CENTER FOR FOOD SAFETY

September 29, 2014

Docket No. APHIS-2014-0056
Regulatory Analysis and Development
PPD, APHIS
Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

Comments on APHIS's Environmental Assessment for Field Release of Genetically Engineered Diamondback Moth (Docket No. APHIS-2014-0056)

To United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS):

Center for Food Safety submits the following comments on behalf of itself and its members in response to APHIS's Environmental Assessment for Field Release of Genetically Engineered Diamondback Moth, 79 Fed. Reg. 51299 (Aug. 28, 2014).[1]

CFS is a nonprofit, public interest advocacy organization dedicated to protecting human health and the environment by curbing the proliferation of harmful food production technologies and promoting sustainable agriculture. In furtherance of this mission, CFS uses legal actions, groundbreaking scientific and policy reports, books and other educational materials, and grassroots campaigns on behalf of its 500,000 farmer and consumer members across the country. CFS is a recognized national leader on the issue of genetically engineered (GE) organisms, and has worked on improving their regulation and addressing their impacts continuously since the organization's inception in 1997.

Dr. Anthony Shelton of Cornell University, on behalf of the British company Oxitec, has applied to APHIS for an environmental release permit to allow the field release of GE diamondback moth strains OC4319L-Pxy, OX4319N-Pxy and OX4767A-Pxy on release sites within the grounds of the Cornell University New York State Agricultural Experiment Station. These GE moth strains have been genetically engineered for repressible female lethality and to express red fluorescence as a marker. APHIS has conducted an Environmental Assessment (EA) prior to approving the permit. The EA concludes that the release of GE diamondback moths is unlikely to impact the physical, biological, and human health environment; that no cumulative impacts are anticipated; and that the release will have no effect on Threatened and Endangered Species or their designated habitat.

[1] CFS requested a thirty-day extension to the deadline for these comments, but did not receive a response from APHIS. We note that the thirty-day period included the Labor Day holiday weekend and the Jewish New Year holiday.

NATIONAL HEADQUARTERS
660 Pennsylvania Avenue, SE, Suite 302
Washington, D.C. 20003
T: 202-547-9359 F: 202-547-9429

CALIFORNIA OFFICE
303 Sacramento Street, 2nd Floor
San Francisco, CA 94111
T: 415-826-2770 F: 415-826-0507

PACIFIC NORTHWEST OFFICE
917 SW Oak Street, Suite 300
Portland, OR 97205
T: 971-271-7372 F: 971-271-7374

HAWAI`I OFFICE
1132 Bishop Street, Suite 2107
Honolulu, Hawaii 96813
T: 808-681-7688

office@centerforfoodsafety.org centerforfoodsafety.org

APHIS's EA is wholly inadequate and based on incomplete and inadequate science and analyses, lacks critical data and vital risk assessments, and ignores potential consequences and uncertainties. Its conclusions are erroneous and indicate APHIS's failure to properly evaluate the potential effects of this release as it is required to do under the National Environmental Policy Act (NEPA), Plant Protection Act (PPA), Endangered Species Act (ESA), and Migratory Bird Treaty Act (MBTA). The information included in the EA raises many questions, identifies significant data gaps, and indicates the potential for significant impacts, all of which warrant a full Environmental Impact Statement (EIS). In light of this, APHIS's failure to conduct an EIS would be arbitrary, capricious, an abuse of discretion, and would violate NEPA, the PPA, the ESA, and the MBTA.

Background: Oxitec and GE Insect Trials

Oxitec is a company developed by researchers from Oxford University, with close links to the multinational seed and agrochemical firm Syngenta.[2] The company's aim is to establish a new method of pest control through GE insects, including mosquitoes and agricultural pests such as diamondback moths.[3] From March 2009 to June 2011, Oxitec received research funding directly from Syngenta for genetic transformation of *Lepidoptera*, the insect order that includes the diamondback moth (*Plutella xylostella*).

Oxitec tried and failed to conduct the same trial for which it currently seeks APHIS approval in the United Kingdom in 2011 and 2012. In 2011, Oxitec sought to make open releases of GE diamondback moths in the U.K. under "contained use" regulations by claiming that its RIDL®[4] technology is equivalent to "biological containment."[5] These proposed releases were

[2] Oxitec. *Our Team*. Retrieved from http://www.oxitec.com/who-we-are/our-team/ (last accessed Sept. 29, 2014).

[3] Oxitec has been granted the patent EP1624749 ("Dilution of Genetic Traits"), which lists more than 50 species of insects it wishes to genetically modify. European Patent Register. *About this file: EP1624749*. Retrieved from https://register.epo.org/espacenet/application?number=EP04732350 (last updated Sept. 27, 2014). However, its main patent EP1690247 ("Expression systems for insect pest control") is still disputed by the European Patent Office. European Patent Register. *All documents: EP1649027*. Retrieved from https://register.epo.org/espacenet/application?number=EP04743590&lng=en&tab=doclist (last accessed Sept. 29, 2014). An earlier patent on the technology filed by Isis Innovation (the company which spun out Oxitec from Oxford University) appears to have lapsed. European Patent Register. *About this file: EP1246927*. Retrieved from https://register.epo.org/espacenet/application?number=EP00979774 (last updated Sept. 27, 2014).

[4] RIDL is the name that Oxitec gave to its genetic engineering technology. Oxitec. *RIDL Science*. Retrieved from http://www.oxitec.com/ridl-science/ (last accessed Sept. 29, 2014).

[5] Oxitec (2011b) Potential UK trial of "genetically sterile" (RIDL®) diamondback moth (Plutella xylostella). Powerpoint presentation to Health and Safety Executive (HSE) Scientific Advisory Committee on Genetic Modification (SACGM); Advisory Committee on Releases to the Environment (ACRE) (2011). Advisory Committee on Releases to the Environment: Minutes of the 134th Meeting of ACRE at Nobel

controversial and did not go ahead. GeneWatch, a U.K. organization with which CFS works closely, documented problems with the proposed releases. These problems have not yet been resolved. Since then, Oxitec has not submitted a formal application to make open releases of its GE moth into the environment in the U.K. or any country aside from the U.S. In effect, by applying for a release of its GE diamondback moth in the U.S., Oxitec is shopping for lax oversight.

As a U.K. company, Oxitec is obligated to file a transboundary notification with the Cartagena Protocol on Biosafety to the Convention on Biological Diversity prior to exporting GE diamondback moth eggs to the U.S. for open release.[6] This notification must include a prior, existing environmental risk assessment that meets European Union (EU) standards. GeneWatch has documented Oxitec's poor record of complying with environmental regulations, particularly the trans-boundary notification of exports of living GE organisms from the U.K. to other countries. GeneWatch found that important issues have been omitted from the relevant environmental risk assessments (ERAs) for export of Oxitec's GE mosquitoes; in some cases the ERA has not been supplied at all.[7] The U.S., as an observer to the meetings of the Cartagena Protocol, should not aid Oxitec in evading the requirements of the Protocol. Such behavior could result in the U.S. having even more limited access to the meetings of the Cartagena Protocol.

Oxitec has made a number of attempts to release GE agricultural pests in other countries, in addition to the open release experiments using Oxitec's GE *Aedes aegypti* mosquitoes that are

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House, London, Thursday, 1st December 2011. Retrieved from http://www.defra.gov.uk/acre/files/ACREMINUTES20111201.pdf; HSE (2011) Potential trial of 'genetically sterile' diamondback moth (Plutella xylostella). Minutes of Scientific Advisory Committee on Genetic Modification (Contained Use) 8th November 2011. With Annexes; HSE (2011) Letter to Oxitec. 5th December 2011. Obtained by GeneWatch UK as the result of a Freedom of Information request; Department for Environment Food and Rural Affairs (2012). *Letter to Camilla Beech, Oxitec Regulatory Manager*. Jan. 24, 2012. Obtained by GeneWatch UK following a Freedom of Information request; Wray, MW, Operations Director, Food & Environment Research Agency (FERA) (2012). Letter to Dr. Wallace and Mr. Riley. Apr. 19, 2012; GeneWatch UK and GM Freeze (2012) Plans for experiments with genetically modified diamondback moths and other GM insects; Wallace, H, Dir. GeneWatch UK. Letter to Rt Hon Caroline Spelman, MP, Secretary of State for the Environment, Food and Rural Affairs. Jan. 27, 2012; Spelman, C (2012). Letter from Rt Hon Caroline Spelman, MP, Secretary of State for the Environment, Food and Rural Affairs to GeneWatch UK. Feb. 25, 2012.

[6] Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32003R1946. The Cartagena Protocol, an additional agreement to the Convention on Biodiversity, entered into force on 11 September 2003. To date, 168 countries are Parties to the Protocol.

[7] Wallace HM (2013). *Genetically Modified Mosquitoes: Ongoing Concerns*. Third World Network. TWN Biotechnology & Biosafety Series 15. Retrieved from http://twnside.org.sg/title2/biosafety/bio15.htm; GeneWatch UK PR (2014*). Lack of risk assessment for GM mosquito experiments is negligent, says GeneWatch*. Feb. 12, 2014. Retrieved from http://www.genewatch.org/article.shtml?als[cid]=566989&als[itemid]=574224.

currently ongoing in Brazil and Panama.[8] So far no releases of GE agricultural pests have taken place other than the limited pink bollworm release in the U.S. (explained below). In 2013, Oxitec applied to release GE olive flies in Spain, but then withdrew its application following a request for further information from Spanish regulators. In 2014, the Brazilian regulator CTNBio approved experimental releases of Oxitec's GE Mediterranean Fruit Fly (Medfly). However, the company has yet to make the trans-boundary notification for export of GE mosquitoes as required by EU law, which requires a risk assessment that meets EU standards to be reviewed and accepted by the importer. The European Commission has notified Brazil that export of fruit contaminated with GE Medfly to the EU would be illegal under EU law and has sought further information about the steps Oxitec will take to ensure such exports do not happen.[9] The proposed releases of GE Medfly in Brazil have been delayed amid these concerns.

