CAUTION, PRECAUTION & COMMON SENSE: SOME THOUGHTS ON *GMOS*, ECOSYSTEMS, AND *REGULATING* THE UNKNOWN[1]

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> "Because biotechnology is such a revolutionary science, and has spawned such a powerful industry, it has great potential to reshape the world around us... Any major mistakes could lead to tragic and perhaps permanent changes in the natural world. For these reasons, future generations are likely to look back to our time and either thank us or curse us for what we do – or don't do – about GMOs and biosafety. Doing the right thing is not simple." - CBD AND UNEP 2003

Abstract: As of 2014, genetically modified crops occupied 448 million acres globally, representing a global market value of 15.7 billion dollars. The United States planted 170 million acres of genetically engineered crops in 2012, including 95% of the nation's sugar beets, 94% of the soybeans, 90% of the cotton and 88% of the feed corn. While many argue that biotechnology is essential to ensuring long-term food security in the climate change era, little is known of its impact on ecosystems. Potential risks such as changes in adaptive characteristics, gene flow, pest resistance, genotypic or phenotypic instability and adverse effects on non-target organisms must be balanced with the benefits of genetically modified crops. Despite much perseveration about the risks and benefits of GMOs, the United States regulatory regime has remained stagnant, unable to adapt to new innovations in the field. This lack of adequate oversight cannot go on. We propose shifting responsibility to a single agency charged with implementing science-based regulations that embrace the precautionary principle and promote early collaboration among stakeholders, multidisciplinary research, and well-designed monitoring. Part I of this Article provides an overview of biotechnology in modern agriculture. More specifically, it evaluates potential benefits and risks associated with genetically modified crops. Part II outlines the United States regulatory regime as it applies to genetically modified crops. Part III analyzes the current regulatory process, focusing specifically on the Department of Agriculture's ineffective role in the environmental review process. Last, Part IV offers several potential adjustments to improve our ability to identify and mitigate the unforeseeable consequences of implementing this revolutionary technology.
Keywords: Genetically modified crops. Genetically modified organisms. Environmental Impacts

INTRODUCTION

As of 2014, genetically modified crops occupied 448 million acres globally, representing a global market value of 15.7 billion dollars.[4] The United States

1 This article was published in the *e-book:* O Estado no mundo globalizado: soberania, transnacionalidade e sustentabilidade. Org. CRUZ, Paulo Márcio; GARCIA, Heloise Siqueira; GUASQUE, Bárbara. Available at: http://emeron.tjro.jus.br/capa/952-emeron-lanca-primeiro-e-book-com-artigos-de-magistrados-rondonienses.
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4 Int'l Serv. for the Acquisition of Agri-Biotech Applications (ISAAA), Global Status of Commercialized Biotech/GM Crops in 2014 (2014), *available at* http://www.isaaa.org/resources/publications/pocketk/16/ [hereinafter "ISAAA Report"].

planted 170 million acres of genetically engineered crops in 2012, including 95% of the nation's sugar beet, 94% of the soybean, 90% of the cotton and 88% of the feed corn.[5] While many argue that biotechnology is essential for ensuring long-term food security in this era of climate change, little is known about its impact on ecosystems. Potential risks, such as changes in adaptive characteristics, gene flow, pest resistance, genotypic or phenotypic instability, and adverse effects on non-target organisms, must be balanced with the benefits of genetically modified crops.

Despite much perseveration about the risks and benefits of GMOs,[6] the United States regulatory regime has remained stagnant, unable to adapt to new innovations in the field. This lack of adequate oversight cannot continue. We propose shifting responsibility to a single agency charged with implementing science-based regulations that embrace the precautionary principle and promote early collaboration among stakeholders, multidisciplinary research, and well-designed monitoring.

Part I of this Article provides an overview of biotechnology in modern agriculture. More specifically, it evaluates the potential benefits and risks associated with genetically modified crops. Part II outlines the United States regulatory regime as it applies to genetically modified crops. Part III analyses the current regulatory process, focusing specifically on the Department of Agriculture's ineffective role in the environmental review process. Lastly, Part IV offers several potential adjustments to improve our

5 WEISE, Elizabeth. Genetically Modified Crops had Bumper Year in 2001. **USA Today**, Feb. 8, 2012. Available at: <http://usatoday30.usatoday.com/money/industries/food/story/2012-02-06/biotech-crops/53005000/1>.

6 *See generally* BALBOA, Maria Gabriela. *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.** v. 255, 2012; LEE-MURAMOTO, Maria R., *Reforming the "Uncoordinated" Framework for Regulation of Biotechnology*, **17 Drake J. Agric. L.** v. 311, 2012; MARRAPESE, Matha E.; KRASNY, Leslie T., **Addressing the Complexities of Regulatory Schemes for GMOs and Products Derived from Them**, Aspatore 2014 WL 7247056, 2014; KUNICH, John Charles. *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, **74 S. Cal. L. Rev**. v. 807, 2001; HECKMAN, Christopher, **Tying its Own Hands: APHIS's Inability to Regulate Genetically Modified Crops**, 41 Ecology L.Q. 325, 2014; FAURE, Michael; WIBISANA, Andri, *Liability for Damage Caused by Gmos: An Economic Perspective*, **23 Geo. Int'l Envtl. L. Rev.** v. 1, 2010; MANDEL, Gregory N., *Toward Rational Regulation of Genetically Modified Food*, **4 Santa Clara J. Int'l L.** v. 21, 2006; MANDEL, Gregory N., *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, **45 Wm. & Mary L. Rev**. v. 2167, 2004.

ability to identify and mitigate the unforeseeable consequences of implementing this revolutionary technology.

GENETICALLY MODIFIED ORGANISMS

Humans have a long history of influencing genetic expression in domesticated species. Humans have historically influenced genomes indirectly through breeding programs aimed at creating offspring with desirable traits.[7] By contrast, genetic engineering – or biotechnology[8] - enables the direct manipulation of an organism's genome to express "desired physiological traits or the production of desired biological products."[9] This technique marks a drastic departure from conventional breeding because it allows scientists to overcome reproductive barriers, creating a universal gene pool accessible to all organisms.[10]

GMO USE IN AGRICULTURE

Biotechnology has become an integral part of modern agriculture. Hailed as the "fastest adopted crop technology" in agricultural history, the use of genetically modified crops ("GM crops") has grown exponentially since it was first commercialized in 1996.[11] Currently, more than 18 million farmers in 28 countries plant GM crops.[12] The United States is the largest producer and user of GM crops, which account for

7 NATIONAL HUMAN GENOME RESEARCH INSTITUTE. **Genetic Engineering.** Available at: http://www.genome.gov/glossary/index.cfm?id=82 (last visited Aug. 5, 2015).

8 Biotechnology is defined as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use" Food & Agric. Org. of U.N.: UN. **Biosafety Resource Book 1**, 2011, available at http://www.fao.org/3/a-i1905e.pdf [hereinafter "FAO Biosafety Resource Book"].

9 BRITANNICA DICTIONARY. **Genetically Modified Organisms**. Available at: http://www.britannica.com/science/genetically-modified-organism

10 FAO Biosafety Resource Book, *supra* note 7, at 7-8.

11 FERNANDEZ-CORNEJO, Jorge; *et al.*, **U.S. Dep't of Agric., ERR-162, Genetically Engineered Crops in the United States 1**, 2014, *available at* http://www.ers.usda.gov/media/1282246/err162.pdf [hereinafter "USDA Report"]; WEISE, Elizabeth. Genetically Modified Crops had Bumper Year in 2001. **USA Today**, Feb. 8, 2012. Available at: <http://usatoday30.usatoday.com/money/industries/food/story/2012-02-06/biotech-crops/53005000/1>. ("Biotech crops have set a precedent in that the biotech area has grown impressively every single year for the past 19 years, with a remarkable 100-fold increase since commercialization began in 1996.")

