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14 UNITED STATES DISTRICT COURT
 15 FOR THE NORTHERN DISTRICT OF CALIFORNIA
 16 SAN FRANCISCO DIVISION

17 NATIONAL FAMILY FARM COALITION, et
 18 al.,

19 *Plaintiffs,*

20 v.

21 TOM VILSACK, et al.,

22 *Defendants,*

23 and

24 BIOTECHNOLOGY INNOVATION
 25 ORGANIZATION and AMERICAN SEED
 26 TRADE ASSOCIATION,

27 *Intervenor-Defendants.*

28 Case No. 21-5695-JD

**PLAINTIFFS' MOTION AND
 MEMORANDUM FOR SUMMARY
 JUDGMENT**

**Date: April 6, 2023
 Time: 10:00 a.m.
 Courtroom: 11, 19th Floor
 Hon. James Donato**

1 NOTICE OF MOTION AND MOTION

2 PLEASE TAKE NOTICE that on April 6, 2023, or as soon thereafter as counsel can be
3 heard, Plaintiffs National Family Farm Coalition, Center for Food Safety, Pesticide Action
4 Network North America, Center for Environmental Health, Friends of the Earth, and Center for
5 Biological Diversity, will move this Court for summary judgment on Claims 1-4 raised in their July
6 26, 2021 Complaint, ECF No. 1.¹

7 Pursuant to Civil Local Rules 7-2 and 56-1, Plaintiffs respectfully move this Court to grant
8 summary judgment in Plaintiffs' favor on Claims 1-4 alleged in Plaintiffs' Complaint, on the
9 grounds that there is no genuine issue as to any material fact and that Plaintiffs are entitled to
10 judgment as a matter of law. In issuing the new regulations governing genetically engineered (GE)
11 crops (the Revised GE Rule), Defendant United States Department of Agriculture (USDA or
12 APHIS) violated the Plant Protection Act (PPA), the Endangered Species Act (ESA), the National
13 Environmental Policy Act (NEPA), the Food, Conservation, and Energy Act of 2008 (the 2008
14 Farm Bill), and the Administrative Procedure Act (APA). The Revised GE Rule is arbitrary and
15 capricious and contrary to law, and should be remanded and vacated.

16 This Motion is based upon the pleadings and administrative record on file in this case, and
17 the supporting papers therewith, the points and authorities herein, and the declarations submitted
18 herewith.

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25 _____
26 ¹ Given that vacatur of the Revised GE Rule is the default remedy for all of Plaintiffs' claims alike,
27 and in an effort to keep adjudication as streamlined as possible for the Court, Plaintiffs find it
28 unnecessary to move for summary judgment on Plaintiffs' Claim 5 concerning USDA's improper
sub-delegation of its PPA authority.

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GLOSSARY OF ACRONYMS & ABBREVIATIONS

2008 Farm Bill	The Food, Conservation, and Energy Act of 2008
APA	Administrative Procedure Act
APHIS	Animal and Plant Health Inspection Service
EIS	Environmental Impact Statement
ESA	Endangered Species Act
FWS	United States Fish & Wildlife Service
GE	Genetically Engineered
Academy	National Academy of Science
NEPA	National Environmental Policy Act
NRC	National Research Council
PPA	Plant Protection Act
USDA	United States Department of Agriculture

INTRODUCTION

1
2 This case concerns the next chapter of Defendant United States Department of
3 Agriculture's (USDA or APHIS) regulation of genetically engineered (GE) organisms. Or rather,
4 the lack of it. For more than three decades, USDA has overseen the experimental field-testing and
5 commercialization of a wide range of GE organisms—edible and non-edible GE crops, plants
6 flowers, grasses, and trees (collectively, GE crops)—using regulations codified at 7 C.F.R. Part 340
7 (the Part 340 regulations). Despite this oversight, GE crops' thirty-year track record is a damaging
8 one for U.S. agriculture and the environment, as these crops have brought about massive market
9 rejection of U.S. agricultural products when experimental or commercialized GE crops have
10 contaminated non-GE and organic crop supplies, significantly increased herbicide use and their
11 associated harms to human health, agriculture, and the environment, and accelerated the
12 proliferation of uncontrollable superweeds resistant to herbicides.

13 Yet USDA's new Part 340 regulations (the Revised GE Rule) strikingly did not increase
14 nor expand upon USDA's oversight, despite having repeatedly recognized its outdated rules'
15 inadequacies and having Congress and other experts call on USDA to update them time and time
16 again. Instead, the agency passed off oversight for most GE crops' testing and commercialization to
17 self-interested GE developers, without any USDA supervision, introducing broad categories of
18 regulatory exemptions, and requiring only cursory review of the GE crops not exempted.

19 The Revised GE Rule is unlawful, in violation of the Plant Protection Act (PPA), the
20 Endangered Species Act (ESA), the National Environmental Policy Act (NEPA), the Food,
21 Conservation, and Energy Act of 2008 (the 2008 Farm Bill), and the Administrative Procedure Act
22 (APA). The decision flies in the face of USDA's own prior statutory interpretation and scientific
23 conclusion that to adequately consider the harms of this ever-changing GE technology, the agency
24 must incorporate the PPA's broader noxious weed authority into its GE regulations. Moreover,
25 USDA buried its head in the sand regarding the Revised GE Rule's potential effects on our
26 nation's endangered and threatened species and their critical habitat, as well as its foreseeable
27 environmental impacts. USDA's "all vibes, no data" approach violated the scientific rigor required

1 by both the PPA and the ESA. And finally, in abandoning the agency’s prior proposal for more
 2 expansive and detailed GE regulations, USDA violated the 2008 Farm Bill’s express directive to
 3 improve USDA’s GE oversight. For these reasons, Plaintiffs ask this Court to grant summary
 4 judgment in their favor, declare the GE Revised Rule invalid, and vacate the Rule.

5 RELEVANT PROCEDURAL AND FACTUAL BACKGROUND

6 I. The Controversial History of GE Crops in United States.

7 For more than thirty years, the agricultural biotechnology industry (mainly pesticide-seed
 8 conglomerates) has used genetic engineering to alter the makeup and function of plants to
 9 produce GE crops that could not have otherwise been produced by nature or through traditional
 10 plant breeding. *See* Administrative Record (AR)1315; AR1728-29. GE crops have consequently
 11 become a pillar of industrial agriculture and one of the most intractable environmental and
 12 agricultural challenges facing U.S. farmers and regulators. *See* AR697; AR9809-21.² As USDA
 13 recognized, despite other potential uses of genetic engineering, the commercial reality is that the
 14 pesticide companies have predominantly engineered crops to withstand their’ weed-killing
 15 pesticide products (also known as herbicides), so that more can be sprayed and sprayed during the
 16 growing season. AR698, 765-66. The vast majority of U.S. commodity crops—corn, soybean, and
 17 cotton—are of the herbicide-resistant GE variety. *See* AR763, tbl. 3-14, 765, fig. 3-15.

18 These pesticidal GE crop systems carry a myriad of environmental, agricultural,
 19 socioeconomic, and health harms,³ the most well-documented of which are: (1) transgenic
 20 contamination, (2) increased herbicide use and exposure, and (3) the creation of the superweeds
 21 epidemic. *See, e.g.*, AR9809-21; AR1685.⁴ Each is discussed in brief below.

22 _____
 23 ² *See* Attachments from the Center for Food Safety,
 24 <https://www.regulations.gov/comment/APHIS-2018-0034-6153> (last visited Dec. 5, 2022);
<https://www.regulations.gov/comment/APHIS-2018-0034-6151> (last visited Dec. 5, 2022).

25 ³ *See also* Compl. ECF No. 1, ¶¶ 82-85. Given length constraints, where potentially helpful
 Plaintiffs refer back to more detailed treatment of specific topics in the Complaint.

26 ⁴ *See, e.g., Atay v. Cnty. of Maui*, 842 F.3d 688, 693 (9th Cir. 2016) (stating that “the cultivation and
 27 testing of GE plants raise several well-documented concerns,” discussing transgenic contamination

1 Transgenic Contamination:⁵ Time and time again, experimental and commercialized GE
2 crops have shown their ability to escape confinement or isolation efforts and contaminate other
3 crops and/or wild plants of same or closely related species. *See* AR768-771; AR1621.⁶ USDA
4 acknowledged that such transgenic contamination happens easily, as it can result from pollen drift,
5 seed mixing, flooding, seeds in machinery, seed spillage, and a variety of natural events and human
6 errors that may—and do—occur at each stage of the crop production process. AR770. USDA also
7 recognized that, when transgenic contamination inevitably occurs, U.S. farmers, both non-GE
8 conventional and organic crop growers, pay the price. *See* AR6316-17; AR11709. For example, in
9 2006-2007, experimental herbicide-resistant rice known as LibertyLink contaminated U.S. rice
10 supply, causing, in USDA’s words, “significant adverse economic impact to the rice industry.”
11 AR692. The contamination caused massive export market rejection of U.S. rice, nearly \$1.3 billion
12 in economic loss for 11,000 American rice farmers and suppliers. AR6316-17; AR27050-52. Over
13 the past decade, incidents of transgenic contamination of conventional and organic crops have
14 cost U.S. farmers literally billions of dollars in market losses, as food companies, grain traders, and
15 export markets have rejected contaminated supplies. AR1683-85; AR6316-17; AR27050-52.