The release of GE diamondback moth for which Oxitec is currently seeking approval is unique in that, if approved, the proposed experiments would be the first to employ GE insects with a female-killing trait anywhere in the world. The GE mosquitoes being released in the Brazil and Panama experiments differ from Oxitec's GE moth in that both sexes of the GE mosquitoes are genetically engineered to die at the late larval/pupal stage. For Oxitec's GE moth, only the female insects are genetically engineered to die at the late larval stage; males will survive to adulthood. This is known as a "female-killing" approach.[10]

Further, the field trial of GE pink bollworm in the U.S. only assessed the dispersion of the GE insect, not the efficacy of the GE "kill switches" like those in the diamondback moth experiments. In that trial, open releases of a strain of Oxitec's GE pink bollworm, a cotton pest, were attempted in the Southwestern U.S. However, the strain used only the fluorescent trait, not

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[8] Notably, Oxitec did not comply with the Cartagena Protocol requirements (and the EU requirements) for Environmental Assessment before shipping their GE mosquitoes to Panama. *See* Email from Unknown to Helen Wallace, GeneWatch (Sept. 29, 2014).

[9] Communication from the Department of Food and Rural Affairs (Defra) to GeneWatch UK, in response to a request under the Environmental Information Regulations. Andre, Dorothee, Head of Unit, European Commission Health and Consumers Directorate-General, Safety of the Food Chain, Biotechnology. Letter to Dr. Wallace, Jun. 12, 2014.

[10] Morrison N, Alphey L. (2012) Genetically modified insects for pest control: an update. Outlooks on Pest Management 23(2):65–68; Martins S, Naish N, Walker AS, Morrison NI, Scaife S, Fu G, Dafa'alla T, Alphey L (2012) Germline transformation of the diamondback moth, Plutella xylostella L., using the piggyBac transposable element. *Insect Molecular Biology* 21(4): 414–421; Morison, NI, Martins, S, Naish, N, Walker, AS, Alphey, L (2011) Enhancement of the sterile insect technique using germ-line transformation technology. In: Srinivasan R, Shelton AM, Collins HL (Eds) Proceedings of the 6th International Workshop on Management of the Diamondback Moth and Other Crucifer Insect Pests. p.312-315. 21-25 March 2011. Kasetsart University, Kamphaeng Saen campus, Nakhon Pathom, Thailand. Retrieved from http://203.64.245.61/fulltext_pdf/EB/2011-2015/eb0170.pdf; Harvey-Samuel T, Ant T, Gong H, Morrison NI, Alphey L (2014) Population-level effects of fitness costs associated with repressible female-lethal transgene insertions in two pest insects. *Evolutionary Applications*, 7(5), 597–606; Jin L, Walker AS, Fu G, Harvey-Samuel T, Dafa'alla T, Miles A et al. (2013) Engineered Female-Specific Lethality for Control of Pest Lepidoptera. *ACS Synthetic Biology*. doi:10.1021/sb300123m.

the "early lethality" trait, and was made sterile using radiation. These experiments were halted, partly because of concerns raised by organic farmers about contamination of their crops by the GE insects.

The GE pink bollworm trials prompted a critical report by the USDA Office of Inspector General. This report argued that APHIS's controls over GE insect research were inadequate and that regulations needed to be strengthened.[11] The report also criticized APHIS's Center for Plant Health Science Technology (CPHST) for spending about $550,000 on developing GE plant pests such as the pink bollworm, the Mediterranean fruit fly, and the Mexican fruit fly (in collaborations with Oxitec) without any formal process for selecting which projects would receive funding. APHIS accepted the report's recommendations, which included clarifying its role, drafting specific GE insect regulations, and making research funding decisions more transparent. However, APHIS appears to have made no attempt to draft specific regulations. Scientists at the Max Planck Institute also found the Environmental Impact Statement (EIS) that APHIS published for the GE pink bollworm trials in 2008 to be "scientifically deficient."[12] The scientists reported that the EIS reversed an earlier, more cautious view published by APHIS in 2001, yet failed to provide the substantial body of evidence required to back up its assertions. Alarmingly, this "scientifically deficient" 2008 EIS and later APHIS reports made under the framework criticized by the USDA Office of Inspector General are cited and relied upon throughout the current EA.[13]

The novel and unique nature of the traits that Oxitec now seeks to test make it particularly important for APHIS to conduct a thorough NEPA analysis and expose Oxitec's proposal to detailed independent scrutiny. Despite the unprecedented nature of its proposed action, APHIS is attempting to avoid undertaking the legally-required, rigorous, and overarching analysis of the GE diamondback moth, or the foreseeable consequences of its release.

Regulatory Framework

As an initial matter, APHIS does not have regulations specific to GE insects and animals. This is so despite the fact that APHIS agreed to the USDA Inspector General's recommendation that it develop a regulatory framework that covers the scope and coverage of GE animals and insects. In 2002, the National Academy of Sciences published a report on GE animals stating that aquatic organisms and insects present the greatest environmental concerns because their mobility

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[11] USDA Office of Inspector General, *Controls over Genetically Engineered Animal and Insect Research* (May 31, 2011), *available at* http://www.usda.gov/oig/webdocs/50601-16-TE.pdf.

[12] Reeves, R.G. et al. (2012) Scientific Standards and the Regulation of Genetically Modified Insects. PLoS Neglected Tropical Diseases, 6(1), p.e1502. Retrieved from http://www.ploscollections.org/article/info%3Adoi%2F10.1371%2Fjournal.pntd.0001502;jsessionid=C3DC4FD 0650E395B0FD63D275A9703B5#pntd-0001502-g001.

[13] This report is cited some 20 times in the Enviromental Assessment on the GE diamondback moth, despite being soundly criticized by the USDA's own Inspector General. USDA-APHIS (2008) "Use of Genetically Engineered Fruit Fly and Pink Bollworm in APHIS Plant Pest Control Programs: Final Environmental Impact Statement." Riverdale, MD.

poses serious containment problems, and because they easily can become feral and compete with indigenous populations.[14] The report expressed concerns about gaps in regulation. In 2004, the Pew Initiative on Food and Biotechnology published a report on gaps in the regulatory system for GE insects in the U.S., and a report of a workshop on the issues.[15] A central finding of the report was that there are gaps in the current regulatory framework to review the many issues raised by the potential introduction of GE insects into wild populations. There is no specific regulation on the release of GE insects, no law that clearly covers all the risks and all of the types of GE insects and no single regulatory body: USDA, the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) could all play a role.[16]

Despite the criticism in the Pew report and the 2011 USDA Office of Inspector General Report cited above, APHIS appears willing to proceed with consideration of an application without addressing these widely held concerns, or consulting with other agencies that have overlapping regulatory authority.[17]

In the absence of a coherent regulatory framework or any published guidance on how to assess the risks of open releases of GE insects in the U.S., it is worth noting that the European Food Safety Authority (EFSA) has published guidance for environmental risk assessment under the EU's Deliberate Release Directive for genetically modified organisms (GMOs), although this does not yet cover the important area of food safety assessment. The EFSA Guidance outlines the evidence that Oxitec would need to provide for its GE insects to be placed on the EU market.[18] The EFSA Guidance provides details on the following specific areas of risk for GE insects:

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[14] National Academy of Science (2002). Animal Biotechnology: Science Based Concerns. Committee on Defining Science-Based Concerns Associated with Products of Animal Biotechnology, Committee on Agricultural Biotechnology, Health, and the Environment, National Research Council. ISBN: 0-309-50218-7, 201 pages. *Available at* http://www.nap.edu/catalog/10418.html.

[15] Pew Initiative on Food and Biotechnology (2004). Bugs in the System? Issues in the science and regulation of genetically modified insects (Washington, DC, Pew Initiative on Food and Biotechnology). *Available at* http://www.pewtrusts.org/our_work_report_detail.aspx?id=17984; Biotech Bugs. Proceedings from a conference sponsored by the Pew Initiative on Food and Biotechnology, Sept. 20-21, 2004, Washington D.C.

[16] FDA is also considering approval of an Oxitec product, a GE mosquito to help limit the spread of the dengue fever virus. FDA has a guidance that controls its oversight, which includes public meetings before approval. FDA Consumer Health Information. *Regulation of Genetically Engineered Animals*. July 2010. Retrieved from http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048106.htm. APHIS should also hold public meetings before approval of any GE animals, including insects.

[17] USDA-APHIS, *Proposal to Permit the Field Release of Genetically Engineered Diamondback Moth in New York, Environmental Assessment* 7-8 (May 2014) [hereinafter "EA"] (noting FDA and EPA have not reviewed the permit).

[18] European Food Safety Authority (2013). *Guidance on the environmental risk assessment of genetically modified animals* (EFSA Guidance). EFSA Journal 2013;11(5):3200 [190 pp.]. Retrieved from http://www.efsa.europa.eu/en/efsajournal/pub/3200.htm. Placing on the market means making available to third parties, whether in return for payment or free of charge.

- Persistence and invasiveness of GE insects, including vertical gene transfer (VGT);
- Horizontal gene transfer;
- Pathogens, infections and diseases;
- Interactions of GE insects with target organisms;
- Interactions of GE insects with non-target organisms (NTOs);
- Environmental impacts of the specific techniques used for the management of GE insects;
- Impacts of GE insects on human and animal health.[19]

As mentioned above, although the U.S. is not a Party to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Oxitec—as a U.K. company—is still obliged to make a trans-boundary notification compliant with the Protocol under Regulation 1946/2003/EC prior to exporting GE diamondback moth eggs to the U.S. for open release. This notification must include a prior, existing environmental risk assessment that meets EU standards. Thus the EFSA Guidance is of more than academic interest in the context of the current application, and obligates APHIS to be sure that its EA meets the EFSA standards.

Plant Protection Act

APHIS oversees plant pests, including transgenic plant pests, pursuant to the Plant Protection Act (PPA).[20] The PPA provides USDA and APHIS, specifically, with broad authority to "prohibit or restrict . . . movement in interstate commerce of any plant" as necessary to prevent either "plant pest" or "noxious weed" harms, including the agronomic and environmental harms of GE plants and insects.[21] The statute's multifaceted purpose is to protect not only agriculture, but also the "environment, and economy of the United States" through the "detection, control, eradication, suppression, prevention, or retardation" of these harms.[22] Pursuant to the PPA, all of APHIS's decisions "shall be based on sound science."[23]

The PPA and APHIS regulations under 7 C.F.R. Part 340, by their plain language, provide APHIS with ample discretion to address GE moth harms as plant pest risks. The PPA defines "plant pest" as "any living stage [of a list of organisms] that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product."[24] The PPA's plant pest

[19] *Id.* at 73-107.

