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THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

NATIONAL FAMILY FARM COALITION, CENTER FOR FOOD SAFETY, PESTICIDE ACTION NETWORK NORTH AMERICA, CENTER FOR ENVIRONMENTAL HEALTH, FRIENDS OF THE EARTH, and, CENTER FOR BIOLOGICAL DIVERSITY, *Plaintiffs,* v. TOM VILSACK, in his official capacity as Secretary of the United States Department of Agriculture, KEVIN SHEA, in his official capacity as Administrator of the Animal and Plant Health Inspection Service, the UNITED STATES DEPARTMENT OF AGRICULTURE, and ANIMAL AND PLANT HEALTH INSPECTION SERVICES, *Defendants.*	Case No. 21-5695 **COMPLAINT FOR DECLARATORY AND EQUITABLE RELIEF**

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Plaintiffs National Family Farm Coalition, Center for Food Safety, Pesticide Action Network North America, Center for Environmental Health, Friends of the Earth, and Center for Biological Diversity (collectively, Plaintiffs) on behalf of themselves and their members, allege as follows:

INTRODUCTION AND NATURE OF ACTION

1. This case is about whether or not both experimental and commercialized genetically engineered (GE) organisms will remain regulated by the federal government, or if they will now effectively be left to the devices of their manufacturers, to experiment, plant, and sell them as they self-interestedly see fit, without any further oversight by the U.S. Department of Agriculture (USDA), regardless of their agronomic risks to U.S. agriculture or their environmental risks to soils, waterways, native ecosystems, and endangered species.

2. For over twenty-five years, USDA has been charged with overseeing a significant range of genetically engineered organisms, from experimental GE crops, grasses, and tree species to GE commodity crops. And twenty-five years of evidence shows that GE crops carry significant adverse agricultural environmental risks, including but not limited to: transgenic contamination[1] (gene flow from GE crops to related conventional or organic cultivars or wild species); significant increases in herbicide use from genetically engineered herbicide-resistant crop systems, which are the vast majority of all GE crops; and the proliferation of "superweeds"—resistant to these herbicides.

3. Accordingly, among other things, during that time USDA had to approve, or "deregulate" a specific GE crop variety before it could be commercialized. And, before an experimental GE crop could be open-air field tested,

[1] The term "transgenic" is used synonymously with "genetically engineered" or "GE" in this complaint, even though technically GE is the broader term, as it encompasses techniques that introduce genes native to the recipient species, or directly manipulate an organism's genes (*e.g.* gene editing).

USDA had to approve such an experiment and oversee it. These actions required, among other things, the submission of data by the GE crop proponent, public notice and comment, and approval under USDA's GE crop regulations, 7 C.F.R. Part 340, as well as analysis under the National Environmental Policy Act (NEPA) and the Endangered Species Act (ESA). Stakeholders disagreed about the rigor of USDA's oversight of GE crops, but oversight it was.

4. After nearly two decades of proposed rules, withdrawals, stakeholder comments, and government audit reports, the agency announced proposed new GE crop regulations in 2019. However in a radical departure from previous rule iterations, the third proposed rule, among other changes, failed to invoke USDA's noxious weed authority under the Plant Protection Act. Nor did it explain its departure from years of detailed environmental analyses and proposed rules which insisted upon the necessity of incorporating this authority to forestall the harms of GE organisms to U.S. agriculture and the environment.

5. Last year, the Trump administration's final rule amending 7 C.F.R. Part 340 fundamentally altered that regulatory system. Going forward and indefinitely, GE organisms will no longer be subject to USDA oversight and approval before open-air experiments and before commercial sale and planting. Since there will no longer be a USDA final agency approval action under the Administrative Procedure Act (APA), there will not be any analysis or transparency under NEPA or the ESA of GE crops' agricultural or environmental risks. In effect, USDA has attempted to get out of the regulation business entirely in this area.

6. In so doing, USDA unconstitutionally delegated its own duties to protect farmers and the environment to GE crop developers. It also violated the statute it is supposed to be implementing in this area, the Plant Protection Act (PPA), as well as NEPA, the ESA, the APA, and the 2008 Farm Bill, which supplemented the PPA by requiring new protections for GE crop open-air experiments. In fact, as explained later, this final decision is made worse when

shown against the long procedural history of this rulemaking: started in 2004 and long intended to effectuate Congressional intent to improve USDA's oversight, not eliminate it. For all of these reasons, the Court should vacate and remand the final rule.

7. More specifically, this case challenges USDA's final rule on "Movement of Certain Genetically Engineered Organisms," 7 CFR Parts 340 and 372.

8. Plaintiffs National Family Farm Coalition, Center for Food Safety, Pesticide Action Network North America, Center for Environmental Health, Friends of the Earth, and Center for Biological Diversity, on behalf of their adversely affected members, challenge Defendants' May 18, 2020 final rule amending those rules, to remove oversight for GE organisms. The final rule violates the PPA, NEPA, ESA, APA, the 2008 Farm Bill's GE crop provisions, the Constitution, and is arbitrary, capricious, and contrary to law.

9. First, the final rule fails to comply with the ESA because USDA did not undertake the required ESA Section 7 consultation process with the expert Wildlife Services before taking action that may affect listed species and/or their designated critical habitat. The experimental and commercial planting of GE organisms without individual agency approvals allows GE organisms to be released into the environment without individual assessments. The wholesale exemption of many future GE organisms such as GE grasses, trees, and other plants, and the overall relaxation of these regulations has the potential to affect—and likely cause significant harm to—many broad categories of endangered species and their habitat, including endangered plants, insects, birds, and mammals. USDA was required to undertake consultation to understand the effects of its decision on endangered species and their critical habitats and to protect against those effects.

10. Second, the final rule fails to comply with NEPA's mandates, our basic environmental charter, for multiple reasons, including that USDA did not explore reasonable alternatives that would be more protective to the environment than its

chosen action, did not adequately analyze direct, indirect, and cumulative impacts, and improperly relied on voluntary mitigation measures from private entities.

11. Third, the final rule fails to comply with the PPA's mandates because it does not implement a full half of USDA's statutory authority—its noxious weed authority—to fulfill its responsibility to mitigate noxious weed harms of GE organisms, despite the overdue implementation of that PPA authority being a major reason for this rulemaking in the first place. It also violates the PPA's requirement that USDA's decisions be based on sound science.

12. Fourth, the final rule fails to comply with the 2008 Farm Bill, which included specific new strengthening mandates for GE crop experiments because already too lax USDA oversight had caused contamination and market rejection harm to U.S. farmers. Yet, by creating broad exemption categories and instituting a self-determination scheme, USDA failed to implement the Farm Bill's requirements, instead opting for *less* oversight, not more.

13. Fifth and finally, the rulemaking violates the Constitution and the separation of powers principles by placing agency authority in the hands of self-interested private parties without retaining oversight. Because the new rules give private entities carte blanche to "self-determine" their own products' regulation without any future oversight from USDA (or the courts), USDA has unconstitutionally sub-delegated its own regulatory duties to private industry.

14. Accordingly, Plaintiffs ask this Court to: (1) declare that USDA's final rule for the regulation of GE organisms is arbitrary, capricious, and in violation of the, ESA, NEPA, APA, PPA, the 2008 Farm Bill, and the Constitution; (2) vacate the May 18, 2020 final rule; (3) order USDA to implement its noxious weed authority under the PPA and (4) order USDA to undertake ESA consultation and further NEPA analysis before promulgating new, meaningful GE organisms in accordance with the controlling statutes according to a court-mandated schedule.

JURISDICTION AND VENUE

15. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question) and 28 U.S.C. § 1346 (United States as Defendant).

16. Plaintiffs have a right to bring this action pursuant to the APA, 5 U.S.C. § 702.

17. The relief requested is specifically authorized pursuant to 5 U.S.C. § 706(2)(A) (holding unlawful and setting aside agency actions that are arbitrary, capricious, or otherwise not in accordance with law) and 28 U.S.C. §§ 2201-02 (declaratory and equitable relief). An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201.

18. The Court has jurisdiction to review USDA's failure to consult with the Services under the citizen suit provision of the ESA, 16 U.S.C. §1540(g)(1), which provides that the "district courts shall have jurisdiction . . . to enforce any such provision or regulation" of the ESA. As required by the ESA, Plaintiffs provided sixty days' notice of their intent to sue by the letter sent to USDA and the Services on July 28, 2020.[2] USDA has not remedied the violations set out in that sixty-day notice. *See id.* § 1540(g)(2)(A).

19. Venue properly lives in this Court pursuant to 28 U.S.C. § 1391(e) because one or more of the Plaintiffs reside in this District.

PARTIES

Plaintiffs

20. Plaintiff Center for Food Safety (CFS) brings this action on behalf of itself and its members. CFS is a public interest, non-profit, membership organization that has offices in San Francisco, CA; Portland, OR; and Washington,

[2] *See* Center for Food Safety, *Sixty-Day Notice of Intent to Sue APHIS Pursuant to the Endangered Species Act* (July 28, 2020), https://www.centerforfoodsafety.org/files/2020-07-28-aphis-60-day-notice-letter-final_79309.pdf.

D.C. CFS represents over 950,000 members, from every state in the country. USDA's failure to meet the statutory and constitutional requirements outlined above and below has adversely affected CFS and its members.

21. CFS's fundamental mission is to empower people, support farmers, and protect the earth from the harmful impacts of industrial agriculture. CFS is a recognized national leader on the issue of GE crops and other GE organisms, and has worked to improve their regulation and address their impacts continuously since the organization's inception in 1997.

22. For over two decades, CFS has been the leading U.S. public interest organization working on the issue of agricultural biotechnology, a pillar of the current industrial agriculture system. Part of CFS's mission is to ensure that GE organisms that could adversely affect public health, agriculture, and the environment are properly regulated. CFS has a major program area specific to GE organism oversight, and numerous staff members—scientific, policy, campaign, and legal—whose work encompasses the topic. CFS staff members are recognized experts in the field and are intimately familiar with the issue of GE foods, their inadequate oversight, their risks, and their adverse impacts.

23. In accordance with its organizational missions to reduce harms caused by industrial agriculture and champion transparency throughout the food production system, CFS has long been committed to establishing meaningful GE regulations. CFS has worked on dozens of individual GE crop, grass, and tree issues over the past several decades, submitting comments to the agency and when necessary engaging in public interest litigation. Specific to this case on the Part 340 rules themselves, starting in 2004, CFS submitted comments on behalf of its members for each iteration of the proposed rules and environmental analyses at issue here and has submitted multiple Freedom of Information Act requests to USDA regarding the rulemaking. For many years, CFS has spearheaded

nationwide grassroots efforts to inform consumers around the country about GE foods, and the effects of GE organisms on the environment.

24. Pesticide Action Network North America (PANNA) is a nonprofit organization that works with farmers, farmworkers, and rural communities to address the health and economic burdens that pesticide and biotech corporations have put on those communities. With the goal of creating a just, thriving food system, PANNA links local and international consumer, labor, health, environment, and agriculture groups to an international citizens' action network, challenging the global proliferation of pesticides and defending basic rights to health and environmental quality. PANNA has long worked on the issue of GE organism oversight, in particular because of the intertwined nature of GE seeds and pesticides, since the vast majority of GE crops are engineered to tolerate pesticide applications. This program work has included work on numerous specific GE crops as well as this rulemaking process.

25. Center for Environmental Health (CEH) is a nonprofit organization that works with communities, consumers, workers, government, and the private sector to keep people safe from unnatural and malicious chemicals by insisting that laws and policies protect people from harm. CEH advances environmental health and justice for the greater good by encouraging business and government decisionmakers to heed the early warnings of science. As part of its broader mission, CEH has worked on the issue of improving GE crop oversight, acknowledging the many associated environmental and public health hazards, and the need for continuous vigilance to protect people's health and avoid future environmental harm.

26. Friends of the Earth (FOE) is a nonprofit organization that engages in advocacy, legal, political, and organizing work to fight for a healthier and more just world. Implementing its overarching mission, FOE has had a longstanding flagship program advocating for precautionary assessment and oversight of organisms

derived from genetic engineering by federal regulators. FOE has actively led efforts to address negative biodiversity and public health impacts from newer forms of genetically engineered organisms, including synthetic biology, RNA interference, and gene editing. FOE works with frontline communities potentially impacted by genetic engineering applications, FOE's membership, farmers, and federal government agencies to address the need for precautionary regulation and robust oversight of all genetic engineering.

27. Center for Biological Diversity (CBD) is a nonprofit organization that works through science, law, and creative media to secure a future for all species, with a focus on protecting the lands, waters, and climate that species need to survive. Increasingly, imperiled butterfly and native bee species require Endangered Species Act listing, and numerous species are already listed, because of harm caused to them from industrial agriculture. This includes pesticides and pesticide-resistant GE crop systems. As such CBD has a flagship program on environmental health, which protects biodiversity and human health from toxic substances, specifically including pesticides. Since the vast majority of GE crop systems are engineered to resist (and thus promote) pesticides, CBD's environmental health program also works on these GE crop systems and their adverse impacts.

28. The National Family Farm Coalition (NFFC) is a nonprofit organization that represents 30 grassroots farm, ranch, fishing, and rural advocacy organizations across 42 states to policy- and decision-makers in the nation's capital. NFFC champions vibrant rural communities in which growers and workers are paid fairly and can live with dignity; diversity in social, racial, cultural, agrarian, and economic realms; and democratic, community-based control of and responsibility for ecological resources and practices, including seeds, land, and water. Since the 1990s, the coalition has opposed the proliferation of GE crops, particularly those that resist chemical pesticides. In particular, growers lament the loss of heirloom or

hybrid seed varieties for planting due to seed company closures and cross-pollination between GE and non-GE crops, and the pesticide drift that harms or destroys native plants, wildlife, environmental resources, and human health.

Defendants

29. Defendant Tom Vilsack is sued in his official capacity as USDA Secretary. As Secretary, Mr. Vilsack has the ultimate responsibility for USDA's activities and policies and for the implementation of GE organism regulations.

30. Defendant Kevin Shea is sued in his official capacity as the Administrator of USDA's Animal and Plant Health Inspection Service (APHIS). APHIS administers programs at USDA related to GE organisms. As Administrator, Mr. Shea has the ultimate responsibility for APHIS's activities and policies, including the GE organism regulations.

31. Defendant USDA is a federal agency of the U.S. with a mission to provide leadership on food, agriculture, natural resources, and related issues based on sound public policy, the best available science, and efficient management. USDA, including APHIS, is the Agency responsible for the implementation of GE organism regulations.

LEGAL AUTHORITY

I. CONSTUTIONAL

32. Congress delegated to USDA the responsibility of protecting agriculture, the economy, and the environment from plant pest and noxious weed harms through the PPA.

33. The Constitution delegates "all legislative powers" "in a Congress of the United States." Art. I, § 1. Federal agency officials "may not subdelegate [their decisionmaking authority] to outside entities—private or sovereign—absent affirmative evidence of authority to do so." *U.S. Telecom Ass'n v. F.C.C.*, 359 F.3d 554, 566 (D.C. Cir. 2004).

34. The reason for this is clear: when an agency "shifts to another party 'almost the entire determination of whether a specific statutory requirement . . . has been satisfied,' or . . . abdicates its 'final reviewing authority,'" then "lines of accountability may blur, undermining an important democratic check on government decision-making." *Fund for Animals v. Kempthorne*, 538 F.3d 124, 132 (2d Cir. 2008); *see also Nat'l Ass'n of Regulatory Util. Comm'rs v. F.C.C.*, 737 F.2d 1095, 1143 n.41 (D.C. Cir. 1984) (a key purpose of prohibiting delegation to private entities is preventing "the harm done thereby to principles of political accountability.").

35. This is also because, while agencies are charged with acting in the public interest, "outside parties . . . might not 'share the agency's national vision and perspective.'" *Fund for Animals*, 538 F.3d at 132 (quoting *U.S. Telecom Ass'n*, 359 F.3d at 566).

36. Taken together, Article III and VI of the Constitution stand for the concept of judicial review. Article III grants the federal judiciary power to make judgements in all cases pertaining to the Constitution, statutes, and treaties of the United States. Art. III, § 2. Article VI allows federal courts of law to use their judicial power to protect and defend the authority of the Constitution against acts of the government that violate or contradict it, and states that federal governments are bound to support the Constitution. Art. VI.

37. Because judicial review flows from final agency action, when an agency unlawfully sub-delegates its statutory authority to private entities, it thereby prevents judicial review of the decision.

II. PLANT PROTECTION ACT OF 2000

38. Under the PPA, USDA has the responsibility to prevent plant pest risks and noxious weed risks, both of which are broadly defined agricultural and environmental harms. The PPA defines "plant pest" harms broadly, as organisms with the potential to injure or cause disease or damage, directly or indirectly, in or

to any plant or part of a plant. 7 U.S.C. § 7702(14). A "noxious weed" harm is defined even broader, to be "any plant or plant product that can directly or indirectly injure or damage crops, livestock, natural resources, public health, the environment, or other interests of agriculture." *Id.* § 7702(10).

39. In enacting the PPA, Congress found that "biological control is often a desirable, low-risk means of ridding crops and other plants of plant pests and noxious weeds, and its use should be facilitated by [USDA] whenever feasible." *Id.* § 7702(2).

40. Congress realized the threats certain plants could pose. It specifically found that "export markets could be severely impacted by the introduction or spread of plant pests or noxious weeds into or within the United States," *id.* § 7701(6), and that "the unregulated movement of plant pests, noxious weeds, plants, certain biological control organisms, plant products, and articles capable of harboring plant pests or noxious weeds could present an unacceptable risk of introducing or spreading plant pests or noxious weeds." *Id.* § 7701(7).

41. Congress also noted that the existence of "a plant pest or noxious weed new to or not known to be widely prevalent in or distributed within and throughout the United States could constitute a threat to crops and other plants or plant products of the United States and burden interstate commerce or foreign commerce." *Id.* § 7701(8).

42. As such, Congress found that "all plant pests, noxious weeds, plants, plant products, articles capable of harboring plant pests or noxious weeds regulated under [the PPA] are in or affect interstate commerce or foreign commerce." *Id.* § 7701(9).

43. The PPA gives USDA a multiplicity of statutory tools with which to prevent plant pest and noxious weed harms. *Id.* § 7701(3); *id.* § 7702(10), (14); *id.* §§ 7714, 7733, 7731, 7735, 7721. The goals of the PPA include "protection of the agriculture, environment, and economy of the United States" from these broadly

defined harms. *Id.* § 7701(1). The goals also include facilitation of "exports, imports, and interstate commerce in agricultural products" by reducing the risks caused by any plant pest or noxious weed harms. *Id.* § 7701(3), 7701(6).

44. Predominately, the PPA allows USDA to issue regulations to "prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, article, or means of conveyance" in order to "prevent the introduction in to the United States or the dissemination of a plant pest or noxious weed within the United States." *Id.* § 7712(c), (a).

45. In exercising the PPA's authority, the USDA must make all decisions "based on sound science." *Id.* § 7701(4).[3]

III. 2008 FARM BILL

46. Every five years, Congress passes an omnibus, multiyear agricultural and food policy bill called the farm bill.

47. The 2008 Farm Bill directives required USDA to "promulgate regulations to improve the management and oversight of articles regulated under the Plant Protection Act," including the oversight and management of GE crop field-testing within eighteen months of the bill's June 18, 2008 enactment date.[4]

48. These regulations were to address and correct nine problem areas identified by USDA in a report it published following the agency's investigation into a GE rice field trial contamination episode that severely damaged U.S. rice export

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[3] Under Executive Order 13990, agency decision making "must be guided by the best science" and agencies are obligated to "immediately review . . . actions during the last 4 years that conflict with these important national objectives." Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis, 86 Fed. Reg. 7037 (Jan. 25, 2021).