12 ISAAA Report, *supra* note 3.

50% of the country's agriculture.[13] As of 2015, 94% of the soybean, 94% of the cotton and 92% of the corn grown in the United States was genetically modified.[14]

GM crops generally fall into one of three categories: herbicide tolerance, pest resistance, or "stacked" genes.[15] Herbicide tolerance – specifically glyphosate tolerance – is the most widely used trait in agriculture.[16] Once incorporated into a plant's genome, the gene provides resistance to toxic chemicals that would have previously killed the crop along with the targeted weeds.[17] Insect-resistant crops, on the other hand, generally contain a gene derived from the bacterium Bacillus thuringiensis ("Bt"), which secretes a protein that is toxic to many common agricultural pests.[18] To date, more than 200 types of Bt proteins are commercially available, with various levels of toxicity to a wide range of agricultural pests.[19] Lastly, "stacked genes" are the newest development in agricultural biotechnology.[20] With stacked genes, scientists are able to control a broad range of pests and weeds by inserting multiple traits into an organism, increasing herbicide tolerance and insect resistance traits.[21]

BENEFITS OF GENETICALLY MODIFIED CROPS

GM crops offer various promising benefits including, enhanced taste and quality, reduced maturation time, increased nutrients higher yields, abiotic stress

13 USDA Report, *supra* note 10, at 9.
14 USDA, **Recent Trends in GE Adoption, Adoption of Genetically Engineered Crops in the U.S.**, July 9, 2015. Available at: http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx [https://perma.cc/54TY-8KWL]
15 Int'l Union for the Conservation of Nature, Current Knowledge of the Impacts of Genetically Modified Organisms on Biodiversity and Human Health 15-17 (2007). (hereinafter "IUCN Report")
16 USDA Report, *supra* note 10, at 1.; QUE, Qiudeng, *et al*. **Trait Stacking in Transgenic Crops: Challenges and Opportunities**, 1 GM Crops 220, 220 (2010), *available at* http://www.tandfonline.com/doi/pdf/10.4161/gmcr.1.4.13439 [https://perma.cc/MY8G-BLUZ].
17 FERNANDEZ-CORNEJO, Jorge; MCBRIDE, William D. **Genetically Engineered Crops for Pest Management in U.S. Agriculture:** Farm-Level Effects 1, USDA, AER-786, 2000, available at http://www.ers.usda.gov/media/491365/aer786a_1_.pdf
18 "When ingested by the larva of the target insect, the Bt protein is activated in the gut's alkaline condition and punctures the mid-gut leaving the insect unable to eat, killing the insect within a few days." ISAAA, **Bt Insect Resistant Technology 1**, 2015. Available *at* http://isaaa.org/resources/publications/pocketk/6/default.asp [https://perma.cc/7GRG-SJG2]. See also Fernandez-Cornejo & McBride, *supra* note 16, at 1.
19 ISAAA, Bt Insect Resistant Technology, *supra* note 17, at 1.
20 The U.S. has created the largest number of stacked genes in the world and has even introduced the first triple-stacked gene that is resistant to rootworm, corn bearer and Roundup herbicide. IUCN Report, *supra* note 14, at 17.
21 Qiudeng Que et al., *supra* note 15, at 220.

tolerance, and improved resistance to diseases, pests, and herbicides.[22] GM crops may also prove environmentally beneficial, leading to significant reductions in traditional herbicide and pesticide use.[23] Finally, and perhaps most importantly, GM crops could prove essential for feeding the world's growing population and ensuring long-term food security in the Anthropocene era.[24]

CROP IMPROVEMENTS

Genetic engineering offers several ways of improving the viability and productivity of crops. For example, crops can be engineered to resist abiotic stresses, including drought, extreme temperature or salinity.[25] Water stress[26] is one of the most detrimental abiotic factors to crop yields.[27] To alleviate pressures created by water shortages, companies have begun engineering crops with resistance to various drought conditions. Monsanto, for instance, has begun testing a gene that helps corn maintain more normal metabolic levels when drought conditions would otherwise kill it.[28] Biologists have also created a transgenic tomato plant that thrives in salty irrigation water.[29]

22 BALBOA, Maria Gabriela. *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, 2012, p. 257-60.

23 BALBOA, Maria Gabriela. *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, 2012, p. 257-60.

24 *Anthropocene*, Oxford Dictionary ("Relating to or denoting the current geological age, viewed as the period during which human activity has been the dominant influence on climate and the environment").

Although beyond the scope of this article, the vast majority of scientists believe GM crops are as safe as traditional varieties to consume. *See generally* FREEDMAN, David H. *The Truth About Genetically Modified Food*. Sci. American**,** Sept. 1, 2013. Available at: http://www.scientificamerican.com/article/the-truth-about-genetically-modified-food/ [https://perma.cc/3UCJ-8HTW].

25 FOOD & AGRIC. ORG. OF THE UNITED NATIONS. **Status of Research and Application of Crop Biotechnologies in Developing Countries 35-37,** 2005, *available at* http://www.fao.org/docrep/008/y5800e/y5800e06.htm [hereinafter "FAO Report"]

26 Water stress includes both water deficit stress (drought) and excess water stress (flooding, anoxia), as well as salinity. *Id.* at 20.

27 The agricultural industry loses roughly $120 billion annually to abiotic stresses. Main causes of these loses are drought, flood, frosts, nutrient deficiencies, various soil and air toxicities. *Id.*

28 BIELLO, David. *Coming to a Cornfield Near You: Genetically Induced Drought-Resistance*, **Sci. American**, May 13, 2011. Available at: http://www.scientificamerican.com/article/corn-genetically-modified-to-tolerate-drought/ [https://perma.cc/2HFR-PQUP]

29 *See* ZHANG, Hong-Xia; BLUMWALD, Eduardo. *Transgenic Salt-tolerant Tomato Plants Accumulate Salt in Foliage but not in Fruit*, **Nature Biotechnology**, v. 19, 2001, p. 765-768;

Biotic stresses, such as insects and pathogens, also present serious problems.[30] Damage caused by biotic stresses cost the agriculture industry over $500 billion each year, with an additional $120 billion lost post-harvest to insects, fungi, and bacteria.[31] Biotechnology offers a promising alternative to traditional pest control. The use of insect-resistant crops in the United States, for example, has led to area-wide suppression of common agricultural pests such as the pink bollworm[32] and European corn borer.[33]

ENVIRONMENTAL BENEFITS

Agricultural biotechnology could also produce substantial reductions in traditional herbicide and pesticide applications. For example, GM crops have reduced chemical pesticide use by 37%.[34] Bt crops, in effect, have replaced many of the conventional pesticides previously applied. While studies point to similar reductions in herbicide use,[35] the environmental benefits are often lost when the technology is used with modern intensive agricultural

BAILEY, Pat. *Genetically Engineered Tomato Plant Grows in Salty Water.* **UC Davis,** July 25, 2001. Available at: http://news.ucdavis.edu/search/news_detail.lasso?id=5840 [https://perma.cc/X895-2FFM]

30 FAO Report, *supra* note 24, at 20-27

31 FAO Report, *supra* note 24, at 20.

32 CARRIÈRE, Yves; *et al*. *Long-term Regional Suppression of Pink Bollworm by Bacillus thuringiensis Cotton*, **100 PNAS 1519**, 2003, p. 1521-1523. *Available at* http://www.pnas.org/content/100/4/1519.full.pdf [https://perma.cc/BPG3-YSE2].