[20] 7 U.S.C. §§ 7701-7772.

[21] *Id*. § 7712(a).

[22] *Id*. § 7701(1).

[23] *Id.* §§ 7701(4), 7711(b), 7712(b).

[24] *Id*. § 7702(14).

harm definition includes "any living stage" of organisms that can "directly or indirectly injure, cause damage to, or cause disease in any plant or plant product."[25] The PPA places no restriction on how such damage may occur. GE moths may present significant harms to agriculture, the environment, and the economy, the protection of which is the PPA's overarching purpose.[26]

National Environmental Policy Act

NEPA is "our basic national charter for protection of the environment."[27] NEPA emphasizes the importance of comprehensive environmental analysis to ensure that federal agencies make informed decisions, and requires federal agencies to assess the environmental consequences of their actions before those actions are undertaken. NEPA "ensures that the agency . . . will have available, and will carefully consider, detailed information concerning significant environmental impacts; it also guarantees that the relevant information will be made available to the larger [public] audience."[28]

NEPA also established the Council on Environmental Quality (CEQ).[29] The regulations subsequently promulgated by CEQ[30] implement the directives and purpose of NEPA, and "[t]he provisions of [NEPA] and [CEQ] regulations must be read together as a whole in order to comply with the spirit and letter of the law."[31] CEQ's regulations are applicable to and binding on all federal agencies.[32] Among other requirements, CEQ's regulations mandate that federal agencies address all "reasonably foreseeable" environmental impacts of their proposed programs, projects, and regulations.[33] This must include analyses of direct, indirect, and cumulative effects.[34] The assessment must be a "hard look" at the potential environmental impacts of its action.[35]

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[25] *Id.*; *see also* 7 C.F.R. § 340.2.

[26] 7 U.S.C. § 7701(1).

[27] 40 C.F.R. § 1500.1(a).

[28] *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 349 (1989) (emphasis added).

[29] *See* 42 U.S.C. §§ 4321, 4344.

[30] 40 C.F.R. §§ 1500-1508.

[31] *Id.* § 1500.3.

[32] *Id.* §§ 1500.3, 1507.1; *see, e.g., Hodges v. Abraham*, 300 F.3d 432, 438 (4th Cir. 2002).

[33] *See* 40 C.F.R. §§ 1502.4, 1508.8, 1508.18, 1508.25.

[34] *See id.* §§ 1508.8, 1508.9, 1508.13, 1508.18.

[35] *Blue Mountains Biodiversity v. Blackwood*, 161 F.3d 1208, 1211 (9th Cir. 1998); *Nat'l Parks & Conservation Ass'n v. Babbitt*, 241 F.3d 722, 731 (9th Cir. 2001) (quoting 40 C.F.R. § 1508.27).

NEPA requires federal agencies, including APHIS, to prepare an EIS for all "major Federal actions significantly affecting the quality of the human environment."[36] In other words, if the action may significantly affect the environment, APHIS must prepare an EIS.[37] As a preliminary step, an agency may prepare an EA to determine whether the environmental impact of the proposed action is significant enough to warrant an EIS.[38] "An environmental assessment is a 'concise public document' that '[b]riefly provide[s] sufficient evidence and analysis for determining whether to prepare an [EIS] or a finding of no significant impact.'"[39] If an EA establishes that the agency's action may have a significant effect upon the environment, the agency must prepare an EIS.[40] An EIS serves different purposes from the EA already prepared by APHIS.[41] "An EA aims simply to identify (and assess the 'significance' of) potential impacts on the environment." An EIS, on the other hand, balances "different kinds of positive and negative environmental effects, one against the other" and "weighs negative environmental impacts against a project's other objectives."[42] "Preparation of an EIS thus ensures that decision-makers know that there is a risk of significant environmental impact and take that impact into consideration."[43] APHIS' decisions must be "complete, reasoned, and adequately explained."[44]

Here, APHIS has concluded that its proposed action will not significantly affect the environment, and has thus prepared only an EA.

Endangered Species Act

Under § 7(a)(2) of the Endangered Species Act (ESA), federal agencies must ensure, in consultation with the National Marine Fisheries Service (NMFS) or the Fish and Wildlife Service (FWS), that their actions will not jeopardize the survival and recovery of listed species or their habitat. Section 7(a)(2) imposes both procedural and substantive obligations.

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[36] 42 U.S.C. § 4332(2)(C).

[37] *Steamboaters v. FERC*, 759 F.2d 1382, 1392 (9th Cir. 1985); *Idaho Sporting Cong. v. Thomas*, 137 F.3d 1146, 1150 (9th Cir. 1998) (citation omitted).

[38] *See* 40 C.F.R. § 1508.9.

[39] *Id*. § 1508.9(a); *Anderson v. Evans*, 371 F.3d 475, 488 (9th Cir. 2004).

[40] *Sierra Club v. Bosworth*, 510 F.3d 1016, 1018 (9th Cir. 2007) (internal quotations and citations omitted); *see also* 40 C.F.R. § 1508.3.

[41] *See Anderson v. Evans*, 314 F.3d 1006, 1022 (9th Cir. 2002).

[42] *Sierra Club v. Marsh*, 769 F.2d 868, 875 (1st Cir. 1985).

[43] *Anderson*, 314 F.3d at 1022.

[44] *Northwest Coal. for Alts. to Pesticides v. EPA*, 544 F.3d 1043, 1052 n.7 (9th Cir. 2008).

"[A]t the earliest possible time," an agency must determine whether any of its actions "may affect" a listed species.[45] The ESA prescribes a three-step procedure to ensure that an agency proposing to take an action (action agency) comply with ESA's substantive provisions and properly make this determination. Both the first and second steps serve "to determine if the successive steps are required."[46]

The first step requires the action agency to determine whether any threatened or endangered species or critical habitats "may be present" in the action area.[47] To do so, the action agency must inquire with either or both of the appropriate expert agencies, NMFS or FWS.[48] If either expert agency concludes that no threatened or endangered species may be present, the action agency does not have to continue the consultation process. If a listed species or habitat may be present, the action agency must proceed to the second procedural step.

The second step requires the action agency to prepare a "biological assessment," to determine whether the species is "likely to be affected by the action."[49] The action agency is ultimately responsible for this "likely to be affected" determination.[50] In making this determination, the action agency *may* conduct an "informal consultation" with the appropriate Service to assist in determining whether the proposed action will likely affect listed species or critical habitat.[51] The action agency need not engage in further formal consultation if, either after the biological assessment or as a result of informal consultation, expert agency concurs in writing that the action is not likely to affect any listed species or critical habitat.[52] However, the applicable threshold triggering formal consultation is very low.[53] Indeed, "[a]ny possible effect, whether beneficial, benign, adverse, or of an undetermined character, triggers the formal consultation requirement."[54]

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[45] 50 C.F.R. § 402.14(a).

[46] *Thomas v. Peterson*, 753 F.2d 754, 763 (9th Cir. 1985).

[47] *See* 16 U.S.C. § 1536(c)(1).

[48] *Id.*

[49] *Id*.

[50] *See* Interagency Cooperation—Endangered Species Act of 1973, 51 Fed. Reg. 19926, 19949 (June 3, 1986).

[51] 50 C.F.R. § 402.13.

[52] *Id*. § 402.14(b)(1).

[53] *See id*. § 402.14(a); 51 Fed. Reg. at 19949.

[54] 51 Fed. Reg. at 19949; *see also California ex rel. Lockyer v. USDA*, 575 F.3d 999, 1018-19 (9th Cir. 2009) (citing 51 Fed. Reg. 19926 and stating that the threshold for triggering the consultation duty is relatively low); *Nat'l Wildlife Fed'n v. Fed. Emergency Mgmt. Agency*, 345 F. Supp. 2d 1151, 1174-75 (W.D. Wash. 2004) (stating that the threshold for formal consultation is low); *Colo. Envtl. Coalition v.*

The third step requires the action agency to formally consult with the appropriate expert agency if the action meets the low "may affect" threshold. Once the agency initiates formal consultation, the Service must: (1) review all relevant information; (2) evaluate the current status of the listed species or habitat; (3) evaluate the effects of the action and cumulative effects on the listed species or habitat; and (4) formulate a biological opinion (BiOp) "as to whether the action, taken together with cumulative effects, is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat."[55] A BiOp must detail "how the agency action affects the species or its critical habitat," and must consider both the direct and indirect effect of an action.[56]

Migratory Bird Treaty Act

The Migratory Bird Treaty Act (MBTA) implements the obligations of the U.S. under several international treaties and conventions for the protection of migratory birds.[57] The MBTA mandates that proposed projects must avoid the take of migratory birds entirely and must minimize the loss, destruction, and degradation of migratory bird habitat.[58] The vast majority of U.S. native birds are protected under the MBTA, even those that do not participate in international migrations.[59] Under the MBTA, "[n]o person may take, possess, import, export, transport, sell, purchase, barter, or offer for sale, purchase, or barter, any migratory bird, or the parts, nests, or eggs of such bird except as may be permitted under the terms of a valid permit."[60]

Inadequacies in APHIS's EA

I. APHIS Lacks Necessary Information to Approve the Permit Application Under the PPA.

Pursuant to the PPA, all of APHIS's decisions, including the decision to permit release of a plant pest, "shall be based on sound science."[61] In approving a permit for field release, APHIS must also ensure that adequate safeguards are in place.[62]

Office of Legacy Mgmt., 819 F. Supp. 2d 1193, 1222 (D. Colo. 2011) (requiring consultation based upon action agency's conclusion in EA that impacts to listed species would be "highly unlikely").

[55] 50 C.F.R. § 402.14(g)(1-4).

[56] 16 U.S.C. § 1536(b)(3)(A); 50 C.F.R. § 402.02.

[57] 16 U.S.C. § 701.

[58] *Id.* §§ 701-12.

[59] *See* 50 C.F.R. § 10.13.

[60] *Id.* § 21.11.

[61] 7 U.S.C. §§ 7701(4), 7711(b), 7712(b).