16 _____
17 and past transgenic contamination incidents, “harm to beneficial plants and animals caused by the
18 increased use of pesticides sometimes associated with testing and growing GE crops, the
19 proliferation of ‘superweeds’ and other pests resistant to pesticides, and the reduction of
20 biodiversity,” and describing the escape of GE creeping bentgrass from test fields as “hav[ing]
21 detrimental environmental impacts as these plants out-compete other plants.”); *Delaware Audubon*
22 *Soc., Inc. v. U.S. Dept. of Interior*, 612 F.Supp.2d 442, 451 (D. Del. 2009) (in holding that the
23 Department of Interior violated NEPA by failing to assess the environmental impacts of farming
24 GE crops on Prime Hook National Wildlife Refuge, emphasizing that the Department’s “own
25 biologists determined [farming GE crops] posed significant environmental risks to Prime Hook,
26 including biological contamination, increased weed resistance, and damage to soils.”)

27 ⁵ *See also* Compl. ¶¶ 86-91 and footnotes therein.

28 ⁶ *See Geertson Seed Farms v. Johanns*, No. C 06-01075 CRB, 2007 WL 518624, at *5 (N.D. Cal. Feb.
13, 2007) (“Once ... a farmer’s seed crop is contaminated with the Roundup Ready gene, there is
no way for a farmer to remove the gene from the crop or control its further spread.”); *id.* at *12
(requiring an EIS to analyze transgenic contamination of traditional alfalfa and the development of
glyphosate-resistant weeds due to increased use of the herbicide glyphosate on glyphosate-resistant
alfalfa); *Center for Food Safety v. Vilsack*, No. C 08-00484 JSW, 2009 WL 3047227, *9 (N.D. Cal.
Sept. 21, 2009) (same).

1 Harms from Increased Herbicide Use:⁷ Another well-established harm is GE crops’
2 contribution to significant increase in herbicide use and the resulting damage to agriculture and
3 the environment. *See, e.g.,* AR9809-21. USDA admitted that the monopolization of U.S.
4 agriculture with GE commodity crops engineered to withstand the spraying of the herbicides has
5 dramatically increased use of these plant-killing chemicals and the overall pesticide output into our
6 environment. AR786, 805. For example, the first generation GE crops, Monsanto’s “Roundup
7 Ready” crops, which are engineered to withstand glyphosate, have turned glyphosate from a minor
8 herbicide to the most sprayed pesticide in the country, with 280 million pounds applied to nearly
9 300 million acres of farmland annually.⁸ *See also* AR790, fig. 3-23.

10 This excessive use of glyphosate—inconceivable without glyphosate-resistant GE crops—has
11 led to the dramatic, quarter-century decline in Monarch butterflies; harm to sensitive amphibians;
12 and suppression of healthy soil bacteria. Moreover, glyphosate is “probably carcinogenic to
13 humans,” and is implicated in numerous cases of non-Hodgkin lymphoma among its users.⁹

14 And these first generation herbicide-resistant crops have contributed to increased use of
15 even more toxic herbicides on the second generation of herbicide-resistant GE crops. For example,
16 the commercialization of soybean resistant to the herbicide dicamba has not only significantly
17 increased the use of dicamba, but has also caused the incredibly volatile herbicide to drift across
18 millions of acres, harming other crops, trees, and plants. *See* AR797, Fig. 3-29; AR815.¹⁰ *Nat’l*
19 *Family Farm Coal.*, 960 F.3d at 1126-29, 1138-44 (detailing the devastating dicamba drift damage
20 after introduction of dicamba-resistant soybeans).

22 ⁷ *See also* Compl. ¶¶ 92-99 and citations therein. Herbicides are a subclass of pesticides intended to
23 kill weeds; we use pesticides here for simplicity unless only addressing herbicides specifically.

24 ⁸ EPA, Glyphosate: Response to Comments, Usage, and Benefits. Biological and Economic
Analysis Division 13 (Apr. 18, 2019), EPA-HQ-OPP-2009-0361-2342.

25 ⁹ *See* Attachments from the Center for Food Safety, <https://www.regulations.gov/comment/APHIS-2018-0034-5955> (last visited Dec. 6, 2022).

26 ¹⁰ *See* Attachments from Center for Food Safety, [https://www.regulations.gov/comment/APHIS-](https://www.regulations.gov/comment/APHIS-2018-0034-5970)
27 [2018-0034-5970](https://www.regulations.gov/comment/APHIS-2018-0034-5970) (last visited Dec. 4, 2022)

1 Superweeds:¹¹ Herbicide-resistant GE crops also foster rapid emergence of “superweeds”
 2 immune to the GE crops’ companion pesticide(s). For example, glyphosate-resistant weeds,
 3 virtually unknown before, evolved in epidemic fashion with the massive use of glyphosate
 4 accompanying Roundup Ready crops, now infesting at least 120 million acres—nearly 40% of the
 5 nation’s cultivated cropland.¹² See AR819. Controlling these resistant weeds has become the
 6 biotechnology industry’s pretext for developing new GE crops that are resistant to additional
 7 herbicides, spurring a toxic spiral of increasing herbicide use and more weed resistance.
 8 AR980921; *Nat’l Family Farm Coal.*, 960 F.3d at 1123 (explaining Monsanto developed dicamba-
 9 resistant crops “[i]n response” to the widespread development of glyphosate-resistant weeds).

10 And some GE crops have become superweeds themselves.¹³ Herbicide-resistant GE crop
 11 volunteers may persist, while other GE grasses and plants spread beyond farm fields and establish
 12 in the wild. For example, GE herbicide-resistant creeping bentgrass, designed for golf courses, and
 13 GE canola, escaped field trials and established in the wild. See AR772. Similar to invasive species,
 14 these GE superweeds displace native species and their habitats, harming native ecosystems. See *id.*
 15 (USDA stating that “[d]espite intensive eradication efforts by [the GE developer], [GE creeping
 16 bentgrass] has persisted on the banks of irrigation ditches[.]”); *id.* (admitting that GE creeping
 17 bentgrass pollen from the field trial has hybridized with its wild relatives) The U.S. Fish and
 18 Wildlife Service (FWS) concluded escaped GE bentgrass would be impossible to eradicate and
 19 would jeopardize the extinction of two endangered plants and the endangered Fender Blue
 20 Butterfly, while potentially harming dozens more federally protected species.¹⁴

21
 22
 23 ¹¹ See also Compl. ¶¶ 100-103 and citations therein.

24 ¹² See Attachments from Center for Food Safety, <https://www.regulations.gov/comment/APHIS-2018-0034-5970> (last visited Dec. 4, 2022).

25 ¹³ See also Compl. ¶¶ 104-108 and citations therein.

26 ¹⁴ FWS, Draft Biological Opinion on Roundup Ready Creeping Bentgrass, *available at*
 27 http://www.centerforfoodsafety.org/files/fws-biop-on-rr-bentgrass-deregulation_received-via-foia_2011_49385.pdf (attached as Exhibit E to Wu Declaration) (filed concurrently).

1 In addition to the three harms discussed above, there are many other adverse impacts and
 2 risks from current and future GE crops that will go wanting under USDA’s new approach. These
 3 include GE crops engineered as “biofactories” to produce experimental pharmaceutical
 4 compounds; GE plants engineered to produce industrial, non-food enzymes; GE plants produced
 5 through “gene editing,” synthetic biology, and “gene drives”; and GE trees, which also fall under
 6 USDA’s regulation and present their own suite of ecological risks.¹⁵

7 **II. Congress, Experts, and USDA Itself Emphasized the Need to Expand GE Regulation.**

8 There is a reason GE crops have had detrimental agricultural and environmental impacts:
 9 they have been regulated with outdated rules whose scope does not sufficiently address the harms
 10 they cause. At the dawn of GE organisms in the 1990s, the U.S. did not pass any new laws to
 11 govern their oversight; instead oversight was spread amongst several agencies, each charged with
 12 finding ways to apply their existing authority.¹⁶ USDA was charged with overseeing the majority of
 13 GE crops, and up until the Revised GE Rule challenged here, USDA regulated GE crops using
 14 regulations promulgated back in 1987 pursuant to the Federal Plant Pest Act, which narrowly
 15 concerned risks associated with plant pests.¹⁷ AR694. Under the old regulations, a developer had
 16 to notify USDA to conduct experimental field trials, and the GE crop remained regulated—and
 17 could not be commercialized—until the developer formally petitioned USDA and the agency
 18 approved. *See* 7 U.S.C. § 7711(c)(2), 7 C.F.R. § 340.6(d)(3)(i) (2020). This petition process
 19 required detailed information, including laboratory and field trial data, and triggered USDA’s
 20 assessment duties under the PPA, NEPA, and the ESA.¹⁸

21 But by the mid-2000s, it was clear that there were major deficiencies with this outdated
 22 regulatory approach. First, as a legal matter, in 2000, Congress significantly broadened USDA’s

23
 24 ¹⁵ *See also* Compl. ¶¶ 109-116 and citations therein.

25 ¹⁶ *See also* Compl. ¶¶ 117-119.

26 ¹⁷ *See* 52 Fed. Reg. 22,908 (June 16, 1987); 58 Fed. Reg. 17,044 (Mar. 31, 1993); 62 Fed. Reg.
 23,945 (May 2, 1997).

27 ¹⁸ *See also* Compl. ¶¶ 120-126 and citations therein.