33 Initial estimates indicate the cumulative benefits over 14 years will exceed $6 billion for corn growers in Illinois, Minnesota, Wisconsin, Iowa, and Nebraska. HUTCHINSON, William D., *et al*. *Area-wide Suppression of European Corn Borer with BT Maize Reaps Savings to Non-Bt Maize Growers*, **330 Sci**. 2010, p. 222, 224-225. *Available at* http://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=1223&context=entomologyfacpub [https://perma.cc/J79B-Q97V].

34 KLÜMPER, Wilhelm; QAIM, Matin. *A Meta-Analysis of the Impacts of Genetically Modified Crops*, **PLoS ONE**, v. 9, 2014, p. 1, 4. *Available at* http://journals.plos.org/plosone/article/asset?id=10.1371%2Fjournal.pone.0111629.PDF [https://perma.cc/Q2EB-R9KF].

35 *See* BROOKES, Graham; BARFOOT, Peter. *Environmental Impacts of Genetically Modified Crop Use 1996–2013: Impacts on Pesticide Use and Carbon Emissions*. **GM Crops & Food**, v. 6, 2015, p. 103, 105. *Available at* http://www.tandfonline.com/doi/pdf/10.1080/21645698.2015.1025193 [https://perma.cc/B7E3-YW3B] (study found aggregate reductions in the volume of herbicides used from 1996-2013); GILBERT, Natasha. *Case Studies: A Hard Look at GM Crops*, **Nature**, v. 497, 2013, p. 24, 24-26. *Available at* http://www.nature.com/news/case-studies-a-hard-look-at-gm-crops-1.12907 (In the U.K., the introduction of herbicide-tolerant cotton saved 15.5 million kilograms of herbicide between 1996 and 2011, a 6.1% reduction from conventional cotton production).

practices.[36] For example, the abrupt and widespread shift to a single herbicide – glyphosate -, as the sole method of weed control, created serious resistance issues that resulted in an overall increase in herbicide use.[37] However, this is more representative of a modern agricultural mismanagement problem, which should be considered independently from the environmental benefits of biotechnology.

BENEFITS FOR SOCIETY

Biotechnology can also improve food security. Despite global increases in food production, chronic hunger,[38] and malnutrition[39] still plague many developing countries. Implemented locally, biotechnology could improve the quality and quantity of food accessible to the world's most vulnerable communities.[40] For example, the Bill and Melinda Gates Foundation sponsored research to design a transgenic banana with essential nutrients for combating Vitamin A deficiency in several East African nations.[41] Bananas are a staple food in the diets of many East Africans, but contain low levels of critical micronutrients.[42] Transgenic

36 Brookes & Barfoot, *supra* note 34, at 105.

37 In the United States, herbicide-resistant crops have led to a 527 million pound increase in herbicides applied. BENBROOK, Charles M. *Impacts of Genetically Engineered Crops on Pesticide Use in the U.S. – The First Sixteen Years*, **Envtl. Sci. Europe**, v. 24, 2012, p. 1, 7-8. *Available at* http://www.enveurope.com/content/24/1/24.

38 In 2010, an estimated 925 million people were undernourished, almost 16% of the population in developing countries. FOOD & AGRIC. ORG. OF THE U.N. **Global Hunger Declining, But Still Unacceptably High 1,** 2010. *Available at* http://www.fao.org/docrep/012/al390e/al390e00.pdf.

39 Malnutrition contributes to at least half of 10.9 million child deaths each year. FAO Report, *supra* note 24, at 38.

40 E.g., FOOD & AGRIC. ORG. OF THE U.N. **The State of Food and Agriculture 18,** 2004. *Available at* http://www.fao.org/docrep/006/y5160e/y5160e07.htm ("Researchers at Jawaharlal Nehru University in India have developed a genetically engineered potato that produces about one-third to one-half more protein than usual, including substantial amounts of all the essential amino acids such as lysine and methionine. Protein deficiency is widespread in India and potato is the staple food of the poorest people.")

41 AGENCE FRANCE-PRESSE, *'Super Banana' Could Save Millions in Africa*, **TELEGRAPH**, June 16, 2014. Available at: http://www.telegraph.co.uk/news/worldnews/africaandindianocean/10902072/Super-banana-could-save-millions-in-Africa.html; *GM BANANAS: From Nutrition to Disease Resistant*, **Fresh Fruit Portal.com**, Aug. 23, 2013. Available at: http://www.freshfruitportal.com/news/2013/08/23/gm-bananas-from-nutrition-to-disease-resistance/?country=united%20states.

42 *GM Bananas: From Nutrition to Disease Resistant*, **Fresh Fruit Portal.com,** Aug. 23, 2013. Available at: http://www.freshfruitportal.com/news/2013/08/23/gm-bananas-from-nutrition-to-disease-resistance/?country=united%20states;

bananas could raise the nutritional value of indigenous bananas, and provide local subsistence farmers with a profitable agricultural product.[43]

Climate change also poses a serious threat to global food security.[44] Food availability is likely to fluctuate under the intense pressure of crop failures caused by climate change.[45] As a result, food prices could increase up to 84% by 2050.[46] Agricultural biotechnology can mitigate many of these issues, through GM crop varieties that are "resistant to drought and flooding, better able to withstand withering heat, and that respond well to increased concentrations of carbon dioxide in the atmosphere."[47] However, having a strong regulatory scheme is crucial to managing known risks while maximizing the capability to mitigate unknown risks associated with climate change.

ENVIRONMENTAL IMPACTS

Despite its potential benefits, large-scale cultivation of GM crops presents a real, albeit unquantifiable risk to the surrounding environment. Releasing GM crops, accidental or otherwise, could cause unforeseeable and potentially devastating consequences to neighboring ecosystems and even globally.[48] Transfers of modified traits to wild relatives of the same or related species present

43 *MEET THE 'SUPER BANANA' – A Vitamin – Enriched Upgrade that Could Save Lives.* **The Guardian**, June 17, 2014, 10:24 pm. Available at: http://www.theguardian.com/lifeandstyle/shortcuts/2014/jun/17/super-banana-vitamin-enriched-upgrade.

44 *See generally* TENG, Paul P.S. *et al*. **Impact of Climate Change on Food Production: Options for Importing Countries**, 2015. A*vailable at* https://www.rsis.edu.sg/wp-content/uploads/2015/05/PB150529_Impact-of-Climate-Change-on-Food-Production.pdf.

45 PORTER, John R., *et al*. *2014: Food Security and Food Production Systems*, *in* **Climate Change 2014:** Impacts, Adaptation, and Vulnerability, p. 485, 494 (Contribution of Working Group II to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change, 2014). A*vailable at* https://ipcc-wg2.gov/AR5/images/uploads/WGIIAR5-Chap7_FINAL.pdf

46 PORTER, John R., *et al*. *2014: Food Security and Food Production Systems*, *in* **Climate Change 2014:** Impacts, Adaptation, and Vulnerability, p. 485, 494 (Contribution of Working Group II to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change, 2014). A*vailable at* https://ipcc-wg2.gov/AR5/images/uploads/WGIIAR5-Chap7_FINAL.pdf (Contribution of Working Group II to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change, 2014).

