May 19, 2017

Docket No. APHIS-2014-0056
Regulatory Analysis and Development
Plant Protection Division - APHIS
Station 3A–03.8
4700 River Road Unit 118
Riverdale, MD 20737–1238.
http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0056

Re: Animal and Plant Health Inspection Service Docket No. APHIS–2014–0056; Availability of an Environmental Assessment for the Field Release of Genetically Engineered Diamondback Moths

To Whom It May Concern:

The Biotechnology Innovation Organization (BIO) appreciates this opportunity to provide comments to the United States Department of Agriculture (USDA) Animal Plant Health Inspection Service (APHIS). BIO is the world's largest biotechnology trade association, representing small and large companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. BIO represents its members in a number of matters related to agricultural biotechnology, and in particular, has a strong interest in the sound regulation of animal biotechnology. These comments by BIO address the environmental assessment for the field release of genetically engineered diamondback moths and further support BIO's advocacy for the sound regulation of animal biotechnology.

APHIS prepared this environmental assessment (EA) in response to Cornell University's application for a permit[1] to conduct an experimental release of the genetically engineered (GE) diamondback moth (*Plutella xylostella*) strain OX4319L-Pxy. Pursuant to the National Environmental Policy Act of 1969 (NEPA), APHIS thoroughly assessed the potential impacts of its decision to grant or deny a permit on key resource areas: human health, the physical and biotic environments, including threatened and endangered species. BIO concurs with the factual accuracy, scientific validity and thoroughness of APHIS's review and, therefore agrees with the scope, analysis and conclusions described in the EA.

[1] APHIS Number 16-076-101r

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Background

The diamondback (DB) moth is a major lepidopteran pest of agriculture, costing farmers $ 4-5 billion annually due to crop losses and pest management costs[2]. An invasive species in the U.S., the DB moth has a global distribution and is the world's worst insect pest of cruciferous crops, such as cabbage, kale and broccoli, in the plant family *Brassicaceae*. The DB moth is ubiquitous in North America and is especially problematic for vegetable growers in warm climates that allow the moth to over-winter. Like many insect pests, its life history characteristics (short generation time; high fecundity), combined with a supply of sufficient genetic variation, have led to the development of resistance to existing control mechanisms – synthetic chemicals, biocontrol, or plant-based chemicals.

The DB moth strain OX4319L-Pxy has been genetically engineered to contain a single genetic construct that confers two traits:

- a conditional self-limiting trait that prevents female offspring of GE males from reaching adulthood, and
- red fluorescence, which allows researchers to distinguish GE insects from wild counterparts using specialized equipment

Results from mathematical modeling, laboratory, greenhouse and field cage experiments have demonstrated the male-selecting/female-lethal gene can be an effective means of decreasing various insect populations by reducing the number of females[3]. Researchers in the U.K. and the U.S. have assessed the effectiveness of the DB moth strain OX4319L-Pxy in lab and greenhouse-cage studies, and the Cornell scientists who will be responsible for this experimental release conducted in-field cage experiments in 2015. Their work provided "proof of concept" evidence that the self-limiting, genetic approach that has been shown to reduce the population sizes of other insects could be applicable to DB moths. The proposed field release will address the next milestone in product development by studying aspects of field biology, e.g., dispersal and longevity, which are relevant to the efficacy of future pest management efforts with the strain.

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[2] Furlong M., et.al., 2013. Diamondback moth ecology and management: problems, progress, and prospects. Ann. Rev Entom. 58:517–41

[3] Jin, L., et.al., 2013. Engineered female-specific lethality for control of pest Lepidoptera. ACS Syn Biol. 2:160–6; Harvey-Samuel, et.al. 2015. Pest control and resistance management through release of insects carrying a male-selecting transgene. BMC Biology **13**:49. https://bmcbiol.biomedcentral.com/articles/10.1186/s12915-015-0161-1; Alphey, N., et al. 2007. Managing insecticide resistance by mass release of engineered insects. Journal of Economic Entomology, 100: 1642-1649; Alphey, N., et al. 2009. Combining pest control and resistance management: synergy of engineered insects with Bt crops. Journal of Economic Entomology, 102: 717-732x; https://shelton.entomology.cornell.edu/2016/10/06/2015-diamondback-moth-field-cage-trials/