1 regulatory reach through the enactment of the Plant Protection Act, which subsumed three
2 separate plant protection statutes: the Federal Plant Pest Act, from which the prior Part 340
3 regulations were derived, the Plant Quarantine Act, and the Federal Noxious Weed Act. *See*
4 AR694; *see infra* pp. 22-25. As USDA recognized, the combined statute “expands USDA’s
5 authority ... to protect American agriculture” by “increase[ing] [USDA’s] regulatory oversight over
6 noxious weeds,” in addition to plant pests. AR694.¹⁹ However, despite having broader regulatory
7 authority, USDA did not (and still does not under the Revised GE Rule, *see infra* pp. 11-14) assess
8 GE crops for their noxious weed risks. This is because, as USDA itself explained, the federal
9 noxious weed regulations regulate noxious weeds by taxonomic groups, and thus in order to
10 regulate a GE crop as a noxious weed, USDA must regulate its non-GE counterpart as a noxious
11 weed as well. *See* 82 Fed. Reg. 7,008, 7,010 (Jan. 19, 2017) (“The regulations in part 360, while
12 effective, continue to have a significant restriction that limits their applicability to GE organisms:
13 They are predicated on a determination by APHIS that a taxon is a Federal noxious weed.”); *see*,
14 *e.g.*, 7 C.F.R. § 360.500 (describing list a *taxon* as a noxious weed); *see* AR817 (“herbicide resistant
15 weeds are not subject to the regulations ... unless the herbicide resistant weed poses a plant pest
16 risk.”). The inability to utilize its noxious weed authority—and the need to implement Congress’s
17 command and apply it to GE crop oversight—was always one of if not the primary impetuses for
18 USDA’s revisions of the Part 340 regulations. *See* AR1908; *see infra* pp. 9-11.²⁰

19
20 ¹⁹ While the PPA broadly defines a “plant pest” harm to be anything “that can directly or indirectly
21 injure, cause damage to, or cause disease in any plant or plant product,” 7 U.S.C. § 7702(14), the
22 definition of noxious weed risk is even broader, covering “any plant or plant product that can
23 directly or indirectly injure or damage *crops, livestock, natural resources, public health, the environment,*
24 *or other interests of agriculture.*” *Id.* 7702(10) (emphasis added). Notably Congress in the PPA
25 expanded the prior definition of “noxious weeds” to include not just foreign ones, but
26 also *domestic* ones, making clear that USDA is responsible for protecting agriculture and the
27 environment from domestic noxious weed risks like those posed by GE crops. *Int’l Ctr. for Tech.*
28 *Assessment v. Johanns*, 473 F. Supp. 2d 9, 24-26 & n.15 (D. D.C. 2007) (explaining that Congress
expanded the noxious weed definition in the PPA and vacating USDA petition denial of noxious
weed listing petition as too narrow).

²⁰ *See also* Compl. ¶¶ 127-129 and citations therein.

1 Second, and as a factual matter, regulating GE crops only for “traditional” plant pests risks
2 overlooks the myriad of GE crop harms—including transgenic contamination, increased pesticide
3 use, and superweeds—that have had the most detrimental impacts on U.S. agriculture and the
4 environment, even though they fit under the broad category of agronomic and environmental
5 “plant pest” and “noxious weed” harms defined by the statute. *See supra* pp. 2-10. As USDA itself
6 admitted, “some GE plants ... may pose a noxious weed risk.” AR1924 (listing two varieties of GE
7 switchgrass, GE Augustine grass, and GE Kentucky Bluegrass as GE plants that carry potential
8 noxious weed risks), AR1887. And, as new and different forms of genetic engineering techniques
9 are employed, GE organisms are now created without any plant pest involvement, and can be
10 planted and commercialized without any regulatory review. *See* AR1838; AR1919-1923.

11 USDA was well-aware it needed to expand its. In 2000, USDA solicited the National
12 Academy of Sciences (the Academy),²¹ asking the expert body to “review the scientific basis that
13 supports the scope and adequacy of USDA’s oversight of ... transgenic plants and their products.”
14 AR20437. The Academy released its report in 2002 and, amongst many findings, recommended
15 USDA expand regulation to include all GE plants, and not just those that trigger USDA’s
16 narrowly construed plant pest risks. AR20515, 20519; *see infra* pp. 20-22. In 2005, USDA’s Office
17 of Inspector General audited the agency’s GE organism oversight (the 2005 Audit), finding
18 significant weaknesses. AR22951-23025. The 2005 Audit noted APHIS lacked sufficient
19 information regarding GE field trials to ensure containment and called for stronger regulations.
20 AR22954-58. It emphasized “GE crops ... must be carefully regulated,” and sharply criticized
21 USDA’s then-existing regulations as inadequate, concluding “APHIS’s current regulations ... do
22 not go far enough to ensure the safe introduction of agricultural biotechnology” AR22957. The
23 2005 Audit recommended USDA update its rules to comply with the PPA and incorporate its
24 noxious weed authority; USDA agreed. AR22973 (recommending USDA “[u]pdate regulations to

25 ²¹ The National Academy of Sciences is an expert committee mandated by Congress to advise the
26 federal government on scientific and technical matters. AR20417. USDA refers the Academy as
27 the National Research Council (NRC). The two entities are the same: the NRC is the “principal
operating agency of ... [the Academy].” *Id.*

1 incorporate the provisions of the PPA,” and recording USDA’s response that it was developing a
2 proposed rule that “will include the provisions of the [PPA].”).²² A 2008 Governmental
3 Accountability Office study similarly found that “unauthorized releases of GE crops into food,
4 animal feed, or the environment beyond farm fields have occurred, and *it is likely that such incidents*
5 *will occur again.*” AR27032 (emphasis added).

6 Congress also took notice,²³ directing USDA in the 2008 Farm Bill to “promulgate
7 regulations to improve the management and oversight of [GE articles].” 2008 Farm Bill, Pub. L.
8 No. 110-246, Tit. X, § 10204(a)(2). Congress mandated USDA “take action on each issue
9 identified in the document entitled ‘Lessons Learned and Revisions under Consideration for
10 APHIS’ Biotechnology Framework’” (the Lessons Learned Report), within eighteen months of the
11 2008 Farm Bill’s enactment. *Id.* § 10204(a)(1). The 2007 USDA Lessons Learned Report
12 investigated the agency’s mistakes with field trial oversight that led to the catastrophic GE rice
13 contamination discussed above. AR18415-19; *supra* p. 3. It specifically recognized USDA had
14 insufficient information to prevent, and to effectively remedy, contamination incidents, and
15 proposed Part 340 amendments to improve both experimental GE crop data as well as USDA’s
16 remedial capability after a transgenic contamination incident. *See* AR14815-19; *infra* pp. 27-29.

17 **III. Up Until the Revised GE Rule, the Overarching Need and Purpose of the Proposed**
18 **Rule Revision Was to Broaden the GE Rules to Include the Noxious Weed Authority.**

19 The challenged Revised GE Rule ended a multi-round rulemaking USDA started nearly
20 twenty years ago.²⁴ USDA first announced its intention to update the Part 340 regulations in
21 2004. 69 Fed. Reg. 3,271 (Jan. 23, 2004). Specifically, USDA proposed “broadening its regulatory
22 scope ... to include [GE] organisms that may pose a noxious weed risk.” *Id.* USDA released its first
23

24 ²² The Office of Inspector General issued another audit in 2015 (the 2015 Audit) repeating the
25 same criticisms, once again urging USDA to update its regulations to “incorporate[] additional
26 authority to control noxious weeds.” AR23026.

27 ²³ *See also* Compl. ¶¶ 46-52, 140 & 149 and citations therein.

28 ²⁴ *See also* Compl. ¶¶ 132-162 and citations therein.

1 attempt in 2008 (the 2008 Proposed Rule), 73 Fed. Reg. 60,007 (Oct. 9, 2008)²⁵ accompanied by a
2 draft NEPA environmental impact statement (the 2007 EIS).²⁶ In the 2008 Proposed Rule USDA
3 affirmed its intention to cure its deficient regulations “with both the plant pest and noxious weed
4 authorities of the PPA,” explaining that doing so is necessary to address “environmental or other
5 types of physical harm or damage” caused by GE crops that are “covered by the definition of
6 noxious weed,” but not plant pest, in the PPA. 73 Fed. Reg. at 60,011. Similarly, USDA found
7 that “the present scope of the regulations may not be of sufficient breadth to cover the full range
8 of GE organisms and the full range of potential agricultural and environmental risks posed by
9 these organisms,” 2007 EIS at v, and concluded incorporation of the noxious weed authority
10 would enable the agency to “look at the broadest range of possible impacts resulting from releasing
11 a [GE] plant in the environment,” *id.* at 21. USDA also acknowledged that herbicide-resistant
12 weeds have had significant adverse impacts, including “increased weed control and energy costs
13 and reduced crop yields and crop quality,” *id.* at 119; as well as increased environmental costs
14 associated with the need to use more toxic or persistent herbicides to control these superweeds, *id.*
15 at 121. Thus, USDA concluded, “with the increasing diversity of both agronomic and non-
16 agronomic traits being engineered into plants it is appropriate to place regulatory controls upon
17 GE plants proportionate to the likelihood that they may present a noxious weed risk until the
18 potential risk can be appropriately evaluated.” 73 Fed. Reg. at 60014.

19 After years of delay followed by mysteriously withdrawing the first proposed rule, USDA
20 published a second proposed rule in 2017 (the 2017 Proposed Rule), 82 Fed. Reg. 7008 (Jan. 19,
21 2017), with a new draft environmental impact statement (the 2017 EIS).²⁷ Once again, USDA
22

23 ²⁵ For the Court’s convenience, the notice is attached as Exhibit A to the Wu Declaration.

24 ²⁶ USDA, Introduction of Genetically Engineered Organisms: Draft Programmatic Environmental
25 Impact Statement (July 2007) (attached as Exhibit B to the Wu Declaration).

26 ²⁷ USDA, Revisions to USDA-APHIS 7 CFR Part 340 Regulations Governing the Importation,
27 Interstate Movement, and Environmental Release of Genetically Engineered Organisms: Draft
28 Programmatic Environmental Impact Statement (Jan. 2017) (attached as Exhibit C to the Wu
Declaration).