47 LEE-MURAMOTO, Maria R., *Reforming the "Uncoordinated" Framework for Regulation of Biotechnology*, **17 Drake J. Agric.** v. 311, 2012.

48 VERMA, Smita Rastogi, *Genetically Modified Plants: Public and Scientific Perception*, 2013. **Int'l Scholarly Research Notices: Biotechnology**, 2013, p. 1, 3-6. A*vailable at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4393037/#__ref-listid251725title

four potential problems: genetic contamination, genetic erosion, resistance to herbicides and pesticides, and undesirable impacts on non-target species.[49]

GENETIC CONTAMINATION

One of the most prevalent types of harm associated with GM crops involves genetic contamination. Genetic contamination, or gene flow, occurs when newly introduced genetic material gets transferred into organisms or environments beyond those intended to be affected.[50] Genes can be transferred from one crop to other plants of the same or related species via cross pollination, wind, flooding, fire, spillage and human error.[51] Already a problem,[52] genetic contamination will only intensify as the number of GM crops increases.[53]

The transfer of transgenic traits to indigenous populations could result in the hybridization of wild-type species. If hybridization occurred, the same traits inserted into these organisms as desirable features could enable them to out-compete native species, possibly to the exclusion of all other life forms.[54] These dangers are in many ways analogous to those caused by invasive species.[55] Once

49 VERMA, Smita Rastogi, *Genetically Modified Plants: Public and Scientific Perception*, 2013. **Int'l Scholarly Research Notices: Biotechnology**, 2013, p. 1, 3-6. A*vailable at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4393037/#__ref-listid251725title It should be noted, however, that agriculture inevitably impacts the environment and many of these concerns are not specific to GM crops. *Id.*

50 "Gene flow" is "the movement or exchange of genes between different species or between different populations of the same species." FAO Biosafety Resource Book, *supra* note 7, mod. B, at 5. *See also* HECKMAN, Christopher. *Tying its Own Hands: APHIS's Inability to Regulate Genetically Modified Crops*. **Ecology L.Q**. v. 41, 2014, p. 325, 334.

51 Heckman, *supra* note 52, at 332-33.

52 Genetic contamination is both a domestic and international problem. For example, in Hawaii, nearly 20,000 papaya seeds tested positive for GMO contamination, 80% of which came from organic farms and the rest from backyard gardens or wild trees. Press Release, Organic Consumers Association, Hawaii Reports Widespread Contamination of Papaya Crop by GE Varieties (Sept. 9, 2004), *available at* https://www.organicconsumers.org/old_articles/biod/papaya090804.php. *See also* Arne Holst-Jensen et al., *Detecting un-authorized Genetically Modified Organisms (GMOs) and Derived Materials*, 30 Biotechnology Advances 1318, 1324 (2012);

53 As the number and diversity of GM field tests increases, the likelihood of cross-pollination from field tests to commercial fields also increases. USDA Report, *supra* note 10, at 3-5.

54 KUNICH, John Charles. *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, **S. Cal. L. Rev**. v. 74, 2001, p. 807, 819-21.

55 *See generally* Scientific Committee on Problems of the Environment, Invasive Species in a Changing World (Harold A. Mooney & Richard J. Hobbs eds., 2000); Lloyd L. Loope, An Overview of Problems with Introduced Plant Species in National Parks and Biosphere Reserves of the United States (1992).

established, introduced species continually reproduce, disperse and evolve, making it almost impossible to remove them from an ecosystem.[56] To date, there are approximately 50,000 nonindigenous species in the United States, which cause an estimated U.S. $137 billion per year in environmental damage.[57] However, compared with introduced species, the immediate ecological impacts of GM crops could be reduced significantly by limiting their reproductive capabilities.[58]

GENETIC EROSION

Another serious concern with large-scale implementation of GM crops is erosion of genetic diversity among agricultural species. Genetic diversity is essential for evolution, as it provides a greater number of genetic characteristics from which a species may draw to adapt to changes in environmental conditions.[59] While traditional agricultural practices provided thousands of locally adapted crops,[60] genetic diversity among agricultural species has decreased by 75% since 1900.[61] Today, roughly 20 plant species account for more than 90% of human use.[62] Much of this genetic erosion arose from "elite" crop varieties developed during the twentieth century, which subsequently triggered widespread adoption of monocultures.[63] Crops become more susceptible to abiotic and biotic stresses

56 PETERSON, Garry et al. *The Risks and Benefits of Genetically Modified Crops: A Multidisciplinary Perspective*. **Conservation Ecology**, v. 4, 2000, p. 13. *Available at* http://www.consecol.org/vol4/iss1/art13/

57 Of these 50,000 nonindigenous species, 128 were introduced crops that have become serious weeds. *Id.*

58 "GM crops are usually more dependent on human support than nonindigenous species. . . . Furthermore, GM crops can be engineered to be sterile or contain traits to reduce their ability to disperse. However, as the area and diversity of GM crops increase, the risk that genes may escape also increases." *Id.* Furthermore, technological improvements will only make this easier. *See* MORIN, Monte. *Creating a 'Genetic Firewall' for GMOs*, **L.A. Times**, Jan. 21, 2015, 3:18 pm. Available at: http://www.latimes.com/science/sciencenow/la-sci-sn-gmo-escape-20150121-story.html

59 HAMMER, Karl; TEKLU, Yifru. Plant Genetic Resources: Selected Issues from Genetic Erosion to Genetic Engineering, 109 J. **Agric. & Rural Dev. in the Tropics & Subtropics**, 2008, p. 15, 15-16. *Available at* http://jarts.info/index.php/jarts/article/viewFile/72/65

60 HAMMER, Karl; TEKLU, Yifru. Plant Genetic Resources: Selected Issues from Genetic Erosion to Genetic Engineering, 109 J. **Agric. & Rural Dev. in the Tropics & Subtropics**, 2008, p. 15, 15-16. *Available at* http://jarts.info/index.php/jarts/article/viewFile/72/65.

61 FAO Biosafety Resource Book, *supra* note 7, mod. B, at 41.

62 CONNER, Anthony J. *et. al*. *The Release of Genetically Modified Crops into the Environment*, **Plant J.**, v. 33, 2003, p. 19, 34. Available at: http://onlinelibrary.wiley.com/doi/10.1046/j.0960-7412.2002.001607.x/epdf.