The DB moth strain OX4319L-Pxy seeks to control field populations of DB moths through the sterile insect technique (SIT). USDA scientists developed this approach to pest management to control or eliminate insect pests of plant and animal agriculture. According to the United Nation's Joint FAO/IAEA Programme, since being developed by USDA in the 1950's, the SIT has been used globally to control a number of species of fruit flies, moths, mosquitoes, tsetse flies and screwworm flies[4]. With respect to lepidopteran pests, like the DB moth, the SIT "is being applied to control the codling moth (*Cydia pomonella*) in apples and pears in Canada and the false codling moth (*Thaumatotibia leucotreta*) in citrus in South Africa, the pink bollworm (*Pectinophora gossypiella*) in cotton in California, and more recently to eradicate this pest from the south-western USA and north-western Mexico, and to eradicate the invasive Australian painted apple moth (*Teia anartoides*) in New Zealand. It is also being developed to control the invasive cactus moth (*Cactoblastis cactorun*) in Alabama, USA and Yucatan, Mexico, and the carob moth (*Ectomyelois caratonia*) in dates in North Africa[5]."

The difference between DB moth strain OX4319L-Pxy and earlier SIT applications is that the past efforts involve the use of radiation, rather than precise genetic modification techniques, to create male insects incapable of reproducing. By using a transgene in place of irradiation, Cornell University's approach to insect population control circumvents a problem found in radiation-based sterilization: irradiation can affect the male's ability to mate successfully under natural conditions.

Potential Benefits of the Field Release

If the field release confirms results of previous studies on DB moth strain OX4319L-Pxy, vegetable growers will be one step closer to having a much needed, alternative and beneficial tool for controlling DB moths. The United Nation's FAO categorizes sterile insects as "beneficial organisms[6]".

To delay the development of resistance and maintain effective control of insects, or any other pest, a grower must diversify pest control tactics in order to reduce the selection

[4] http://www-naweb.iaea.org/nafa/ipc/sterile-insect-technique.html

[5] http://www-naweb.iaea.org/nafa/ipc/moths.html

[6] According to the International Plant Protection Convention, "sterile insects are categorized as beneficial organisms as the Sterile Insect Technique is among the most environment-friendly insect pest control methods ever developed. It differs from classical biological control, which involves the introduction of non-native biological control agents, in the following ways: Sterile insects are not self-replicating and therefore cannot become established in the environment; Autocidal control is by definition species-specific or intra-specific, and SIT does not introduce non-native species into an ecosystem." Food & Agriculture Organization of the United Nations, International Plant Protection Convention, International Standards for Phytosanitary Measures 3, "Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms" at https://www.ippc.int/en/publications/600/

pressure imposed by repeated use of any tool on the pest population. At the present time, populations of DB moths are becoming increasingly difficult to control, because they have evolved resistance to chemical insecticides approved for conventional and organic production systems, as well as to biocontrol methods. If efficacious, not only will the DB moth strain OX4319L-Pxy provide vegetable growers with a new insect control tool, but also the targeted nature of the control tool will facilitate the use of IPM methods of control. IPM allows ecological approaches to pest control, such as a greater reliance on insect predators and parasitoids that can be killed by broad-spectrum insecticides. By encouraging the use of alternative methods of pest control, IPM lengthens the effective lifespan of each control tool in a grower's toolbox.

USDA Experience Assessing Similar Field Releases

As stated above, USDA has over 60 years of experience using the SIT to control insect pests in plant and animal agriculture.

