests and noxious weeds" and found that APHIS's exercise of authority pursuant to the two distinct regulations for plant pests and noxious weeds was a reasonable interpretation of its mandate. *Id*. at 1014.

pest and weed risks at the pre-commercialization stage. Since weed-related problems—such as "superweed" development—are already established as an adverse impact of GM plants, it would make good sense to ensure that a petition for deregulation raises weed impacts and plant pest risk in tandem.

CONCLUSION

GM plants are now a firmly established part of the American agricultural landscape, but the regulatory approach governing their use has not kept pace with developments in technology. Instead, the United States continues to rely on a patchwork system of laws under the Coordinated Framework that fails to effectively address the risks and concerns—some of which are speculative, but some already established—associated with GM plant use. Oversight of GM plants by APHIS under the PPA could be improved by closing gaps and inefficiencies within the existing regulatory framework.

For instance, the lack of sufficient (or any) environmental review for field testing could be addressed by eliminating the notification process and using a permitting system that would allow for more directed consideration of the impacts of experimental plantings. The regulatory loophole exposed in the bluegrass case could be closed by using genetic modification itself as the trigger for federal authority to review risk instead of the current taxonomic trigger that does not apply where non-pest modification techniques are used. Synthesizing the plant pest and noxious weed regulations such that both risks were considered any time a GM plant was being reviewed for deregulation could improve consideration of transgenic impacts—particularly environmental risks such as weed problems. APHIS could also potentially broaden consideration of transgenic impacts related to weeds if it abandoned the "species-level" policy for noxious weed petitions and considered GM plants independently of conventional counterparts.

In particular, a mechanism for post-market monitoring of GM plants is the most important change that could be made with respect to GM plant regulation. This would allow regulators to watch for and address problems that might arise from a GM plant after it has been approved and put on the market. Many problems associated with GM plants, such as cascade effects like the superweed, are not readily apparent until after the plant has been deregulated and released into the environment. Thus, regulators need to have the ability to deal with unanticipated impacts. This change would strike a balance by still allowing GM plants onto the market despite uncertain later effects while also enabling APHIS to detect and address those impacts where necessary.

However, improvements within the existing system are only a short term fix, and an overhaul of United States biotechnology policy is warranted. Even with improvements to APHIS oversight under the PPA, there would still be many inefficiencies and overlaps at play under the Coordinated Framework.[161] In the meantime, while the nation waits for a cohesive regulatory policy for GMOs, improvements should be made to APHIS regulation of GM plants under the PPA to help address and minimize environmental risks.

161. *See* Mandel, *supra* note 17, at 2230–57 (discussing problems with, and potential fixes to, the Coordinated Framework). An example of such inefficiency is that APHIS, rather that the EPA (the nation's lead environmental agency) is generally responsible for environmental review of GM plant releases. *Id.* at 2231.