Contrary to the plain language of the statute and its own regulations, APHIS here proposes to approve a permit for a field release of a listed plant pest without adequate data, as discussed in detail below, and without considering or requiring any environmental precautions. This is a far cry from the "sound science" upon which the PPA requires that APHIS's actions be based. APHIS's failure to follow the mandates of the PPA is a violation of the statute and contrary to law in violation of the Administrative Procedure Act.

II. The EA Fails to Consider Significant Adverse Effects on the Biological, Physical, and Human Environment as Required by NEPA.

There are a number of fundamental flaws with APHIS's assessment of the potential impacts of Oxitec's proposed field trials. These flaws, as discussed below, include: (1) the use of late-acting lethality (rather than sterility) means food supplies for humans and animals will become contaminated with large numbers of dead female GE larvae; (2) the large numbers of GE adult males required to swamp the wild population pose a risk of swallowing them to farm workers and passersby, as well as wildlife, and may also cause wild-type adult diamondback moths to disperse to surrounding areas; (3) impacts on non-target pests are poorly understood and may include increases in the numbers of such pests or establishment in new areas, and this may include invasive pests; (4) the use of tetracycline as a chemical switch for the genetic killing mechanism is risky because contamination with tetracycline and related antibiotics is widespread in the environment, meaning the killing mechanism may be inactivated; (5) the use of tetracycline to breed the GE diamondback moth in the lab is likely to facilitate the spread of antibiotic resistance via gut bacteria, in breach of FDA Guidance; (6) the use of a female-killing approach is likely to lead to the dispersal of GE males over significant distances in the longer term, especially if contaminated crops enter the food chain; and (7) resistance to the genetic killing mechanism is likely to evolve over time, facilitating greater off-site dispersal.

Potential adverse effects of tTAV on non-target organisms

Release ratios of GE to wild-type diamondback moth males are currently unknown but can expected to be of the order of ten to one or higher. The aim is to replace wild-type offspring with GE offspring that are genetically engineered so that the (majority of the) females die at the larval stage. Of the strains to be released, Jin et al. (2013) reports that OX4319A-Pxy females exhibited substantial survival to pupation (17% relative to wild-type females) with lower female survival to pupation in OX4319L-Pxy, and OX4319N-Pxy (9% and 0%, respectively). For all strains, death of most female diamondback moths at the larval stage will significantly increase the number of larvae dying in the brassica crop (and in wild relative brassica weeds), compared to the no action alternative, since about 50% of the offspring (i.e. all the females) are expected to die

[62] 7 C.F.R. § 340.4(b)(10) ("The [permit] application shall include . . . [a] detailed description of the processes, procedures, and safeguards which have been used or will be used . . . to prevent contamination, release, and dissemination in the production of the: Donor organism; recipient organism; vector or vector agent; constituent of each regulated article which is a product; and regulated article."); *id.* § 340.4(b)(12) ("The [permit] application shall include . . . [a] detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations.").

at this stage, rather than reaching adulthood. The dead larvae will contain the DsRed (fluorescent) and tTAV (early lethality) GE traits. They will be consumed by all species that normally consume diamondback moth larvae or brassica crops, including humans should the crop enter the food chain. Yet no safety data is provided in the EA for consumption of GE diamondback moth larvae. Instead, the EA relies on a statement claiming that the DsRed and tTAV proteins expressed in Oxitec's GE mosquitoes are safe to eat (with no data provided) in the bioinformatics report by Goodman (Appendix VIII), commissioned by Oxitec. The EA also cites one published study by Oxitec, in which its OX513A strain of GE *Ae. aegypti* mosquito larvae were fed to larvae of two different species of mosquito, *Toxorhynchites* (*T. splendens and T. amboinensis*).[63] This falls far short of the data or precautions needed.

The presence of large numbers of dead (and some living) GE larvae in the crop is a significant difference between Oxitec's technology and the Sterile Insect Technique (SIT) to which the EA continually compares it. SIT prevents the insects from reproducing through the use of radiation, rather than genetically programming the offspring to die at the larval stage. Oxitec's approach, in addition to contaminating the crop with large numbers of dead larvae, will likely result in considerable crop damage before the intended population suppression effect is observed in the wild population.[64]

Although a reference has been provided for toxicity testing of the red fluorescent marker, DsRed2, no evidence exists regarding the safety of the RIDL genetic mechanism and the high level expression of tTA that kills the insects at the larval stage. The mechanism of action is not fully understood and no safety data appears to be available. There is some evidence that enhanced tTA expression can have adverse effects (loss of neurons affecting cognitive behavior) in transgenic mice.[65] Other mouse studies have detected adverse effects on the lung.[66] Considerably more data, based on specific feeding trials in relevant species, are needed to establish that consumption of GE diamondback moth adults or larvae is not harmful to humans or wildlife. Consistent with this need, as noted above, Oxitec withdrew its application for a permit to release

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[63] Nordin O, Donald W, Ming W H, Ney TG, Mohamed KA, Halim NAA et al. (2013) Oral ingestion of transgenic RIDL *Ae. aegypti* larvae has no negative effect on two predator *Toxorhynchites* species. *PloS One*, 8(3), e58805.

[64] Benedict M, et al. (2010) Defining Environmental Risk Assessment Criteria for Genetically Modified Insects to be placed on the EU Market. Environment Agency Austria, University of Bern, International Atomic Energy Agency. Scientific/Technical Report submitted to the European Food Safety Agency (EFSA). Sept. 10, 2010. Retrieved from http://www.efsa.europa.eu/en/scdocs/doc/71e.pdf.

[65] Han HJ, Allen CC, Buchovecky CM, et al. (2012) Strain background influences neurotoxicity and behavioral abnormalities in mice expressing the tetracycline transactivator. *J Neurosci.* 32(31):10574-10586.

[66] Sisson TH, Hansen JM, Shah M, Hanson KE, Du M, Ling T et al. (2006) Expression of the Reverse Tetracycline-Transactivator Gene Causes Emphysema-Like Changes in Mice. *American Journal of Respiratory Cell and Molecular Biology*, 34(5), 552 –560; Whitsett JA, Perl A-KT. Conditional Control of Gene Expression in the Respiratory Epithelium: A Cautionary Note. *American Journal of Respiratory Cell and Molecular Biology*. 34(5):519–520. Retrieved from http://www.atsjournals.org/doi/pdf/10.1165/rcmb.F310.

GE olive flies genetically engineered with the same female-killing trait in Spain in 2013 following a request for further information from the regulator, including toxicity testing using feeding trials in relevant species. [67]

The EA provides no information on whether or how brassica crops in the proposed experimental area will be disposed of and prevented from entering the human food chain. This is a major omission, both in terms of potential risk to human health and the risk of dissemination of GE diamondback moths off-site, as discussed further below. Even if the unstated intention is to guarantee no human consumption of the crop, the concern remains that it could enter the food chain unintentionally, as has been the case with many past field trials of GE crops.[68] Further, since the aim of the release is to assess the suitability of GE diamondback moth releases as a pest control measure, it makes little sense to proceed unless the safety of any diamondback moth larvae entering the human food chain has been fully tested. Under Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks," this must include testing safety for children consuming brassica crops.

Further, when referencing the Goodman report, Oxitec notes that two matches were identified using the FASTA bioinformatics tool and the Food Allergy Research and Resource Program (FARRP) Allergenonline.org database: tropomyosin from *Neptunia polycostata* (a gastropod); and a salivary protein of *Aedes albopictus*.[69] It is unclear why these matches did not appear to merit further investigation. Further, more adequate allergenicity testing is a prerequisite to approval and must be a part of any EA.

The EA incorrectly states that no FDA consultation is necessary because the GE diamondback moths released are not food or feed, and no EPA review is needed because they are not a pesticide. EA at 7-8. In reality, GE diamondback moths will be present in large numbers as a contaminant in food and feed, and potential future use of this approach on the commercial market would certainly lead to its widespread human consumption. Further, a wide variety of wildlife will consume GE diamondback moth either directly as food (adults or larvae) or as contaminants on brassicas.

Failure to conduct human safety tests prior to conducting open release experiments, and to ensure that contaminated crops do not enter the market, could damage markets far more widely than in the local area of the trial, due to frequent difficulties in tracing the source of contamination incidents. This will have implications for international as well as domestic markets, including

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[67] Joint Research Centre: Deliberate Release and Placing on the EU Market of GMOs – GMO Register. Notification report: Notification Number B/ES/13/07. Retrieved from http://gmoinfo.jrc.ec.europa.eu/gmo_report.aspx?CurNot=B/ES/13/07.

[68] Lambrecht, Bill. *GMO experiments receive questionable oversight*. SFGate. Sept. 8, 2014. Retrieved from http://www.sfgate.com/science/article/GMO-experiments-receive-questionable-oversight-5740478.php; Greenpeace & GeneWatch UK GM Contamination Register, *available at* http://www.gmcontaminationregister.org/ (last visited Sept. 29, 2014).

[69] Oxitec, *Environmental Risk Assessment For the Open Field Release of Genetically Engineered Diamondback Moths in the United States* 28-29 [hereinafter "Oxitec Report"].

organic markets, since most overseas markets, including the EU, have a regulatory approvals process that may require assessment of new GE insect parts or larvae present in the food product and limits on the amount of such materials in the food. Further, as discussed below, there may be cross-border issues with Canada if GE moths spread across the border, with implications for the canola industry as well.

Journalists have reported that in Brazil, where GE mosquito trials are taking place, "it's impossible to talk during the liberation sessions without accidentally swallowing a few" due to the very large numbers of GE mosquitoes being released to try to swamp the wild population.[70] Therefore, the risk posed to workers or passers-by of swallowing adult GE diamondback moths is legitimate and needs to be assessed. It is of particular concern that staff will be required to wear masks during contained production, but members of the public may be exposed to large numbers of GE diamondback moth during open releases without any protective measures. For example, during Oxitec's experiments with GE mosquitoes in the Cayman Islands, local residents complained about the nuisance caused by the very large number of GE mosquitoes released, which was far higher (by an order of magnitude or more) than the normal expected population density of the wild species.[71]

Off-site dissemination of GE Diamondback Moth

The EA relies heavily on claims that the GE diamondback moth cannot be disbursed offsite and will not overwinter. These are unproven assumptions.