1 proposed implementing its PPA noxious weed authority, stating that “evaluating [GE] plants solely
 2 for plant pest risk, is not sufficient to properly identify all risks that these plants present” and
 3 therefore it was “both appropriate and *necessary* to begin to evaluate GE plant for noxious weed
 4 risk.” 82 Fed. Reg. at 7010 (emphasis added). USDA explained that incorporation of its noxious
 5 weed authority was scientifically necessary and “legally justified” to accommodate the increasingly
 6 diverse GE technologies. 2017 EIS at ES-4. Critically, USDA concluded that expanding its
 7 regulations to include its noxious weed authority would “reduce[] the potential risks to physical
 8 and biological resources” from GE plants as compared to the pre-existing regulations examining
 9 GE plants for their plant pest risks only. *Id.* at ES-8. However, despite having two rounds of
 10 rulemaking and two lengthy EISs, USDA once again withdrew the 2017 Proposed Rule. AR1-2.

11 **IV. USDA’s Complete About-Face in the Challenged Rule.**

12 After repeatedly affirming the legal and scientific necessity of expanding its GE regulatory
 13 authority for over fifteen years, in 2019 USDA pulled a 180-degree reversal in what would become
 14 the challenged Revised GE Rule. And despite receiving nearly 7,000 public comments—most of
 15 which strongly opposed USDA’s latest proposal, USDA finalized the Revised GE Rule and
 16 published a final EIS (the 2020 EIS) in May 2020. *See* AR603-51 (Revised GE Rule Federal
 17 Register notice); AR652-1129 (the 2020 EIS).

18 *The Revised GE Rule*²⁸

19 Contrary to its own prior findings, Congressional mandate, and the expert opinions that
 20 the Part 340 regulations should be updated to expand and improve USDA’s oversight, the agency
 21 did just the *opposite*, deciding to significantly narrow its regulation, in four critical ways:

22 Failure to Implement the PPA: First—contrary to its consistent position since 2004 when it
 23 first announced proposed amendments, and against the repeated recommendations from its two
 24 audit reports, the Government Accountability Office, and the expert Academy, USDA rejected
 25 expanding the regulations to incorporate its PPA noxious weed authority. AR635. USDA did not
 26

27 ²⁸ *See also* Compl. ¶¶ 157-176 and citations therein.

1 offer *any* explanation for its radical departure from a decade and a half of detailed environmental
2 analyses, two prior rounds of rulemaking, and audits, all of which had emphasized the necessity of
3 incorporating USDA’s noxious weed authority to address the risks of GE organisms.

4 Reducing, not Increasing, Oversight: Second, whereas USDA had, again, consistently for
5 fifteen years and through two prior rounds of rulemaking, recognized the need for more—not less—
6 assessment and information on GE plants before their commercialization, USDA instead
7 significantly *reduced* the scope of its oversight by: (1) exempting large swathes of GE plants from all
8 regulation, 7 C.F.R. § 340.2(b)-(d); (2) allowing GE developers to self-apply the exemptions
9 without any consultation or approval from USDA, *see* 7 C.F.R. § 340.2(e); and (3) for those
10 non-exempt GE plants, significantly curtailing USDA’s review process, 7 C.F.R. § 340.4.²⁹

11 Exemption from Any Regulation: Third, a GE plant is now exempt from regulation if the
12 GE developer believes (1) that its engineered trait “could practically been achieved by conventional
13 breeding methods,” AR604, 607; 7 C.F.R. § 340.1(b)1)-(3); or (2) if it is in the same species as a
14 previously deregulated or exempted GE plant, and shares the same engineered trait created
15 through the same mechanism of action, *id.* § 340.1(c). Again, a GE developer can self-determine
16 these findings without any USDA confirmation (or notice) required. *See id.* § 340.1(e).³⁰

17 Less Science and Data: Fourth and finally, whereas USDA previously named specific
18 amendments increasing its ability to obtain information and better react to GE contamination
19 incidents (and even though Congress specifically mandated that USDA take such action in the
20 2008 Farm Bill), the Revised GE Rule *disavows* any such increased data requirements and actually
21 significantly reduces USDA’s regulatory oversight.³¹ Instead—even for those GE crops still within
22 USDA’s purview and not entirely exempted—USDA significantly reduced the data necessary.

24 ²⁹ *See also* Compl. ¶¶ 162-169 and citations therein.

25 ³⁰ USDA also reserved the ability to create *additional* categories of exempted GE crops, *id.*
26 § 340.1(b)(4), and has already proposed three additional broad exemption classes, *see* 86 Fed. Reg.
37,988 (July 19, 2021).

27 ³¹ *See also* Compl. ¶¶ 168-176 and citations therein.

1 Under the prior rules, a petition for deregulation (i.e., to commercialize) required detailed
2 laboratory data and all prior field trial reports, required public notice and comment, as well as
3 NEPA assessment. *See* 7 C.F.R. § 340.6 (2020). The Revised GE Rule replaces this system with a
4 perfunctory status review process that makes do with “much less information” and specifically
5 “with no requirement for laboratory or field-test data.”³² AR621; *see* 7 C.F.R. § 340.4.

6 Crucially, a GE developer need not submit *any* laboratory or field data to USDA, nor is
7 there any guaranteed process for public input, NEPA review, or ESA consultation, until and unless
8 USDA decides that such processes are applicable. Instead, USDA can—and has already—deregulate
9 a GE crop and authorize its commercialization if it determines based on the initial review that that
10 the proposed GE crop “would [not] pose an increased plant pest risk relative to the plant pest risk
11 posed by the respective non-GE or other appropriate comparator.” 7 C.F.R. § 340.4(b)(1). Thus,
12 developers can commercialize GE crops without having to submit any real-world data on impacts.

13 *The 2020 EIS*

14 USDA did a similar reversal in the 2020 EIS. Whereas the two previous EISs specifically
15 proposed broadening USDA’s regulatory scope to include the noxious weed authority—in fact the
16 2017 EIS identified this as the agency’s preferred alternative—the 2020 EIS mysteriously does not
17 even mention that alternative. *Compare* 2007 EIS at ES-4, 19-20 *with* AR703-30. Likewise, whereas
18 both prior EISs named utilizing the PPA’s noxious weed authority as major part of the purpose
19 and need for the rulemaking, the 2020 EIS is entirely silent on that point. *Compare* 2007 EIS at ii
20 *and* 2017 EIS at ES-1 *with* AR667.

22 ³² For example, using the new truncated process, USDA deregulated a GE potato after receiving a
23 28-page request, without any real-world planting data and without any public input. Under the
24 previous Part 340 Regulations, the deregulation of a GE potato required the same GE developer to
25 prepare a 199-page petition with laboratory and field trial data, and USDA itself prepared risk
26 assessments—and sought public comment on them—pursuant to the PPA and NEPA. *Compare* J.R.
27 Simplot Co., Request for a Regulatory Status Review for BG25 Potato (Sept. 24, 2021),
<https://www.aphis.usda.gov/brs/pdf/rsr/21-270-01rsr-review-submission.pdf> *with* J.R. Simplot
28 Co., Petition for Determination of nonregulated Status for Innate Potatoes (Mar. 28, 2014),
https://www.aphis.usda.gov/brs/aphisdocs/14_09301p.pdf.

1 The 2020 EIS also lacks any meaningful analysis of the Revised GE Rule’s deleterious
2 impacts. It readily admits the practical effect of the Revised GE Rule is that most GE crops would
3 be field tested and commercialized without any oversight. *See* AR893 (explaining that GE
4 organisms exempted or deregulated under the new review “may be field tested” without oversight),
5 AR988 (stating that exemptions are “outside of the Agency’s purview”). Yet, it is entirely silent on
6 the direct, indirect, and cumulative impacts of the Rule’s broad exemptions and cursory review.
7 Instead, USDA simply asserted that the environmental impacts of “regulatory decisions and
8 actions taken in the future would be evaluated ... on a case-by-case basis, ... as appropriate.”
9 AR881. Similarly, USDA acknowledged that “individual decisions made during implementation
10 of the revised regulation could potentially impact [threatened and endangered] species[.]” AR1028.
11 USDA claimed that individual decisions under the regulations will receive ESA analysis, but at the
12 same time admits “[i]t is impossible to predict all varieties of GE organisms that may be submitted
13 to APHIS in the future” given the GE Revised Rule’s exemptions. AR1025, 1028.

14 As a result of the Revised GE Rule, developers can test and commercialize most new GE
15 crops without the need to notify, let alone obtain approval, from USDA. And for those GE crops
16 that still fall within USDA’s purview, developers can and already have released them from any
17 further governmental regulation without any real-world data. Because of USDA’s drive-by
18 “nothing-to-see-here, move-along” approach, GE crops—including those similar to ones that have
19 caused significant harms to U.S. agriculture and the environment—can for the first time be planted
20 without any reporting to or oversight by USDA, increasing the risk of transgenic contamination,
21 the associated harms from the increased herbicide use on these unregulated herbicide-resistant
22 crops, and hastening the development of herbicide-resistant weeds,³³ among other future risks.

23 STANDARD OF REVIEW

24 Summary judgment is appropriate if there is no genuine issue of material fact, and the
25 moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v.*

26
27 ³³ *See also* Compl. ¶¶ 177-194.