63 FAO Biosafety Resource Book, *supra* note 7, mod. B, at 40-41.

when cultivated in monocultures because there is less genetic variation available for the population to adapt to environmental changes.[64] Furthermore, monocultures negatively impact soil quality by depleting essential nutrients in the soil.[65]

There is a legitimate fear that GM crops will form the next generation of "elite" crops, and will further encourage monocultures.[66] Reductions in genetic variation limits species' are able to persist in the face of abiotic and biotic environmental change and hamper the ability of populations to cope with short-term challenges such as pathogens and herbivores.[67] Additionally, genetic erosion reduces the possibilities for crop improvements, particularly for small farmers who depend, in many cases, on wild species and natural habitats to subsist.[68]

GENETIC RESISTANCE

Genetic resistance occurs when the same pesticide and/or herbicide is consistently applied over an extended period of time. Only those pests that possess genetic resistance to the chemicals applied are able to survive, passing these resistant traits on to subsequent generations.[69] As a result, pest resistance has proliferated under the production practices of modern intensive agriculture.[70] Biotechnology may only exacerbate this problem. Over 99% of GM crops planted in the U.S. contain glyphosate tolerance and/or produce Bt toxins.[71] This widespread adoption of uniform pest management practices generates a massive selection pressure, further increasing the likelihood and frequency that targeted organisms will develop resistance to the pathogens that have been genetically inserted into the crops.[72]

64 FAO Biosafety Resource Book, *supra* note 7, mod. B, at 40-41.
65 FAO Biosafety Resource Book, *supra* note 7, mod. B, at 40-41.
66 Benbrook, *supra* note 36, at 2.
67 FAO Biosafety Resource Book, *supra* note 7, mod. B, at 40-41.
68 FAO Biosafety Resource Book, *supra* note 7, mod. B, at 40-41.
69 SNOW, A. A.; *et al*., Ecological Society of America, *Genetically Engineered Organisms and the Environment: Current Status and Recommendations*, **Ecological Applications**, v. 15, 2005, p. 377, 392.
70 SNOW, A. A.; *et al*., Ecological Society of America, *Genetically Engineered Organisms and the Environment: Current Status and Recommendations*, **Ecological Applications**, v. 15, 2005.
71 BRONNER, David. *Herbicide and Insecticide Use on GMO Crops Skyrocketing While Pro-GMO Media Run Interference*, **Huffington Post**, Sept. 15, 2014, 10:00 AM. Available at: http://www.huffingtonpost.com/david-bronner/herbicide-insecticide-use_b_5791304.html
72 BRONNER, David. *Herbicide and Insecticide Use on GMO Crops Skyrocketing While Pro-GMO Media Run Interference*, **Huffington Post**, Sept. 15, 2014, 10:00 AM. Available at: http://www.huffingtonpost.com/david-bronner/herbicide-insecticide-use_b_5791304.html.

HERBICIDE RESISTANCE

Indeed, in the U.S. alone, more than 150 weed biotypes have evolved resistance to various herbicides during the past 30 years.[73] Glyphosate-resistant weeds – also called "superweeds" - are particularly problematic,[74] covering more than 2 million acres of cropland in nineteen states.[75]

INSECTICIDE RESISTANCE

Insect pests have also developed resistance to the pesticides imbedded or used in conjunction with GM crops.[76] For example, resistance to Bt formulations has been observed in species such as the diamondback moth and bollworms, and demonstrated in the laboratory for other species.[77] These problems will intensify as GM crops become more prevalent and the same pesticides are used in conjunction with GM crops.

HARM TO NON-TARGET ORGANISMS

Potential harm to non-target organisms is another concern related to large-scale implementation of GM crops. Effects on non-target organisms can range from positive to negative, depending on biological, physical, and geographical factors.[78] Non-target species can experience negative effects from direct exposure to a GM crop or its byproducts, or indirectly, if a GM crop alters the habitat or food supply of the non-target species.[79] For example, pollen from Bt corn is

73 *WEED Resistance by Country and Site Action*, **Int'l Survey of Herbicide Resistant Weeds**, May 9, 2016. Available at: http://weedscience.org/summary/countrysummary.aspx.

74 One example of a glyphosate-resistant weed is Palmer amaranth (*Amaranthus palmeri*), which has become a particular problem for transgenic cotton farmers in the southeastern United States. The herbicide-resistant weed has spread throughout 76 counties. Gilbert, *supra* note 34.

75 Heckman, *supra* note 52, at 336. Glyphosate-resistant weeds are also found in 18 countries worldwide, with significant impacts in Brazil, Australia, Argentina and Paraguay. Gilbert, *supra* note 34.

76 FAO Report, *supra* note 24, at 28.

77 FAO Report, *supra* note 24, at 28.

78 Snow, *supra* note 72, at 18.

79 Snow, *supra* note 72, at 18. ("Indirect effects can also arise from changes in food supply or habitat quality (e.g., soil properties, plant communities, etc.).")

toxic to monarch butterfly larva.[80] This means that the monarch butterfly, whose survival is already jeopardized by habitat loss, faces even greater challenges to its survival. Furthermore, it is difficult to target pests without harming friendly organisms, such as pollinators and biological control agents, since many non-target microbes and insects harbor on flowers and other plant surfaces.[81]

CURRENT GMO REGULATIONS

The United States has no comprehensive federal statute governing biotechnology. Rather, the Coordinated Framework for Regulation of Biotechnology of 1986 ("Framework") allocates responsibility for managing GMOs among several federal agencies: the U.S. Department of Agriculture, the U.S. Environmental Protection Agency ("EPA"), and Food and Drug Administration ("FDA").[82] Under the Framework, agencies have the authority to regulate genetically modified organisms under existing statutes as they would conventional products. However, because the FDA's role is very limited with respect to managing the environmental impact of GMO crops, this Article focuses on the USDA and EPA.

USDA-APHIS

Within the United States Department of Agriculture ("USDA"), the Animal and Plant Health Inspection Service ("APHIS") is responsible for protecting agriculture from pests and diseases.[83] Under the Plant Protection Act,[84] APHIS regulates organisms and products that are known or suspected to be plant pest risks, including those that have been genetically modified.[85] These are called "regulated articles."[86] A GM crop is considered a regulated article "if the donor organism,

80 LEE-MURAMOTO, Maria R., *Reforming the "Uncoordinated" Framework for Regulation of Biotechnology*, **17 Drake J. Agric.** v. 311, 2012, p. 311, 346-347.
81 Verma, *supra* note 50, at 5.
82 *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).
83 *About APHIS*, USDA – Animal & Plant Health Inspection Serv. (Aug. 3, 2015), https://www.aphis.usda.gov/aphis/banner/aboutaphis
84 Plant Protection Act, Pub. L. No. 106-224, tit. IV, 114 Stat. 438 (2000).
85 7 U.S.C. §§ 7711-7712 (2000); 7 C.F.R. § 340.0 (2016).
86 7 C.F.R. § 340.1.

recipient organism, vector or vector agent used in engineering the organism belongs to one of the taxonomic groups listed in the regulation and is also a plant pest, or if there is a reason to believe it is a plant pest."[87] APHIS reviews regulated articles to ensure the organism will not impact agricultural production at any point in the stream of commerce.[88]

The APHIS issues authorizations for field releases of GM crops that are "regulated articles," so as to allow applicants to pursue field-testing.[89] After successful field-testing, technology providers can petition APHIS for a determination of "non-regulated" status.[90] If APHIS determines that the organism is unlikely to pose a plant pest risk, it is deregulated and can be moved and planted without APHIS oversight.[91] As of September 2013, APHIS had received 145 petitions for deregulation and had granted 96 (31 were withdrawn, 17 were pending, and 1 was incomplete).[92]

ENVIRONMENTAL PROTECTION AGENCY

The Environmental Protection Agency ("EPA") regulates GM crops under the Federal Insecticide Fungicide and Rodenticide Act ("FIFRA").[93] FIFRA serves as the primary federal law for the regulation of pesticides. It governs the manufacture, sale, and use of a broad range of chemical and biological pest control agents, as well as substances used to control plant growth.[94] Accordingly, EPA regulates the

87 Animal & Plant Health Inspection Service, USDA, White Paper on Tier-Based Testing for the Effects of Proteinaceous Insecticidal Plant-Incorporated Protectants on Non-Target Invertebrates for Regulatory Risk Assessments 2 (2007), *available at* https://www.aphis.usda.gov/brs/pdf/NTO_White_Paper_1.pdf [hereinafter "APHIS-USDA White Paper"]

88 Animal & Plant Health Inspection Service, USDA, White Paper on Tier-Based Testing for the Effects of Proteinaceous Insecticidal Plant-Incorporated Protectants on Non-Target Invertebrates for Regulatory Risk Assessments 2 (2007), *available at* https://www.aphis.usda.gov/brs/pdf/NTO_White_Paper_1.pdf [hereinafter "APHIS-USDA White Paper"].