Firstly, the EA completely omits consideration of dispersal via the food chain, although transport and sale of brassica produce is the main mechanism through which this pest has been transported worldwide. To prevent spread of GE diamondback moth via the deliberate or accidental marketing of crops, or transfer of seedlings, APHIS must require that no food crops from the site will be allowed to enter the food chain, and must provide a credible process for destruction of the crop to destroy any GE diamondback moth onsite.

Oxitec's report states that it intends to clear all brassica crops and weeds for 10m around the site, followed by spraying over 100m around the site.[72] However, no mention is made in the EA itself of the need to destroy the crop and all wild relatives at the site to prevent dissemination. APHIS has not proposed any specific, enforceable conditions to this effect, nor provided any justification for the assumption that the GE moth will not travel farther from the field than 10m. Mechanisms for spread include transfer on human clothing or by wildlife moving through the crop or wild relatives, as well as independent flight of adult diamondback moth and dispersal by the wind. Oxitec and, more importantly, APHIS both ignore these viable mechanisms and the

[70] Bevins, Vincent. *Dengue, where is thy sting?* Los Angeles Times. Nov. 1, 2012. Retrieved from http://articles.latimes.com/2012/nov/01/world/la-fg-brazil-mutant-mosquitoes-20121102.

[71] Supplementary information. Harris AF, et al. (2012) Successful suppression of a field mosquito population by sustained release of engineered male mosquitoes. *Nat. Biotech.*, 30(9), 828–830. Retrieved from http://www.nature.com/nbt/journal/v30/n9/extref/nbt.2350-S1.pdf.

[72] Oxitec Report, *supra* note 69, at 10.

legitimate potential of spread. Strict conditions for full destruction of the test crop and wild brassicas and study of the dispersal of existing wild type diamondback moths at the site are essential prior to any release. Without such a detailed study it is impossible to confirm whether the seemingly implausible assumption that diamondback moths will not disperse farther than 10m is in any way adequate.

One of the more questionable assumptions in the EA is the claim that the strong wind currents that facilitate dispersal of diamondback moths across geographic regions do not occur at the proposed release site. In fact, migration into Canada from the proposed release site is not implausible, given that one predominant direction for wind currents in the area is south to north, as APHIS acknowledges.[73] Thus, there may be potential for GE diamondback moth to contaminate the Canadian canola crop[74] as well as brassica production. In Ontario, diamondback moths generally arrive from the south, although they sometimes also overwinter.[75]

Likewise, claims regarding the inability of diamondback moths to overwinter in the area are also incorrect. In Canada, Alberta's Department of Agriculture and Rural Development reports that overwintering diamondback moths were found in central Alberta in the early 1990s, i.e. considerably farther north than the proposed trial site and in an area with lower average winter temperatures.[76] Adults have also recently been found in spring emergence traps in Saskatchewan and have been collected in small numbers very early in spring in Manitoba. Thus, although the main mechanism for crop damage in northern climates is re-infestation via long-distance dispersal by the wind, it is clear that small numbers may overwinter in cold climates, allowing survival of the GE trait. The average temperature in January—the coldest month—in Geneva, New York, where the proposed experiments are sited, is -8.9^0 Celsius,[77] compared to a lower lethal temperature of -15.2^0 Celsius in laboratory tests where 25% survived (LLT_{25}).[78] This undermines APHIS's repeated assumption that GE diamondback moth cannot overwinter,

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[73] EA, *supra* note 17, at 11.

[74] Canola Council of Canada. Canola Encyclopedia: Diamondback Moth. Retrieved from http://www.canolacouncil.org/canola-encyclopedia/insects/diamondback-moth/ (last updated Mar. 17, 2014).

[75] Ontario Ministry of Agriculture, Food & Rural Affairs. Ontario CropIPM: Diamondback Moth. Retrieved from http://www.omafra.gov.on.ca/IPM/english/brassicas/insects/diamondback-moth.html (last updated Mar. 12, 2009).

[76] Alberta Agriculture & Rural Development. Information: Diamondback Moth. Retrieved from http://www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/agdex2540 (last updated Jan. 31, 2014); Dosdall LM (1994). Evidence for successful overwintering of Diamondback Moth, *Plutella Xylostella* (L.) (*Lepidoptera: Plutellidae*), in Alberta. *The Canadian Entomologist*, 126 (01), 183-185.

[77] U.S. Climate Data. Climate Geneva – New York. Retrieved from http://www.usclimatedata.com/climate/geneva/new-york/united-states/usny0548/2014/1(last visited Sept. 29, 2014).

[78] Nguyen C, et al. (2014) Thermal Tolerance Limits of Diamondback Moth in Ramping and Plunging Assays. *PLoS ONE*, 9(1), e87535.

particularly if there is unintentional survival of females due to failure of the killing mechanism (discussed below). A field release is clearly premature in the absence of a study of diamondback moth overwintering at the site, not least because the applicant relies heavily on claims that diamondback moths do not overwinter to mitigate risks of dispersal beyond the trial area. These claims appear implausible in the light of the current literature.

In addition, as discussed further below, the EA is inadequate insofar as it fails to address the potential for wild-type diamondback moths to move to surrounding areas in response to the releases.

Unintentional survival of female GE Diamondback Moths

Oxitec's female GE moths are genetically programmed to die at the late larval stage. However, there are several mechanisms that could allow many more of the female diamondback moths to survive to adulthood. There is a fundamental flaw in Oxitec's approach in using tetracycline as a chemical switch to allow breeding of the GE moth in the laboratory, because tetracycline and related antibiotics are widespread in the environment. This omission is especially concerning in light of the EFSA Guidance, which counsels consideration of the "[r]eduction in efficacy of the GM insect mediated trait that may result in adverse effects."

Unintentional survival of female GE moths can occur due to failure of the genetic killing mechanism. This can occur if resistance develops to the trait or if the GE moths encounter sufficient levels of the antibiotic tetracycline, or its derivatives, to inactivate the killing mechanism.

The applicant wishes to undertake open experimental releases of three of Oxitec's GE diamondback moth strains: OX4319L-Pxy, OX4319NPxy, and OX4767A-Pxy. Jin et al. (2013) give female survival rates to adulthood in the absence of chlortetracycline (CTC, a tetracycline analogue) of 1%, 0%, and 5%, relative to wild type, for these GE strains (Figure 2c). This means, at least for two of the strains, some females are expected to survive to adulthood, even in the absence of tetracycline. However, contamination with tetracycline and related antibiotics is widespread in the environment and could lead to significantly increased survival rates.

Jin et al. (2013) investigated female-specific lethality at different CTC concentrations for the OX4319L-Pxy strain of GE diamondback moth (although numbers tested are not reported). In these tests, no OX4319-Pxy-heterozygous females survived to adulthood at CTC concentrations up to 0.01 μg/mL, while at or above 10 μg/mL CTC OX4319L-Pxy heterozygous female survival to adulthood, relative to wild-type, was similar to that of males. At concentrations of 0.1 μg/mL and 1 μg/mL female survival to adulthood was around 15% and 55% respectively (Figure 6), relative to wild-type. Oxitec claims that the level of CTC needed for survival far exceeds that which diamondback moth might be expected to encounter in the wild. This claim is incorrect.

When Oxitec's GE mosquito larvae were fed cat food containing industrially-farmed chicken, the survival rate increased to 15-18%. Oxitec originally hid this information,[79] but later admitted to an 18% survival rate of larvae fed on cat food—which is assumed to contain industrially-farmed chicken contaminated with tetracycline or related antibiotics—in a published paper.[80] The tetracycline derivatives oxytetracycline (OTC) and doxycycline (DOX, used to prevent malaria) could also allow Oxitec's GE insects to breed. Oxytetracycline can be found at concentrations above 500 µg/g in animal manure and doxycycline at up to 78.5 µg/g dry weight in broiler manure.[81] A global review reports lower but still relevant concentrations of tetracyclines of up to 0.88 µg/g in pig manure, 11.9 µg/g in poultry manure and 0.208 µg/g in cattle manure.[82] These concentrations are likely to be more than enough to inactivate the killing mechanism in the female GE diamondback moth if the larvae come into direct contact with contaminated manure. Moreover, it would not be surprising if behavioral adaption beneficial for survival was selected for in the field, leading to females seeking tetracycline contaminated areas in which to lay their eggs.

The percentage of surviving GE diamondback moth could also increase if resistance to the genetic killing mechanism evolves over time. This concern is dismissed as unlikely in the EA, EA at 44, despite prior evidence of behavioral resistance developing in a SIT program, i.e. females unreceptive to mating with irradiated males.[83] APHIS dismisses this evidence as rare, but there has been little investigation of this phenomenon, which shows the expected development of an evolutionarily-advantageous behavior in the field. Resistance can also develop through the evolution of resistance alleles.[84] This risk must be considered because radiation-induced sterility using the traditional SIT has built-in redundancy that is not provided by molecular genetic approaches.[85] A number of authors have therefore speculated that any genetic or molecular event

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[79] GeneWatch, Friends of the Earth, Third World Network PR: Company conceals evidence that genetically modified mosquitoes may have high survival rate in wild (12th January 2012).

[80] Massonnet-Bruneel B, et al. (2013) Fitness of Transgenic Mosquito Aedes aegypti Males Carrying a Dominant Lethal Genetic System. *PLoS ONE*. 8(5):e62711. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3653897/.

[81] Kyselkova, M., et al. (2013) Cow excrements enhance the occurrence of tetracycline resistance genes in soil regardless of their oxytetracycline content. *Chemosphere*. 93(10): 2413-8; Ho, Y.B., et al. (2012) Simultaneous determination of veterinary antibiotics and hormone in broiler manure, soil and manure compost by liquid chromatography-tandem mass spectrometry. *J Chromatogr A*. 1262: 160-8.

[82] Kim K-R, et al. (2011) Occurrence and Environmental Fate of Veterinary Antibiotics in the Terrestrial Environment. *Water, Air, & Soil Pollution*, 214(1-4), 163-174.

[83] Hibino Y, Iwahashi O (1991) Appearance of wild females unreceptive to sterilized males on Okinawa Is. In the eradication program of the melon fly, *Dacus cucurbitae* Coquillett (Diptera: Tephritidae). *Applied Entomology and Zoology*, 26(2), 265-270.