[4] Food, Conservation, and Energy Act of 2008, Pub. L. No. 110-246, Tit. X § 10204(a)(2).

markets. This document is entitled, LESSONS LEARNED AND REVISIONS UNDER CONSIDERATION FOR APHIS' BIOTECHNOLOGY FRAMEWORK ("LESSONS LEARNED").

49. While preparing the report, the agency took the opportunity to review the lessons it learned from its investigation as part of an initiative to explore revisions to its biotechnology regulations in 7 C.F.R. Part 340. Section 10204 of the 2008 Farm Bill entitled *Regulations to Improve Management and Oversight of Certain Regulated Articles*, codified the LESSONS LEARNED report by incorporation.

50. The LESSONS LEARNED report enumerates considerations to enhance the agency's regulatory framework and include, but are not limited to, the following:

(1) Additional recordkeeping requirements

(2) Regulatory revisions to improve availability of physical samples

(3) Mandated procedures for unauthorized release events

(4) Mandated corrective actions for unauthorized release events

(5) Enhanced agency protocols for conducting molecular forensics after unauthorized release

(6) Required maintenance of contractual relationships for access during later investigations

(7) Ensuring the use of the latest science for isolation as a confinement tool

(8) Improving quality management systems to manage research effectively

(9) Using permits to store important documents and other information related to the permit and notification processes

51. The 2008 Farm Bill states that within eighteen months of enactment, USDA "shall – (1) take action on each issue identified in the document entitled 'Lessons Learned and Revisions under Consideration for APHIS' Biotechnology Framework.'"

52. The APA states that a reviewing court "shall" interpret statutes and "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

IV. NATIONAL ENVIRONMENTAL POLICY ACT

53. NEPA is our "national charter for protection of the environment." 40 C.F.R. § 1500.1(a). Its purpose is to "promote efforts which will prevent or eliminate damage to the environment." 42 U.S.C. § 4321.

54. When enacting NEPA, Congress expressed great concern for the "profound impact of man's activity on the interrelations of all components of the natural environment, particularly the profound influences of . . . new and expanding technological advances. . . ." 42 U.S.C. § 4331(a). Congress was specifically wary of "[a] growing technological power which is far outstripping man's capacity to understand and ability to control its impact on the environment." S. Rep. No. 91-296, 91st Cong., 1st Sess., at 6, 1969 U.S. Code Con. & Admin. News 1969.

55. Regulations promulgated by the Council on Environmental Quality (CEQ) implement NEPA and govern USDA's decision making.[5] *See* 40 C.F.R. §§ 1500-1508; 21 C.F.R., Part 25. Agencies like USDA also have their own NEPA regulations, applying the controlling CEQ regulations but specific to their own agency actions. *See* 7 C.F.R. § 372.

56. The twin pillars of NEPA are the requirements that agencies (1) carefully evaluate the environmental impacts of proposed actions before undertaking the action, and (2) fully advise the public of the potential impacts of those actions, and of alternatives. NEPA requires federal agencies to fully consider and disclose the environmental consequences of an agency action before proceeding

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[5] CEQ issued new implementing regulations for NEPA in July, 2020. 85 Fed. Reg. 43,304 (July 16, 2020). The revised regulations apply to NEPA processes begun *after* the September 14, 2020 effective date. The Part 340 regulations were finalized before September 2020, and thus are subject to the old regulations and relevant case law. Additionally, the current administration is in the process of walking back the Trump Administration's NEPA regulations. As such, the implementation of those regulations is delayed, and additional rulemaking is forthcoming. *See* Deadline for Agencies to Propose Updates to National Environmental Policy Act Procedures, 86 Fed. Reg. 34,154 (June 29, 2021).

with the action—to take a "hard look." 42 U.S.C. § 4332(2)(C); 40 C.F.R. §§ 1501.2, 1501.4, 1502.5. An agency's evaluation of environmental consequences must be based on "accurate scientific" information of "high quality." 40 C.F.R. § 1500.1(b). If there are not sufficient data available, the agency must follow the requisite procedure for addressing or evaluating the impacts in view of incomplete or unavailable information. *Id.* § 1502.22.

57. NEPA requires federal agencies to prepare an environmental impact statement (EIS) for all "major Federal actions significantly affecting the quality of the human environment. 42 U.S.C. § 4332(2)(C); 40 C.F.R. § 1501.4. Major federal actions "include new and continuing activities, including projects and programs . . . conducted, regulated, or approved by Federal agencies; new or revised agency rules, regulations, plans, policies, or procedures[.]" 40 C.F.R. § 1508.1(q)(2).

58. In determining whether an action "significantly" affects the environment, the agency must analyze significance in several contexts "such as society as a whole (human, national), the affected region, the affected interests, and the locality." *Id.* § 1508.27(a). Determining the significance of an action also requires the agency to consider the intensity of the impact by evaluating factors enumerated at 40 C.F.R. § 1508.27(b).

59. An EIS must "serve as the means of assessing the environmental impact of proposed agency actions, rather than justifying decisions already made. *Id.* § 1502.2(g). "To the fullest extent possible, agencies shall prepare draft environmental impact statements concurrently with and integrated with environmental impact analyses and related surveys and studies required by . . . the Endangered Species Act of 1973." *Id.* § 1502.25(a).

60. In a NEPA analysis, the federal agency must identify the direct, indirect, and cumulative impacts of the proposed action, consider alternative actions and their impacts, and identify all irreversible and irretrievable commitments of resources associated with the proposed action. 42 U.S.C. § 4332(2)(C); 40 C.F.R. §§

1508.7, 1508.8, 1502.14. Direct effects are those "which are caused by the action and occur at the same time and place." 40 C.F.R. § 1508.8(a). Indirect effects are "caused by the action and are later in time or farther removed in the distance, but are still reasonably foreseeable." *Id.* 1508.8(b). Cumulative impacts are impacts from "past, present and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions." *Id.* § 1508.7. "Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time." *Id.* "Effects" or "impacts" (synonymous) include "ecological (such as the effects on natural resources and on the components, structures, and functioning of affected ecosystems), aesthetic, historic, cultural, economic, social, or health, whether direct, indirect, or cumulative." *Id.* § 1508.8.

61. NEPA also requires agencies to evaluate economic or social and natural or physical environmental effects that are interrelated. *Id.* § 1508.14.

62. NEPA requires agencies to consider "alternatives to the proposed action." 42 U.S.C. § 4332(2)(C)(iii) & (E); 40 C.F.R. § 1502.14. The analysis of alternatives is the "heart" of the NEPA process and must provide for "a clear basis for choice among options by the decisionmaker and the public." 40 C.F.R. § 1502.14.

63. NEPA also requires agencies to disclose and analyze measure to mitigate the impacts of proposed actions. *Id.* §§ 1502.14(f), 1502.16(h). An agency's analysis of mitigation measures must be reasonably complete in order to properly evaluate the severity of the adverse effects of an agency's proposed action prior to the agency making a final decision.

64. Agencies may conduct NEPA review on a broader "programmatic" level to assess the environmental impacts of "policies, plans, programs, or projects for which subsequent actions will be implemented" based on a programmatic EIS (PEIS). *Id.* § 1502.4(b) ("Environmental impact statements may be prepared, and are sometimes required, for broad Federal actions such as the adoption of new

agency programs or regulations"). PEIS's are subject to "the same regulations and guidance that apply to non-programmatic NEPA reviews."[6]

65. NEPA requires that an agency incorporate its environmental analysis into its decision-making process. "NEPA's purpose is not to generate paperwork—even excellent paperwork—but to foster excellent action." *Id.* §1500.1(c); *see also id.* ("Ultimately . . . it is not better documents but better decisions that count."); *id.* § 1502.1 ("primary purpose" of an EIS is to "serve as an action-forcing device to insure that the policies and goals defined in the Act are infused into the ongoing programs and actions of the Federal Government. . . . An environmental impact statement is more than a disclosure document. It shall be used by Federal officials in conjunction with other relevant material to plan actions and make decisions.").

V. ENDANGERED SPECIES ACT

66. When a species is listed as threatened or endangered under the ESA, section 7(a)(2) of the Act requires that all federal agencies "insure" that their actions "are not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of" their critical habitat. 16 U.S.C. § 1536(a)(2). The "institutionalized caution" embodied in the ESA requires federal agencies to give the benefit of the doubt to listed species and places the burden of risk and uncertainty on the proposed action.[7]

67. The Act establishes an interagency consultation process to assist federal agencies in complying with their substantive section 7(a)(2) duty to guard against jeopardy to listed species or destruction or adverse modification of critical habitat. Under section 7(a)(2), federal agencies must consult with the appropriate expert fish and wildlife agency to determine whether their actions well jeopardize

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[6] CEQ, Guidance: Effective Use of Programmatic NEPA Reviews 7 (Dec. 18, 2014), https://obamawhitehouse.archives.gov/sites/default/files/docs/effective_use_of_programmatic_nepa_reviews_final_dec2014_searchable.pdf.

[7] H.R. Rep. No. 93-412, pp. 4-5 (1973).

any listed species' survival or adversely modify designated critical habitat and, if so, to identify ways to modify the action to avoid that result. *See* 50 C.F.R. § 402.14. The National Marine Fisheries Service is the expert fish and wildlife agency with respect to most anadromous and marine species and the Fish and Wildlife Service (collectively, the Services) is the expert agency with respect to many terrestrial and freshwater species.

68. The Services have adopted joint regulations governing the section 7(a)(2) consultation process. Under the joint regulations, a federal agency must initiate a section 7(a)(2) consultation with the expert agencies whenever it undertakes an "action" that "may affect" a listed species or critical habitat. 50 C.F.R. § 402.14(a). The threshold for a "may affect" determination and the required ESA section 7(a)(2) is low. *See* 51 Fed. Reg. 19,926, 19,949 (June 3, 1986) ("Any possible effect, whether beneficial, benign, adverse, or of an undetermined character, triggers the formal consultation requirement."). *See also* FWS, *Endangered Species Consultation Handbook* at 3-13, 4-26 (1998). An agency is relieved of the obligation to consult only if the action will have "no effect" on listed species or designated critical habitat.

69. The joint regulations broadly define the scope of agency actions subject to ESA section 7(a)(2) mandates to encompass "all activities or programs of any kind authorized, funded, or carried out, in whole or in part by Federal agencies," including the promulgation of regulations and granting licenses. 50 C.F.R. § 402.02 (definition of "action").

70. Under the ESA, "action area" is broadly defined as "all areas to be affected directly or indirectly by the federal action and not merely the immediate area involved in the action." *Id.* § 402.02. The potential "effects" of an agency action that an agency must consider are similarly broad and include both "direct" and "indirect" effects of the action and all activities "interrelated or interdependent" with that action. *Id.*

71. In insuring that any action is not likely to jeopardize a listed species or result in the adverse modification of critical habitat, the ESA requires every agency to use only the best scientific and commercial data available at every step in the process. 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14(g)(8).

72. If an agency determines that its action "may affect" but is not likely to adversely affect" a listed species or its critical habitat, ESA regulations permit "informal consultation," in which there is no requirement for a biological opinion, so long as the expert service concurs in writing with the "not likely to adversely affect" determination. 50 C.F.R. § 402.13. If the service does not concur in the "not likely to adversely affect" determination or if the action agency determines that the action is "likely to adversely affect" the listed species, the agencies must engage in "formal consultation." *Id.* §§ 402.12; 402.14(a), (b).

73. Formal consultation "is a process between the Service and the Federal agency that commences with the Federal agency's written request for consultation under section 7(a)(2) of the Act and concludes with the Service's issuance of the biological opinion under section 7(b)(3) of the Act." *Id.* § 402.02.

74. Compliance with the procedural provisions of the ESA—identifying the likely effects of the action through the consultation process—is integral to compliance with the substantive requirements of the Act. Under the statutory framework, federal actions that "may affect" a listed species or critical habitat may not proceed unless and until the federal agency ensures, through completion of the consultation process, that the action is not likely to cause jeopardy or adverse modification of critical habitat. 16 U.S.C. § 1536(a); 50 C.F.R. §§ 402.14; 402.13; *see also* 16 U.S.C. § 1536(d).

75. The ESA mandates that agencies use the "best scientific and commercial data available" in fulfilling the above requirements. 6 U.S.C. § 1536(a)(2).

VI. ADMINISTRATIVE PROCEDURE ACT

76. The APA grants a right of judicial review to "[a] person suffering legal wrong because of agency action, or adversely aggrieved by agency action. . . ." 5 U.S.C. § 702.

77. Under the APA, a court must "hold unlawful and set aside agency action . . . found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. . . ." *Id.* § 706(2)(A). An agency action is "arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicles Mfrs. Assoc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

78. "[A]n agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance." *Id.* at 42.

79. Under the APA, a court must also "hold unlawful and set aside" any agency action taken that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

80. Finally, under the APA, a court shall also "hold unlawful and set aside" any agency action that was promulgated "without observance of procedure required by law." *Id.* § 706(2)(D).

FACTUAL ALLEGATIONS

I. GE ORGANISMS IN THE U.S.

81. The first GE crops were approved in the U.S. in the 1990s. Now, the genetic engineering of organisms looms as one of the greatest and most intractable environmental and agricultural challenges of the 21st century.

82. By taking genetic material from one organism and inserting it into the permanent genetic code of another, or manipulating plant DNA via gene editing, the biotechnology industry has created an astounding number of organisms that are not produced by nature or traditional breeding practices.[8] These creations are now being patented and released into our environment and food supply at an alarming rate. The vast majority of U.S. commodity crops—corn, soybeans, and cotton—are genetically engineered. It is estimated that upwards of 75% of processed foods on supermarket shelves contain GE ingredients.

83. All GE crops are developed using imprecise techniques that are known to produce unpredictable and unintended effects, which can have adverse health impacts.[9] In some cases, this can lead to large-scale mutations in crop genomes.[10] According to the U.S. Food and Drug Administration, the unintended effects of genetic engineering include increased levels of plant toxicants, creation of novel toxins or allergens, and nutritional deficits.[11]

84. Further, independent scientists are prohibited from conducting risk assessments of GE materials used in food products due to industry restrictions on research of those materials.[12] There are no long-term or epidemiological studies in

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[8] Allison Snow, *Genetic Engineering: Unnatural Selection*, 424 NATURE 619 (2003), http://goo.gl/Fn6hs3.

[9] Inst. of Med. & Nat'l Research Counsel of the Nat'l Acads., *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects*, 64, 65 n. 3 (2004), http://goo.gl/g9AuE1.

[10] Allison K. Wilson et al., *Transformation-Induced Mutations in Transgenic Plants: Analysis and Biosafety Implications*, 23 BIOTECH. & GENETIC ENG'G REV. 209-234 (2006), http://goo.gl/JtDyk8.

[11] FDA, Statement of Policy: Foods Derived From New Plant Varieties; Notice, 57 Fed. Reg. 22,984, 22,986-87 (May 29, 1992).

[12] Emily Waltz, *Under Wraps*, 27 NATURE BIOTECH 880, 880-82 (2009); Andrew Pollack, *Crop Scientists Say Biotechnology Seed Companies Are Thwarting Research,* N.Y. TIMES (Feb. 19, 2009), http://goo.gl/Nz7tWu.

the U.S. that have examined the safety of human consumption of GE foods, despite scientific recommendations for post-market surveillance.

85. GE organisms pose a range of risks to public health, the environment, and the interests of agriculture—risks attributable to both genetic engineering *per se*, and the ends to which the organism is engineered. The great majority of GE organisms to date are GE plants, particularly GE crops. Some of these risks are summarized below.

Contamination Harms

86. GE crops cause substantial harms via transgenic contamination, which occurs when a GE plant disperses its pollen to cross-pollinate a crop or wild plant of the same or closely related species through wind, insect pollinators, or when it disperses its seed to propagate itself in a new area. Time and time again, experimental and commercialized GE plants have shown their ability to escape confinement and contaminate conventional crops and wild relatives, or colonize wild places.[13] GE contamination is a living pollution that can propagate itself via gene flow.

87. Transgenic contamination of conventional or organic crops has cost U.S. farmers billions of dollars in market losses, as food companies, grain traders, and export markets have rejected contaminated supplies.[14] USDA's current decision

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[13] Carey Gillam, *U.S. Organic Food Industry Fears GMO Contamination*, REUTERS (Mar. 12, 2008), https://www.reuters.com/article/us-biotech-crops-contamination-idUSN1216250820080312.

[14] Michelle Marvier & Rene C. Van Acker, *Can Crop Transgenes Be Kept on a Leash?*, 3 FRONTIERS ECOLOGY & ENV'T 99, 100-01 (2005), https://www.centerforfoodsafety.org/files/can-crop-transgenes-be-kept-on-aleash_82326.pdf; Andrew Harris, *Bayer Agrees to Pay $750 Million to End Lawsuits Over Gene-Modified Rice*, BLOOMBERG (July 2, 2011), http://goo.gl/ymErOa; K.L. Hewlett, *The Economic Impacts of GM Contamination Incidents on the Organic Sector* (2008), http://goo.gl/jf2F5E; Stuart Smyth et al., *Liabilities & Economics of Transgenic Crops*, 20 NATURE

to deregulate most GE crops stands in sharp contrast to most of the rest of the world; before the current rule, too lax U.S. oversight lead to market harm: foreign markets with restrictions on GE foods have rejected imports of U.S. crops and shut down export markets when GE contamination was discovered.[15] Some foreign markets are choosing to purchase agricultural products from countries other than the U.S. due to GE-contaminated supplies.

88. To give just a few examples:[16] Field trials of an experimental, GE-herbicide resistant rice known as LibertyLink601 led to contamination of 30% of U.S. long-grain rice supplies in 2006 and 2007, resulting in massive export market rejection of contaminated shipments, and huge losses estimated at up to $1.3 billion to 11,000 American rice farmers and others in the rice food chain. It took farmers five years of class action damages litigation to obtain only partial compensation,[17] and led Congress to add a new mandate in the 2008 Farm Bill, requiring USDA to improve its GE experiment oversight, *see infra*.

89. More recently, USDA deregulated a GE corn known as MIR 162, and its developer Syngenta began selling seed to farmers for unregulated cultivation, even though China, a major buyer of U.S. corn, had not approved it for import.

BIOTECH. 537 (2002), https://www.centerforfoodsafety.org/files/liabilities-and-economics-of-transgeniccrops_82369.pdf.

[15] Tom Polansek, *China Rejections of GMO U.S. Corn Cost up to $2.9 Billion*, REUTERS (Apr. 16, 2014), https://www.reuters.com/article/syngenta-corn-costs/chinarejections-of-gmo-u-s-corn-cost-up-to-2-9-bln-group-idUSL2N0N82DF20140416.

[16] U.S. GAO, GENETICALLY ENGINEERED CROPS (Nov. 2008), https://www.gao.gov/assets/gao-09-60.pdf (GAO report giving contamination incident examples); Andrew Pollack, *Lax Oversight Found in Tests of Gene-Altered Crops*, N.Y. TIMES (Jan. 3, 2006), https://www.nytimes.com/2006/01/03/science/lax-oversight-found-in-tests-of-genealtered-crops.html.

[17] Harris & Beasley, *Bayer Will Pay $750 Million to Settle Gene-Modified Rice Suits*, BLOOMBERG (July 1, 2011), https://www.bloomberg.com/news/articles/2011-07-01/bayer-to-pay-750-million-to-end-lawsuits-over-genetically-modified-rice.