1 *Catrett*, 477 U.S. 317, 322-23 (1986). Under the APA, a court must “hold unlawful and set aside”
 2 agency decisions that are “arbitrary, capricious, an abuse of discretion, or otherwise not in
 3 accordance with law,” or adopted “without observance of procedure required by law.” 5 U.S.C.
 4 § 706(2). In determining whether an action is “arbitrary and capricious,” courts evaluate whether
 5 the agency “examine[d] the relevant data and articulate[d] a satisfactory explanation for its action
 6 including a ‘rational connection between the facts found and the choice made.’” *Motor Vehicle*
 7 *Mfrs. Assoc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). An agency action is “arbitrary
 8 and capricious if the agency has relied on factors which Congress has not intended it to consider,
 9 entirely failed to consider an important aspect of the problem, offered an explanation for its
 10 decision that runs counter to the evidence before the agency, or is so implausible that it could not
 11 be ascribed to a difference in view or the product of agency expertise.” *Id.*

12 **ARGUMENT**³⁴

13 The Revised GE Rule is arbitrary and capricious, and contrary to the ESA, PPA, NEPA,
 14 and the 2008 Farm Bill. The Revised GE Rule’s “out of [over]sight, out of mind” regulatory
 15 framework violates the ESA, PPA, and NEPA in three major ways: (1) USDA failed to consider the
 16 impacts of the Revised GE Rule on ESA-protected species and the environment; (2) USDA failed
 17 to base its Revised GE Rule on science; and (3) USDA failed to implement its PPA noxious weed
 18 duty. Additionally, USDA unlawfully disregarded Congress’s directive in the 2008 Farm Bill. For
 19 all these reasons the Court should grant Plaintiffs’ summary judgment motion and vacate the rule.
 20
 21

22 ³⁴ Plaintiff member organizations have standing because the Revised GE Rule injures Plaintiffs’
 23 members’ professional, economic, health, aesthetic, recreational, and environmental interests.
 24 *Hunt v. Wash. State Apple Advert. Comm’n*, 432 U.S. 333, 342-43 (1977). *See* Donley Decl.; Burd
 25 Decl.; Buse Decl.; Newman Decl.; Freese Decl.; DiFrisco Decl.; Bentlage Decl.; Ritte Decl.;
 26 Redfeather Decl.; Hess Decl.; Limberg Decl.; Baumer Decl.; Krohn Decl.; Squire Decl.; Perls Decl.;
 27 Crouch Decl.; Griffith Decl.; Ishii Decl. (filed concurrently). Plaintiffs Center for Food Safety and
 28 Center for Biological Diversity also have standing because the Revised GE Rule has caused a
 “consequential drain” on their organizational resources. *Havens Realty Corp. v. Coleman*, 455 U.S.
 363, 379 (1982). *See* Donley Decl & Freese Decl.

1 I. **USDA Failed to Consider the Impacts on ESA-Protected Species and the Environment.**

2 A. **USDA Violated Section 7 of the ESA by Failing to Consult. (Claim 1)**

3 The ESA requires USDA to *ensure* the Revised GE Rule will not jeopardize imperiled
4 species. The ESA “reveals a conscious decision by Congress to give endangered species priority
5 over the ‘primary missions’ of federal agencies.” *Tennessee Valley Auth. v. Hill*, 437 U.S. 153, 185
6 (1978). In the ESA, Congress made it “abundantly clear that the balance has been struck in favor
7 of affording endangered species the highest of priorities.” *Id.* at 194.

8 Section 7, known as the “heart” of the ESA, *California ex rel. Lockyer v. U.S. Dep’t of Agric.*,
9 575 F.3d 999, 1018 (9th Cir. 2009), sets forth USDA’s consultation duties: *Before* issuing its rule,
10 USDA must determine whether its actions “may affect” any ESA-protected species or their critical
11 habitat, and if so, must consult with the other agencies Congress designated as having special
12 expertise in endangered species.³⁵ 16 U.S.C. § 1536(a); 50 C.F.R. §§ 402.14(a), 402.01(b). Strict
13 compliance with the ESA consultation *procedure* is integral to compliance with the statute’s
14 *substantive* “no jeopardy” requirements. *Thomas v. Peterson*, 753 F.2d 754, 764 (9th Cir. 1985).

15 USDA violated its core Section 7 duties, failing to consult with the expert wildlife agencies
16 in issuing its seismic new rule. 5 U.S.C. § 706(2)(A); *Karuk Tribe of California v. U.S. Forest Serv.*,
17 681 F.3d 1006, 1017 (9th Cir. 2012). First, contrary to their legal position, USDA actually *did*
18 make a “may affect” determination; it just violated Section 7 by failing to consult after so finding.
19 Specifically, USDA claimed the Revised GE Rule “in and of itself would not result in direct or
20 indirect impacts to threatened and endangered (T&E) species,” but then admitted “individual
21 decisions made during the implementation *could potentially* impact T&E species.” 2020 EIS at 7-8
22 (emphasis added), ES-27 (same). Disclaimer aside, USDA’s confession that the Revised GE Rule’s
23 implementation “could potentially impact” ESA-protected species constitutes by its plain language
24 and ordinary meaning a ‘may affect’ determination, triggering USDA’s duty to consult. *Karuk*
25 *Tribe*, 681 F.3d at 1027 (whether mining “may affect” endangered fish habitat could “almost be

26 _____
27 ³⁵ The agencies are FWS and the National Marine Fisheries Service (NMFS) (collectively FWS for
28 simplicity). *Id.* § 1536(a)(2); 50 C.F.R. §§ 402.14(a), 402.01(b).

1 resolved as a textual matter” because “[i]f the phrase ‘might cause’ disturbance of fisheries habitat
2 is given an ordinary meaning, it follows almost automatically that mining pursuant to the approved
3 NOIs ‘may affect’ critical habitat of the coho salmon.”).

4 Notably the “may affect” triggering consultation is a “low threshold.” *Karuk Tribe*, 681 F.3d
5 at 1027. “Any possible effect,” including those “of an undetermined character” leads to consultation.
6 *Karuk Tribe*, 681 F.3d at 1027 (quotation marks omitted) (emphasis added). The potential effects
7 an agency must consider are broad, including “direct” and “indirect” effects of the action and all
8 “interrelated or interdependent” activities. 50 C.F.R. § 402.02. A controversial rule change of this
9 magnitude—significant deviations to decades of GE crop regulation, including completely
10 exempting some and decreasing oversight dramatically on the rest; a rule covering all U.S.
11 agriculture, millions of acres of farmland and all future GE crops—easily surpasses this low bar as a
12 matter of law and common sense. *W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 496 (9th
13 Cir. 2011) (“The sheer number of acres affected by the 2006 Regulations and number of special
14 status species who reside on those lands alone suggest that the proposed amendments ‘may affect’
15 a listed species or its critical habitat.”).

16 Second, nor can USDA pass the buck to a later implementation stage simply because this is
17 a rulemaking, not an individual GE crop approval or license. It is well settled that the ESA’s
18 consultation duty applies to “any action authorized, funded, or carried out” by USDA. *Pac. River*
19 *Council v. Thomas*, 30 F.3d 1050, 1054 (9th Cir. 1994) (quoting 16 U.S.C. § 1536(a)(2)) (emphasis
20 in original). ESA regulations specify that “the promulgation of regulations” is an agency action that
21 may trigger the duty to consult. 50 C.F.R. § 402.02. That is why, whatever may come later, courts
22 have repeatedly confirmed that a programmatic action, such as the issuance of the Revised GE
23 Rule here, independently triggers an agency’s ESA duty to consult in the first instance. *Cottonwood*
24 *Envtl. Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075, 1082 (9th Cir. 2015) (explaining potential
25 consultation on subsequent individual projects does not alleviate the defendant Forest Service’s
26 duty to consult on the programmatic level); *Citizen for Better Forestry v. USDA*, 481 F. Supp. 2d,
27 1059, 1095 (N.D. Cal 2007) (“The Ninth Circuit has undeniably interpreted ESA to require

1 consultation on programmatic actions and rules.”); *Pac. River Council*, 30 F.3d at 1055 (holding
2 that programmatic documents constituted agency action triggering ESA consultation because they
3 “set forth criteria” for future activities.).

4 And consultation on the Revised GE Rule is particularly critical because, as explained *supra*
5 pp. 11-14, in many cases, there will be nothing to which to pass the buck, even if it were lawful to
6 so pass, because *there will be no later individual action upon which to consult and assure no jeopardy to*
7 *endangered species*. If a GE crop falls within one of the exemption categories under the Revised GE
8 Rule, it can be commercialized and planted with zero USDA input, even if its cultivation “may
9 affect” ESA-protected species, as there now is no USDA “action” to trigger consultation duties.

10 For example, FWS previously concluded that GE creeping bentgrass—which escaped field
11 trials and spread uncontrollably—could jeopardize the existence of three endangered species and
12 adversely affect dozens of others. *See supra* p. 5. Yet FWS only prepared the ESA Biological
13 Opinion because the GE developer had to petition USDA to deregulate the GE grass, and USDA
14 had to take agency action on it. In contrast, under the Revised GE Rule, there is nothing to stop a
15 GE developer from engineering its own creeping bentgrass for the same resistance to glyphosate
16 using the same mechanism, “self-determine” its approval, and commercialize it without any ESA
17 consideration.

18 Beyond that example, the history of GE crops makes abundantly clear that there are many
19 pathways for a GE crop to potentially injure our nation’s imperiled species, pathways USDA has
20 now decided in its discretion not to regulate under the Revised GE Rule’s narrow scope. *See supra*
21 pp. 2-11. USDA admitted that the Revised GE Rule, when implemented, “could potentially
22 impact” ESA-protected species, but still refused to consult, violating the heart of the ESA.

23 B. USDA Also Violated NEPA by Failing to Consider the Revised GE Rule’s
24 Reasonably Foreseeable Impacts. (Claim 2)

25 Just as USDA unlawfully avoided consulting on the Revised Rule’s potential endangered
26 species’ impacts, USDA also violated NEPA’s directive that USDA consider the environmental
27 effects of the Revised GE Rule *before* its implementation. *Lands Council v. Powell*, 395 F.3d 1019,

1 1026 (9th Cir. 2005) (NEPA requires agencies to “carefully weigh environmental considerations ...
2 *before* the government launches any major federal action.”) (emphasis added). The environmental
3 effects USDA must consider under NEPA is broad, and includes “indirect effects, which are
4 caused by the action and are later in time or farther removed in distance, but are still reasonably
5 foreseeable,” as well as direct and cumulative effects. *Id.* §§ 1508.7; 1508.8; 1508.27(b)(7). NEPA
6 demands USDA take a “hard look” at these effects. *Metcalf v. Daley*, 214 F.3d 1135, 1141 (9th Cir.
7 2000) (quoting *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 348 (1989)); *Pac. River*
8 *Council*, 689 F.3d at 1026 (“hard look” test applies to programmatic rulemaking analyses).