89 USDA Report, *supra* note 10, at 3 fig.1.

90 APHIS-USDA White Paper, *supra* note 97, at 2.

91 USDA Report, *supra* note 10, at 4.

92 USDA Report, *supra* note 10. at 7.

93 Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), ch. 125, 61 Stat. 163 (1947). The EPA also regulates genetically modified microorganisms under the Toxic Substances Control Act ("TSCA"), but that is beyond the purview of this Article.

94 MARRAPESE, Matha E.; KRASNY, Leslie T., **Addressing the Complexities of Regulatory Schemes for GMOs and Products Derived from Them**, Aspatore 2014 WL 7247056, 2014, at *12.

distribution, sale, and use of pesticide products, and mandates the registration of pesticides before distribution or use.[95]

Under Section 2 of FIFRA, "pesticide" is broadly defined as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, . . . [or] . . . intended for use as a plant regulator, defoliant, or desiccant."[96] However, the EPA has adopted a narrow approach to regulating GM crops with pesticide properties.[97] The EPA's interpretation is that if a plant is engineered to produce a substance that prevents, destroys, repels, or mitigates a pest, the substance is a "pesticide" subject to regulation under FIFRA.[98] Thus, the EPA does not regulate the GM crop itself, only the pesticide component of the plant genome.[99] As a result, the EPA does not evaluate potential environmental impacts of the plant, just the pesticide genes. This is an issue, because genetic expression varies depending on the host plant; by limiting its environmental assessment to the gene itself, the EPA cannot evaluate the unique expression of the genetic trait in different crop species.

FLAWS WITH CURRENT REGULATIONS

At present, the environmental risks posed by GM crops are not coherently addressed.[100] Without a comprehensive federal statute, agencies employ existing statutes to regulate a wide range of biotechnology products.[101] As a result, there is unnecessary overlap among agencies and significant gaps in regulatory

95 7 U.S.C. §§ 136-136y.
96 7 U.S.C.. § 136(u).
97 *See* Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37,772 (July 19, 2001) (to be codified at 40 C.F.R. pts. 152, 174).
98 *I* Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37,774 (July 19, 2001) (to be codified at 40 C.F.R. pts. 152, 174).
99 *See* 40 C.F.R. § 152.20(a); Marrapese & Krasny, supra note 104, at *15.*15-16.
100 Kunich, *supra* note 57, at 823; U.S. Gov't Accountability Off., GAO-09-60, Genetically Engineered Crops: Agencies are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring 46 (2008), *available at* http://www.gao.gov/assets/290/283060.pdf.
101 KUNICH, John Charles. *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. Cal. L. Rev. v. 807, 2001, p. 807-823.

coverage.[102] The sections that follow focus on two major defects in the regulatory regime: (1) a lack of a coordinated and systematic risk assessment, and (2) the absence of a post-release monitoring program.

GAPS IN REGULATORY RISK ASSESSMENT

Several reasons exist for the gaps in GM crop regulation. First, the current regulatory regime is inherently inconsistent. For example, there is no uniform interagency definition for GM crops.[103] Each agency defines GM crops, and the scope of its regulatory power, in terms consistent with its own statutory authority.[104] While the USDA appears to have broad statutory authority to regulate GM crops, it has repeatedly circumscribed its own ability to regulate GM crops, with excessively narrow interpretations of its statutory mandate.[105] Moreover, the USDA and EPA have further narrowed their coverage through categorical exemptions.[106] For example, the EPA – the agency charged with protecting the nation's environment – has no role in the approval or field-testing and widespread planting of GM crops containing traits such as, herbicide tolerance, drought tolerance, salinity tolerance, virus-resistant, temperature tolerance, or disease-resistant.[107] In addition, the USDA relinquishes its authority to regulate a genetically modified species when it approves a petition for deregulation.[108] This seems absurd, given that it will require many more years of research, from multiple generations, to discover any unintended negative impacts.[109] These

102 MANDEL, Gregory N., *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, **Wm. & Mary L. Rev**. v. 45, 2004, p. 2167, 2231. *available at* http://scholarship.law.wm.edu/cgi/viewcontent.cgi?article=1341&context=wmlr; KUNICH, John Charles. *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, **74 S. Cal. L. Rev**. v. 807, 2001, p. 807-823.

103 Kunich, *supra* note 57, at 861.

104 Kunich, *supra* note 57, at 861.

105 Heckman, supra note 52, at 328-29.

106 Kunich, *supra* note 57, at 833-34, 839-40.

107 MANDEL, Gregory N., *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, **Wm. & Mary L. Rev**. v. 45, 2004, p. 2167, 2231. *Available at* http://scholarship.law.wm.edu/cgi/viewcontent.cgi?article=1341&context=wmlr

108 MANDEL, Gregory N., *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, **Wm. & Mary L. Rev**. v. 45, 2004, at 2234

109 Conner et. al., *supra* note 65, at35.

inconsistences and exemptions have created significant gaps in regulatory coverage, limiting the government's ability to detect potential public health and environmental issues.[110]

Another gap emerges from the USDA's refusal to regulate GM crops that contain genes from organisms the agency has previously determined are not plant pests. The agency maintains that the modified organism will be essentially the same as the organism from which the gene derived.[111] This rationale lacks scientific justification and increases the uncertainty of an already imprecise process.[112] Furthermore, when the number of traits inserted in a genome increases, the expression of each gene and efficacy of each trait becomes less predictable.[113] Simply put, the more variables in play, the more likely the crop will have a different genetic expression than that of the original organism. Thus, as "stacked genes" become more prevalent, it makes less sense to assume the genetic expression of a GM crop will be that of its donor organism.

Another regulatory gap arises because, the USDA only regulates biotechnology products, not the process itself.[114] Historically, GM crops have been subject to USDA regulation as a "regulated article" if the genetic material or the organism, such as a virus or bacteria, used to transfer the desired trait falls within the definition of a plant pest.[115] The agency, however, has determined that newer

110 See generally, Mandel, *supra* note 119.

111 Pew Initiative on Food & Biotechnology, Guide to U.S. Regulation of Genetically Modified Food and Agricultural Biotechnology Products 2 (2001) [hereinafter "Pew Initiative"]

112 LATHAM, Jonathan R.; *et. al*., *The Mutational Consequences of Plant Transformation*, 2006 **J. Biomedicine & Biotechnology,** v. 1, n. 1, 2006.