Chinese testing detected this GE corn in American shipments, and rejected 1 million tons, wreaking havoc on the U.S. corn trade.[18] The National Grain & Feed Association estimates overall losses at $6.3 billion, and China began importing corn from Brazil in response—a major setback for the U.S. corn industry.[19]

90. In another instance, Monsanto's GE "Roundup Ready" alfalfa was found contaminating alfalfa seed fields and lots in 63 different contamination events in California and other western states from 2006 to 2009.[20] Feral GE alfalfa was also widely detected near alfalfa seed production fields in California, Idaho, and Washington in 2011 and 2012.[21] Thus, it is not surprising that GE alfalfa was found contaminating conventional alfalfa supplies, jeopardizing annual American exports of roughly $200 million worth of this valuable commodity to nations that reject the GE contaminant.[22] Transgenic contamination of seed is particularly insidious,

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[18] Nick McCain, *Syngenta Agrees to Pay $1.5B Over Modified Corn Seeds*, COURTHOUSE NEWS SERV. (Mar. 13, 2018), https://www.courthousenews.com/syngenta-agrees-to-pay-1-5b-over-modified-corn-seeds/.

[19] Megan Durisin & Jeff Wilson, *U.S. Grain Losses Seen up to 6.3 Billion on China Ban*, BLOOMBERG (Apr. 16, 2014), https://www.bloomberg.com/news/articles/2014-04-16/u-s-group-says-losses-may-be-6-3-billion-on-china-corn.

[20] Final Environmental Impact Statement on Roundup Ready Alfalfa, USDA APHIS, Dec. 2010, Appendix V, V-64 to V-65; Cal/West Seeds Newsletter, Winter Issue 2010; "Roundup Ready Contamination of Feral Alfalfa," report and affidavit by Phil Geertson, May 28, 2009.

[21] Stephanie L. Greene et al., *Occurrence of Transgenic Feral Alfalfa (*Medicago sativa *subsp.* sativa *L.) in Alfalfa Seed Production Areas in the United States*, 10 PLOS ONE 12 (Dec. 2015), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0143296.

[22] Jesse Newman, *China's Hard Line on Biotech Burns U.S. Hay*, WALL ST. J. (Dec. 15, 2014), https://www.wsj.com/articles/u-s-hay-exports-to-china-shrivel-up-1418598477; AP, *Genetically Modified Alfalfa Confirmed in Washington Test Sample*, OREGON LIVE (Sept. 13, 2013), https://www.oregonlive.com/business/2013/09/genetically_modified_alfalfa_c.html.

because farmers who plant what they believe is pure seed line are unwittingly propagating the GE contaminant throughout the alfalfa production system.

91. Repeated GMO contamination incidents in other U.S. crops have cost farmers literally billions[23] over the past decade in rejected sales,[24] lost exports,[25] and closed agricultural markets, with new episodes[26] "cropping" up regularly.[27]

A Pesticide-Promoting System

92. The last twenty-five years of use has also proved that GE crops are a key pillar of inherently unsustainable industrial agriculture, and cause significant adverse environmental impacts. Contrary to the industry's hype about various potential public good uses for GE crops, in reality the overwhelming majority of commercial GE crops are created and marketed by pesticide companies to survive direct application of plant-killing pesticides (herbicides), produce insecticidal toxins in their tissues, or both.[28]

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[23] Harris & Beasley, *Bayer Will Pay $750 Million to Settle Gene-Modified Rice Suits*, BLOOMBERG (July 1, 2011), https://www.bloomberg.com/news/articles/2011-07-01/bayer-to-pay-750-million-to-end-lawsuits-over-genetically-modified-rice.

[24] Carey Gillam, *U.S. Organic Food Industry Fears GMO Contamination*, REUTERS (Mar. 12, 2008) https://www.reuters.com/article/us-biotech-crops-contamination-idUSN1216250820080312.

[25] Jesse Newman, *China's Hard Line on Biotech Burns U.S. Hay*, WALL ST. J. (Dec. 15, 2014), https://www.wsj.com/articles/u-s-hay-exports-to-china-shrivel-up-1418598477.

[26] Tom Polansek, *China Rejections of GMO U.S. Corn Cost up to $2.8 Billion: Group*, REUTERS (Apr. 16, 2014), https://www.reuters.com/article/us-syngenta-corn-costs-idUSBREA3F20P20140416.

[27] Steven Mufson, *Unapproved Genetically Modified Wheat from Monsanto Found in Oregon Field*, WASHINGTON POST (May 30, 2013), https://www.washingtonpost.com/business/economy/unapproved-genetically-modified-wheat-from-monsanto-found-in-oregon-field/2013/05/30/93fe7abe-c95e-11e2-8da7-d274bc611a47_story.html.

[28] Jung, C., et al., *Recent Developments in Genome Editing and Applications in Plant Breeding*, 137 PLANT BREEDING 1-9 (2017); Kaskey, J., *BASF to Crank Up R&D 'Two Gears' With Bayer Seeds, Next CEO Says*, BLOOMBERG TECH. (Apr. 12,

93. The well-established impacts of GE crops (and their companion pesticides) are widespread and dire. Reliance on these pesticide-promoting GE crop systems has caused a number of harms, including widespread pollution of our waterways and ecosystems,[29] injury to beneficial insects such as pollinators,[30] and harm to soil health.[31]

94. The great majority of corn, soybeans, cotton, canola, and sugar beets grown in the U.S. are GE herbicide-resistant varieties that have dramatically increased use of these weed-killing chemicals and the overall pesticide output into our environment.[32] Herbicide-resistant seeds and their companion herbicides are marketed together as a crop system. It is estimated that GE corn, soybeans, and

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2018), https://www.bloomberg.com/news/articles/2018-04-12/basf-to-crank-up-r-d-two-gears-with-bayer-seeds-next-ceo-says.

[29] Feng-Chih Chang et al., *Occurrence and Fate of the Herbicide Glyphosate and its Degradate Aminomethylphosphonic Acid in the Atmosphere*, 30 ENV'T TOXICOLOGY & CHEMISTRY 548, 548-50 (2011), http://goo.gl/bZZTve; Richard H. Coupe et al., *Fate and Transport of Glyphosate and Aminomethylphosphonic Acid in Surface Waters of Agricultural Basins*, 68 PEST. MGMT. SCI. 16, 16-17 (2012), http://goo.gl/WSvHO2.

[30] Richard Coniff, *Tracking the Causes of Sharp Decline of the Monarch Butterfly*, YALE ENV'T 360 (Apr. 1, 2013), http://goo.gl/EBCU33; J.M. Pleasants & K.S. Oberhauser, *Milkweed Loss in Agricultural Fields Because of Herbicide Use: Effect on the Monarch Butterfly Population*, 6 INSECT CONSERVATION AND DIVERSITY, 135-144 (2013), http://home.cc.umanitoba.ca/~frist/PLNT4600/biodiversity/icad196.pdf.

[31] Robert J. Kremer, *Soil and Environmental Health After Twenty Years of Intensive Use of Glyphosate*, 6 ADV. PLANTS AGRIC. RES. 00224 (2017).

[32] *See* 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?_r=1&pagewanted=all ("Today, Roundup Ready crops account for about 90 percent of the soybeans and 70 percent of the corn and cotton grown in the United States.").

cotton alone have led to a 527 million pound increase in herbicide use over the first sixteen years of their cultivation, from 1996 to 2011.[33]

95. The first generation of Monsanto's "Roundup Ready" crops, resistant to the pesticide glyphosate, have transformed glyphosate from a minor agricultural pesticide to by far the most intensively and extensively sprayed weed killer in the country, with 280 million pounds applied to nearly 300 million acres of farmland, annually.[34]

96. Glyphosate-containing Roundup formulations are extremely toxic to tadpoles and frogs, and likely have contributed to the worldwide decline in frog populations.[35] Glyphosate is also harmful to organisms beneficial to agriculture. For instance, glyphosate is toxic to *Bradyrhizobium japonicum*, an important nitrogen-fixing symbiont that colonizes soybean roots, due to sensitivity of its EPSPS enzyme to inhibition by glyphosate.[36] Suppression of this important symbiont is likely related to the finding that glyphosate application to glyphosate-resistant soybeans reduces foliar nitrogen content, seed nitrogen content, biomass and yields, especially under conditions of water stress, early application of glyphosate, and high application rates.[37]

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[33] Charles M. Benbrook, *Impacts of Genetically Engineered Crops on Pesticide Use in the U.S. – the First Sixteen Years*, 24 ENV'T SCI. EUR. 1, 3 (2012), https://enveurope.springeropen.com/articles/10.1186/2190-4715-24-24.

[34] EPA, Glyphosate: Response to Comments, Usage, and Benefits. Biological and Economic Analysis Division 13 (Apr. 18, 2019), EPA-HQ-OPP-2009-0361-2342.

[35] Rick A. Relyea, *The Lethal Impact of Roundup on Aquatic and Terrestrial Amphibians*, 15 ECOLOGICAL ADAPTIONS 1118, 1120-23 (2005), http://goo.gl/ZjYiHG.

[36] Zablotowicz, R.M. and K.N. Reddy, *Nitrogenase Activity, Nitrogen Content, and Yield Responses to Gyphosate in Glyphosate-Resistant Soybean*, CROP PROTECTION 26: 370-376 (2007).

[37] Zablotowicz et al. (2007), op. cit.; King, C.A., L.C. Purcell and E.D. Vories, *Plant growth and Nitrogenase Activity of Gyphosate-Tolerant Soybean in Response to Foliar Glyphosate Applications*, AGRON. J. 93: 179-186 (2001).

97. GE glyphosate-resistant crop systems were not introduced with the intention of harming N-fixing symbionts, but as noted above can do so. A second example also illustrates this point: the genetic engineering of Arctic apple to resist browning (the intended purpose) involved the silencing of a family of genes that generate enzymes that are critical to plant defense against disease and insect pests in some plants. Thus, their silencing may well have the unintended effect of rendering Artic apple trees more susceptible to disease or insect pests, creating plant pest risks. This is true even though the engineering of the Arctic apple trees was not intended to make them more susceptible to pest attack.

98. Glyphosate sprayed over the top of Roundup Ready crop systems has nearly eradicated the common milkweed from farm fields in the Midwest, thereby contributing to the dramatic, quarter-century decline in Monarch butterflies that critically depend on milkweed for survival; Monarchs have consequently been driven so near to extinction that in December 2020 the U.S. Fish and Wildlife Service (FWS) found that their listing under the ESA was "warranted" and that they will be listed in coming years, only precluded by more immediate species currently.[38]

99. The massive use of glyphosate has had substantial adverse impacts on human health. The World Health Organization's International Agency for Research on Cancer concluded that glyphosate is "probably carcinogenic to humans,"[39] based in part on epidemiology studies showing increased risk of the cancer non-Hodgkin

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[38] *Petition to Protect the Monarch Butterfly Under the Endangered Species Act* (Aug. 26, 2014) https://www.centerforfoodsafety.org/files/monarch-esa-petition-final_61585.pdf; 79 Fed. Reg. 78,775 (Dec. 31, 2014) (finding listing may be warranted); 85 Fed. Reg. 81,813 (Dec. 17, 2020) (finding listing is warranted but precluded; to be listed by 2024).

[39] World Health Organization, *IARC Monographs Volume 112: Evaluation of Five Organophosphate Insecticides and Herbicides* (Mar. 20, 2015), http://goo.gl/KRhWNX.

lymphoma among farmers who used glyphosate formulations. In three lawsuits against Monsanto, juries ruled that use of Roundup and other glyphosate formulations contributed to the development of non-Hodgkin lymphoma in California users of these products.[40] The amount of glyphosate permitted in the food supply has increased dramatically since the 1980s. To take one prominent example, the Environmental Protection Agency (EPA) has raised the amount of glyphosate residue permitted on wheat grain from 0.1 part per million (ppm) in 1983,[41] to 5 ppm in 1993,[42] and to 30 ppm in 2008,[43] a 300-fold increase. A growing number of registrant and independent studies indicate that long-term glyphosate exposure

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[40] Burger & Bellon, *Bayer to Pay up to $10.9 Billion to Settle Bulk of Roundup Weedkiller Cancer Lawsuits*, REUTERS (June 24, 2020), https://www.reuters.com/article/us-bayerlitigation-settlement/bayer-to-pay-up-to-10-9-billion-to-settle-bulk-of-roundupweedkiller-cancer-lawsuits-idUSKBN23V2NP.

[41] EPA, Glyphosate (Roundup) on Wheat; PP#3F2809; Reg. #524-308; Winnie Teeters, Ph.D., Toxicology Branch (Mar. 3, 1983).

[42] EPA, Reregistration Eligibility Decision (RED): Glyphosate, EPA 738-R-93-014, (Sept. 1993), https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-417300_1-Sep-93.pdf.

[43] Benfluralin, Carbaryl, Diazinon, Dicrotophos, Fluometuron, Formetanate Hydrochloride, Glyphosate, Metolachlor, Napropamide, Norflurazon, Pyrazon, and Tau-Fluvalinate; Proposed Tolerance Actions; Proposed Rule, 73 Fed. Reg. 29,456, 29,643 (May 21, 2008).

poses risks to the liver,[44] kidney,[45] and reproductive system.[46] These are serious health impacts that fall disproportionately on farmers, farmworkers, and other users of glyphosate herbicides.

100. Herbicide-resistant GE crop systems also foster rapid emergence of "superweeds" immune to the GE crop's companion herbicide(s). Weeds resistant to glyphosate, virtually unknown through the mid-1990s, evolved in epidemic fashion with the massive use of glyphosate accompanying widespread planting of Roundup Ready crops, and now infest at least 120 million acres—nearly 40% of the nation's cultivated cropland (*see* Fig. 1).[47] Efforts to control these resistant weeds involve spraying increasingly toxic herbicides and soil-eroding tillage operations, imposing

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[44] Robin Mesnage et al., *Multiomics Reveal Non-Alcoholic Fatty Liver Disease in Rats Following Chronic Exposure to an Ultra-Low Dose of Roundup Herbicide*, 7 SCI. REPORTS 39,328 (2017), https://www.nature.com/articles/srep39328; see also Paul J. Mills et al., *Glyphosate Excretion is Associated With Steatohepatitis and Advanced Liver Fibrosis in Patients with Fatty Liver Disease*, 18 CLINICAL GASTROENTEROLOGY AND HEPATOLOGY 741-743 (2019).

[45] EPA, Addendum to Pathology Report for a Three-Generation Reproduction Study in Rats with Glyphosate, R.D. #374 (July 21, 1982), https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/103601/103601-135.pdf; Gabriel A. Dedeke et al., *Comnparative Assessment on Mechanism Underlying Renal Toxicity of Commercial Formulation of Roundup Herbicide and Glyphosate Alone in Male Albino Rat*, 37 INT'L J. OF TOXICOLOGY 285-295 (2018).

[46] R.M Romano et al., *Prepubertal Exposure to Commercial Formulation of the Herbicide Glyphosate Alters Testosterone Levels and Testicular Morphology*, 84 ARCHIVES OF TOXICOLOGY 309-317 (2010); Folarin O. Owagobriaye et al., *Reproductive Toxicity of Roundup Herbicide Exposure in Male Albino Rat*, 69 EXPERIMENTAL AND TOXICOLOGIC PATHOLOGY 461-468 (2017).

[47] K. Fraser, *Glyphosate Resistant Weeds – Intensifying* (Jan. 25, 2013) STRATUS AG RESEARCH, http://www.stratusresearch.com/newsroom/glyphosate-resistant-weeds-intensifying/; J. Pucci, *The War Against Weeds Evolves in 2018* (Mar. 20, 2018) CROPLIFE, https://www.croplife.com/crop-inputs/the-war-against-weeds-evolves-in-2018/.

huge costs on farmers and the environment.[48] Because herbicide-resistant weeds can spread, they also impact growers who played no role in their development.

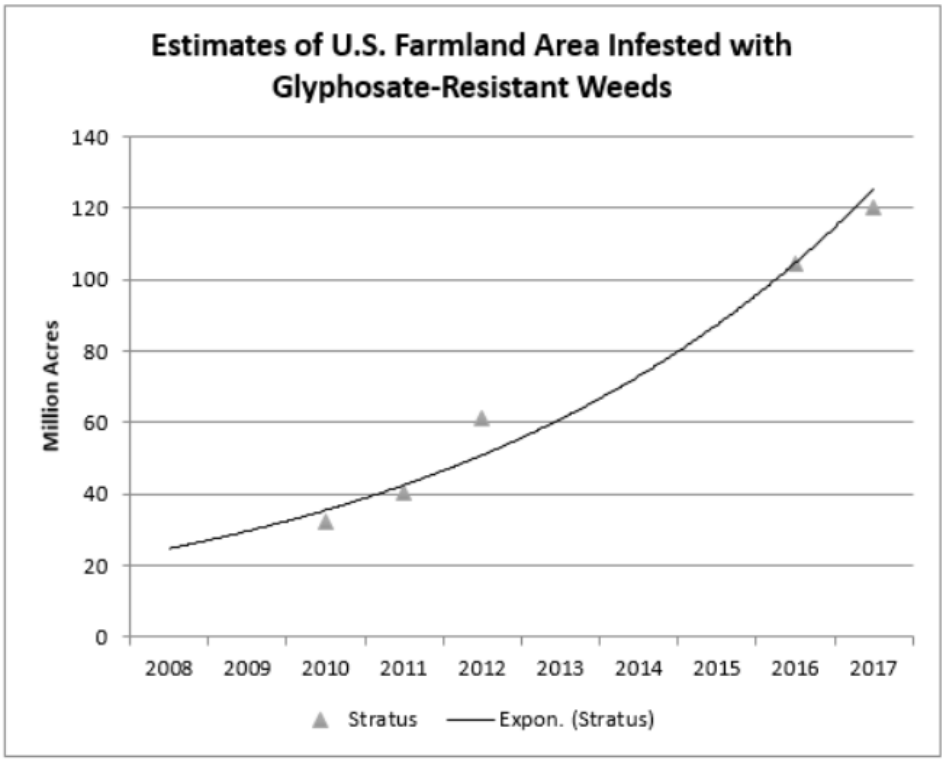

Figure 1

101. Glyphosate-resistant weeds have also driven widespread introduction of a second generation of GE crops, resistant to additional toxic herbicides like dicamba or 2,4-D as well as to glyphosate.[49] The number of discrete herbicide-resistance traits ratchets up as the overuse of weedkillers characteristic of these crop systems selects for further weed resistance. These GE crop systems facilitate the use of cocktails of multiple different herbicides, sprayed at increased frequency

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[48] David Mortensen et al., *Navigating a Critical Juncture for Sustainable Weed Management*, 62 BIOSCIENCE 75-84 (2012), http://goo.gl/RxZVM2; Scott Kilman, *Superweed Outbreak Triggers Arms Race*, WALL ST. J. (June 4, 2010), http://goo.gl/Fcolxd.