With respect to GE insects for pest population control, APHIS Biotechnology Regulatory Services (BRS) has reviewed and approved permit applications for field trials of a GE pink bollworm (*Pectinophora gossypiella*) submitted by APHIS's Plant Protection and Quarantine, Center for Plant Health Science and Technology[7]. Those permit decisions were based on EAs, which resulted in Finding of No Significant Impacts. Recognizing the potential of GE insects for controlling pests that represent ongoing threats to U.S. agriculture, APHIS prepared an Environmental Impact Statement for field releases of four species of fruit flies in addition to pink bollworm.[8]

Finally, with respect to GE diamondback moths, APHIS has previously issued the applicant permits authorizing the importation of diamondback moth strains OX4319L-Pxy, OX4319N-Pxy, and OX4767A-Pxy from the United Kingdom to the New York State Agriculture Experiment Station (APHIS Numbers 12-227-102m, 13-297-101m). Renewals were issued for OX4319L-Pxy only (15-098-101m and 16-098-101m).

BIO Agrees with the Scope and Conclusions of APHIS's NEPA Analysis

BIO and its members have reviewed the EA thoroughly, leading us to affirm the scope of the EA, the accuracy and appropriateness of the science that APHIS used to reach its conclusions, and the analyses and conclusions in the EA.

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[7] 67 FR 1434–1435, Docket No. 01–024–2, January 11, 2002; 71 FR 20068–20069, Docket No. APHIS–2006– 0015, April 19, 2006. https://www.aphis.usda.gov/brs/aphisdocs/05_09801r_ea.pdf

[8] https://www.aphis.usda.gov/plant_health/ea/downloads/eis-gen-pbw-ff.pdf

The scope of the *Purpose and Need* section in the EA is appropriate. APHIS-BRS is responsible for regulating the importation, interstate movement and environmental release of GE organisms, under the plant pest authorities in the Plant Protection Act (PPA), to ensure that they do not pose a plant pest risk. The purpose of the proposed field release is to assess the feasibility and efficacy of strain OX4319L-Pxy in reducing the numbers of diamondback moths, which is a known plant pest and serious threat to U.S. agriculture. Strain OX4319L-Pxy contains a recombinant DNA construct and, therefore, is genetically engineered. Thus, the diamondback moth strain OX4319L-Pxy meets both of the APHIS requirements for qualifying as a regulated article as defined in 7 CFR 340.

When APHIS receives an application for a permit for an environmental release of a GE organism, it reviews the application and determines if the release can occur without spreading or establishing plant pests. Under 7 CFR 340.4(e) APHIS shall grant or deny the permit after it has reviewed the application, which, in turn, prompts a NEPA analysis. Therefore, the two alternatives APHIS considered, "no action – deny the permit request" and "preferred alternative – grant the permit request," are the only two alternatives that meet APHIS's need to respond appropriately to the permit applications, based on its responsibilities under 7 CFR 340.4 and the authorities in the part 340 regulations and the PPA.

The draft EA contains a comprehensive analysis of the underlying scientific issues, particularly as they relate to any potential negative impacts to human health and the environment that might be associated with the proposed field release. The biological factors that limit the environmental impact of the proposed release include the following:

- Only male GE moths will be released. These releases will not increase DB moth population in the area, because even without the release, wild female DB moths will mate with wild DB males and lay eggs. For the same reason, the releases will not increase crop losses in the area.

- When the released GE males mate with wild females, the female offspring will not survive. Therefore, the populations will be reduced in both the short term (female mortality) and long term due to removal of females from the population.

- The inserted gene is self-limiting and cannot be maintained in wild populations.

- DB moths are weak flyers, and few are therefore likely to travel beyond the field release site. The few that may be carried away from the field test site by air currents will not survive the winter.

In summary, the scope of APHIS's NEPA analysis in the EA is appropriate, and BIO supports science-based conclusions reached by APHIS in its EA.

BIO appreciates the opportunity to provide these comments.

Sincerely,

Dana O'Brien
Executive Vice President