9 The 2020 EIS failed NEPA’s “hard look” test because USDA entirely failed to analyze the
10 Revised GE Rule’s effects. USDA simply kicked any analysis down the road to future regulatory
11 actions. AR881. But there *are no* guaranteed future actions for the majority of future GE crop
12 plantings under USDA’s new “non-regulation” scheme: most GE crops will be exempted based on
13 developers’ self-determinations, and as USDA acknowledged, will not trigger NEPA analysis.
14 AR637 (“APHIS will not complete a NEPA analysis for [any exempted GE] plant.”).

15 Nor is there any guaranteed trigger for NEPA review even for the GE crops still regulated.
16 AR637 (stating opaquely that under the new review process, “only some outcomes will require
17 [NEPA] analysis.”). In fact, since the Revised GE Rule’s effective date, USDA has not conducted
18 *any* NEPA analysis for any of the GE crops approved under the new cursory process.³⁶ USDA’s
19 promise that the direct, indirect, and cumulative impacts of the Revised GE Rule will be reviewed
20 in future regulatory decision rings decidedly hollow, and its lack of impacts analysis in the 2020
21 EIS violates NEPA.

22
23
24 ³⁶ To Plaintiffs’ knowledge, five GE crops have been deregulated under the new procedure by
25 submitting cursory applications without any field trial data, and without any NEPA or ESA review.
26 USDA, Regulatory Status Review Table,
27 <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/rsr-table/rsr-table>
28 (last visited Dec. 6, 2022). And there is no way to know how many new GE crops have already
been “self-determined” ready to be experimented on in open air field trials or be commercialized
by developers without any USDA or public notice.

1 **II. The Revised GE Rule Violated the ESA's and PPA's Science Mandates. (Claims 1 and 3)**

2 Both ESA and PPA require that the Revised GE Rule be based on accurate and reliable
3 scientific data. The ESA commands USDA apply the “best scientific and commercial data
4 available” in making its ESA determination. 16 U.S.C. § 1536(a)(2). The ESA’s “best science”
5 mandate “prohibits [an agency] from disregarding available scientific evidence that is in some way
6 better than the evidence [it] relies on.” *Kern Cty. Farm Bureau v. Allen*, 450 F.3d 1072, 1080 (9th
7 Cir. 2006). Instead, agencies “must support their conclusions with accurate and reliable data.”
8 *Conservation Congress v. Finley*, 774 F.3d 611, 620 (9th Cir. 2014). The PPA too commands that
9 USDA’s “decisions ... shall be based on sound science.” 7 U.S.C. § 7701(4); 7 U.S.C. §§ 7711(b),
10 7712(b). The sound science mandate requires USDA to “conduct[] various scientific studies and
11 analyses which the agency expressly relied upon, analyzed, and discussed in reaching its
12 conclusion.” *Cactus Corner, LLC v. USDA*, 346 F. Supp. 2d 1075, 1117-18 (E.D. Cal. 2004).

13 USDA’s Revised GE Rule fails the statutorily mandated scientific rigor, in three critical
14 ways. First and most fundamentally, the Revised GE Rule is without scientific support because, as
15 discussed *supra* pp. 11-14., USDA (1) *deferred* any analysis of the Rule’s impacts until its
16 implementation, and then (2) *eliminated* any meaningful data review at the implementation stage.
17 Exempted GE crops are shielded entirely, while non-exempt GE crops receive only cursory review,
18 without any real-world data. This “leaping-without-looking” decision-making lacks any scientific
19 support, let alone the best and soundest scientific support needed to pass muster.

20 Second, USDA’s decision to exempt broad GE crop categories from any further oversight
21 and to reduce the scope of review for those remaining defied the recommendations of the
22 Academy that USDA solicited (and repeatedly referenced in its Revised GE Rule explanation), as
23 well as contradicted USDA’s own prior scientific conclusion. Both the Academy and USDA’s own
24 decade-plus of analysis concluded that to adequately address the multitudes of risks associated with
25 GE crops, USDA should expand its regulatory authority to regulate *more*, not *less*, GE crops.
26 Specifically, the Academy, the gold standard of U.S. science, urged USDA to regulate *all* GE crops.
27 AR20515 (arguing that “transformation” (i.e., genetic engineering) “is both a useful and logical

1 justifiable regulatory trigger), 20519 (concluding, after noting that many products of genetic
2 engineering may not carry significant risks, that nonetheless “there is a scientific basis to
3 examining *all* genetically engineered crops.”) (emphasis added). USDA repeatedly reached the
4 same conclusion: advances in biotechnology require the agency expand its regulatory purview. *See*
5 2007 EIS at 21; 2017 EIS at ES-4; AR1797 (proposing revisions so that that would “a broader
6 range of GE organisms [would be] required to come in for review.”).

7 Yet, USDA did just the opposite: broadly exempting most GE crops from review, even
8 allowing developers to self-determine if their GE products are exempt. And reducing oversight for
9 GE crops still subjected to USDA’s review, eliminating the need for any field trial data. Critically,
10 the Academy had concluded that “there is no scientific basis” to exempt any GE crops without at
11 least an initial review of the interactions between the “trait, organism, and the environment.”
12 AR20515. But USDA *eliminated this very analysis*, exempting GE developers from having to submit
13 field trial studies showing how the GE organisms and engineered trait interacts in the real world.
14 AR631 (explaining that under the Revised GE Rule, “there is no requirement that developers
15 submit field-trial data to APHIS.”); AR20447 (the Academy emphasizing that USDA should assess
16 GE Crops based on “criteria specific to the regulated article and the environments to which it
17 could be exposed.”); *see supra* pp. 11-14.

18 The exemptions too, elude best/sound science. The Revised GE Rule exempts GE crops
19 from review if they could have been developed via conventional breeding, 7 C.F.R. § 340.1(b)(1)-
20 (3), but the Academy specifically *rejected* this rationale, because it found that both traditional
21 breeding and genetic engineering carry unknown risks, and thus there is no scientific basis for
22 USDA to exempt GE crops from any regulatory review solely because the same crop could have
23 been produced via traditional breeding methods.³⁷ AR20485. The other exemption, the plant-trait-

24
25 ³⁷ For example, a GE developer engineered *Nicotinia attenuatum*, a tobacco relative, to be more
26 susceptible to fungal infection under the “could have been created via conventional breeding”
27 exemption, even though increased susceptibility to fungal diseases falls squarely within USDA’s
28 plant pest authority. USDA, Confirmation Letter to Ian T. Baldwin (June 10, 2021) (confirming

1 mechanism of action exemption, similarly ignores that Academy’s recommendation that USDA
2 analyze the interactions between the specific GE organism and the environment.³⁸ See AR20515.

3 Third and finally, USDA’s failure to incorporate its noxious weed authority was
4 scientifically unsound. In 2017 USDA emphasized that “*the best available science*” compelled the
5 agency to incorporate its noxious weed authority into the regulations AR1794 (emphasis added).
6 Now USDA inexplicably claims that it can continue to assess the potential weediness of a GE
7 plant using its preexisting approach, on a case-by-case basis, rather than analyzing their noxious
8 weed risks as part of the default assessment, AR635, but nothing in the Revised GE Rule or its
9 supporting documentation points to any new analysis or data demonstrating how maintaining the
10 status quo of not considering a GE crop’s noxious weed risks is more scientifically sound. USDA’s
11 failure to incorporate the PPA’s noxious weed authority contradicts what the agency claimed to be
12 the best available science, as well as the Academy’s expert opinion. And as detailed below, USDA
13 failed to provide any meaningful justification for its sudden change of heart. See *infra* pp. 22-27.

14 III. USDA’s Unexplained Reversal Violated the PPA and NEPA.

15 A. USDA’s Failure to Incorporate Its Noxious Weed Authority Violated the PPA. 16 (Claim 3).

17 In issuing the Revised GE Rule, USDA failed to utilize its broader noxious weed authority,
18 in contravention to the PPA’s clear statutory command and USDA’s prior interpretation of its

19 GE plant qualifies for exemption under 7 C.F.R. §340.1(b)(1)); 7 C.F.R. § 340.3 (definition of
20 “plant pest risk” includes “the potential for exacerbating the impact of a plant pest”).

21 ³⁸ For example, USDA exempted a GE soybean engineered to withstand a class of herbicides
22 known as HPPD inhibitors based on two previous GE soybean varieties. However the prior two
23 varieties were resistant to *one* HPPD inhibitor; the newly exempted GE soybean can withstand *at*
24 *least five different* HPPD inhibitor herbicides. Yet USDA never assessed the implications of this
25 broader resistance. USDA, Confirmation Letter to Dror Shalitin, Ph.D (December 28, 2021)
26 (confirming plant-trait-mechanism of action exemption and citing prior deregulated petitions 09-
27 328-01p and 12-215-01p). USDA, Determination of Nonregulated Status for Bayer Event FG72
28 Soybean (Petition No. 09-328-01p) (Aug. 13, 2013),
https://www.aphis.usda.gov/brs/aphisdocs/09_32801p_det.pdf; USDA, Determination of
Nonregulated Status for Syngenta and Bayer Double Herbicide-Tolerant SYHT0H2 Soybean
(Petition No. 12-215-01p) (July 17, 2014),
https://www.aphis.usda.gov/brs/aphisdocs/12_21501p_det.pdf.