[49] David Mortensen et al., *Navigating a Critical Juncture for Sustainable Weed Management*, 62 BIOSCIENCE 75-84 (2012), http://goo.gl/RxZVM2; Brandon Keim, *New Generation of GM Crops Put Agriculture in a 'Crisis Situation,'* WIRED (Sept. 25, 2014), http://goo.gl/ejbTLF.

and greater volume than has ever been possible before. Accordingly, per-acre use of herbicides in soybeans has *doubled* since the GE crop era began, from 1.2 to 2.4 pounds per acre annually (*see* Fig. 2).[50]

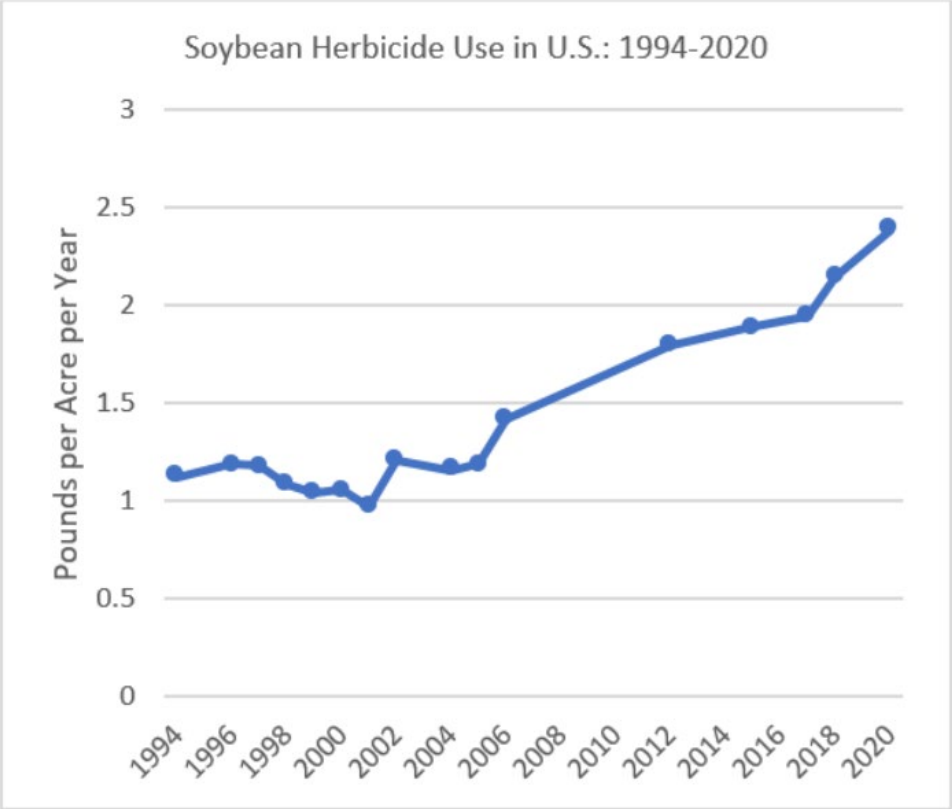

Figure 2

102. Besides increasing the amount of weedkiller that is sprayed, herbicide-resistant crop systems also shift applications to later in the growing season, when more plants are vulnerable to damage from direct contact with spray or from drift. Through these different pathways, GE crop systems have caused immeasurable harm to a wide spectrum of wild plants that are important to hundreds of pollinators and endangered species, not to mention farmers' crops.

[50] Agricultural Chemical Usage: Field Crops, U.S. Dept. of Agriculture, National Agricultural Statistics Service, selected years from 1994 to 2020, https://www.nass.usda.gov/Surveys/Guide_to_NASS_Surveys/Chemical_Use/. "Selected years" because herbicide usage on soybeans was not reported every year.

103. Use of dicamba has skyrocketed since widespread introduction of dicamba-resistant soybeans and cotton in 2017 (*see* Fig. 3)[51]. Notorious for its volatility, dicamba has caused rampant drift damage to all manner of crops across millions of acres, resulting in huge economic losses to farmers.[52] Additionally, dicamba damage to wild flowering plants has robbed bees of nectar and pollen resources, causing huge drops in beekeepers' honey production in several states, with likely impacts on other pollinators as well. Dicamba drifting from GE crop fields where it is sprayed has also damaged millions of trees throughout the Midwest and South, has forced soybean farmers to buy dicamba-resistant seeds for protection from drift, and torn apart the fabric of rural communities by inciting strife between farmers who spray it and others whose crops and residential plants incur damage.[53] These herbicidal impacts are direct, indirect, interrelated, and interdependent impacts of these GE crops.

[51] Fig. 3 was created using data from the following documents: EPA, Over-The-Top Dicamba Products for Genetically Modified Cotton and Soybeans: Benefits and Impacts at 5 (Oct. 31, 2018); EPA, Assessment of the Benefits of Dicamba Use in Genetically Modified, Dicamba-Tolerant Soybean Production at 11, Table 3b (Oct. 26, 2020); EPA, Assessment of the Benefits of Dicamba Use in Genetically Modified, Dicamba-Tolerant Cotton Production at 11, Table 3b (Oct. 26, 2020).

[52] *Nat'l Family Farm Coal. v. EPA*, 960 F.3d 1120, 1123, 1135 (9th Cir. 2020).

[53] *Id.* at 1143.

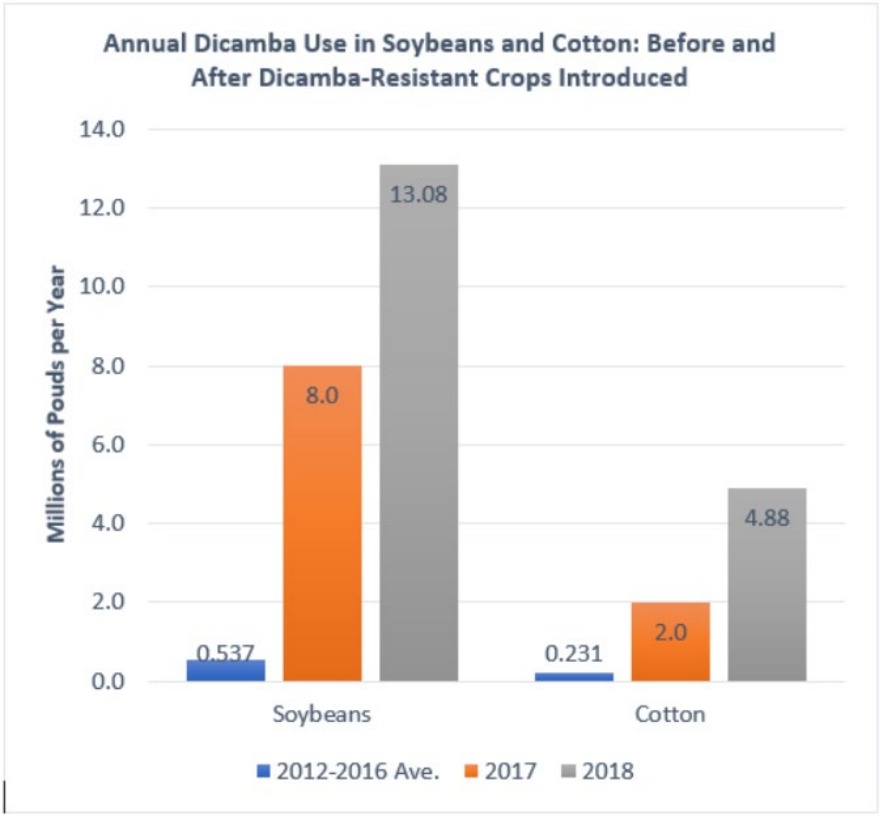

Figure 3

Other GE Harms

104. The most well-known and well-established adverse environmental and agricultural impacts of GE crop systems are transgenic contamination, increased use of pesticides, and the creation of the superweeds epidemic. But they are not alone.

105. For example, GE crops not only promote rapid emergence of herbicide-resistant weeds, but in some cases can actually be weeds themselves. For instance, plants can be endowed with traits that increase their fitness, such as their ability to persist and propagate, in both agricultural and non-agricultural contexts. Herbicide-resistant GE crop volunteers, which sprout from grain left in the field after the previous season's harvest, may well persist in farm fields due to the difficulty, cost or inability to control them, while GE grasses may spread far beyond a field's boundaries to become established in the wild, which contributes to displacement of native vegetation.

106. To give one example, in the mid-2000s, USDA permitted open-air field trials of a GE "Roundup Ready" bentgrass proposed for golf courses and lawns. Public interest organizations successfully challenged the legality of the field trials, with the Court holding that USDA had failed to comply NEPA and the PPA in approving them.[54] During that litigation, EPA scientists found that the GE grass had escaped the trial, cross-pollinated with wild varieties, and contaminated a protected national grassland over twelve miles away.[55] Despite continued and longstanding eradication efforts by the Scotts Company and USDA, the feral GE bentgrass populations continue to be found in the wild years later by farmers in eastern Oregon and western Idaho.[56]

107. When USDA entered into ESA Section 7 consultation on the GE bentgrass, FWS found in a 2010 Biological Opinion that if it was ever commercialized, the GE grass would escape, spread, and edge-out native species and take over their habitat, becoming impossible to eradicate—likely causing the extinction of at least three endangered species (two endangered plants and a

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[54] *Int'l Ctr. for Tech. Assessment v. Johanns*, 473 F. Supp. 2d 9, 28 (D.D.C. 2007).

[55] Christopher Doering, *Scotts to Pay $500,000 Fine Over Biotech Bentgrass*, REUTERS (Nov. 7, 2007), https://www.reuters.com/article/us-scotts-usda-idUSN2643698720071127; Andrew Pollack, *Genes from Engineered Grass Spread for Miles, Study Finds*, N.Y. TIMES (Sept. 21, 2004), https://www.nytimes.com/2004/09/21/business/genes-from-engineered-grass-spread-for-miles-study-finds.html?_r=1; Jay R. Reichman et al., *Establishment of Transgenic Herbicide-Resistant Creeping Bentgrass (Agrostis solonifera L.) in Nonagronomic Habitats*, 15 MOLECULAR ECOLOGY 4243, 4245 (2006).

[56] *GMO Bentgrass Found in Eastern Oregon*, CAPITAL PRESS (Nov. 9, 2010), https://www.capitalpress.com/state/oregon/gmo-bentgrass-found-in-eastern-oregon/article_ae4be0b2-98bd-56a2-badf-193236d2342c.html; Mitch Lies, *Coba Presses Scotts for Bentgrass Plan*, CAPITAL PRESS (Feb. 10, 2011), http://www.capitalpress.com/oregon/ml-coba-letter-021111; Mitch Lies, *Feds Mum on GMO Spread*, CAPITAL PRESS, https://www.capitalpress.com/ag_sectors/feds-mum-on-gmo-spread/article_734706ac-8b5a-578c-8551-9576c32a6368.html.

butterfly, the Fender Blue Butterfly), and potentially imperiling dozens more endangered species.[57]

108. In another example, in the summer of 2010, two scientists from the University of Arkansas sampled feral canola plants growing along the roadside in North Dakota. They found that 80% of the plants they tested carried GE herbicide-resistance traits, illustrating widespread gene flow from cultivated GE canola fields and the establishment of these GE plants in the wild.[58]

109. To provide another type of risk example, some GE crops are engineered as "biofactories" for experimental production of pharmaceutical compounds, such as insulin, which are extracted from the plant's grain or leaf tissue. While these have not yet been commercialized, GE pharmaceutical crops could contaminate food crops by cross-pollination or other avenues, posing potential threats to human health and wildlife from consumption of the experimental pharmaceutical. Such contamination episodes have already occurred, even from limited field trials.[59] Pharmaceutical crop contamination also results in economic losses because contaminated supplies cannot be used for food production.[60]

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[57] FWS, BiOp on Roundup Ready Bentgrass, http://www.centerforfoodsafety.org/files/fws-biop-on-rr-bentgrass-deregulation_received-via-foia_2011_49385.pdf

[58] Meredith Schafer et al., *Presentation of Results, Evidence for the Establishment and Persistence of Genetically Modified Canola Populations in the U.S.* (Aug. 6, 2010); Meredith Schafer et al., *Evidence for the Establishment and Persistence of Genetically Modified Canola Populations in the U.S.*, 6 PUB. LIB. SCI. ONE 1, 2 (2011); Andrew Pollack, *Canola, Pushed by Genetics, Moves into Uncharted Territories*, N.Y. TIMES, (Aug. 9, 2010) http://www.nytimes.com/2010/08/10/science/10canola.html.

[59] GAO, *Genetically Engineered Crops: Agencies are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring*, Appendix VII (2008).

[60] Karen Charman, *Down on the Biopharm*, IN THESE TIMES (Feb. 13, 2003), https://inthesetimes.com/article/down-on-the-biopharm.

110. Other GE plants are engineered to produce industrial enzymes, either for extraction as with pharmaceutical plants, or for use embedded in the crop's grain. For instance, a GE corn grown exclusively for ethanol production contains ultra-high levels of an enzyme, amylase, that helps transform corn starch into ethanol.[61] USDA deregulated the GE corn in 2011 despite the likelihood it would contaminate food-grade corn, degrade the quality of tainted corn products, and potentially trigger allergies.[62] The corn did in fact contaminate white corn in Nebraska years later, triggering market losses for affected farmers, while tainted corn flour was reportedly ruined, with some people falling ill from eating products made from it.[63] As with pharmaceutical-producing GE crops, those engineered to express industrial enzymes pose economic, environmental, and food safety risks.

111. In one type of gene editing process, where genes are inserted to give an organism a particular trait, it is possible for several functional genes to be inserted at once, resulting in extensive changes to the genome. These changes could make the genome almost unrecognizable compared to the original organism, and fall within the scope of "synthetic biology."[64] This has already been achieved in bacteria

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[61] Union of Concerned Scientists, *Comments to USDA APHIS on Draft Environmental Assessment and Preliminary Decision to Deregulate Syngenta's Genetically Engineered Ethanol Corn* (July 6, 2009).

[62] Ken Roseboro, *StarLink 2: Approval of GM Biofuel Corn Threatens Food Supply*, THE ORGANIC & NON-GMO REPORT (Mar. 1, 2011), https://non-gmoreport.com/articles/march2011/gmbiofuelcornthreatensfoodsupply.php.

[63] Ken Roseboro, *GMO-Ethanol Corn Contamination Raises Concerns About Another "StarLink" Disaster*, THE ORGANIC & NON-GMO REPORT (Feb. 22, 2017), http://non-gmoreport.com/articles/gmo-ethanol-corn-contamination-raises-concerns-another-starlink-disaster/.

[64] FRIENDS OF THE EARTH & ETC GROUP, GMOS 2.0: SYNTHETIC BIOLOGY: A GUIDE TO PROTECTING NATURAL PRODUCTS (2017), https://1bps6437gg8c169i0y1drtgz-wpengine.netdna-ssl.com/wp-content/uploads/2017/12/SynbioFreeCompanyGuide.pdf; European Network of Scientists for Social and Environmental Responsibility, *Products of New Genetic Modification Techniques Should be Strictly Regulated as GMOs* (2018),

and yeast, and shows that even small edits through gene editing can result in significant changes.[65]

112. Gene editing techniques have also facilitated the possibility of "gene drives," which use a few gene-edited individuals to spread new genes through the entire population of a species.[66] This mechanism that the new genes will be inherited by each offspring in the next generation, rather than the expected half in normal inheritance.[67] This means that genetic changes in a population are likely to persist for longer periods of time, even permanently. Scientists are already warning that the consequences of gene drives could be severe, including adverse environmental outcomes and harmful effects on vegetable crops.[68] These newer types of future genetically engineered organisms would also fall under USDA's new regulatory regime (or now lack thereof).

113. GE trees under USDA's purview present their own unique risks separate and apart from GE plants. Trees are long-lived and can reproduce over

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Secretariat of the Convention on Biological Diversity, *Synthetic Biology*, CBD Technical Series no. 82, Montreal (2015), https://www.cbd.int/ts/cbd-ts-82-en.pdf.

[65] Bao, Z., et al., *Genome-Scale Engineering of Saccharomyces Cerevisiae with Single-Nucleotide Precision*, 36 NATURE BIOTECHNOLOGY 505-508 (2018); Garst, A.D., et al., *Genome-Wide Mapping of Mutations at Single-Nucleotide Resolution for Protein, Metabolic and Genome Engineering*, 35 NATURE BIOTECHNOLOGY 48-55 (2017).

[66] FRIENDS OF THE EARTH, GENE-EDITED ORGANISMS IN AGRICULTURE: RISKS AND UNEXPECTED CONSEQUENCES 14 (2018), https://1bps6437gg8c169i0y1drtgz-wpengine.netdna-ssl.com/wp-content/uploads/2018/09/FOE_GenomeEditingAgReport_final.pdf; NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, GENE DRIVES ON THE HORIZON: ADVANCING SCIENCE, NAVIGATING UNCERTAINTY, AND ALIGNING RESEARCH WITH PUBLIC VALUES, National Academies Press, Washington, D.C. (2016), https://www.nap.edu/download/23405.

[67] NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, GENE DRIVES ON THE HORIZON: ADVANCING SCIENCE, NAVIGATING UNCERTAINTY, AND ALIGNING RESEARCH WITH PUBLIC VALUES, National Academies Press, Washington, D.C. (2016), https://www.nap.edu/download/23405.

[68] *Id.*

great distances via wind, water, and animals, raising even more significant and different in kind risks from contamination, including contamination of forests and wild relatives.[69]

114. Trees are a key species comprising forest ecosystems that regulate air quality, stabilize climate, preserve water quality and abundance, and harbor much of the world's biodiversity, including endangered species. These essential functions of forests are threatened by GE trees, which will mainly be designed to increase profitability of industrial tree plantations.[70]

115. For example, plantations of proposed but never deregulated "freeze-tolerant" GE eucalyptus trees previously tested in USDA-permitted field trials could cause broad, long-term ecosystem changes, such as increased fire risks, and water table depletion. This alteration would allow the trees to grow in areas they could not survive naturally, at growth rates that are much faster than pine populations in the southeastern U.S.[71] Eucalyptus plantations are extremely water-intensive and could exacerbate water scarcity if grown in new regions.[72]

116. Finally, juxtaposed against these facts, the U.S. public is discovering that the industry's hype about GE foods is false: despite billions of dollars in research and two decades of commercialization, no GE crops are commercially produced to increase yields, reduce world hunger, or mitigate the climate crisis.[73]

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[69] CENTER FOR FOOD SAFETY, GENETICALLY ENGINEERED TREES: THE NEW FRONTIER OF BIOTECHNOLOGY 8 (2013), http://www.centerforfoodsafety.org/files/ge_trees_2016_93322.pdf.

[70] *Id.* at 5.

[71] *Id.* at 31.

[72] *Id.* at 40.

[73] Doug Gurian-Sherman, *Union of Concerned Scientists, Failure to Yield: Evaluating the Performance of Genetically Engineered Crops*, at 1-5 (Apr. 2009), https://www.ucsusa.org/resources/failure-yield-evaluating-performance-geneticallyengineered-crops; Jack A. Heinemann, *Reply to Comment on Sustainability and Innovation in Staple Crop Production in the US Midwest*, 12 INT'L J. OF AG. SUSTAINABILITY 387-390 (2014), http://goo.gl/GruWvv.

Rather, the commercial reality is that agrochemical companies have largely succeeded in engineering these crops to be resistant to the companies' own products—pesticides—in order to reap huge profits.

II. PROCEDURAL HISTORY

117. The final Part 340 regulations challenged in this case are the first comprehensive revision of USDA's GE organism regulations since 1987, when they were established under the Federal Plant Pest Act, a precursor statute to the PPA of 2000.