113 AGAPITO-TENFEN, Sara Zanon; *et. al*. *Effect of Stacking Insecticidal Cry and Herbicide Tolerance epsps Transgenes on Transgenic Maize Proteome*, **BMC Plant Biology**, v. 14, n. 1, 2014. A*vailable at* http://bmcplantbiol.biomedcentral.com/articles/10.1186/s12870-014-0346-8; QUE, Qiudeng, *et al*. **Trait Stacking in Transgenic Crops: Challenges and Opportunities**, 1 GM Crops 220, 220 (2010), *available at* http://www.tandfonline.com/doi/pdf/10.4161/gmcr.1.4.13439 [https://perma.cc/MY8G-BLUZ]

114 Pew Initiative, *supra* note 123, at 6.

115 "For instance, the Agrobacterium tumefaciens bacterium and the Cauliflower 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." MONTGOMERY, Emily. *Genetically Modified Plants and Regulatory Loopholes and Weaknesses Under the Plant Protection Act*, **Vt. L. Rev**. v. 37, 2012, p. 351. POLLACK, Andrew. *By 'Editing' Plant Genes, Companies Avoid Regulation*, **NY Times**, Jan. 2, 2015, at B1, *available at* http://www.nytimes.com/2015/01/02/business/energy-environment/a-gray-area-in-regulation-of-genetically-modified-crops.html?_r=0

genetic transfer techniques, such as genome editing[116] or modification through the use of a gene gun, are beyond its statutory authority.[117]

Companies have adapted to avoid regulations, using newer techniques to create the same GM crop that would be subject to regulatory oversight had the company used an older biotechnology technique.[118] For example, Scott's Miracle-Gro Company, in its second attempt to commercialize a transgenic creeping bentgrass, was able to avoid federal oversight by inserting the genetic material with a gene gun rather than using bacteria to transfer the target gene.[119] Scott managed to escape regulatory oversight despite the fact that its first attempt ended with a $500,000 penalty for damages resulting from the accidental release of transgenic bentgrass during field trials.[120] While the first incident devastated the company's prospects of USDA approval, the new genetic transfer method enables Scott's to produce essentially the same transgenic bentgrass without federal approval.[121] This lack of monitoring creates a dangerous regulatory vacuum.

LACK OF MONITORING

In its 2008 report, the U.S. Government Accountability Office ("GAO") highlighted the need for a coordinated program for monitoring and evaluating the undesirable effects of GM crops on the environment.[122] Despite acknowledging

116 WALTZ Emily. *Gene-edited CRISPR Mushroom Escapes US Regulation*, **Nature**, v. 532, 2016, p. 293. A*vailable at* http://www.nature.com/news/gene-edited-crispr-mushroom-escapes-us-regulation-1.19754.

117 *See* Montgomery, *supra* note 127, at 351; Pollack, *supra* note 127.

118 Mateusz Perkowski, *Biotech Critics Claim GMO Loophole will Backfire*, Capital Press (Feb 11, 2015), http://www.capitalpress.com/Nation_World/Nation/20150211/biotech-critics-claim-gmo-loophole-will-backfire; Pollack, *supra* note 125.

119 Press Release, USDA, USDA Concludes Genetically Engineered Creeping Bentgrass Investigation: USDA Assesses The Scotts Company, LLC $500,000 Civil Penalty (Nov. 26, 2007), *available at* http://www.usda.gov/wps/portal/usda/usdamediafb?contentid=2007/11/0350.xml&printable=true&contentidonly=true; Pollack, *supra* note 125

120 Press Release, USDA, USDA Concludes Genetically Engineered Creeping Bentgrass Investigation: USDA Assesses The Scotts Company, LLC $500,000 Civil Penalty (Nov. 26, 2007), *available at* http://www.usda.gov/wps/portal/usda/usdamediafb?contentid=2007/11/0350.xml&printable=true&contentidonly=true; Pollack, *supra* note 125.

121 Perkowski, *supra* note 130; Pollack, *supra* note 127.

122 U.S. Gov't Accountability Off., GAO-09-60, Genetically Engineered Crops: Agencies are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring 44-46 (2008), *available at* http://www.gao.gov/assets/290/283060.pdf.

the GAO's recommendation, the USDA, EPA and FDA refused to do so, each stating that neither agency was not required to conduct risk-based monitoring, nor was it necessary.[123] However, the evidence suggests otherwise. A report by the International Union for the Conservation of Nature cited numerous reports of companies neglecting to follow permit procedures, including planting experimental crops too closely to other crops, failing to construct adequate buffers between fields, failing to plan for extreme weather events, and failing to keep wild animals out of the experimental fields.[124] Furthermore, the APHIS, which has overseen more than 10,000 GMO field tests since 1987, is often unware of whether, and where field tests are being carried out.[125] These concerns were confirmed in a recent audit conducted by the USDA's Office of Inspector General, which concluded that APHIS lacked adequate controls to prevent the introduction of GM crops into the environment.[126]

These failures of oversight occur despite the fact that delays in discovering escaped populations of transgenic plants drastically increase the risk that GM crops will inadvertently persist in the environment.[127] Many believe this is the reason transgenic canola is growing freely in parts of North Dakota.[128] Delays in discovery time also limit USDA's mitigation options. For example, violations of testing procedure forced USDA to order the destruction of 155 acres surrounding an Iowa test site, and 500,000 bushels of soybean in Nebraska.[129]

Furthermore, the USDA does not take into consideration past permit violations when approving new field trials.[130] For instance, one organization was

123 U.S. Gov't Accountability Off., GAO-09-60, Genetically Engineered Crops: Agencies are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring 44-46 (2008), *available at* http://www.gao.gov/assets/290/283060.pdf. at 6.

124 IUCN Report, *supra* note 12, at 41 (2007). (hereinafter "IUCN Report")

125 IUCN Report, *supra* note 12, at 41 (2007). (hereinafter "IUCN Report").

126 Off. of Inspector General, USDA, Audit Report 50601-0001-32, Controls Over APHIS' Introduction of Genetically Engineered Organisms 9 (2015), *available at* https://www.usda.gov/oig/webdocs/50601-0001-32.pdf [hereinafter "USDA Audit Report"]

127 Pollack, *supra* note 125

128 GILBERT, Natasha. *GM Crop Escapes into the American Wild*. **Nature**, Aug. 6, 2010. Available at: http://www.nature.com/news/2010/100806/full/news.2010.393.html.

129 Press release, USDA, USDA Investigate Biotech Company for Possible Permit Violations (Nov. 13, 2002); GILLIS, Justin, *Biotech Firm Mishandled Corn in Iowa*, **Wash. Post,** Nov. 14, 2002. Available at: https://www.washingtonpost.com/archive/business/2002/11/14/biotech-firm-mishandled-corn-in-iowa/eba672e1-5a42-42c6-a1da-70d00d2fa5ba/.

130 USDA Audit Report, *supra* note 136, at 25.

repeatedly approved to conduct field trials despite having previously been cited for 122 incidents of non-compliance.[131] In fact, it appears there are little to no repercussions for permit violators. Since 2010, USDA-APHIS has issued only two civil penalties despite delivering hundreds of notices of non-compliance.[132] This industry-friendly approach not only weakens the few legal restrictions in place, but encourages the agricultural industry to take even greater risks.

NECESSARY CHANGES

Though major changes are needed to ensure coherent regulation of GMOs, the Plant Protection Act does potentially provide sufficient statutory authority to enable UDSA-APHIS to regulate effectively.[133] However, the USDA must interpret its regulatory authority more broadly and establish procedures to facilitate collaboration among stakeholders, multidisciplinary research, and well-designed monitoring. To that end, we offer the following recommendations to identify, manage, and mitigate environmental risks, without inhibiting ingenuity and growth in the industry.