1 statutory duty. *See supra* pp. 9-14. Congress specifically broadened and strengthened USDA’s
2 authority with the PPA of 2000, including noxious weed harms, leaving USDA’s Part 340
3 regulations in need of the update that USDA painstakingly undertook for 15 years but then
4 suddenly dropped. *See id.* USDA entirely failed to explain why maintaining the existing noxious
5 weed regulations—which, as past history shows, means that for nearly all GE crops the noxious
6 weed risks go unassessed and *none* have ever been regulated³⁹—is better than subjecting all GE
7 crops to some noxious weed risk assessment, the position USDA had maintained since 2004. This
8 was arbitrary and capricious. *Organized Village of Kake v. USDA*, 795 F.3d 956, 966 (9th Cir. 2015)
9 (policy changes can be a reason for finding an action arbitrary and capricious).

10 For a change in agency policy to pass APA muster, the agency must show: (1) “awareness
11 that it is changing position”; that (2) “the new policy is permissible under the statute”; that (3) “the
12 agency believes [the new policy] to be better”; and that (4) there are “good reasons for the new
13 policy.” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009). And where an agency’s
14 new position disregards facts underlying its prior position, to demonstrate “good reasons” for the
15 change, the agency must provide “a more detailed justification than what would suffice for new
16 policy created on a blank slate.” *Id.* at 515. USDA failed to meet factors 2, 3, and 4. *See, e.g.*,
17 *California v. U.S. Dep’t of Interior*, 381 F. Supp. 3d 1153, 1165-66 (N.D. Cal. 2019) (finding that the
18 Department’s change of position in repealing regulations governing the payment of royalties on
19 oil, gas and coal extracted from federal and Indian land leases arbitrary and capricious).

20 As to the second factor, for more than a decade-plus USDA interpreted incorporation of
21 its noxious weed authority as necessary and proper to meet its statutory duties under the PPA. *See*
22 *supra* pp. 9-11. USDA made clear that it understood that in combining the Federal Plant Pest Act
23 and Federal Noxious Weed Act into the Plant Protection Act, Congress specifically directed
24 USDA to regulate *both* plant pest and noxious weed risks for the protection of U.S. agriculture,
25

26 ³⁹ In more than three decades of USDA’s regulation, in which USDA deregulated over 130 GE
27 crops, only one GE plant—Roundup Ready Kentucky Bluegrass, belonged to a taxon that was listed
28 as a federal noxious weed. *See* 7 C.F.R. § 361.1 (list of federal noxious weeds).

1 economy, and the environment. *See id.* And USDA admitted that its preexisting structure, with
2 plant pest risks and noxious weed risks analyzed through separate processes, was insufficient to
3 fulfill its statutory command. For example, USDA explained in the 2008 Proposed Rule that the
4 agency “needs to exercise” its noxious weed authority “[i]n order to best evaluate the risks
5 associated with these GE organisms and regulate them when necessary.” 73 Fed. Reg. at 60,0011.
6 USDA said again in 2017 that the agency considers it “necessary ... to evaluate GE plants for
7 noxious weed risk.” 82 Fed. Reg. at 7,010.

8 Yet USDA inexplicably abandoned this position now declaring it was not statutorily
9 required to combine the noxious weed and plant pest regulations. AR635. However the existence
10 of discretion does not authorize USDA to evade its duties under the PPA, and Congress
11 unequivocally directed USDA to, in its regulation of agricultural products, “reduce, to the extent
12 practicable, as determined by the Secretary, the risk of dissemination of plant pest or noxious
13 weeds.” 7 U.S.C. § 7701(3). Far from the “more detailed justification” required, *Fox Television*, 556
14 U.S. at 515, USDA offered exactly *zero* explanation as to why it is no longer necessary nor
15 practicable for the agency to combine the two regulatory schemes in order to fulfill its statutory
16 duty of protecting U.S. agriculture, environment, and the economy from both the plant pest and
17 noxious weed risks of GE crops. *See* 7 U.S.C. § 7701(1); *Nat’l Cable & Telecomms. Ass’n v. Brand X*
18 *Internet Servs.*, 545 U.S. 967, 981 (2005) (“an unexplained inconsistency is ... a reason for holding
19 an interpretation to be an arbitrary and capricious change from agency practice under the [APA].”) *”*
20 Instead, USDA simply stated that it would continue to maintain its preexisting approach, which,
21 as explained *supra*, meant that USDA basically *never* considers a GE crop’s noxious weed risks.
22 That is why USDA itself had interpreted the preexisting approach as insufficient to fulfill its PPA
23 duties since 2004. *See* 69 Fed. Reg. at 3,271; *supra* pp. 9-11.

24 USDA also failed to meet the third and fourth factors—that the agency believes the new
25 policy is better and provides good reasons for it. Other than gesturing to its discretion and stating
26 that it will continue with the status quo, USDA had zero explanation for why maintaining that
27 approach is “better.” In fact, it found just the opposite: the “best available science” *required* USDA

1 to incorporate noxious weed authority. AR1794; *see supra* pp. 9-11. It is not surprising there is no
 2 record comparison of whether using the preexisting Part 360 regulations would be better than
 3 incorporating the noxious weed authority in its regulatory revisions or why/how, because it is not.
 4 USDA also utterly failed to show that there are “good reasons” for not incorporating the noxious
 5 weed authority. Again the agency reached the *opposite* conclusion, explaining the existing
 6 standalone noxious weed regulations were inadequate to address the harms associated with current
 7 and future GE crops. 82 Fed. Reg. 7008, 7010 (pointing out that the listing of noxious weeds
 8 under 7 C.F.R. part 360 is by taxonomic groups but that “genetic engineering can ... enhance the
 9 weediness traits that are already present in a plant ... , there is a correspondingly higher risk that
 10 such a plant may be genetically engineered into a noxious weed.”); *id.* (describing existing noxious
 11 weed regulations, which did not differentiate between a GE crop and its non-GE counterpart, a
 12 “significant limitation” on the agency’s ability to assess GE crop risks).⁴⁰ USDA’s unexplained and
 13 unsupported failure to explain why the agency jettisoned its noxious weed authority in the Revised
 14 GE Rule is arbitrary and capricious, in violation of the PPA and the APA. *Motor Vehicles Mfrs.*
 15 *Ass’n*, 463 U.S. at 34 (explaining that an “agency changing its course must supply a reasoned
 16 analysis” for that change) (citation and internal quotation marks omitted)); *Kake*, 795 F.3d at 967,
 17 969 (finding APA violation where agency failed to provide reasoned explanation for policy
 18 change).

19 B. The 2020 EIS’s Stated Purpose and Need and Its Narrow Alternative Analysis
 20 Violated NEPA. (Claim 2)

21 As previously explained, USDA’s 2020 EIS falls short of the “hard look” NEPA demands
 22 because USDA played a shell game with its effects analysis, promising that the effects of the
 23 Revised GE Rule would be analyzed later, while stripping the agency (and the public) of the
 24 opportunity to engage in any future NEPA analysis. *See supra* pp. 11-14. But additionally, the 2020
 25 EIS also violates NEPA, because USDA improperly eliminated from the 2020 EIS’s purpose the

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 27 ⁴⁰ And as noted *supra*, the Academy also urged USDA to evaluate each GE crop in each interaction
 28 with the environment, and not “general weediness characteristics.” *See supra* p. 7; AR20447.

1 need to update the Part 340 regulations to effectuate the PPA, and then failed to consider as a
2 reasonable alternative utilizing its noxious weed authority to regulate GE crops. Finally, even for its
3 remaining stated purpose—the fulfillment of USDA’s prior audit recommendations and
4 Congressional directive in the 2008 Farm bill, the 2020 EIS is still deficient, because neither of the
5 two considered alternatives—the Revised GE Rule or no action, (i.e., maintaining the preexisting
6 Part 340 regulations) would actually further these objectives.

7 First, whereas USDA’s earlier NEPA analysis specified as one the key purposes the need to
8 “align” its Part 340 regulations with the new, broader scope of the PPA, 2017 EIS at ES-1 , the
9 2020 EIS inexplicably drops this purpose, instead only identifying Congressional mandate in the
10 2008 Farm Bill, the findings of the NAS report and its two audits, as well as advances in
11 biotechnology as the purpose and need for revisions to the Part 340 regulations, AR667.⁴¹ USDA’s
12 ultimate failure to include the alignment of the regulations with the PPA as part of the purpose of
13 updating the Part 340 regulations—when such alignment was the *very genesis* of the rulemaking
14 history, directly following from the PPA’s passage in 2000—contradicts the agency’s consistent
15 interpretation of its own statutory duties, is unsupported by the record, and is unreasonable. *See*
16 *supra* pp. 9-11; *Westlands Water Dist. v. U.S. Dep’t of Interior*, 376 F.3d 853, 866 (9th Cir. 2004)
17 (purpose and need statements evaluated under a reasonable standard).

18 Second, missing from the 2020 EIS’s alternative analysis is an alternative that would
19 incorporate the PPA’s noxious weed authority into the Part 340 regulations. NEPA requires that
20 an EIS “rigorously explore and objectively evaluate all reasonable alternatives.” *Methow Valley*
21 *Citizens Council v. Regional Forester*, 833 F.2d 810, 815 (9th Cir. 1987). Incorporation of its noxious
22 weed authority was a primary objective in USDA’s prior rulemaking rounds, *see supra* pp. 9-11, and
23 USDA twice considered it in its earlier impact statements, even selecting it as the preferred

24 _____
25 ⁴¹ USDA also violated NEPA because the Revised GE Rule does not further the purposes that the
26 final rule *does* list. Namely, the 2008 Farm Bill and the two audits uniformly called on USDA to
27 *increase* oversight in order to stop transgenic contamination and agricultural market losses from it.
28 The Revised GE Rule undermines these purposes by dramatically decreasing protections, in some
cases completely deregulating future GE crops. *See supra* pp. 11-14.