118. In the U.S., no single overarching law or federal agency oversees biotechnology. Instead, the U.S. government oversees its products using a mosaic of laws, implemented by several agencies, pursuant to executive order known as the Coordinated Framework for the Regulation of Biotechnology.[74] These agencies are mainly USDA, EPA, and the Food & Drug Administration (FDA). FDA is charged with vetting the safety of GE foods, as well as oversight of GE animals. EPA oversees GE plants that are engineered to themselves act as pesticides by producing pesticidal substances, as well as GE microbes. And USDA regulates GE plants, whether food or feed, as well as GE trees and grasses, overseeing their field trials and granting permission for unregulated commercial cultivation (or at least, it used to do so).[75]

119. Because the U.S. lacked a biotechnology-specific law, the coordinated framework called for these agencies to apply their existing statutes, using existing definitions and authorities to promulgate regulations and oversee transgenic products. FDA was to classify GE food ingredients as "food additives" under the

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[74] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

[75] *See infra* paragraphs 120-121.

Federal Food Drug and Cosmetic Act.[76] EPA was to regulate the pesticidal substances expressed in transgenic plants as "pesticides" under the Federal Insecticide, Fungicide, and Rodenticide Act.[77] Transgenic microorganisms would be regulated by EPA as "toxic chemicals" under the Toxic Substances Control Act.[78] Transgenic animals would be regulated by FDA as "new animal drugs."[79] And most relevant here and as discussed below, USDA would oversee all other transgenic plants as "plant pests" under the former Plant Pest Act.

The Prior Regulations

120. Accordingly, the prior USDA Part 340 regulations governed outdoor planting of GE organisms whose development involved the use of plant pest organisms.[80] As a practical reality, that covered virtually all GE plants,[81] because bacteria and viruses that infect plants—plant pests—and DNA derived from them were invariably needed to successfully engineer the GE plant to express the desired trait. For instance, a soil bacterium known as *Agrobacterium*, which naturally infects plants, has been repurposed through genetic engineering to "infect" plants with genetic material that lends the GE plant the desired trait(s), most commonly

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[76] *Id.* at 23,304; 21 U.S.C. § 301 et seq.

[77] Plant-Incorporated Protectants (Formerly Plant Pesticides), Supplemental Proposal, 66 Fed. Reg. 37,855-69 (July 19, 2001); 7 U.S.C. § 136 et seq.

[78] 40 C.F.R. § 725.

[79] *See Inst. for Fisheries Res. v. USDA*, 499 F. Supp. 3d 657, 663 (N.D. Cal. 2020).

[80] A plant pest is 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." 40 C.F.R § 340.1.

[81] The vast majority of GE organisms under USDA jurisdiction belong to the plant kingdom, and include crops like corn, soybeans, and cotton as well as grasses and trees.

herbicide-resistance. On this basis, USDA regulated GE crops during field testing and prior to commercialization, as presumptive "plant pests."

121. Because of their presumptive status as plant pests, outdoor field trial experiments of GE plants required permits issued by USDA.[82] The ultimate goal of permitting was containment: to prevent the GE plant from propagating itself outside the field trial plot via seed escape or cross-pollination. To this end, USDA permits would require measures like no-plant buffer zones around the GE crop test plots, and mandated crop destruction at the end of field trials.[83]

122. In 1993, a streamlined system was introduced in which developers could submit "notification" to USDA of upcoming GE crop field trials, to which USDA would respond with "acknowledgement."[84] By 2004, 97% of field trials were conducted under notification, versus only 3% under the more rigorous permit system.[85]

123. Each permit or notification was limited to only one crop, but often encompassed: (1) several to dozens of genetic modifications, (2) multiple field tests in several to dozens of states, conducted on (3) anywhere from fractions of an acre to thousands of acres.[86] GE organism field tests were conducted under more than

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[82] 40 C.F.R. § 340.4 (2003).

[83] *Id.* § 340.3; *see* USDA OFFICE OF INSPECTOR GENERAL, AUDIT REPORT: ANIMAL AND PLANT HEALTH INSPECTION SERVICE CONTROLS OVER ISSUANCE OF GENETICALLY ENGINEERED ORGANISM RELEASE PERMITS 44 (2005) (finding that applicants did not destroy remaining GE crops appropriately).

[84] USDA OFFICE OF INSPECTOR GENERAL, AUDIT REPORT: ANIMAL AND PLANT HEALTH INSPECTION SERVICE CONTROLS OVER ISSUANCE OF GENETICALLY ENGINEERED ORGANISM RELEASE PERMITS 2 (2005).

[85] *Id.*

[86] USDA, *Biotechnology Regulatory Services Interstate/Release and Release Permits and Notifications*, https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/sa_permits/status-update/release-permits.

20,000 notifications and permits from the 1980s until this year, when the new regulations took effect.[87]

124. The terms "movement" in the PPA and "introduce" in Part 340 have been defined broadly and among other definitions, refer to the act of releasing regulated articles into the environment.[88] The old regulations defined "release into the environment" as "the use of a regulated article outside the constraints of physical confinement that are found in a laboratory, contained in a greenhouse, or a fermenter or other contained structure.[89] The regulations, therefore, apply specifically to the field-testing of GE plants.

125. The old regulations also provided a pathway to commercial approval and sale of GE crops, called deregulation.[90] The developer would submit a petition to USDA containing voluminous information about the GE crop, including molecular characterization, and years of field trial data it had collected. USDA would assess this information to determine whether or not the GE crop posed "a greater plant pest risk than the unmodified organism from which it was derived."[91] "Plant pest risk" was defined in broad terms, and included GE plant characteristics involving susceptibility to diseases or pests, weediness, changes to plant metabolism, and GE plant-induced changes in agricultural or cultivation practices, among others. USDA would then conduct a Plant Pest Risk Assessment and invariably concluded that the GE crop did not pose a plant pest risk, based on extremely narrow criteria, and grant a determination of nonregulated status, which

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[87] USDA, *Permitting and the Regulatory Process / Check Status* (last visited July 6, 2021), https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/check-status.

[88] 7 U.S.C. § 7702(9) and 7 C.F.R. § 340.1.

[89] 7 C.F.R. § 340.1. The new regulations simplify this definition, but the meaning remains the same.

[90] *See* 58 Fed. Reg. 17,044-59.

[91] 40 C.F.R. § 340.6.

authorized unregulated commercial cultivation of the GE crop.[92] It would also perform an analysis of the broader environmental effects pursuant to NEPA.

126. The 1987 regulations were issued under the authority of the Federal Plant Pest Act of 1957 and Plant Quarantine Act of 1912. At that time, USDA's authority to regulate noxious weeds came from the Federal Noxious Weed act of 1974, which limited USDA's noxious weed authority to plant that were of foreign origin and new to the U.S. Most GE plants during that era were modified crops that were already present in the U.S., meaning USDA did not have authority to regulate them.

New Authority: The Plant Protection Act

127. In 2000, Congress subsumed the Plant Pest Act and Noxious Weed Act into the Plant Protection Act (PPA).[93] In doing so, Congress provided USDA with powerful new authority to regulate GE organisms not only as potential plant pests, but for the noxious weed risks they may pose. The PPA's broadened definition of noxious weed is: "Any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment."[94] The PPA gives USDA explicit authority to issue regulations regarding noxious weeds.[95]

128. Under the PPA, USDA has the responsibility to prevent plant pest risks and noxious weed risks, both of which are broadly defined agricultural and

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[92] USDA has granted nonregulated status to 133 GE plants from the early 1990s to June 26, 2021, and has never denied a petition for nonregulated status (though some have been withdrawn by the crop developer).

[93] 7 U.S.C. §§ 7701-7786.

[94] *Id.* § 7702(10).

[95] *Id.* § 7712(c).

environmental harms. USDA has a multiplicity of statutory tools with which to prevent those harms.[96]

129. However, it took USDA 20 years to finally update its Part 340 regulations. Up until the very final rule, the impetus of this entire process was to implement its new broader authority over GE organisms. In the meantime, USDA continued to operate under its older, pre-PPA regulations, which only regulated GE organisms for plant pest risks.

130. In 2002, the National Academy of Sciences recommended the use of genetic engineering (i.e. "transformation") as "both a useful and logically justifiable regulatory trigger" because "there is no scientific basis" on which to exclude GE organisms from regulatory review prior to evaluation of data on the interactions between "trait, organism and environment."[97]

131. Over the past two decades, USDA repeatedly acknowledged the need to implement its PPA noxious weed authority to address a wide variety of risks posed by GE organisms that it does not regard as plant pest risks, and thus have not been addressed under the plant pest regulatory framework. USDA accordingly made repeated attempts to implement its noxious weed authority, as described below, but ultimately abandoned this path in the final rule.

The Long Road to New PPA Implementing Regulations

132. USDA first proposed updating its regulations to implement its noxious weed authority over 15 years ago, in 2004.[98] In this EIS scoping notice, the agency took the first step towards implementing its noxious weed authority for GE organisms, suggesting that its noxious weed authority could be used to regulate GE plants that produce experimental pharmaceutical and industrial compounds, as

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[96] *Id.* § 7701(3); *id.* §§ 7702(10), (14); *id.* §§ 7714, 7733, 7731, 7735, 7721, 7714.

[97] National Academy of Sciences, NRC, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS 79 (2002).

[98] *See* Environmental Impact Statement; Introduction of Genetically Engineered Organisms, 69 Fed. Reg. 3271 (Jan. 23, 2004).

well as nonviable GE plant material. USDA also suggested it would regulate GE biological control organisms.

133. Some Plaintiffs and many other interested parties participated in public comment on the 2004 scoping notice, urging USDA to broaden its regulatory scope to include noxious weed risks. Particularly, Plaintiffs emphasized that stress tolerance genes can increase the fitness of GE plants and wild relatives they interbreed with, creating possible noxious weed risks associated with their potential to spread into natural areas and displace other species.

134. In 2005, USDA's Office of Inspector General (OIG) released an audit report on USDA's oversight of GE organisms.[99] The OIG report found numerous grave deficiencies in inspection, enforcement, and transparency, and concluded that USDA's existing regulations were inadequate: "APHIS' current regulations, policies, and procedures do not go far enough to ensure the safe introduction of agricultural biotechnology."[100] Specifically, the report noted that USDA still needed to update its regulations to comply with the PPA and reflect the PPA's noxious weed authority, and made a formal recommendation to this effect.[101]

135. In 2007, USDA released a draft PEIS analyzing the potential environmental impacts resulting from potential revisions to its Part 340 regulations. The 2007 PEIS was the eventual result of the process begun with USDA's 2004 scoping notice. The agency found that historically, it has only used its

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[99] OIGs were created by Congress as "independent and objective units" charged with conducting and supervising audits and investigations into the programs and operations of agencies. OIGs are to "provide leadership and coordination and recommend policies" to agencies and keep "Congress fully and currently informed about problems and deficiencies" in agency programs. Inspector General Act of 1978, Pub. L. No. 95-452 § 2.

[100] USDA OFFICE OF INSPECTOR GENERAL, AUDIT REPORT: ANIMAL AND PLANT HEALTH INSPECTION SERVICE CONTROLS OVER ISSUANCE OF GENETICALLY ENGINEERED ORGANISM RELEASE PERMITS at iv (2005).

[101] *Id.* at 8, 11.

plant pest authority as a basis for GE regulation but that the PPA "redefined authorities and responsibilities for the agency."[102] As such, USDA preliminarily determined that it would broaden its regulatory scope to include GE plants that could pose a noxious weed risk. USDA acknowledged that, "[g]iven the rapid advances in biotechnology, the present scope of regulations may not be of sufficient breadth to cover the full range of GE organisms and the full range of potential agricultural and environmental risks posed by these organisms."[103]

136. Specifically, USDA made a preliminary determination to increase oversight of GE organisms by utilizing the PPA's noxious weed authority, which would allow for a broader consideration of risks.[104] Again, USDA referenced as an example the need to regulate GE plants that produce pharmaceutical or industrial compounds that could pose human health or environmental risks. More generally, USDA found that "it is possible for a plant to be genetically engineered with genes that might give the plant the characteristics of a noxious weed, and APHIS wants the ability to ask not only whether a GE organism is a plant pest, but also whether a GE plant may be considered a noxious weed."[105]

137. USDA acknowledged that its noxious weed authority would allow it to "look at the broadest range of possible impacts resulting from releasing [a GE] plant in the environment."[106] The agency recognized that plants can be engineered with genes to increase fitness, and the risk that such a plant would become invasive in the wild. Additionally, USDA was particularly interested in using the noxious weed

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[102] USDA, INTRODUCTION OF GENETICALLY ENGINEERED ORGANISMS: DRAFT PROGRAMMATIC ENVIRONMENTAL IMPACT STATEMENT at v (2007).

[103] *Id.*

[104] *Id.* at ix.

[105] *Id.* at 21.

[106] *Id.*

provision to consider public health effects of GE plants.[107] Invoking its noxious weed authority would allow USDA to regulate for these risks because the definition of "noxious weed" is broader than that for a "plant pest." For instance, plant pests are defined as living, while the definition of noxious weeds includes both plants and non-living "plant products."

138. The 2007 draft PEIS also shows the agency's concern with the proliferation of herbicide-resistant weeds. It recognized that herbicide-resistant transgenes in GE crops could pass to weeds, creating problems for farmers who must cope with herbicide-resistant weeds.[108] USDA also acknowledged the environmental costs of this problem, noting that individuals would be forced to use higher toxicity or persistent herbicides to control these new weed variations.[109]

139. Finally, the draft PEIS acknowledged that approvals of petitions for nonregulated status (permitting unrestricted planting), could have effects on threatened or endangered species. It found that USDA must determine which listed species would come into contact with a deregulated plant, and whether contact would affect the species or its habitat.[110] If so, USDA would need to consult with the expert services.

140. In June 2008, Congress passed the 2008 Farm Bill, which set agricultural policy for a period of five years. The 2008 Farm Bill directives required USDA to "promulgate regulations to improve the management and oversight of articles regulated under the Plant Protection Act," including the oversight and management of GE crop field-testing.[111] This Congressional action was prompted by

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[107] *Id.*

[108] *Id.* at 120-21.

[109] *Id.* at 121.

[110] *Id.* at 177-78.

[111] Food, Conservation, and Energy Act of 2008, Pub. L. No. 110-246, Tit. X § 10204(a)(2).

the disastrous LibertyLink rice contamination incidents discussed above,[112] and the dire need for the agency to establish better confinement, monitoring and record-keeping procedures. After the LibertyLink rice incidents, USDA conducted an investigation and issued a LESSONS LEARNED report with a list of considerations to enhance its regulatory framework.[113] The 2008 Farm Bill required USDA to take action on each of the issues identified in that document, many of which focused on field-trial containment and documentation.

141. A 2008 Government Accountability Office study analyzed the more impactful of numerous contamination episodes from field trials of GE organisms in the preceding decade, concluding that "the ease with which genetic material from crops can be spread makes future releases likely," and recommended that USDA address the unintended release of GE organisms and coordinate strategies for post-commercialization monitoring.[114]

First Proposed Rule

142. USDA issued its first proposed rule later in 2008, in which it recognized that new regulations were necessary to apply the PPA and more effectively regulate GE organisms.[115] In the proposed rule, USDA found that "it is appropriate to align the regulations with both the plant pest and the noxious weed authorities of the PPA," for many of the same reasons it indicated in the 2007

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[112] *See supra* paragraph 88.

[113] USDA, LESSONS LEARNED AND REVISIONS UNDER CONSIDERATION FOR APHIS' BIOTECHNOLOGY FRAMEWORK 2007, https://www.aphis.usda.gov/biotechnology/downloads/supportingdocs/LessonsLearned10-2007.pdf.

[114] U.S. GAO, GENETICALLY ENGINEERED CROPS (Nov. 2008), https://www.gao.gov/assets/gao-09-60.pdf.

[115] *See* Importation, Interstate Movement, and Release Into the Environment of Certain Genetically Engineered Organisms; Proposed Rule, 73 Fed. Reg. 60,007 (Oct. 9, 2008).

PEIS.[116] Particularly, it explained that "with the increasing diversity of both agronomic and non-agronomic traits being engineered into plants it is appropriate to place regulatory controls upon GE plants proportionate to the likelihood that they may present a noxious weed risk until the potential risk can be appropriately evaluated."[117]

143. Here, USDA also recognized Congress's new mandate for it and proposed to implement changes that would "reflect provisions of the 2008 Farm Bill recently enacted," and aligned its proposal with recommendations from the 2005 OIG audit.[118]

144. The 2008 proposed rule noted that most of the public comments on the draft PEIS urged USDA to expand its scope to include noxious weeds, and that even though the agency can technically assess "weediness" in relation to a GE plant's plant pest potential, that trait is "more properly a noxious weed risk characteristic than a plant pest one." Accordingly, "the proposed revision of the regulations will more clearly align the regulations with the plant pest and noxious weed risk pursuant to the PPA."[119]

145. The agency solicited public comment on the proposed rule for over eight months and received over 88,300 comments from stakeholders. During that time, USDA held public meetings with stakeholders to discuss the regulation of GE organisms. There, USDA discussed the "goal of incorporating the noxious weed authority" of the PPA into Part 340, and indicated that its "current thinking" was to revise the regulations to incorporate that authority.[120]

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[116] *Id.* at 60,011.

[117] *Id.* at 60,014.

[118] *Id.* at 60,007.

[119] *Id.* at 60,029.

[120] USDA, Issue Paper 2: Incorporation of the Plant Protection Act Noxious Weed Provisions (Apr. 28, 2009).

146. However after taking no action for nearly 7 years to finalize the rule, in 2015, USDA instead withdrew the 2008 proposed rule, announcing a new plan for further "stakeholder engagement."[121]

147. Later in 2015, USDA's OIG released another audit report on USDA's regulation of GE organisms and internal management controls. The 2015 report again criticized USDA for not implementing its additional authority to control noxious weeds and recommended that the agency implement the corrective actions it agreed upon in the previous 2005 assessment. This included a commitment to updating its regulations and "incorporating additional authority to control noxious weeds."[122] USDA's response to the audit agreed with OIG's recommendations and committed to proposing revised Part 340 regulations.

Second Proposed Rule

148. In January 2017, USDA published a second proposed rule.[123] In line with OIG's recommendations and its previous proposals, USDA again proposed to invoke and implement its PPA noxious weed authority in the revised Part 340 regulations. As its basis for the proposed rule, the agency stated that its past evaluations had provided evidence that most genetic engineering techniques do not result in GE organisms that present plant pest risks. Additionally, USDA explained that genetic engineering techniques have been developed that could create GE organisms with plant pest risks without falling into the scope of regulation.[124]

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[121] Importation, Interstate Movement, and Release Into the Environment of Certain Genetically Engineered Organisms; Proposed Rule; Withdrawal, 80 Fed. Reg. 11,598 (Mar. 4, 2015).

[122] USDA, OFFICE OF INSPECTOR GENERAL, CONTROLS OVER APHIS' INTRODUCTION OF GENETICALLY ENGINEERED ORGANISMS 7 (Sept. 2015).

[123] Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms; Proposed Rule, 82 Fed. Reg. 7008 (Jan. 19, 2017).

[124] *Id.* at 7009.

149. An entire section of the proposed rule discusses the OIG audits and the 2008 Farm Bill and their influence on the agency's approach to its new regulations. Specifically, it references the need to minimize "dissemination" from field trials.[125]

150. The 2017 proposed rule admitted that USDA's "current regulatory structure, which entails evaluating such plants solely for plant pest risk, is *not sufficient to properly identify all risks* that these plants present to other plants and plant products."[126] In fact, under that scheme, USDA found that "such plants may entirely escape regulation." Therefore, USDA found it "both appropriate and necessary to begin to evaluate GE plants for noxious weed risk."[127]

151. Along with the 2017 proposed rule, USDA released yet another draft PEIS on the environmental impacts of revising the Part 340 regulations. This document shows the agency's commitment to invoking its noxious weed authority and further elaborates on the importance of doing so. It cites the 2015 OIG report's recommendation to incorporate its authority to control noxious weeds, noting that, "[a]mong the recommendations provided [to] APHIS in the 2015 audit report, OIG stated that APHIS needed to revise its regulations (7 CFR part 340) to consolidate all requirements for conducting field tests of regulated material in order to minimize the inadvertent release of GE material; . . . and that APHIS update its regulations to incorporate the provisions of the Plant Protection Act of 2000, to specifically include incorporation of authority to control noxious weeds. APHIS agreed with these recommendations (USDA-OIG 2015), and has, as part of implementing the recommendations, issued proposed revisions for 7 CFR part 340."[128]

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[125] *Id.* at 7011.

