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United States Department of Agriculture
Animal & Plant Health Inspection Service
Regulatory Analysis and Development, PPD
Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

Submitted via https://www.federalregister.gov/documents/2017/04/19/2017-07840/availability-of-an-environmental-assessment-for-the-field-release-of-genetically-engineered

This letter provides comments to Docket No. APHIS-2014-0056.

The Diamondback Moth (DBM; *Plutella xylostella*) is one of the most difficult and expensive pests of cruciferous vegetables in the United States and around the world. Crop losses caused by this pest, and associated control and management costs approximate $4 to $5 billion per year. Available control measures rely on pesticide applications that require careful handling to be safe, and which can have significant non-target and environmental impacts while delivering often imperfect results.

Cornell University has requested permission to conduct a field trial to assess the feasibility and efficacy of reducing pest populations by releasing two new strains of DBM. These have been "genetically engineered to exhibit red fluorescence (DsRed2) as a marker and repressible female lethality, also known as female autocide." If successful, this would provide a species-specific control measure that could dramatically reduce reliance on pesticide sprays—a measure that would provide a high degree of safety for human applicators, farm animals, non-target insect species, and the environment in general. This is exactly the kind of approach urged by renowned biologist Rachel Carson in her landmark call to environmental action *Silent Spring*.[1] Similar technologies have been field tested and commercially deployed in mosquitoes, fruit flies, screwworms, tsetse flies, and other pests with good results, no unexpected side effects, and no negative safety or environmental impacts.

[1] Rachel Carson, "Chapter 17: The Other Road," paragraph 3, in *Silent Spring*, Houghton Mifflin Company, New York, 1962, 368pp.

With an abundance of precaution, the Agriculture Department's Biotechnology Regulatory Services examined the Cornell proposal carefully, building on experience with this particular sterile insect system, itself grounded in more than 50 years of experience with sterile insect-release techniques that have been safely and productively applied with good results on six continents.[2] The major difference between the present proposal and the sterile insect-control measures that have been used before is that those in the Cornell proposal were developed with state-of-the-art genetic techniques that provide unprecedented precision, predictability, and therefore safety assurance. The earlier sterile-insect technologies relied on random mutagenesis by irradiation, which is neither precise nor predictable, but which nevertheless delivered excellent and safe results.

As noted by the United Nations' joint FAO/IAEA program, "Under the International Standard for Phytosanitary Measures No. 3 of the International Plant Protection Convention,[3] 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."

USDA has documented its analysis of Cornell's proposal in strict compliance with the requirements of the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*); the Council on Environmental Quality's regulations for implementing NEPA (40 CFR parts 1500–1508); USDA regulations implementing NEPA (7 CFR part 1b); and APHIS' NEPA Implementing Procedures (7 CFR part 372).

ITIF has conducted a detailed review of the NEPA documentation offered for comment by USDA. We find it to be comprehensive, omitting no relevant questions or considerations, weighing all reasonable issues and even some of little or no merit. If there is any problem with the USDA's NEPA documentation, it is that it applies a level of scrutiny and a degree of risk aversion that is far greater than can be justified by the merits of the Cornell proposal. This extraordinary scrutiny shows clearly that the proposal presents no unreasonable

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[2] Joint FAO/IAEA Programme: Nuclear Techniques in Food and Agriculture – Sterile Insect Technique, accessed on 3 May, 2017 at http://www-naweb.iaea.org/nafa/ipc/sterile-insect-technique.html.

[3] 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/ and https://www.ippc.int/largefiles/adopted_ISPMs_previousversions/en/ISPM_03_1995_En_1998-07-13.pdf.

risks of the sort the Coordinated Framework for the Regulation of Biotechnology was established to manage. To the contrary, it offers considerable benefits and improvements over the status quo.[4]

For these reasons, ITIF concurs with USDA's finding of no significant impacts, and urges that the field trial be promptly approved and carried out.

Sincerely,

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[4] Office of Science and Technology Policy (OSTP), "Update to the Coordinated Framework" (OSTP, 1992, 57 FR at 6753).