[84] Alphey N, Bonsall B, Alphey A (2011) Modeling resistance to genetic control of insects. *Journal of Theoretical Biology*, 270, 42-55.

[85] Benedict MQ, Robinson AS (2003) The first releases of transgenic mosquitoes: an argument for the sterile insect technique. *Trends in Parasitology*, 19(8), 349-355.

that allows the GE moth to survive and breed successfully could be rapidly selected for during mass production.[86] No laboratory or caged studies have been published to investigate the potential development of resistance through either of these mechanisms. These studies should have taken place before Oxitec even applied for an open release trial. At the very least, they must be conducted before APHIS can approve such a trial.

Oxitec claims that there is no adverse impact if female lethality fails,[87] but as explained above, such failure could facilitate the establishment or spread of GE diamondback moth offsite. This would exacerbate any adverse impacts such as toxicity or allergenicity to humans or wildlife, as discussed above, and make it impossible to retrieve GE diamondback moth or reverse any unintended effects.

Target organisms: response of diamondback moth population to the proposed releases

The EFSA Guidance counsels APHIS to consider "[c]hanges in [target organism] populations caused by the GM component of the releases (size, age structure, sex ratio, fertility, mortality) that may result in adverse effects leading to environmental harm."[88] Whilst the unstated intention of the releases is to reduce crop losses by suppressing the target population of diamondback moth, in practice the response of the target population is likely to be complex.

The EA fails to address whether or not releases of GE diamondback moths could cause an increase in the numbers of diamondback moths in surrounding areas. This effect is predicted by some models for the release of sterile insects.[89] For releases of GE mosquitoes, Oxitec's Cayman Islands' paper[90] and its graph from Mandacaru, Brazil—the details of which are unpublished, but the graph is in a company brochure[91]—both show increases in *Aedes aegypti* mosquitoes in the control area as population suppression in the target area begins to occur. In the Cayman Islands the control area was next to the target area for the releases, but for Mandacaru there is no public information about the location of the control area. The number of mosquitoes trapped in the

[86] Robinson AS, Franz G, Atkinson PW (2004) Insect transgenesis and its potential role in agriculture and human health. *Insect Biochemistry and Molecular Biology*, 34(2), 113-120.

[87] Oxitec Report, *supra* note 69, at 13.

[88] *EFSA Guidance*, *supra* note 18, at 87.

[89] Yakob L, Alphey L, Bonsall MB (2008) *Aedes aegypti* control: the concomitant role of competition, space and transgenic technologies. *Journal of Applied Ecology* 45(4):1258–1265.

[90] Harris AF, McKemey AR, Nimmo D, Curtis Z, Black I, Morgan SA, Oviedo MN, Lacroix R, Naish N, Morrison NI, Collado A, Stevenson J, Scaife S, Dafa'alla T, Fu G, Phillips C, Miles A, Raduan N, Kelly N, Beech C, Donnelly CA, Petrie WD, Alphey L (2012) Successful suppression of a field mosquito population by sustained release of engineered male mosquitoes. *Nat. Biotech.*, 30(9), 828–830.

[91] Dengue Fever: The Fastest Growing Mosquito Borne Disease. Oxitec. October 2013. http://www.oxitec.com/wpcms/wp-content/uploads/OXITEC-Dengue-booklet1.pdf.

untreated area also increased in the final phase of the experiments conducted in Iteraba, Brazil according to the PAT report, which provides the only published information on these experiments.[92] Thus, there appears to be a real possibility that wild-type males, when swamped by very high releases of GE males, simply migrate to mate in the surrounding area. More information is needed to either confirm or rule out this possibility. Since Oxitec calculates population suppression based on the difference between the target area and the control area, it is possible that claims of significant drops in population partly reflect significant increases being caused elsewhere. In the context of the EA, it is important to consider the risk that wild-type diamondback moths will cause increased damage outside the target area. Assessment of this risk requires prior modelling of this potential effect and an altered trial protocol and monitoring to establish whether or not this adverse effect occurs. Further, long-term monitoring of diamondback moth populations in the presence of brassica plots is required in advance of any trials to establish the baseline for assessment of efficacy, and to avoid reliance on a neighboring control that might itself be affected by wild-type diamondback moth dispersal from the target site.

Risk of increase in non-target pests in response to GE diamondback moth releases

The EA incorrectly claims that introduction of the GE moth will only affect the target pests. The PPA requires APHIS to consider whether the proposed releases of GE diamondback moth will facilitate the dissemination and establishment of other, non-target pests. To do this correctly, the EA must consider not only exposure of wildlife to direct effects such as potential toxicity, but ecosystem responses to the releases, i.e. indirect effects on the population dynamics of non-target species.

The EFSA Guidance states: "Considering the aim and type of GM insect releases, and also accounting for possible accidental releases, potential impacts on NTO [non-target organisms] that may cause adverse effects include: …(b) a change in abundance or species composition of competitors (e.g. insects exploiting the same ecological niches) of GM insects and the ecological functions they provide,"[93] and adds "Other pest species (e.g. secondary pests) might exploit the available resource and build up high populations which might have an adverse effect on the environment and on human health."[94]

This situation could be regarded as analogous to problems with GE insect-resistant crops (Bt crops) that have developed in China and Brazil. In China, secondary pests that are not affected by the Bt toxins in its GE cotton crop have become a major problem.[95] In Brazil, the Agricultural

[92] PAT (2012) Transgenic Aedes Project Progress Report, Feb. 2011-Mar. 2012.

[93] EFSA Guidance, *supra* note 18, at 94.

[94] *Id.* at 98.

[95] Wang S, Just DR, Andersen PP (2008) Bt-cotton and secondary pests. *International Journal of Biotechnology* 10(2/3):113; Lu Y, Wu K, Jiang Y, et al. (2010) Mirid Bug Outbreaks in Multiple Crops Correlated with Wide-Scale Adoption of Bt Cotton in China. *Science* 328(5982):1151–1154; Zhao JH, Ho P, Azadi, H (2011) Benefits of Bt cotton counterbalanced by secondary pests? Perceptions of ecological change in China. *Environ Monit Assess*, 173:985–994.

Ministry has issued warnings about a massive explosion in corn ear worm (*Helicoverpa armigera*) in areas growing Bt maize.[96] These examples show how reductions in competition or natural enemies can lead to an explosion in another type of pest. These concerns arise as a result of the proposed "single species" approach and do not apply to methods that are effective against multiple pest species.

Potential increases in competitor species have been a major concern in debates about the risk of releasing Oxitec's GE *Aedes aegypti* mosquitoes.[97] However, such effects have been omitted from the EA for GE diamondback moths altogether, despite the use of a single-species approach in the likely presence of numerous other brassica pest species such as those listed on page 34 of the EA: cabbage root maggot (*Delia radicum*); flea beetle (*Phyllotreta striolata* and *P. cruciferae*); imported cabbage worm (*Pieris rapae*); cabbage looper (*Trichoplusia ni*); cabbage and green peach aphids (*Brevicoryne brassicae* and *Myzus persicae*); onion thrip (*Thips tabaci*); and Swede midge (*Contarinia nasturii*). In some cases, these competitor species are invasive species and the impact of the proposed releases on their populations therefore requires consideration under Executive Order 1311 on invasive species, as well as the PPA.

Should releases of GE diamondback moth lead to the expansion or establishment of other pests, these adverse effects may be difficult to mitigate or reverse. Prior knowledge of the distribution and population dynamics of other pests, including any competitive effects, at the proposed field site is therefore <u>essential</u> before the release can be approved and conducted. Without such data, combined with credible attempts to model likely population responses, open releases of GE diamondback moths are premature and APHIS's approval of such is unlawful.

Potential transfer of antibiotic resistance via diamondback moth microbiota

The use of tetracycline to breed the GE diamondback moth in the lab carries the risk of spreading antibiotic resistance, which could pose a major risk to human and animal health. Insect guts are reservoirs for antibiotic resistance genes with potential for dissemination. Insect production in factories exposed to antibiotics could lead to drug resistance in their microbiota so that the insects disseminate antibiotic resistance when released into the environment. This issue has been omitted entirely from the EA, despite growing recognition that antibiotic resistance poses a serious, worldwide threat to public health.[98] Reliance on antibiotics for breeding the GE

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[96] MDA previne agricultores sobre aparição da lagarta Helicoverpa em plantações. 9th August 2013 [In Portuguese]. Retrieved from http://portal.mda.gov.br/portal/noticias/item?item_id=13900955.

[97] Beech CJ, Nagaraju J, Vasan SS, Rose RI, Othman RY, Pillai V, Saraswathy TS (2009) Risk analysis of a hypothetical open field release of a self-limiting transgenic *Aedes aegypti* mosquito strain to combat dengue. *Asia Pacific Journal of Molecular Biology and Biotechnology*, 17, 99-111; Technical Opinion on Examination Request presented at the 171st Plenary Meeting of the National Technical Commission on Biosafety (CTNBio). 10th April 2014. http://aspta.org.br/wp-content/uploads/2014/08/Critical- vote-GM-Mosquito-jul2014.pdf; Bonsall MB, Yakob L, Alphey N, Alphey L (2010) Transgenic control of vectors: The effects of inter-specific interactions. *Israel Journal of Ecology and Evolution*, 56, 353-370.

[98] Wooldridge, M. (2014). Evidence for the circulation of antimicrobial resistant strains and genes in nature and especially between humans and animals. REVUE SCIENTIFIQUE ET TECHNIQUE-OFFICE INTERNATIONAL DES EPIZOOTIES, 31(1), 231-247; Zurek, L. and A. Ghosh (2014)

diamondback moth in the lab is a serious downside compared to the use of the traditional SIT based on the use of radiation, or compared to the "No Action" alternative that does not contribute to the spread of antibiotic resistance. In its Guidance for Industry #209, FDA recognizes that "the administration of medically important antimicrobial drugs to entire herds or flocks of food-producing animals would represent a use that poses qualitatively higher risk to public health than the administration of such drug to individual animals or targeted group of animals."[99] Combined with the potential for survival of female diamondback moths in the presence of tetracycline contamination in the environment, as discussed above, this suggests a fundamental flaw in Oxitec's technology.