[126] *Id.* at 7010.

[127] *Id.*

[128] USDA, REVISIONS TO USDA-APHIS 7 CFR PART 340 REGULATIONS GOVERNING THE IMPORTATION, INTERSTATE MOVEMENT, AND ENVIRONMENTAL RELEASE OF

152. The agency further explained that, "[b]ecause noxious weed risk has become an important aspect of the regulation of GE plants, and the fact that it is *more scientifically and legally justified* to consider weed risk under noxious weed authority rather than under the plant pest authority, APHIS considers it both appropriate and necessary to incorporate the noxious weed authority provided [to] APHIS under the PPA, and to begin to evaluate GE plants for noxious weed risk."[129]

153. USDA also found that increasing diversity and number of traits in GE crops necessitated the application of its noxious weed authority.[130]

154. In comparing the proposed regulations to the "No Action" alternative, USDA found that the "No Action alternative does not provide for sufficient incorporation of recommendations by USDA OIG audits," and that providing regulatory oversight for noxious weed risks would "reduce[] the potential risks to physical and biological resources," providing environmental protections that could not be realized under the status quo.[131]

155. Finally, as it did in its 2007 environmental analysis, USDA acknowledged that the agency would need to make determinations regarding individual deregulation decisions' effects on threatened or endangered species and critical habitat.[132]

GENETICALLY ENGINEERED ORGANISMS: DRAFT PROGRAMMATIC ENVIRONMENTAL IMPACT STATEMENT at ES-2 (2017).

[129] *Id.* at ES-4 (emphasis added).

[130] *Id.* at 1-4 to 1-5.

[131] *Id.* at ES-8.

[132] *Id.* at ES-35 to ES-36.

156. However rather than proceed to a final rule, in November 2017, USDA withdrew the second proposed rule, once again claiming it needed to deliberate further on its revision of the Part 340 regulations.[133]

Third Proposed Rule

157. In June 2019, USDA published yet another proposed rule, and an accompanying draft PEIS.[134] The PEIS rejected an alternative that would incorporate USDA's noxious weed authority and mitigate GE contamination and resulting economic harm. Rather than analyzing this as a true alternative, USDA glossed over the option without conducting a cost-benefit analysis, which would reveal benefits that would protect farmers. USDA failed to fully evaluate this alternative, included in the section, "Alternatives Considered But Dismissed from Further Consideration."[135]

158. In contrast to prior iterations, in the third proposed rule, among other changes, USDA failed to invoke the PPA's noxious weed authority. Nor did it provide any explanation for its radical departure from 15 years of detailed environmental analyses, prior proposed rules, and OIG mandates, all of which insisted upon the necessity of incorporating USDA's noxious weed authority to forestall the harms of GE organisms—harms not captured by USDA's plant pest authority.

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[133] Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms; Proposed Rule; Withdrawal, 82 Fed. Reg. 51,582 (Nov. 7, 2017).

[134] Movement of Genetically Engineered Organisms; Proposed Rule, 84 Fed. Reg. 26,514 (June 6, 2019).

[135] USDA, REVISIONS TO USDA-APHIS 7 CFR PART 340 REGULATIONS GOVERNING THE IMPORTATION, INTERSTATE MOVEMENT, AND ENVIRONMENTAL RELEASE OF CERTAIN GENETICALLY ENGINEERED ORGANISMS: DRAFT PROGRAMMATIC ENVIRONMENTAL IMPACT STATEMENT at 2-20 to 2-24 (May 2019), https://www.aphis.usda.gov/brs/pdf/340_proposedrule_draftEIS_2019.pdf.

159. Instead, USDA proposed a bevy of exemptions, whereby a host of GE organisms that purportedly could have been developed via traditional breeding techniques escape regulation altogether. These exemptions were not based in science, but rather were crafted to comply with a statement made by then-Secretary of Agriculture, Sonny Perdue on March 28, 2018.[136] Other GE organisms were excluded if USDA had previously cleared a GE plant with the same plant-trait-mechanism of action combination. These exemptions replaced USDA's former system of assessing each and every unique GE plant—known as an "event"—under its purview, which was based in part on the unintended, unpredictable, and potentially hazardous changes that occur with any GE technique.

160. Also prominent in the third proposed rule was the great leeway given to companies to "self-determine" whether or not their GE crops even met either of the above broad exemption categories, which would allow potentially risky crops to be planted without USDA's consent or knowledge.

161. Due to these changes and others, as Plaintiffs explained in its comments, the proposed rule represented the "opposite of regulation" because, instead of exercising its broad PPA authority to regulate GE crops and provide better regulatory oversight, developers of GE technologies will have free rein to self-determine whether or not their GE experiments should be subject to regulations, and the vast majority of GE plants would be exempted from any meaningful regulatory oversight.[137] Moreover, Plaintiffs explained that the proposed rule would allow these GE plants to be commercialized and planted without any regulation or

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[136] Secretary Perdue Issues USDA Statement on Plant Breeding Innovation, USDA, Mar. 28, 2018, https://www.usda.gov/media/press-releases/2018/03/28/secretary-perdue-issues-usda-statement-plant-breeding-innovation; Movement of Genetically Engineered Organisms; Proposed Rule, 84 Fed. Reg. 26,519 (June 6, 2019).

[137] Center for Food Safety, *Comments on Proposed Rule on Movement of Certain Genetically Engineered Organisms, 7 CFR Parts 340 and 372*, Docket No. APHIS-2018-0034.

monitoring based only on a streamlined review that does not capture the myriad of biological, agricultural, socioeconomic, and environmental harms of new GE technologies, falling woefully short of USDA's duties to prevent noxious weed risks and plant pest harms under the PPA.

The Final Rule

162. USDA published the final rule in May 2020, codifying these hugely problematic changes, with only minor changes from the proposed rule.[138] Under the final rule, USDA exempts numerous GE organisms from being subject to any regulation at all.[139] The final rule also excludes from regulation those GE plants with plant-trait-mechanism of action combinations that have previously been exempted after a cursory regulatory status review, and allows GE plant developers to self-determine whether regulations apply to their products.[140] The major changes from the old regulatory regime are a dramatically reduced scope of regulation, empowerment of crop developers to make their own regulatory determinations, and a far weaker assessment of non-exempted GE plants made in the absence of real-world data. The overriding rationale for these changes is to provide "regulatory relief" to crop developers.[141]

163. USDA reduces its scope of regulation in two major ways. First, in compliance with a brief 2018 statement by former Secretary of Agriculture Sonny Perdue, USDA exempts from regulation plants that were developed with GE technology, but purportedly could have been developed by conventional breeding methods,[142] as well as plants that have a plant-trait mechanism of action

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[138] Movement of Certain Genetically Engineered Organisms; Final Rule, 85 Fed. Reg. 29,790 (May 18, 2020).

[139] *Id.* at 29,791.

[140] *Id.* at 29,798.

[141] *Id.* at 29,791.

[142] 7 C.F.R. § 340(b)(4).

combination that is the same as in a plant USDA has previously exempted from regulation.[143] Second, it allows GE developers to make exemption determinations for their experiments without consultation or approval from USDA.[144]

Exemptions

164. The three initial exemption classes carved out to comply with Perdue's statement are GE plants resulting from: (1) Intentional DNA strand breakage, followed by cellular repair of the break without a provided template;[145] (2) A single base pair substitution; and (3) Introduction of a gene from the plant's gene pool, or modification of a gene to correspond to a gene variant present in the gene pool.[146] USDA also incorporated a mechanism by which it can create new exemptions on the same grounds, initiated by it or by other parties,[147] and recently proposed three additional exemption classes.[148]

165. This exemption rationale—"if it could have been developed via conventional breeding"—is not grounded in science. USDA concedes that "there is no universally applicable, sharp delineation between what is and what is not possible to achieve with traditional breeding methods."[149] Judgments as to whether

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[143] *Id.* § 340.1(c)(1).

[144] 85 Fed. Reg. at 29,798-99.

[145] This exemption was expanded from that in the proposed rule, and includes GE plants in which DNA segments of "any size" have been deleted, as well as DNA insertions or combinations of both deletions and insertions, as effected by cellular repair mechanisms in the absence of a provided repair template. *Id.* at 29,791, 29,794.

[146] 7 C.F.R. § 340.1(b)(1)-(3).

[147] *Id.* § 340.1(b)(4).

[148] USDA, Movement of Organisms Modified or Produced Through Genetic Engineering; Notice of Exemptions, 86 Fed. Reg. 37,988 (July 19, 2021).

[149] 84 Fed. Reg. at 26,519. Moreover, the "traditional" or "conventional" breeding methods USDA cites in support of all six exemption classes are highly disruptive mutagenesis techniques, little used today, whereby radiation or chemicals are

some facsimile of an existing GE plant *could have* been generated via conventional techniques are not informative regarding whether or not it poses risks cognizable under the PPA, and thus are not legitimate grounds for exemption.

166. A GE plant is also exempted from regulation if USDA has previously determined that a GE plant of the same species, with the same plant trait (observable characteristic of an organism) and same mechanism of action (the biochemical process(es) through which genetic material determines a trait) is unregulated.[150] However, two GE plants that share the same plant-trait-mechanism of action combination may nonetheless pose different direct and indirect risks under the PPA.

167. These and likely future exemptions mean a growing class of GE plants can be grown experimentally and commercially without any regulatory review. In contrast, the old rule captured all GE organisms initially, provided plant pests were involved in their development (as nearly all were).

Self-Determination & Data Requirements

168. GE plant developers are empowered to make these critical exemption decisions or self-determinations entirely on their own, as a regulatory relief measure, without consulting USDA or USDA approval.[151] In contrast, under the old regulations, any GE plant classified as a regulated article could only be grown outdoors in field tests with use of gene confinement measures under authorizations issued by USDA, either under the notification or permit system.[152] And, in order to

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used to induce large-scale, random and mostly deleterious mutations in crop genomes. 85 Fed. Reg. at 29,794; 86 Fed. Reg. 37,988-89.

[150] 7 C.F.R. § 340.4. *See also id.* § 340.3 for definitions of trait and mechanism of action.

[151] 85 Fed. Reg. at 29,798-99 (May 18, 2020).

[152] 7 C.F.R. §§ 340.3, 340.4 (2003).

be commercialized, a plant had to be "deregulated" by USDA through a formal approval process.[153]

169. Now, while a developer may request "confirmation" from USDA that a GE plant is exempted,[154] it is not required to do so.

170. With no obligation to seek USDA's approval or even consult USDA, developers are free to field test and commercialize exempted GE plants anytime, anywhere, entirely without USDA's awareness. With no obligation to practice containment, neighboring farmers are at risk of GE contamination.

171. GE plants that are not exempted in these ways would normally undergo a regulatory status review, for which developers submit genetic sequence information on their engineered plant's modification to USDA.[155] However this status review requires "much less information" than the old deregulation process, which required submission of a petition containing "information regarding a broad range of possible harms."[156]

172. For example, the old deregulation process required data from all field tests,[157] while the new regulatory status review requires neither laboratory nor field-test data, and thereby reduces "a developer's data submission burden."[158]

173. The lack of real-world data on a GE plant's characteristics and effects during cultivation makes it likely that USDA will miss many harms caused by GE

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[153] *See* 58 Fed. Reg. 17,044-59.

[154] 7 C.F.R. § 340.1(e).

[155] 85 Fed. Reg. at 29,808-09.

[156] *Id.* at 29,808.

[157] 7 C.F.R. § 340.6 (2003).

[158] 85 Fed. Reg. at 29,808.

crops that are cognizable under the PPA, and does not heed the recommendations of the National Academy of Sciences for GE plant regulation.[159]

174. USDA states that real-world information typically does not influence deregulation decisions,[160] but this is because, in the past and in the new regulations, it has narrowly construed its plant pest authority, and now refuses to implement its noxious weed authority. The risks posed by GE organisms that USDA once acknowledged required the noxious weed authority to address are also the kind for which high-quality, real-world field-test data are essential.

175. Under the old rule's petition process, developers would submit a petition requesting an agency determination of non-regulated status, and USDA would hold notice and comment, review the individual GE organism under the PPA as well as NEPA, and make a final agency approval determination, that was subsequently subject to judicial review.[161] The new regulatory status review does not involve notice and comment or culminate in a judicially reviewable decision.[162] This portion of the new rule took effect on April 5, 2021.

176. Now, in those few cases in which the regulatory status review does *not* clear a GE plant of posing a plant pest risk, it could still be grown under a permit.[163] Developers can also request a permit to grow a GE plant in lieu of a regulatory status review.[164]

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[159] NATIONAL ACADEMY OF SCIENCES, NRC, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS 79 (2002).

[160] 85 Fed. Reg. at 29,797.

[161] 7 C.F.R. § 340.5(c)(2) (2003); *id.* § 372.5(b)(4) (2014).

[162] *See* 85 Fed. Reg. at 29,791.

[163] 7 C.F.R. § 340.4(b)(3)(iii).

[164] USDA, *Secure Rule Regulatory Changes: About the Secure Rule, Determining Regulatory Status for GE Plants/Organisms*, https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/biotech-rule-revision/secure-rule/secure-reg-changes (last updated June 12, 2020).

Major Problems with the Final Rule

177. First, under USDA's new deregulatory regime, a growing number of experimental GE crops will no longer be regulated for confinement, even at the field trial stage. That is, in sharp contrast to the prior regulations, GE crop experiments will no longer be regulated under the PPA or analyzed under NEPA or the ESA. This will result in high risks of transgenic contamination, leading to market rejection of contaminated food supplies, and attendant economic losses to farmers, food companies, and others in the food supply chain. In some cases, transgenic contamination will compromise the safety and quality of the contaminated food.

178. One example that bodes ill for the future is the GE industrial crop, Enogen corn, which is meant exclusively for production of ethanol for biofuels use. Enogen produces high levels of a bacteria-derived enzyme that initiates the process of converting corn starch to ethanol. Even low-level contamination of food-grade corn with Enogen degrades the agricultural quality of the corn by converting starches to sugars, rendering it potentially unfit for food use. USDA deregulated Enogen corn over the strong objections of major corn commodity and public interest groups on the strength of assurances from Syngenta, its developer, that it would be managed in a "closed loop" production system that would prevent contamination of food-grade corn.[165] Despite these assurances, Enogen has widely contaminated white corn in Nebraska, resulting in substantial losses to white corn growers. Corn

[165] Ken Roseboro, *StarLink 2: Approval of GM Biofuel Corn Threatens Food Supply*, THE ORGANIC & NON-GMO REPORT (Mar. 1, 2011), https://non-gmoreport.com/articles/march2011/gmbiofuelcornthreatensfoodsupply.php; *see also Comments to USDA APHIS on Environmental Assessment for the Determination of Syngenta Seeds, Inc. Alpha-Amylase Maize Event 3272*, Center for Food Safety (Jan. 20, 2009), https://www.centerforfoodsafety.org/files/cfs_comments_on_biofuel_corn_1-20-09.pdf.

flour contaminated with Enogen was detected in California and reportedly made some people sick.[166]

179. GE crops that would evade regulation entirely under the plant-trait-mechanism of action exemption include hypothetical new versions of GE crops that have caused enormous harm to U.S. agriculture.

180. For instance, the GE herbicide-resistant rice contamination debacle that triggered losses of over $1 billion to the rice industry involved gene flow from an experimental rice variety grown in field tests authorized by USDA.[167] Because USDA subsequently deregulated this line,[168] it or a new GE rice variety with the same trait and mechanism of action could be grown today, with absolutely no gene confinement and without even notifying USDA,[169] sharply increasing the risks of another costly transgenic contamination catastrophe.

181. A similar situation exists with GE herbicide-resistant flax, approved in Canada in 1998 and deregulated by USDA in 1999.[170] Despite being de-registered in

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[166] Ken Roseboro, *GMO-ethanol Corn Contamination Raises Concerns About Another "StarLink" Disaster*, THE ORGANIC & NON-GMO REPORT (Feb. 22, 2017), https://non-gmoreport.com/articles/gmo-ethanol-corn-contamination-raises-concerns-another-starlink-disaster/.

[167] *See supra* paragraph 88.

[168] ANIMAL AND PLANT HEALTH INSPECTION SERVICE, USDA, FINDING OF NO SIGNIFICANT IMPACT: EXTENSION OF NONREGULATED STATUS TO RICE LINE LLRICE601 (Nov. 24, 2006).

[169] 7 C.F.R. § 340.1(c)(2). *See also* Plant-Trait-Mechanism of Action (MOA) combinations that have been determined by APHIS not to require regulation under 7 CFR Part 340, https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/confirmations/moa/moa-table.

[170] University of Saskatchewan, Availability of Determination of Nonregulated Status for Flax Genetically Engineered for Tolerance to Soil Residues of Sulfonylurea Herbicides, 64 Fed. Reg. 28,794-95 (May 27, 1999).

Canada in 2001 over concerns it could disrupt exports,[171] this GE flax somehow turned up in shipments to Europe in 2009, triggering massive rejection of Canadian flaxseed, a development that "threatened the very existence of the [Canadian flax] industry."[172] It took six years to flush most of this GE contaminant from the flax seed supply, but only after estimated losses to Canadian flax growers of $29.1 million.[173] A new GE flax variety with the same trait and mechanism of action combination could be grown today in the U.S., without notifying the USDA or making any effort to prevent contamination.

182. Even in less drastic circumstances, as discussed above, transgenic contamination can have significant financial consequences to farmers and U.S. agricultural markets domestic and export that are sensitive to contamination, as shown time and time again.[174]

183. Gene flow from a GE plant to natural areas can also have serious adverse environmental impacts, as discussed above with regard to GE bentgrass.[175]

184. In contrast, implementation of its noxious weed authority would permit USDA to forestall or mitigate these harms, since unlike its plant pest authority, which applies only to living organisms, noxious weeds encompass "plant products" that would include unwanted GE plant material that contaminates a food supply, or invades natural areas via movement of seeds or pollen.

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[171] R. Kamchen, *Flax on the Road to Recovery in a Post-Triffid World*, COUNTRY GUIDE (Mar. 31, 2016) https://www.country-guide.ca/crops/flax-on-the-road-to-recovery-in-a-post-triffid-world/.

[172] Flax Council of Canada, *Flax: 2009-2015 the Triffid Years*, 23(1) (2015), https://flaxcouncil.ca/wp-content/uploads/2015/07/Flax-focus-July-2015LR.pdf.

[173] Canadian Biotechnology Action Network, *Flax: GM Contamination Crisis*, https://cban.ca/gmos/products/not-on-the-market/flax/.

[174] *See supra* paragraphs 87-91.

[175] *See supra* paragraphs 106-107.

185. Because permits only apply to those GE crops where the developer opts to apply for a permit, or those few that USDA determines carry plant pest risks on extremely narrow grounds, the regulations result in permits for only a minority of previously-regulated GE plant field trials. The practical effect of exempting GE plants from regulation is to permit experimental varieties to be grown in field tests without gene confinement, and often without reporting to or oversight by USDA. This will have dramatically negative effects in terms of harm to farmers, markets, and the environment from GE escapes and contamination.