1 alternative in the 2017 EIS. See 2007 EIS at ES-7; *supra* pp. 9-11. Yet USDA mysteriously dropped
2 the alternative entirely from consideration in the 2020 EIS. See *Muckleshoot Indian Tribe v. U.S.*
3 *Forest Serv.*, 177 F.3d 800, 813 (9th Cir. 1999) (holding that the Forest Service’s alternative analysis
4 inadequate, and stating that the court was “troubled” that the agency “failed to consider an
5 alternative that was more consistent with its basic policy objectives.”). Instead, the 2020 EIS only
6 presented two alternatives: maintaining the status quo, or adoption of the Revised GE Rule. The
7 2020 EIS’s illusory all-or-nothing comparison—missing the core option that USDA had repeatedly
8 considered and even favored—violates NEPA. See *‘Ilio’ulaokalani Coal. v. Rumsfeld*, 464 F.3d 1083,
9 1102 (9th Cir. 2006) (holding that the failure to consider other alternatives other than the
10 proposed action and no action unlawful).

11 **IV. USDA Violated Its 2008 Farm Bill Mandates.**

12 It took something extraordinary for Congress to add a specific section to the Farm Bill
13 ordering USDA to clean up its act: a GE crop contamination debacle that cost American rice
14 farmers over a billion dollars. See *supra* p. 9. Congress was unequivocal about the need for USDA
15 to improve its GE regulations. And Congress’s instructions were timely: USDA was right in the
16 middle of this rulemaking. The Revised GE Rule violates the 2008 Farm Bill’s overarching
17 mandate as well as Congress’s specific directives.

18 First, Congress’s mandate was clear: USDA was to consider “promulgat[ing] regulations to
19 improve the management and oversight of articles regulated under the [PPA].” 2008 Farm Bill, Tit.
20 X, § 10204(a)(2). And the context here matters: Congress was concerned with stopping harm to
21 American farmers from GE crop contamination. See *supra* pp. 3-9. Yet USDA decidedly failed to
22 improve its management and oversight in the Revised GE Rule. Rather than *increasing*
23 management and oversight, the Revised GE Rule significantly *reduces* what will be regulated by
24 USDA. See *supra* pp. 11-14. If left standing, the Revised GE Rule will worsen GE contamination
25 woes for American farmers, not improve protections. And as explained *supra*, USDA has no
26 meaningful explanation for abandoning its prior consistent interpretation of how it should
27 improve its regulatory oversight of GE crops in following Congress’s orders. See *supra* pp. 22-27.

1 Second, USDA failed to meet the 2008 Farm Bill’s specific directives. Congress directed
2 USDA “shall ... take action on each issue identified in the [Lessons Learned Report.]” 2008 Farm
3 Bill, Tit. X, § 10204(a)(1) (emphasis added). USDA had proposed very specific revisions to its GE
4 regulations to remedy the issues it identified in that report, and Congress’s directives in the 2008
5 Farm Bill closely tracked USDA’s proposals. Congress explained USDA “shall take actions that are
6 designed to enhance ... (1) the quality and completeness of records; (2) the availability of
7 representative samples; (3) the maintenance of identity and control in the event of an
8 unauthorized release; [and] (4) corrective actions in the event of an unauthorized release.”⁴² *Id.*

9 Contrary to USDA’s claims otherwise, the Revised GE Rule utterly fails to carry out the
10 proposed revisions from the Lessons Learned Report that Congress codified in the Farm Bill. The
11 Revised GE Rule includes a subsection titled “Record Retention, Compliance, and Enforcement,”
12 but as USDA itself readily admitted, the requirements largely mirror the previous rules and *did not*
13 *actually add* any additional recordkeeping nor inspection requirements. *See* AR19 (explaining “the
14 information requirements [for permits] would be very similar to those for current permits”); AR20
15 (explaining the inspection requirement “is *functionally the same* as the current one”) (emphasis
16 added); AR21 (explaining the reporting requirements are “drawn from the current regulations”).
17 Even though USDA previously recommended requiring developers to submit contingency and
18 corrective action plans as part of their experiment permit applications, the Revised GE Rule *did not*
19 *require them*. AR18416.⁴³ And again, even these small, unresponsive changes by USDA will only

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21 ⁴² As to (1), USDA had proposed in the Lessons Learned Report “*additional* recordkeeping
22 requirements” be added in its Part 340 revisions. AR18415. As to (2) and (3), the Lessons Learned
23 Report proposed rule revisions enabling USDA to quickly obtain physical evidence, such as
24 requiring developers to retain seed samples. AR18415-16. And as for (4), corrective actions in the
25 event of an unauthorized release, recognizing the insufficient response from developers in dealing
26 with GE contamination, USDA had proposed rule revisions to require a developers to submit
27 “contingency plan” to address GE contamination, and “a comprehensive, written correction action
28 plan” to remedy any incidents of GE contamination. AR18416.

⁴³ And even though the regulations did increase the length of time for record retention, even here
USDA strayed from its own prior position and *reduced* the length of time necessary from the
previous proposed 10 years to 5 years. *See* 82 Fed. Reg. at 7,028 (explaining in the 2017 Proposed

1 apply to a small subset of GE crop experiments now, since USDA otherwise has removed field trial
2 oversight entirely for most GE crops, *see supra* pp. 11-14. USDA’s failure to carry out Congress’s
3 command to increase GE oversight and implement the agency’s own proposed revisions in the
4 2008 Farm Bill is arbitrary and capricious and contrary to law. *Motor Vehicles Mfrs. Ass’n*, 463 U.S.
5 at 43 (“[A]n agency rule would be arbitrary and capricious if the agency ... entirely failed to
6 consider an important aspect of the problem, [or] “offered an explanation for its decision that runs
7 counter to the evidence before the agency.”).

8 **V. The Court Should Vacate the Revised GE Rule.**

9 The APA expressly provides that a reviewing court “shall ... hold unlawful and set aside
10 agency” actions found to be “arbitrary, capricious, an abuse of discretion, or otherwise not in
11 accordance with law; [or] without observance of procedure required by law.” 5 U.S.C. § 706(2)
12 (emphasis added). As such, vacatur and remand is the textual, default remedy for agency action
13 held unlawful, and thus Defendants, not Plaintiffs, carry the burden to show why another result,
14 such as remand without vacatur, is appropriate instead. *All. for the Wild Rockies v. U.S. Forest Serv.*,
15 907 F.3d 1105, 1121-22 (9th Cir. 2018).

16 The Ninth Circuit has authorized remand without vacatur only in “rare” or “limited”
17 circumstances, *Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 532 (9th Cir. 2015) (“limited
18 circumstances”); *Humane Soc’y of U.S. v. Locke*, 626 F.3d 1040, 1053 n.7 (9th Cir. 2010) (“rare
19 circumstances”), and only when the agency can show that “equity demands” a departure from the
20 presumptive remedy, *Pollinator*, 806 F.3d at 532 (emphasis added) (quoting *Idaho Farm Bureau Fed’n*
21 *v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995)). To determine if such “rare” circumstances are
22 present, courts “weigh the seriousness of the agency’s errors against the disruptive consequences of
23 an interim change that may itself be changed.” *Nat’l Family Farm Coal.*, 960 F.3d at 1144.
24 Defendants cannot carry their burden to prove that this is such a “rare” circumstance.

25
26
27 Regulations that in past investigations of transgenic contamination, it had been necessary for
28 USDA to require field trial data up to 10 years prior).

1 First, the “seriousness of the agency’s errors” weighs heavily in favor of vacatur because
 2 USDA’s failure to adhere to the requirements of NEPA and the ESA cut to the core of those two
 3 statutes, and the Revised GE Rule’s lack of any meaningful GE oversight eviscerates USDA’s
 4 duties under the PPA and directly contradicts Congress’s commands in the 2008 Farm Bill. *See*,
 5 *e.g.*, *Coal. to Protect Puget Sound Habitat v. U.S. Army Corps. of Eng’rs*, No. C16-0950RSL, 2020 WL
 6 3100829, at *3-5 (W.D. Wash. June 11, 2020) (failure to take hard look was serious NEPA
 7 violation warranting vacatur); *Nat’l Parks Conservation Ass’n v. Jewell*, 62 F. Supp. 3d 7, 20-22
 8 (D.D.C. 2014) (failure to consult under ESA Section 7 was serious error justifying vacatur).

9 Second, in environmental cases, the cognizable “disruptive consequences” are
 10 environmental: remand without vacatur may be proper where vacating a rule or decision would
 11 itself result in more harm to *the environment* or result in less protection; it is not warranted based
 12 on purely economic considerations. *Pollinator*, 806 F.3d at 532; *All. for the Wild Rockies*, 907 F.3d at
 13 1122 (vacatur “appropriate when leaving in place an agency action risks more environmental harm
 14 than vacating it”). Defendants cannot show any adverse environmental consequences from vacatur;
 15 to the contrary it is plainly the environmentally protective remedy. Finally, even if alleged
 16 economic consequences to developers could outweigh environmental safety, vacatur only returns
 17 GE crop regulation to the *status quo ante*, under which developers operated for decades prior. *Ctr.*
 18 *for Env’t Health v. Vilsack*, 2016 WL 3383954, at *12-13 (N.D. Cal. June 20, 2016) (vacating for
 19 failure to have notice and comment, holding that disruption to industry alone insufficient,
 20 “undermined by the fact that any prospective vacatur would put the industry in the same position”
 21 as it was before the challenged rule).

22 CONCLUSION

23 For the above reasons, Plaintiffs respectfully request this Court grant summary judgment in
 24 their favor and vacate the Revised GE Rule.
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1 Respectfully submitted this 6th day of December, 2022.

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