Strain of Diamondback Moth

In the U.K., Oxitec was prevented from releasing its GE diamondback moth partly because of concerns about the use of a North American background strain, which is subject to controls under plant pest control regulations.[100] Using a non-native strain can introduce undesirable traits such as pesticide resistance.

The strain described in Jin et al. (2013) is not local to New York, but originates in Vero Beach, Florida. According to the Oxitec document appended to the EA, this strain has been tested for susceptibility to Bt and is unlikely to have developed resistance to other insecticides, as it is a laboratory strain.[101] However, no tests of resistance to other insecticides have been reported. This information should have been provided and considered in the EA. Release of this strain in New York could inadvertently spread this new strain of this invasive species if diamondback moths escape into the wild.

Restricted purpose, inadequate monitoring and lack of prior studies

The stated purpose of the requested field release is to assess the efficacy of GE diamondback moth strains OX4319L-Pxy, OX4319N-Pxy, and OX4767A-Pxy in reducing pest

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Insects represent a link between food animal farms and the urban environment for antibiotic resistance traits. *Appl Environ Microbiol*. 80(12): 3562-7; Allen, H.K., et al. (2009) Resident microbiota of the gypsy moth midgut harbors antibiotic resistance determinants. *DNA Cell Biol*. 28(3): p. 109-17; Tian, B., et al. (2012) Long-term exposure to antibiotics has caused accumulation of resistance determinants in the gut microbiota of honeybees. *mBio*, 3(6) :e00377-12; Levy, S.B. and B.M. Marshall (2013) Honeybees and tetracycline resistance. *mBio*, 4(1): e00045-13; WHO's first global report on antibiotic resistance reveals serious, worldwide threat to public health. WHO Press Release. 30th April 2014. Retrieved from http://www.who.int/mediacentre/news/releases/2014/amr-report/en/.

[99] FDA, Guidance for Industry #209: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals (2012), *available at* http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm216936.pdf.

[100] HSE (2011) Letter to Oxitec. 5 December 2011. Obtained by GeneWatch UK as the result of a Freedom of Information request.

[101] Oxitec Report, *supra* note 69, at 16.

populations of non-GE diamondback moth. However, biosafety issues are still not yet fully understood for this new technology and must also be assessed. This requires greater prior assessment of the release environment, especially background populations and fluctuations in both target and non-target organisms, and of the GE diamondback moth strains proposed for release, as detailed above (in particular, thorough safety testing of the impacts of ingestion on humans and animals) prior to any release. The application for open release is therefore premature. Further, were the releases to proceed following the provision of this important additional data, additional monitoring would be required to detect potential adverse effects, i.e. the purpose of the experiment would need to be extended to include additional monitoring. This should include for example, monitoring to detect potential adverse effects on beneficial insects, predators and wildlife; monitoring to detect any migration of diamondback moths to neighboring areas and persistence or dispersal of GE diamondback moths; monitoring of non-target pests to detect any unintended increases in such pests due to population suppression of a competitor; and monitoring of antibiotic resistance and its spread through gut bacteria.

Lack of prior studies on all transgenic strains

Jin et al. (2013) report tests of longevity on OX4319L-Pxy and OX4319N-Pxy and tests of mating competitiveness on OX4319L-Pxy. Survival to adulthood of the OX4319L-Pxy strain is reported for different concentrations of CTC in larval diet and Harvey-Samuel et al. (2014) report caged trials of fitness costs for OX4319L-Pxy. However, no such trials have been reported for OX4319N-Pxy and OX4319A-Pxy. The proposed open releases are premature in the absence of more extensive laboratory and caged testing of all strains.

These severe inadequacies in Oxitec's application and the EA render APHIS's potential approval of the release premature, arbitrary and capricious, and in clear violation of NEPA.

III. The EA Fails to Consider Cumulative Impacts as Required by NEPA.

NEPA requires agencies to consider the cumulative impacts of proposed actions.[102] "A cumulative impact is defined as 'the impact on the environment which results from the incremental impact of the section when added to other past, present, and reasonably foreseeable future actions regardless of what agency…or person undertakes such other actions. Individually minor, but collectively significant actions, taking place over time, can generate cumulative impacts."[103] Cumulative impacts must be fully considered in an EA. "Given that so many more EAs are prepared than EISs, adequate consideration of cumulative effects requires that EAs address them fully."[104] Specifically, an EA must provide a quantified assessment of a project's environmental impacts when combined with other projects.[105] The EA cannot simply discuss the

[102] 40 C.F.R. § 1508.27(b)(7).

[103] *Id.*

[104] *Kern v. U.S. Bureau of Land Mgmt*., 284 F.3d 1062, 1076 (9th Cir. 2002) ("We have held that an EA may be deficient if it fails to include a cumulative impact analysis….").

[105] *Great Basin Mine Watch v. Hankins*, 456 F.3d 955, 972 (9th Cir. 2006).

direct effect of the project and conclude that there are no cumulative impacts.[106] Instead, cumulative impacts must be evaluated along with the direct and indirect effects of a project and its alternatives. As the United States Court of Appeals for the District of Columbia Circuit has explained,

> "[A] meaningful cumulative impact analysis must identify (1) the area in which the effects of the proposed project will be felt; (2) the impacts that are expected in that area from the proposed project; (3) other actions—past, present, and proposed, and reasonably foreseeable—that have had or are expected to have impacts in the same area; (4) the impacts or expected impacts from these other actions; and (5) the overall impact that can be expected if the individual impacts are allowed to accumulate."[107]

In stark contrast to what NEPA requires in an EA, APHIS's EA cursorily concludes that "no cumulative impacts are anticipated at this time from the proposed action and future requests to extend the permit from the applicant."[108] As discussed at length above, APHIS has failed to consider many potential impacts on the physical, biological, and human health environments, and has erroneously concluded that such impacts are unlikely to occur. Likewise, APHIS has failed to adequately examine the significant cumulative impacts that its action will have on the environment. Just one potential effect includes the potential for GE moths to survive, as discussed above. Oxitec's male GE moths have the potential to survive for multiple generations, even in the absence of problems with the genetic killing mechanism for the female moths. Further, dead GE larvae and a smaller number of live insects potentially can contaminate the food chain via transports of crops produced using this method of GE pest control. The risks associated with these and other cumulative actions must be considered comprehensively in an EIS prior to approval of the release.

IV. The EA Fails to Identify Alternatives as Required by NEPA.

APHIS has failed to take the required "hard look" at possible alternatives to approving the release of GE moths. Section 102(2)(E) of NEPA requires all agencies to "[s]tudy, develop, and describe appropriate alternatives to recommended courses of action in any proposal which involves unresolved conflicts concerning alternative uses of available resources."[109] Regardless of whether an EA or EIS is prepared, NEPA "requires that alternatives be given full and meaningful consideration."[110] In fact, the alternatives section is considered the heart of an

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[106] *Id.*

[107] *Grand Canyon Trust v. FAA*, 290 F.3d 339, 345-46 (D.C. Cir. 2002) (internal citations omitted).

[108] EA, *supra* note 17, at 51.

[109] 42 U.S.C. § 4331(2)(E).

[110] *Bob Marshall Alliance v. Hodel*, 852 F.2d 1223, 1229 (9th Cir. 1988).

environmental analysis.[111] "[I]t should present the environmental impacts of the proposal and the alternatives in comparative form, thus sharply defining the issues and providing a clear basis for choice among options by the decisionmaker and the public." *Id*. Agencies must therefore rigorously explore and objectively evaluate all reasonable alternatives, including the no action alternative.[112]

Despite the rigor required by NEPA, APHIS's EA presents no serious analysis of potential alternatives. Instead, APHIS merely provides a cursory review of just two options it purports to have "evaluated" to satisfy this requirement: the proposed release approval action and the "no action" disproval action. EA at 21-22. It is a classic NEPA violation to limit the consideration of alternatives simply to (1) action or (2) no action.[113]

APHIS's alternatives analysis is also fundamentally flawed because it is—like the rest of the EA—far too limited in scope. An agency's alternatives analysis should be a function of the "purpose and need" of the action under review.[114] APHIS identifies the purpose of the release as "basic research to assess the feasibility and efficacy of this GE diamondback moth in reducing pest populations of non-GE diamondback moths. . . . The release of these GE diamondback moths will allow the applicant to gauge efficacy of this system in reducing pest diamondback moth populations."[115] This is an overly-narrow purpose that ignores the larger problem of the presence of diamondback moths as an agricultural pest, which would require APHIS to consider alternatives in addition to the release of GE varieties to address the problem.

Even with that aside, however, APHIS fails to assess any of the numerous other feasible means of testing the efficacy of GE moths. Some of these alternatives include a closed release in an indoor facility or closed-net greenhouses, or siting the release in a more isolated location with respect to other Brassica species. APHIS instead inexplicably assumes that an open-air field release is the <u>only</u> viable option, and in doing so improperly restricts itself from considering any other options that could feasibly, effectively, and safely fulfill its identified purpose.

APHIS's failure to consider other options is thus arbitrary and capricious and in violation of NEPA.

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[111] 40 C.F.R. § 1502.14.

[112] *Id.*

[113] *See, e.g., Am. Oceans Campaign v. Daley*, 183 F. Supp. 2d 1, 17-21 (D.D.C. 2000); *Muckleshoot Indian Tribe v. U.S. Forest Serv.*, 177 F.3d 800, 813-14 (9th Cir. 1999) (consideration of only unqualified deregulation and the no action alternative is presumptively too limited to comply with NEPA).

[114] *See* 40 C.F.R. § 1502.13 (agency must "specify the underlying purpose and need to which the agency is responding in proposing the alternatives…."); *City of Carmel-By-The-Sea v. U.S. Dep't of Transp*., 123 F.3d 1142, 1155 (9th Cir. 1995) ("The stated goal of a project necessarily dictates the range of 'reasonable' alternatives and an agency cannot define its objectives in unreasonably narrow terms.") (citation omitted).

[115] EA, *supra* note 17, at 4.