186. Additionally, because of these rampant exemptions from regulation, the final rule also fails to implement the requirements from the 2008 Farm Bill for regulation and oversight of GE crop field-tests, to prevent contamination episodes. The final rule's only reference to the 2008 Farm Bill mandates is a conclusory statement that the new regulations will provide the agency with "sufficient information to monitor compliance with its regulations and maintain effective oversight of regulated GE organisms, in accordance with provisions of the 2008 Farm Bill [and 2015 OIG report]." However, by completely exempting broad categories from regulation and allowing developers to self-determine regulatory status, USDA misses the entire point of these requirements, opting instead for surface-level changes that apply only to the select few "regulated" articles in the scheme.

187. Second, in refusing to implement its noxious weed authority, USDA also rejects a critical tool in the fight against the growing epidemic of herbicide-resistant weeds generated by the cultivation of herbicide-resistant GE crops. Weeds immune to glyphosate from the first generation of GE crops are legion, while weeds that have developed in the second generation of GE crops are rapidly fostering additional resistance to dicamba. The remarkable rise in weeds resistant to multiple herbicides—leading to still more herbicide use and resistance—will only

accelerate without USDA action to check these often noxious weeds, which burden farmers with increased costs while degrading the environment.

188. Another indirect cost of GE herbicide-resistant crops is indirect and intertwined herbicidal drift damage, which is tremendously increased by the late-season herbicide use pattern characteristic of GE crop systems. USDA's regulations do not account for the fact that the minutia of genetic modifications can trigger huge and adverse changes in real-world farming practice that it has the power to address and cannot continue to ignore. Two decades of experience with GE crop systems now show that they have dramatically increased the overall output of pesticides into the environment, including in new "over the top" spraying ways, at new times of the year, all leading to dramatic environmental harms.[176] USDA's new rules ignore this cost and will worsen it by removing oversight and approval completely.

189. Third, the lack of noxious weed regulations will also hamstring USDA from regulating GE crops that themselves might become weeds. Crops like switchgrass, genetically engineered for potential uses such as biofuels or feedstock, are already quite weedy in their unmodified forms, but could become far more invasive and difficult to control with GE traits that improve fitness. GE crop volunteers (plants sprouting from seed left unharvested the prior season) may also become weeds, particularly if they are endowed with herbicide-resistance traits that render them more difficult and costly to control. Indeed, USDA recently received a petition to deregulate corn genetically engineered to withstand five different herbicides, volunteers of which would be quite troublesome and even noxious weeds.[177]

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[176] *See supra* paragraphs 93-103.

[177] *See* USDA-APHIS, Bayer; Notice of Intent to Prepare an Environmental Impact Statement for Determination of Nonregulated Status for Maize Developed Using Genetic Engineering for Dicamba, Glufosinate, Quizalofop, and 2,4-

190. Fourth, the elimination of the petition for nonregulated status process means no GE organism will receive the degree of scrutiny it deserves. For instance, GE crops will be commercialized without consideration of field trial data and observations, which informed deregulation decisions under the old regulations. USDA's substitute process, the regulatory status review, largely eschews any consideration of the direct and indirect agricultural and environmental impacts of GE crops, impacts that could be addressed if USDA were to properly implement its noxious weed authority to regulate GE organisms.

191. USDA's failure to do so—despite this being the *overriding goal of the regulatory revision process since it began in 2004*—represents an abdication of its statutory duty to provide meaningful oversight of GE organisms.

192. Fifth, in the "self-determination" scheme, there is no opportunity for the agency to conduct ESA and NEPA analyses, as it formerly had in the old deregulation context, to determine whether cultivation of the GE crop affects endangered species or their habitat. It will likewise be impossible to challenge and receive judicial review, absent later decisions or analyses. In other words, should future adverse environmental and agronomic harms flow from USDA's regulatory abdication, in many cases there will be no agency action to challenge and no judicial review to remedy those harms to farmers and the environment.

193. In its previous environmental analyses, and again in the final PEIS, USDA avoided ESA analysis at the programmatic level, claiming it would undertake them at the individual project level. However, with broad exemptions and "self-determination," the agency plays no role in deregulation and thus has no opportunity to conduct the required inquiries. Neither will the limited number of GE plants that initially fall under USDA's purview be adequately regulated, as the

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Dichlorophenoxyacetic Acid Resistance, With Tissue-Specific Glyphosate Resistance Facilitating the Production of Hybrid Maize Seed, 86 Fed. Reg. 34,714 (June 30, 2021).

regulatory status review is a superficial document-based evaluation that fails to adequately vet GE plants for the risks they may pose.

194. For future GE crops that fall under the new exemptions, there will be no NEPA or ESA analysis done. And for those few GE crops that still go thru the new regulatory review process, at best it is entirely unclear whether any NEPA or ESA analyses will be done or required.

Effects of the Decision on Endangered Species and their Habitats

195. Endangered species and their critical habitats will likely face the effects of adverse environmental impacts from the deregulation of GE organisms, including, but not limited to: transgenic contamination; significant increases in herbicide use in GE herbicide-resistant crop systems; and the proliferation of weeds resistant to these herbicides.

196. Transgenic contamination: When gene flow from GE crops to non-GE crops and wild species occurs, the GE-contaminated plants can establish themselves or colonize in wild places—similar to the effect of invasive species. GE organisms could infest habitat for endangered species and critical habitat, and may outcompete the endangered species, or native plants and animals essential to the species, or otherwise adversely modify the habitat. They might also transfer different genetic traits, such as weediness or pesticide resistance traits. GE traits like insect resistance, herbicide resistance, or stress tolerance traits can increase the hardiness, weediness, plant pest potential, and/or competitive ability of the GE plant that escapes cultivation into wild places, or of the wild relative to which the GE plant transfers its trait(s) via cross-pollination.[178] GE plants engineered to

[178] *See supra* paragraphs 106-107 for the GE creeping bentgrass example. Future GE grasses and other GE plants will present similar risks, but because of the 2020 regulatory revision, will now undergo even less regulation, or be entirely exempted.

produce experimental pharmaceutical or industrial compounds could have direct adverse impacts on organisms that come into contact with or consume them.

197. Herbicide-Resistant Crop Systems: Herbicides used with herbicide-resistant crops kill different spectra of plants, and used in combinations leave few if any plants unscathed. By facilitating increased and later-season use of an increasing array of herbicides, on a massive geographic application footprint of millions of acres, GE crop systems pose unprecedented threats to listed plants and critical habitats for listed species, including through spray drift, volatilization, and runoff, harming wild plants and contaminating waterways and soils.

198. These landscapes cover literally hundreds of endangered species at risk from future GE crops' agricultural use.

199. Examples of threatened or endangered species that are potentially put at risk by the dicamba-resistant soybean and cotton systems include but are not limited to Mead's milkweed, dwarf-flowered heartleaf, green pitcherplant, Texas prairie dawn-flower, the Indiana bat, Karner blue butterfly, whooping crane, rusty patched bumble bee, Southwestern willow flycatcher, yellow-billed cuckoo, and Chiricahua leopard frog.

200. GE Trees: Future GE trees approved under USDA's new rules present their own unique endangered species risks. Trees are a key species comprising ecosystems that regulate air quality, stabilize climate, preserve water quality and abundance, and harbor much of the world's biodiversity, including endangered species. These essential functions of forests are threatened by GE trees, which will mainly be designed to increase profitability of industrial tree plantations. Significant endangered species issues were raised by the first proposed GE forest tree, which has still not been commercially approved. Because trees are long-lived and can reproduce over long distances, there are significant concerns about GE contamination of forests and wild relatives and the associated impacts on endangered species and habitat.

201. USDA acknowledged that "individual decisions made during implementation of the revised regulation could potentially impact T&E species[.]"[179] However it still erroneously determined that its final rule decision would have "No Effect" on any of hundreds of endangered species or their habitat across the U.S. near and around U.S. farmland. USDA claims that individual decisions under the regulations will receive ESA analysis, but this will not occur for any "decisions" made through self-determination.

Harm to Plaintiffs

202. Plaintiffs and their members have been and continue to be injured by the Part 340 regulations and USDA's failure to adequately regulate GE organisms.

203. Plaintiffs' organizational purposes are adversely affected by USDA's action, which prevents Plaintiffs from obtaining access to information about new GE organisms which are "self-determined" to be exempt from regulation, that they would use to more effectively advocate for public health, food safety, and the environment. But for USDA's actions, Plaintiffs would not have to spend as much of their resources seeking basic information about GE organism exemptions, and could direct these resources to other priorities.

204. The Court can craft equitable relief that will redress Plaintiffs' informational and organizational injuries.

205. Plaintiffs' members are injured because, among other things, the Part 340 regulations have allowed potentially unsafe GE organisms to be tested in open air experiments and in the market and environment without any oversight or approval.

[179] USDA, REVISIONS TO USDA-APHIS 7 CFR PART 340 REGULATIONS GOVERNING THE IMPORTATION, INTERSTATE MOVEMENT, AND ENVIRONMENTAL RELEASE OF CERTAIN GENETICALLY ENGINEERED ORGANISMS: FINAL PROGRAMMATIC ENVIRONMENTAL IMPACT STATEMENT 7-8 (May 2020).

Farmers

206. Plaintiffs' members comprise thousands of individuals, many of whom are farmers who now experience an increased risk of GE-contamination of their crops, and the corresponding economic loss from the inability to sell contaminated crops on the market. The lack of GE crop regulation burdens them even if they are not contaminated, because they have to take additional cost and resource measures to try and avoid such contamination, such as buffer zones, DNA testing of their crops, or declining to plant some crops because of the risks of cross-pollination. These farmers sell their crops to GE-sensitive export and domestic markets and risk the loss of those markets based on contamination or perceived increased risk of contamination. These farmers also include organic farmers, who are harmed by increases in pesticide use that go hand in hand with the expansion of GE crops. Those farmers now face increased risk of herbicide drift and damage to crops, as well as the loss of organic certifications and ability to sell their product in the organic market.

207. Many of Plaintiffs' farmer members grow vulnerable crops, such as tomatoes, grapes, and conventional soybeans, which are at risk of pesticide drift harms due to GE crop systems. Other Plaintiff members are gardeners that also grow vegetables, fruits, herbs, native and ornamental plants, trees, shrubs, and other plants that are at risk of pesticide drift damage. These members enjoy the benefits of pollinators, birds, and other wildlife that rely on vulnerable plants for food, nesting, or breeding. They are at risk of pesticide drift damage to their crops, hedgerows, gardens, and surrounding ecologically important flora.

208. GE crop systems promote the use of types, quantities, and combinations of pesticide, which have already caused unprecedented damage to farmers and gardeners' crops and plants across millions of acres. Some of Plaintiffs' members include farmers and gardeners who live and grow crops that have already been damaged by drift caused by pesticide application to GE crops, and USDA's

regulations will make it more likely that Plaintiffs' farmer and gardener members who cultivate crops near areas of pesticide application will suffer crop or land use damage.

209. Such members may have to adjust their planting season, impose costly measures such as buffer strips, or forego the planting of certain crops, in order to try to reduce the negative impacts of pesticide drift onto their crops. The livelihoods and economic interests of Plaintiffs' members who cultivate and farm such crops are injured by the final rule.

210. Plaintiffs' farmer members are also injured by the anti-competitive, monopolistic impacts of the final rule to the seed market. The final rule increases the likelihood of contamination of non-GE crops. Contamination could mean loss of heirloom varieties and an inability to sell their crops in their preferred markets, thus loss of revenues.

211. GE crop systems are responsible for a superweed epidemic that harms Plaintiffs' farmer members, as these herbicide-resistant weeds are extremely difficult and costly to control and spread beyond the boundaries of where pesticides are initially sprayed. Many of Plaintiffs' members are organic farmers who do not use herbicides to control weeds on their farms, and in order to maintain organic certification must implement more expensive measures for weed control to fight increasingly stubborn weeds driven by GE crop systems that promote the overuse of pesticides.

Consumers

212. Many of Plaintiffs' members regularly and purposefully consume non-GE foods and are exposed to an increased risk of harm as a result of consuming GE-contaminated products due to the decreased regulation of GE organisms. This includes the potential contamination of the food supply by experimental GE plantings, or "biopharma" crops engineered with drugs like insulin.

Conservationists

213. Plaintiffs' members are people with strong interests in environmental conservation because of their aesthetic, recreational, vocational, spiritual, and personal stakes in the protection of the environment from the adverse impacts of GE organisms and increased pesticide usage. Those members are deeply invested in the environment remaining inhabitable for many species of animals, plants, and trees. The proliferation of GE crops and other plants will harm wild plants, trees, animals, insects, and their native habitats, injuring Plaintiffs' members' recreational and aesthetic interests. The intensive use of pesticides on GE pesticide-resistant crops compromises Plaintiffs' members' ability to use and enjoy the ecosystems that maintain biodiversity and protect sensitive species.

214. USDA's regulatory scheme will continue to cause an increase in the release of GE organisms without appropriate regulatory oversight and proper evaluation of direct and indirect environmental harms.

215. Plaintiffs' members are concerned about the adverse impacts to the environment and to wild plants and trees from exposure to rogue GE organisms, as well as adverse impacts to insects, birds, and other animals whose habitat is harmed by the release of GE organisms into the wild. They are also concerned about the effects of increased pesticide use in GE crop systems, and their effects on water quality and human health, particularly to children and farmworkers. They live and regularly hike and recreate around areas where new GE crops may be grown and sprayed.

216. A great number of Plaintiffs' members are concerned about the rapid decline of pollinators and endangered or threatened species, and their personal, professional, spiritual, aesthetic and recreational interests are harmed by the loss of these species due to GE crop systems.

217. An increase in GE organisms creates an increased risk of escape and harm to threatened or endangered plants or species habitat through spread of GE

crops or traits to wild relatives. Because of USDA's final rule, these species and habitats are also at an increased risk of exposure to pesticide drift from use on GE crops. Plaintiffs' conservationist members are concerned about the survival of these species and their personal, professional, spiritual, aesthetic, and recreational interests are harmed by these species' decline.

Procedural Injuries

218. This is both a substantive and procedural case and Plaintiffs' concrete harms illustrated above are also closely tied to procedural injuries from USDA's action. Namely, Plaintiffs' members are injured by USDA's failure to comply with the procedural requirements of NEPA and the ESA. By failing to adequately analyze and assess the environmental impacts of the final rule, USDA prevented Plaintiffs' members from being fully informed and able to participate in agency decisionmaking.

219. Similarly, by jumping to a "no effect" determination and failing to undertake the required consultation with the expert wildlife agencies, Plaintiffs' members are deprived of the ability to understand the effects of the final rule on threatened and endangered species and their habitats.

220. Also, because of the exemption and self-determination scheme in the final rule, Plaintiffs' members will not have the opportunity to review or comment on future individual-level NEPA or ESA analyses.

Constitutional Injuries

221. Finally, Plaintiffs' members are injured by USDA's unlawful sub-delegation of its PPA responsibilities to private entities. Not only are Plaintiffs' members deprived of judicial review because sub-delegation eliminates the agency action necessary to bring a challenge, but Plaintiffs' members are also harmed by the lack of any transparency and process for future individual GE crop approvals.

222. These injuries are actual, concrete, ongoing, and particularized, and monetary damages cannot redress them. The requested relief will redress these injuries.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION
VIOLATION OF ESA:
FAILURE TO CONSULT/ARBITRARY AND CAPRICIOUS "NO EFFECT" DETERMINATION

223. Section 7(a)(2) of the ESA prohibits agency actions that jeopardize the survival of listed species or that destroy or adversely modify their critical habitat. 16 U.S.C. § 1536(a)(2). To assist in complying with this duty, federal agencies, like USDA, must consult with the expert Services whenever they take an action that "may affect" a listed species or the species' critical habitat. *Id.*; 50 C.F.R. § 402.14(a).

224. The ESA and its implementing regulations broadly define agency action. 50 C.F.R. §§ 402.02; 402.03. USDA's promulgation of new GE organism regulations at issue in this case constitute "agency action" under ESA section 7(a)(2). *Id.*

225. Under the ESA, agency actions that "may affect" a listed species or critical habitat may not proceed unless and until the federal agency first ensures, through completion of the consultation process, that the action is not likely to cause jeopardy or adverse modification of critical habitat. 16 U.S.C. § 1536(a), (d); 50 C.F.R. §§ 402.14; 402.13. The threshold for a "may affect" determination and the required ESA section 7(a)(2) consultation is low. *See* 51 Fed. Reg. 19,926, 19,949 (June 3, 1986) ("Any possible effect, whether beneficial, benign, adverse or of an undetermined character, triggers the formal consultation requirement.").

226. USDA committed both procedural and substantive violations of the ESA. First, by issuing new Part 340 regulations, USDA has taken action that "may affect" listed species without consulting the expert Services, in violation of the ESA.

227. As explained at length above, the final rule considerably weakens regulation of GE organisms in several respects, among other things by entirely exempting a majority of future GE plants from any oversight or approval process. This wholesale exemption of future GE organisms such as GE plants, grasses, and trees, and relaxing of already weak regulation on the rest that will result from the new regulations may affect, and likely will cause significant harm, to many broad categories of endangered species and their habitats.

228. GE crops carry significant adverse environmental impacts, including but not limited to transgenic contamination; significant increases in herbicide uses in GE herbicide-resistant crop systems; and the proliferation of weeds resistant to these herbicides. Examples of these risks to endangered species are numerous.[180]

229. Because USDA acknowledged that decisions made under the revised regulations "could potentially impact T&E species,"[181] yet went on to make a "No Effect" determination for the final rule, the agency failed to meet the ESA's requirements.

230. "Could potentially impact" is synonymous with "may affect," triggering the consultation requirement. The agency's reliance on consultation at project-level actions rings hollow. Under the new regulatory framework, developers may self-determine wither a GE plant is exempt from regulation. Thus for many future commercial and experimental GE crops, will be no other future agency action to trigger ESA analysis and protections. And for other USDA actions with regard to GE crops, at best it is far from clear that there will be any further consultation duty for any future individual actions in this scheme.

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[180] *See supra* paragraphs 195-200.

[181] USDA, REVISIONS TO USDA-APHIS 7 CFR PART 340 REGULATIONS GOVERNING THE IMPORTATION, INTERSTATE MOVEMENT, AND ENVIRONMENTAL RELEASE OF CERTAIN GENETICALLY ENGINEERED ORGANISMS: FINAL PROGRAMMATIC ENVIRONMENTAL IMPACT STATEMENT 7-8 (May 2020).

231. Accordingly, USDA has violated the ESA by finalizing the new Part 340 regulations without first completing consultation with the expert Services regarding an action that "may affect" listed species and/or their critical habitat. USDA's failure to consult with the Services to insure that its action is not likely to jeopardize endangered or threatened species or adversely modify their critical habitat violates the ESA, 16 U.S.C. § 1536(a)(2), its implementing regulations; and the APA, 5 U.S.C. §§ 701-706.

232. Second, USDA also violated the ESA's mandate to use the "best scientific and commercial data available," an independent mandate of Section 7. 16 U.S.C. § 1536(a)(2).

233. In complying with Section 7, agencies must "give the benefit of the doubt to the species." [182]

234. First, USDA violated the best scientific data mandate by not using any scientific data to make its "no effect" determination in the PEIS, instead claiming that analyses would be done later, at the individual level. However, with exemption and self-determination, there will be not later action to review to determine effects on endangered species or critical habitat. This, coupled with the lack of any scientific analysis rendered USDA's "no effect" determination arbitrary and capricious, and contrary to the best scientific data mandate.