COORDINATED ASSESSMENT OF GM CROPS

Effectively managing the potential risks of GM crops will require a systematic approach that ensures risk assessments are performed collaboratively and focus on the unique aspects of each GM crop, rather than a general understanding of the foreign trait itself.[134] As part of this approach, USDA-APHIS must first, assert itself as the primary regulator of GM crops. It must abandon its narrow interpretation of its statutory authority to regulate GM crops under the Plant Protection Act, and adopt an approach emphasizing the precautionary principle.[135] Additionally, EPA

131 USDA Audit Report, *supra* note 136, at 25.

132 WILSON, Julie. *Experimental GMO Crops Sprouting Up Across America, while USDA, the Overseeing Agency, Takes 'Industry-Friendly Approach,'* **Natural News,** Apr. 1, 2016. Available at: http://www.naturalnews.com/053508_GMO_crops_USDA_Monsanto.html.

133 "Under the Plant Protection Act, APHIS has jurisdiction over 'plant pests' and 'noxious weeds.' The definitions for both terms of art are very broad." Heckman, *supra* note 50, at 328.

134 LEE-MURAMOTO, Maria R., *Reforming the "Uncoordinated" Framework for Regulation of Biotechnology*, **Drake J. Agric.** v. 17, 2012, p. 311, 359-61.

135 LEE-MURAMOTO, Maria R., *Reforming the "Uncoordinated" Framework for Regulation of Biotechnology*, **Drake J. Agric.** v. 17, 2012, at 357-58.

must stop regulating GM crops as pesticides under FIFRA.[136] Separating various traits into distinct categories regulated by multiple agencies creates needless confusion for applicants. Furthermore, it reinforces the separation of crucial information among various agencies. Designating USDA-APHIS as the primary regulator of GM crops will assist applicants in navigating the regulatory process and channel all relevant documents and data to one central location.[137]

Next, the USDA must establish application review procedures that assign risk assessment responsibilities according to agency expertise.[138] All GM crops must undergo a case-by-case assessment that integrates laboratory and field studies while acknowledging that many risks are organism and site-specific.[139] These procedures should also specify the role of each agency and create protocols to ensure reviewing agencies have access to all relevant information.[140] For example, USDA would assess all agricultural implications, while EPA would evaluate the potential impacts to the environment. Each GM crop would be evaluated holistically - not by the foreign genetic component added -- with each agency assessing potential repercussions within their respective areas of expertise. Ultimately, all participating agencies would come together to make a decision.

This interagency approach would provide greater opportunities for environmental review throughout the regulatory process. A new product, for example, could present no risk to human consumption but pose a significant threat to wild-populations if released into the environment. In such a scenario, the EPA would have an expanded role in the assessment, advising the USDA-APHIS on the environmental risks of a release and the ecological consequences if it were to impact wild-populations. A meeting at this stage would allow each agency to share concerns and any information needed to address those concerns. Furthermore, early interagency discussions could help to avoid problems and delays later.[141]

136 Committee on Genetically Modified Pest-Protected Plants, National Research Council, Genetically Modified Pest-Protected Plants: Science and Regulation (2000), available at http://www.ncbi.nlm.nih.gov/books/NBK208354/ [hereinafter "NRC Report"]

137 Lee-Muramoto, supra note 144, at 360-6.

138 Lee-Muramoto, supra note 144*.* at 359-61

139 Balboa, *supra* note 19, at 257.

140 Lee-Muramoto, *supra* note 144, at 359-61..

141 NRC Report, *supra* note 146, at ES15-17.

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A second opportunity for interagency coordination would arise during formal product review, when the agencies formulate their regulatory decisions.[142] Meeting after initial testing and data collection has been completed gives agencies the opportunity to work together with applicants to develop mitigation plans and establish monitoring programs to improve scientific understanding.[143]

ENHANCED MONITORING

We also recommend creating a comprehensive monitoring program to improve the ability to identify, manage and mitigate potential adverse impacts on the environment. In the short term, post-release monitoring may help APHIS detect permit violations and environmental risks that were not evident in small-scale, pre-commercial risk evaluations.[144] Perhaps more importantly, well-designed monitoring requirements will improve agencies' ability to regulate biotechnology, and generate real data that can be applied to future regulatory decisions.

Assessing ecosystem/ecological risk is no easy task.[145] The difficulty in predicting ecological risk stems from a lack of understanding of the complete function of ecosystems, and how novel organisms can affect them cumulatively over time.[146] Because of the inherent complexity of ecological systems, research is needed over a range of spatial and temporal scales.[147] Moreover, data from multiple generations of a genetically modified species is necessary to identify any potential unintended negative impacts.[148] Comprehensive monitoring offers the opportunity for regulators to improve their understanding of the indirect impacts GM crops have on ecosystem functions, and in turn, improve regulations.[149]

142 NRC Report, *supra* note 146, at ES15-17.
143 NRC Report, *supra* note 146, at ES15-17.
144 Balboa, *supra* note 19, at 283-84; Lee-Muramoto, *supra* note 144, at 358-59.
145 Lee-Muramoto, *supra* note 144, at 357 ("assessing human health and environmental risks associated with the release of a novel GM crop is even more complex and problematic.")
146 Lee-Muramoto, *supra* note 144, at 357.
147 Committee on Envtl. Impacts Associated with Commercialization of Transgenic Plants, Bd. on Agric. & Natural Res., Nat'l Research Council, Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation 49 (2002)("screening of all crops with added genetic variation must be conducted over a number of years and locations because undesirable economic and ecological traits may only be produced under specific environmental conditions.").
148 Conner et. al., *supra* note 63, at 35.
149 U.S. Gov't Accountability Off., GAO-09-60, Genetically Engineered Crops: Agencies are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring 46 (2008), available at http://www.gao.gov/assets/290/283060.pdf.

However, environmental monitoring is expensive. Monitoring requirements should be applied only as needed in order to avoid burdensome and unnecessary costs. All GM crops should be subject to basic long-term monitoring of ecosystem effects but additional requirements should be as needed for new genetic sources or risky GM crops. Monitoring requirements could vary from general federally funded ecological studies to site or organism specific obligations. This might include monitoring "the timing of pollen release, the types of insect species that would be harmed by ingesting pollen at observed concentrations, and the magnitude of mortality due to pollen versus other factors that limit nontarget populations."[150] Ultimately, under our suggested scenario, all monitoring data would be collected by USDA and used to improve regulatory decisions.

CONCLUSION

Despite the concerns of many, GM crops appear to be here to stay. Biotechnology is a revolutionary science but, with great power comes great responsibility. While we must proceed with both caution and precaution, it would be impossible and unwise to suffocate the development and implementation of GM crops. Therefore, regulations must acknowledge the needs of the rapidly evolving biotechnology industry while providing agencies the tools to ensure biotechnology is implemented safely. Creating this new regulatory matrix will require a fundamental shift in our approach to managing GM crops.

USDA must abandon its notion that all crops are the same, and instead adopt a regulatory regime better suited to the technological advancements in the field. This will involve close collaboration among all stakeholders throughout the regulatory process. Regulations must also be tailored toward fostering a better understanding of biotechnology and its ecological impacts without ignoring the potential for unforeseen consequences.

In the short-term, enhanced monitoring will improve our ability to detect non-compliance and unauthorized releases into the environment. In addition, data collection from multiple generations of a genetically modified species will

150 NRC Report, *supra* note 146, at 142.

help identify any potential unintended negative impacts that might manifest in the future.[151] In sum, comprehensive monitoring offers an opportunity for regulators to improve their understanding of the indirect impacts GM crops have on ecosystem functions, and in turn, improve regulation.[152]

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151 Conner et. al., *supra* note 63, at 35.

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