V. The EA Fails to Consider and Prescribe Adequate Mitigation Measures.

APHIS dismisses the few risks that it does acknowledge in the EA nearly out-of-hand, rather than applying its authority to require mitigation measures to address known risks. CEQ defines "mitigation" to include:

> (a) Avoiding the impact altogether by not taking a certain action or parts of an action.
> (b) Minimizing impacts by limiting the degree or magnitude of the action and its implementation.
> (c) Rectifying the impact by repairing, rehabilitating, or restoring the affected environment.
> (d) Reducing or eliminating the impact over time by preservation and maintenance
> operations during the life of the action.
> (e) Compensating for the impact by replacing or providing substitute resources or environments.[116]

Despite this expansive definition, which gives APHIS broad power to impose conditions on its approval of the permit, APHIS has failed to prescribe <u>any</u> mitigation measures to address the known risks of the release.

To the extent that the scope of the release could possibly be construed as a mitigation measure, the EA fails to adequately explain or analyze how APHIS will monitor compliance with this condition in the field. Mitigation must be enforceable, which includes the duty of on-going monitoring to ensure compliance,[117] and is essential where mitigation is part of the justification for the agency's determination not to prepare an EIS.[118] Even if APHIS had prescribed mitigation measures, such measures would not substitute for actually analyzing environmental impacts.[119] Yet here APHIS relies on Oxitec's claims that the release is low-risk and mitigation measures mostly unnecessary due to the natural environment. APHIS also fails to analyze the potential impacts should/when any or all of those conditions fail or change, and has not conducted a failure mode analysis to test the reliability of these conditions.

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[116] 40 C.F.R. § 1508.20.

[117] CEQ, Appropriate Use of Mitigation and Monitoring and Clarifying the Appropriate Use of Mitigated Findings of No Significant Impact 7 n.18 (2011); *id.* at 2 (explaining that when agencies do not "monitor mitigation commitments to determine if mitigation was implemented or effective, the use of mitigation may fail to advance NEPA's purpose of ensuring informed and transparent environmental decisionmaking").

[118] *Id.* at 10.

[119] *See, e.g., Northern Plains Res. Council, Inc. v. Surface Transp. Bd.*, 668 F.3d 1067, 1085-86 (9th Cir. 2011).

To evade the required analyses, APHIS repeatedly relies on the assertion that future actions concerning releases that could significantly affect the environment will be subject to additional NEPA analyses. Yet the agency does not provide any true assurance that a full environmental consequences analysis for future releases at other sites will be prepared and made available for public review. APHIS fails to carefully explain precisely how its regulations require such analysis, or how it intends to assure this review. Absent such complete explanation, APHIS's attempt to delay adequate review at this time—before the release—is arbitrary, capricious, and unlawful.

VI. The EA Fails to Adequately Consider Effects on Endangered and Threatened Species Under the ESA.

The EA acknowledges that APHIS has a duty to consult with FWS if its action "may affect" listed species or designated critical habitat. The EA then goes on to conclude that APHIS's proposed action will not affect any listed species or critical habitat because (1) pesticide use and its effects on the environment within the Environmental Protection Agency's (EPA) exclusive purview under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); (2) the GE moth and larvae are safe for wildlife to consume, including the proposed listed species that could consume the moth; and (3) wind patterns make it unlikely that listed or proposed Brassicaceae species will be exposed to the moth. Each of these conclusions is erroneous.

First, under the PPA, APHIS has the authority to regulate direct and indirect risks associated with GE organisms. The agency's position that it only has the authority to regulate GE organisms that it believes may pose a plant pest risk under 7 C.F.R. 340.1 flatly conflicts with the Supreme Court's *Monsanto v. Geertson Seed Farms* decision, in which the Court held that APHIS had ample authority under the PPA to impose restrictions to minimize risks from GE crops. Likewise, APHIS has ample authority to impose restrictions on field trials to minimize risks from GE insects. This includes the option of denying a release permit that specifically prescribes the use of certain pesticides at the conclusion of the trial. APHIS cannot pass its responsibility to EPA to assess the effects of any aspect of the permitted release on threatened or endangered species or their habitat.

Second, APHIS states simply that GE moth adults and larvae are safe for consumption by wildlife. EA at 57. As explained more fully below, more adequate allergenicity testing is required before APHIS can determine whether this is true. Without such testing and data, APHIS cannot rely on this assumption to justify its failure to carry out its obligations under the ESA.

Third, and as explained more fully above, APHIS's claim that the strong wind currents that facilitate dispersal of diamondback moths across geographic regions do not occur at the proposed release site, and therefore will not expose listed or proposed Brassicaceae species to GE moth adults and larvae, EA at 57, is questionable at best. APHIS cannot base its decision not to conduct a formal ESA consultation on such an erroneous assumption.

In addition, adverse ecosystem effects cannot be ruled out without assessing the impacts of consuming GE diamondback moth on all of the main predator species for adult and larval

diamondback moth, plus species that will consume moth larvae primarily by eating brassicas. These include species that are engendered, threatened, or of special concern and that may feed on diamondback moths or larvae or on brassicas, such as the northern long-eared bat (*Myotis septentrionalis*), grasshopper sparrow (*Ammodramus savannarum*) and the new cottontail rabbit (*Sylvilagus transitionalis*).

APHIS's failure to carry out its duties to consider the effects of its action on threatened and endangered species and their habitat constitutes a violation of the ESA.

VII. The EA Fails to Properly Consider Migratory Birds Under the MBTA.

In the EA, APHIS fails to properly consider and disclose its obligations to migratory birds, never even mentioning its responsibilities under the MBTA. The MBTA prohibits the take of migratory birds entirely and mandates that the loss, destruction, and degradation of migratory bird habitat must be minimized. The release of GE moths into cruciferous crop acreage has the potential to affect species of birds protected under the MBTA. Rather than determining whether the release would have adverse effects on species protected under the MBTA, APHIS simply ignores this significant issue.

Further, APHIS's consideration of impacts to migratory birds pursuant to its obligations under Executive Order 13186 is cursory at best. While the EA notes that a consultation between APHIS and FWS took place for the release of GE pink bollworm, it does not indicate that any consultation took place for GE diamondback moth.[120] Relying exclusively on its erroneous assumptions that the introduced traits do not encode for any known toxin or allergen and that moths cannot overwinter, APHIS concludes that all wildlife, including migratory birds, are unlikely to be affected adversely by ingesting the moth or moth larvae.[121] This conclusion stands unsubstantiated, and APHIS did not make any attempt to review applicable literature or conduct research to determine whether this industry-supplied conclusion is in fact an accurate depiction of the potential impacts.

APHIS also fails to consider the effect on migratory birds of authorizing the use of chlorantraniliprole at the conclusion of the field trial. That migratory birds heavily rely on agricultural fields, common agricultural birds are in decline, and pesticide use in agricultural fields is a significant factor in this decline are well known facts.[122] APHIS acknowledges in the EA that migratory birds may be found in fields containing cruciferous crops, where they may forage for insects and weed seeds found in and adjacent to the fields.[123] APHIS must therefore

[120] EA, *supra* note 17, at 59.

[121] *Id.* at 23, 59.

[122] *See e.g.*, Pierre Mineau & Mélanie Whiteside, *Pesticide Acute Toxicity is a Better Correlate of U.S. Grassland Bird Declines than Agricultural Intensificiation*, 8 PLOS One 2 (Feb. 2013), *available at* http://www.plosone.org/article/fetchObject.action?uri=info%3Adoi%2F10.1371%2Fjournal.pone.0057457&representation=PDF.

[123] EA, *supra* note 17, at 59.

consider an assessment of larval and adult GE diamondback moth toxicity to migratory birds. Yet APHIS makes no attempt to consider the actual impacts of the proposed action on these species, instead relying on assumptions to deny the potential for impacts.[124] APHIS failed to provide any data or actually consider the risks to migratory birds. This constitutes a failure to take the required hard look at impacts to migratory birds and could potentially lead to take under the MBTA, and also violates the APA.

Recommendations

CFS has identified numerous, significant gaps in APHIS's EA. The proposed release therefore carries unnecessary risks and is premature. Prior to considering any application for open release of GE diamondback moths, APHIS should require and consider the following additional information:

- Safety testing for consumption of GE diamondback moth adults or larvae by humans and wildlife, including children and threatened species;
- Prior baseline assessment of diamondback moth and non-target baseline pest populations over several years in the presence of brassica crops;
- Modelling of population responses of target and non-target species to the proposed releases;
- Studies of overwintering of diamondback moth in the proposed test area;
- Studies of dispersal of diamondback moth from the test site to other sites;
- Studies of dose responses of all strains proposed for release to tetracycline and its analogues;
- Studies of insecticide resistance in the parent strain;
- Studies on human allerginity to the proteins in the GE diamondback moth
- Studies on effects on the GE diamondback moth on endangered species
- Studies on the toxicity of the GE diamondback moth moths to humans who might eat their larvae in brassicas.
- Physically well contained caged trials of all GE diamondback moth strains;
- Laboratory studies of resistance mechanisms;
- Laboratory studies of antibiotic resistance;
- Physically well contained caged studies of the competitive effects on target and non-target pests.

A strict protocol for the destruction of all contaminated or potentially contaminated crop plants and wild brassicas is also essential for any trial, to avoid contamination of the food chain.

Conclusion

APHIS's EA is wholly inadequate and based on incomplete and inadequate science and analyses, lacks critical data and vital risk assessments, and ignores potential consequences and uncertainties. The EA's conclusions are erroneous and indicate APHIS's failure to properly

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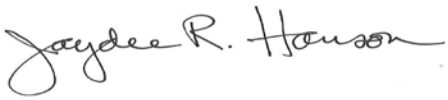
[124] *Id.*

evaluate the potential effects of this release under NEPA, the PPA, the ESA, and the MBTA. APHIS must conduct an EIS to fully evaluate the impacts of its proposed action, and failure to do so would be arbitrary, capricious, an abuse of discretion, and a violation of the statutes discussed herein.

In the alternative, APHIS's EA and the literature discussed herein reveals that the proposed release carries unnecessary risks as compared to the "No Action" Alternative. This, at a minimum, warrants a denial of the permit.

We thank you for the opportunity to comment on this EA, but urge APHIS to delay further consideration of this release permit until the deficiencies detailed herein have been corrected and until APHIS has developed regulations for the oversight of GE animals and insects.

Sincerely,



Jaydee R. Hanson
Senior Policy Analyst

Cristina Stella
Staff Attorney