235. Second, USDA ignored the recommendation of a National Academy of Science committee, which conducted an exhaustive review of USDA plant regulation and recommended that USDA regulate all GE plants because those that did not involve use of plant pests could also cause harm to public health or the

[182] H.R. Conf. Rep. No. 96-697, 96th Cong., 1st Sess. 12, *reprinted in* 1979 U.S. Code Cong. & Admin. News 2572, 2576.

environment, and because there is no scientific basis on which to forecast which ones might pose risk.[183]

236. Next, in order to be scientifically sound, the definition of genetic engineering must be robust and include all methods that use *in vitro* manipulation of nucleic acids and proteins to alter genetic material or its expression, including methods on the horizon, so the regulations are inclusive and durable. Based on this proper definition, all GE organisms should begin and stay regulated and not be eligible for commercialization absent USDA analysis, affirmative approval, and continued monitoring conditions. The National Academies of Sciences, Engineering, and Medicine recently produced reports using a suitably inclusive definition of genetic engineering that USDA should have used to capture all GE organisms for assessment and regulation:

> *Genetic engineering* means the introduction or change of DNA, RNA, or proteins by human manipulation to effect a change in an organism's genome or epigenome; where *genome* means the complete sequence of the DNA in an organism, and *epigenome* means the physical factors affecting the expression of genes without affecting the actual DNA sequence of the genome.[184]

237. Finally, the final rule violates the ESA's best scientific data mandate by ending petitions for deregulation and replacing it with a regulatory scheme that would end regulated status for the vast majority of GE organisms. This is not grounded in the best scientific data available. An agency needs adequate data to assess risks, and the streamlined regulatory review process dramatically narrows data requirements. USDA must regulate and assess each GE organism on an

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[183] NATIONAL ACADEMY OF SCIENCES, NRC, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS 79 (2002).

[184] NATIONAL ACADEMIES OF SCIENCE, ENGINEERING, AND MEDICINE, GENETICALLY ENGINEERED CROPS: EXPERIENCES AND PROSPECTS 36, Glossary at 384-88 (2016), available at http://www.nap.edu/24605.

individual basis, and must include an assessment of their actual direct and indirect harms.

SECOND CAUSE OF ACTION
VIOLATION OF NEPA AND APA

238. Plaintiffs re-allege, as if fully set forth, each and every allegation set forth in paragraphs 1 through 237 of this Complaint.

239. NEPA is our "basic national charter for protection of the environment." 40 C.F.R. § 1500.1(a).

240. NEPA requires all federal agencies to prepare a "detailed statement" that discusses the environmental effects of, and reasonable alternatives to, all "major federal actions significantly affecting the quality of the human environment," commonly known as an EIS. 42 U.S.C. § 4332(2)(C). Major federal actions include "new or revised agency rules," as here. 40 C.F.R. § 1508.

241. The environmental effects that must be considered in an EIS include "indirect effects, which are caused by the action and are later in time or farther removed in distance, but are still reasonably foreseeable," as well as direct and cumulative effects. *Id.* §§ 1508.7; 1508.8; 1508.27(b)(7). The purpose of an EIS is to inform decision-makers and the public of the significant environmental impacts of the proposed action, means to mitigate those impacts, and reasonable alternatives that will have lesser environmental impacts.

242. NEPA and its implementing regulations require an agency to "[r]igorously explore and objectively evaluate all reasonable alternatives." 40 C.F.R. § 1502.14(a). *See also* 42 U.S.C. § 4332(C), (E); 40 C.F.R. § 1508.25.

243. NEPA requires federal agencies to use high quality, accurate scientific information and ensure the scientific integrity of the analysis in an EIS. *See id.* §§ 1500.1(b); 1502.24.

244. Here, Defendants failed to undertake the required analysis in the final PEIS and violated NEPA in the following ways:

1. USDA improperly cabined its purpose and need for the revised regulations to, among other things, exclude its authority to prevent or mitigate noxious weed risks.

2. USDA failed to consider reasonable alternatives, 40 C.F.R. § 1502.14, that would be more protective to agriculture and the environment by only considering the "Preferred Alternative" and "No Action Alternative." Among other things, USDA arbitrarily failed to consider alternatives that would prevent or limit the future proliferation of herbicide-resistant "superweeds" or the future occurrences of transgenic contamination from GE organisms.

3. USDA failed to analyze the direct and indirect, *id.* § 1502.1, of the Preferred Alternative in the final PEIS, including and especially the effects of exempting broad categories of GE plants from any future oversight. Other direct and indirect that USDA failed to rigorously analyze and consider include impacts to agricultural land use, impacts from climate change, impacts from increased pesticide use, and impacts from gene flow or transgenic contamination.

4. USDA also violated NEPA's cumulative impact requirements. *Id.* § 1508.25(c)(3). Rather than analyze the cumulative impacts of the regulations on various environmental (and other) resources when combined with past, present, and reasonably foreseeable impacts to those resources, USDA merely concluded that there are no reasonably foreseeable impacts of a cumulative nature that could result from authorized field testing of GE organisms.

5. USDA also violated NEPA's mitigation requirements. *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 351 (1989). USDA improperly relies on the agricultural biotechnology industry's "best interests" and "stewardship" efforts to self-regulate GE experimental and commercial organisms as mitigation measures, creating an improper baseline for USDA's analysis of the regulations and their impacts.

6. For any and all of these reasons, USDA failed to take the required "hard look" at the effects of its action. *Metcalf v. Daley*, 214 F.3d 1135, 1142 (9th Cir. 2000).

245. Finally, the NEPA regulations allow agencies to establish "categorical exclusions," which are categories of actions "which do not individually or

cumulatively have a significant effect on the human environment" and therefore do not require environmental analysis under NEPA. 40 C.F.R § 1507.3.

246. USDA's revisions to the agency's implementing NEPA regulations under 40 C.F.R Part 372, included in the final rule challenged here, include a categorical exclusion for field trials as "research and development activities." 7 C.F.R. § 372.5(c). Given past incidences of escape and tremendous harm from field trials, and the likelihood of future episodes, it is arbitrary and capricious for USDA to categorically exempt field trials from NEPA analysis.

247. Defendants' failure to prepare an adequate PEIS and comply with NEPA, in connection with the final rule, violates NEPA and its implementing regulations and is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" in violation of the APA. 5 U.S.C. § 706(2)(A).

THIRD CAUSE OF ACTION
VIOLATION OF PPA AND APA

248. Plaintiffs re-allege, as if fully set forth, each and every allegation set forth in paragraphs 1 through 247 of this Complaint.

249. USDA violated the PPA in two ways: (1) by failing to apply its authority to regulate GE crops for noxious weed harms and (2) by failing to base its regulations in "sound science."

Failure to Incorporate Noxious Weed Authority

250. In 2000, Congress provided USDA broader, more robust authority with the passage of the PPA. Specifically, the PPA provides USDA the authority to not just address the plant pest harms of GE crops, but also the noxious weed harms they may cause.

251. Noxious weed harms are very broadly defined, to include "damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment." 7 U.S.C. § 7702(10).

252. USDA is charged with implementing the PPA's purpose to "protect[] the agriculture, environment, and economy of the United States." *Id.* § 7701(1). In enacting the PPA, Congress found that "the detection, control, suppression, prevention, or retardation of the spread of plant pests or noxious weeds is necessary" to fulfill this purpose. *Id.*

253. Because Congress was specifically concerned about "the unregulated movement of plant pests, [and] noxious weeds," USDA has an obligation to regulate GE organisms that fall under those categories.

254. USDA has not met its statutory obligations by failing to implement half of its PPA authority—the noxious weed authority—to regulate GE organisms and capture the full range of risks they present.

255. Throughout the Part 340 rulemaking, USDA acknowledged that the main reason for the new revisions to the 1996 Part 340 rules was to bring them in compliance and make them consistent with the PPA's new statutory authority.

256. Repeatedly, USDA in prior proposed rules and supporting documentation concluded that it should apply its noxious weed authority and to do so was necessary to fulfill its duties in overseeing GE crops.

257. In the 2008 and 2017 proposed rules and accompanying decision documents, USDA recognized the duty to implement its noxious weed authority in order to reach all potential risks these organisms present. In fact, USDA found that "it is more scientifically and legally justified to consider weed risk under the noxious weed authority rather than under the plant pest authority."[185]

258. Yet in the final rule, USDA's about-face reversal of the entire 15 years prior of rulemaking is mostly unexplained. Nowhere in the final rule itself or record

[185] USDA, REVISIONS TO USDA-APHIS 7 CFR PART 340 REGULATIONS GOVERNING THE IMPORTATION, INTERSTATE MOVEMENT, AND ENVIRONMENTAL RELEASE OF GENETICALLY ENGINEERED ORGANISMS: DRAFT PROGRAMMATIC ENVIRONMENTAL IMPACT STATEMENT at ES-4 (2017).

of decision does USDA explain why it decided to not apply the noxious weed authority and integrate it into its Part 340 regulations.

259. In the response to comments, USDA said only that it now believes it can fully regulate for weediness risks using only the plant pest authority, a reversal from its prior proposed rules and contrary to the 2005 and 2015 OIG audit reports. 85 Fed. Reg. 29,822.

260. An agency "must examine the relevant data and articulate a satisfaction for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)).

261. This explanation is not sufficient, nor is it legally or scientifically sound. The final rule is arbitrary, capricious, and contrary to law, and violates the PPA and APA.

Failure to Base Decisions on Sound Science

262. The PPA mandates that all USDA decisions under the PPA that "decisions affecting imports, exports, and interstate movement of products regulated under [the PPA] shall be based on sound science." 7 U.S.C. § 7701(4). The Part 340 regulations affect the imports, exports, and interstate movement of GE organisms through the PPA's authority, and therefore must be based on sound science.

263. The final rule is contrary to the PPA's core "sound science" mandate in multiple ways. First, it is contrary to sound science for USDA to exempt broad categories of GE plants from regulation entirely, based on the purported ability to generate such GE plants through conventional breeding methods. Because each GE plant is a unique event, which carries both intended modifications as well as its own array of off-target mutations, it is impossible to re-create the exact result by conventional means. Additionally, the similarity of a GE plant to a conventionally

bred plant says nothing about the GE plant's potential plant pest or noxious weed harms under the PPA. USDA grounded these exemptions, and hence a major part of its new rule, not on any scientific principle, but rather on an unscientific statement by a former Secretary of Agriculture intent upon weakening or eliminating regulation of GE crops.

264. Neither is it consistent with sound science to exempt from regulation one GE plant based on prior deregulation of a second GE plant with the same plant-trait-mechanism of action combination, because additional factors such as pattern and level of gene expression in various plant tissues may differ between the two and render one—but not the other—a plant pest or noxious weed risk.

265. Instead, USDA must use genetic engineering, broadly defined, as the trigger for regulation. This approach would follow the recommendation of a National Academy of Sciences committee, which determined that USDA should regulate all GE plants because there is no scientific basis on which to forecast which ones might pose a risk to public health and the environment. USDA chose to disregard this recommendation to follow sound science, in favor of its deregulatory scheme that does not achieve the purpose of the statute.

266. Alternatively and at a minimum, it was contrary to sound science for the agency to completely exempt many future GE crops and GE crop experiments from any oversight.

267. Second, USDA's decision not to invoke its noxious weed authority under the PPA is also not based in sound science. The agency itself admitted in its previous proposed rules that using this authority is the most scientifically sound course of action to address a broader range of risks presented by new GE experiments. Applying that authority would have provided the agency the sounder footing it needed for regulation, as the agency previously acknowledged.

268. Third, it is contrary to sound science to base regulatory status assessments overwhelmingly on the minutia of the genetic modification itself, at the

molecular level, vis-à-vis an unmodified crop, while ignoring the significant changes in agricultural practice that the genetic modification often triggers—changes that can have enormously adverse impacts, such as the herbicide-resistant weed epidemic and rampant herbicidal drift damage ensuing from the insertion of herbicide-resistance genes into crops.

269. The PPA specifies that USDA is to protect "the agriculture, environment, and economy of the United States," *Id.* § 7701(1), and must make decisions based on sound science in doing so. By refusing to implement half of its authority and setting up a deregulatory exemption scheme, USDA does not even attempt to meet these protective goals. USDA purposely created regulatory holes and has abdicated its duty to protect American agriculture, the economy, and the environment through its regulation of GE organisms.

270. For all these reasons, USDA's decision violated the PPA and the APA as it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" in violation of the APA. 5 U.S.C. § 706(2)(A).

FOURTH CAUSE OF ACTION
VIOLATION OF THE 2008 FARM BILL:
FAILURE TO IMPLEMENT REQUIRED OVERSIGHT OF GE ORGANISMS

271. Plaintiffs re-allege, as if fully set forth, each and every allegation set forth in paragraphs 1 through 270 of this Complaint.

272. The 2008 Farm Bill directives required USDA to "promulgate regulations to improve the management and oversight of articles regulated under the Plant Protection Act," including the oversight and management of GE crop field-testing.[186]

[186] Food, Conservation, and Energy Act of 2008, Pub. L. No. 110-246, Tit. X § 10204(a)(2).

273. The 2008 Farm Bill also required USDA to take action on each of nine problem areas in its LESSONS LEARNED document, detailing inadequacies in reporting and field-test containment.

274. In the final rule, USDA fails to implement the 2008 Farm Bill's requirements. The 2008 Farm Bill expressly directs USDA to strengthen its regulation of GE crop field trials to forestall GE contamination events. Instead, USDA ended the notification process and replaced it with a system where, in many cases, field trials will occur completely without USDA's knowledge or approval.

275. By instituting a scheme of deregulation through exemption and self-determination, USDA violated the 2008 Farm Bill's mandate to act on each of the nine issues identified in its LESSONS LEARNED document in response to its investigation of the massive rice contamination episode.

276. For all these reason the final rule violated the 2008 Farm Bill and the APA as it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" in violation of the APA. 5 U.S.C. § 706(2)(A).

FIFTH CAUSE OF ACTION
UNCONSTITUTIONAL SUB-DELEGATION
OF STATUTORY AUTHORITY

277. Plaintiffs re-allege, as if fully set forth, each and every allegation set forth in paragraphs 1 through 276 of this Complaint.

278. The Constitution delegates "all legislative powers" "in a Congress of the United States." Art. I, § 1. Federal agency officials "may not subdelegate [their decisionmaking authority] to outside entities—private or sovereign—absent affirmative evidence of authority to do so." *U.S. Telecom Ass'n v. F.C.C.*, 359 F.3d 554, 566 (D.C. Cir. 2004).

279. The Part 340 final rule allows future decisions regarding the regulatory status of GE organisms, including GE crops but also GE trees and

grasses, their experimentation and commercialization, to be made by private parties (developers) without USDA oversight or knowledge.

280. In the Part 340 regulations, USDA has sub-delegated to private, self-interested parties the responsibility given to it by Congress to "facilitate exports, imports, and interstate commerce in agricultural products and other commodities that pose a risk of harboring plant pests or noxious weeds in ways that will reduce . . . the dissemination of plant pests or noxious weeds." 7 U.S.C. § 7701(3).

281. USDA's abdication of responsibility with regard to determining the regulatory status of GE organisms prevents the agency from carrying out its duties under the PPA to protect "the agriculture, environment, and economy of the United States." *Id.* § 7701(1). Nothing in the PPA states that USDA may sub-delegate to regulated entities these responsibilities.

282. Because Congress did not expressly authorize it the regulations' sub-delegation of authority for regulatory status determinations is flatly impermissible. "A general delegation of decision-making authority to a federal administrative agency does *not*, in the ordinary course of things, include the power to subdelegate that authority beyond federal subordinates." *U.S. Telecom Ass'n*, 359 F.3d at 566. The key purpose of prohibiting delegation to private entities is preventing "the harm done thereby to principles of political accountability." *Nat'l Ass'n of Regulatory Util. Comm'rs v. F.C.C.*, 737 F.2d 1095, 1143 n.41 (D.C. Cir. 1984). Sub-delegations that render agency oversight "neither timely, nor assured" cannot stand. *U.S. Telecom Ass'n*, 359 F.3d at 567.

283. The self-determination aspect of the final rule allow developers to determine regulatory status without notifying USDA. *See* 7 C.F.R. § 340.1(e) ("Developers *may* request confirmation from APHIS that a plant is not within the scope of this part." (emphasis added)); 85 Fed. Reg. 29,798-99 (discussing the self-determination aspect of the regulations). The existence of a voluntary confirmation process does not guarantee transparency or agency review.

284. This sub-delegation eliminates USDA oversight, public accountability, and judicial review—all constitutional necessities. The result is a complete erosion of the PPA's structure and purpose with respect to protecting agriculture and the environment.

285. USDA has foreclosed from judicial review actions it is required to carry out, undermining the constitutional balance between the federal branches. The system of separated powers and checks and balances established in the Constitution was regarded by the Framers as "a self-executing safeguard against the encroachment or aggrandizement of one branch at the expense of the other." *Buckley v. Valeo*, 424 U.S. 1, 122 (1976).

286. The Part 340 regulations offend core precepts of democratic accountability for agency actions, contradict the language and goals of the PPA, impede USDA from doing its job, and permit self-interested private parties to be the guardians of GE organisms. As such, the regulations violate the doctrine against sub-delegation and the separation of powers principle by placing agency authority in the hands of self-interested entities without retaining oversight.

RELIEF REQUESTED

WHEREFORE, the Plaintiffs respectfully request that the Court:

287. Adjudge and declare that USDA's failure to undertake ESA consultation with the expert services prior to finalizing its Part 340 regulations is contrary to the ESA and constitutes a violation of the ESA and APA.

288. Adjudge and declare that USDA's PEIS is inadequate, in violation of NEPA and the APA.

289. Adjudge and declare that USDA's final rule unlawfully fails to implement its noxious weed authority under the PPA and fails to fulfill its mandate to promulgate regulations based on sound science, in violation of the PPA and APA.

290. Adjudge and declare that USDA's final rule unlawfully fails to implement the requirements of the 2008 Farm Bill to provide more oversight of GE organism field testing and recordkeeping, and constitutes a violation of the 2008 Farm Bill and APA.

291. Adjudge and declare that USDA's final rule unlawfully sub-delegates agency decision making to private entities, and constitutes a violation of the Constitution.

292. Set aside or vacate the final rule based on Defendants' violations of the ESA and APA.

293. Set aside or vacate the final rule based on Defendants' violations of NEPA and the APA.

294. Set aside or vacate the final rule based on Defendants' violations of the PPA and APA.

295. Set aside or vacate the final rule based on Defendants' violations of the 2008 Farm Bill and APA.

296. Set aside or vacate the final rule based on Defendants' violation of the Constitution and separation of powers principles.

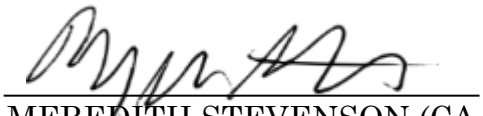
297. Order USDA to finalize and issue meaningful GE regulations that comply with these statutes as soon as reasonably practicable, according to a Court-ordered timeline, or, in the alternative, order USDA to initiate ESA consultation with the expert services;

298. Retain jurisdiction of this action to ensure compliance with its decree;

299. Award Plaintiffs their fees, costs, expenses, and disbursements, including reasonable attorneys' fees, associated with this litigation under the Equal Access to Justice Act, 28 U.S.C. § 2412; and

300. Grant such further and additional relief as the Court deems just and proper.

Respectfully submitted this 26th day of July, 2021, in San Francisco, California.



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