NATIONAL ENVIRONMENTAL POLICY ACT DECISION
AND
FINDING OF NO SIGNIFICANT IMPACT

Permit application 13-297-102r
received from Dr. Anthony Shelton of Cornell University

Field release of genetically engineered
Diamondback moth strains
OX4319L-Pxy, OX4319N-Pxy, and OX4767A-Pxy

United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services

United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), has developed a decision document to comply with the requirements of the National Environmental Policy Act of 1969, as amended, the Council of Environmental Quality's (CEQ) regulations implementing NEPA, and the USDA and APHIS' NEPA implementing regulations and procedures. This NEPA decision document is intended to state APHIS' NEPA decision and present the rationale for its selection.

In accordance with APHIS procedures implementing the NEPA Regulations (7 CFR part 372), APHIS has prepared an Environmental Assessment (EA) to evaluate and determine if there are any potentially significant impacts to the human environment in response to an environmental release permit application (13-297-102r) received from Dr. Anthony Shelton of Cornell University to authorize the field release of genetically engineered (GE) diamondback moth strains OX4319L-Pxy, OX4319N-Pxy, and OX4767A-Pxy on release sites within the grounds of the Cornell University New York State Agricultural Experiment Station (NYSAES). The purpose of the requested field release is for the applicant to assess the efficacy of GE diamondback moth strains OX4319L-Pxy, OX4319N-Pxy, and OX4767A-Pxy in reducing pest populations of non-GE diamondback moths. According to the applicant, these GE diamondback moths may serve as an insecticide-free means of controlling field populations of diamondback moths in a species-specific manner.

The EA assesses alternatives to issuing an environmental release permit with permit conditions to allow the field release of a GE diamondback moth engineered to reduce pest populations of non-GE diamondback moths. A maximum of six release sites are being requested by the applicant, with total acreage not exceeding 10 acres per site (60 acres in total). GE diamondback moth strains OX4319L-Pxy, OX4319N-Pxy, and OX4767A-Pxy have been genetically engineered with a single construct each to confer red fluorescence and repressible female lethality. The proposed action of USDA APHIS, Biotechnology Regulatory Services (BRS) is to issue the APHIS field release permit for specified GE diamondback moth strains with supplemental permit conditions in accordance with 7 CFR part 340.4[1]. The field release permit

[1] http://www.gpo.gov/fdsys/granule/CFR-2012-title7-vol5/CFR-2012-title7-vol5-sec340-4/content-detail.html Last accessed May, 2014

would be valid for a three-year period. Comments from the public involvement process were reviewed for substantive issues which were considered in developing this NEPA decision.

Since 1986, the United States government has regulated GE organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302, 57 FR 22984). The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products and explains how federal agencies will use existing Federal statutes in a manner to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework is based on several important guiding principles: (1) agencies will define those transgenic organisms subject to review to the extent permitted by their respective statutory authorities; (2) agencies will focus on the characteristics and risks of the biotechnology product, not the process by which it is created; (3) agencies will exercise oversight of GE organisms when there is evidence of "unreasonable" risk.

The Coordinated Framework explains the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: USDA's APHIS, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).

APHIS is responsible for regulating GE organisms and plants under the plant pest provisions in the Plant Protection Act of 2000, as amended (7 USC § 7701 et seq.) and prevent a plant pest risk to the environment. APHIS regulations at 7 Code of Federal Regulations (CFR) part 340, which were promulgated pursuant to authority granted by the Plant Protection Act, as amended (7 United States Code (U.S.C.) 7701–7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have information to determine if the GE organism is unlikely to pose a plant pest risk.

When APHIS receives an application for a permit for environmental release and movement, the application is evaluated to determine whether the environmental release and movement, with appropriate conditions imposed, can be carried out while preventing the dissemination and establishment of plant pests. The receipt of a permit application to introduce a genetically engineered organism requires a response from the Administrator:

> *Administrative action on applications*. After receipt and review by APHIS of the application and the data submitted pursuant to paragraph (a) of this section, including any additional information requested by APHIS, a permit shall be granted or denied (7 CFR 340.4(e)).

The applicant has provided the required information associated with this request in the permit application. This information has been reviewed by APHIS-BRS and is analyzed in the EA.

FDA regulates under the authority of the Federal Food, Drug, and Cosmetic Act. The FDA policy statement concerning regulation of products derived from new plant varieties, including

those genetically engineered, was published in the Federal Register on May 29, 1992 (57 FR 22984-23005). Under this policy, FDA uses what is termed a consultation process in which the developers conclude that food and feed derived from the new food is not materially different in composition, safety, and other relevant parameters from similar food and feed products currently on the market, and that the genetically engineered product does not raise issues that would require premarket review or approval by FDA prior to commercial distribution of bioengineered food. The EPA regulates plant-incorporated protectants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain biological control organisms under the Toxic Substances Control Act (TSCA). Because GE diamondback moth is not used of food or feed purposes and does not contain any genetically engineered pesticides or tolerance to herbicides, FDA and EPA consultation is not required. Under APHIS' Part 340 regulations, APHIS only has the authority to regulate GE organisms as long as APHIS believes they may pose a plant pest risk (7 CFR § 340.1). APHIS has no regulatory jurisdiction over any other risks associated with GE organisms including risks resulting from the use of pesticides on those organisms, or used for other purposes.

Public Involvement

In a notice published in the *Federal Register* (FR Vol. 79, No. 167, 51299-51300, Docket No. APHIS–2014–0056), APHIS announced the availability of an EA for public review and comment for a proposed field release of GE diamondback moth. Comments on the environmental assessment were required to be received on or before September 29, 2014. APHIS received a total of 287 comments during the 30-day comment period. Comment documents may be viewed at http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=PS;D=APHIS-2014-0056;refD=APHIS-2014-0056-0001.

All comments were analyzed to identify new issues, alternatives, or information. Responses to the substantive comments are included as an attachment to this Finding of No Significant Impact.

Major Issues Addressed in the EA

The EA describes the alternatives considered and evaluated using the identified issues. The list of resource areas considered in this EA were developed by APHIS through experience in considering public concerns and issues raised in public comments submitted for other NEPA documents of GE organisms (USDA-APHIS, 2014b), including NEPA documents for the release of GE insects (USDA-APHIS, 2008; 2009; 2011a). The resource areas considered also address concerns raised in previous and unrelated lawsuits, as well as issues that have been raised by various stakeholders in the past. The resource areas considered in this EA are:

Environmental Considerations:

- Soil resources;
- Water resources;
- Air quality;
- Climate change;
- Plant communities;
- Wildlife; and
- Biological diversity.

Human Population Considerations:

- Farmworker health; and
- Health of the general public.

Affected Environment:
The action area for the field release of GE diamondback moth consists of six potential release sites[2] described within the permit application #13-297-102r (see Section 2.4 of the EA). The action area is contained within the NYSAES in Geneva, NY. The NYSAES itself consists of 870 total acres and is located on the north-western edge of Geneva, NY, approximately 2 miles from suburban/urban areas.

The potential release sites are generally surrounded by other agricultural fields. The action area, like much of the land managed by the NYSAES, has been subject to constant agricultural activities for much of its 134-year history (NYSAES, 2014). In the present day, over 700 acres of the NYSAES is planted to row/vegetables crops, orchards, and vineyards (NYSAES, 2014), including the proposed field release sites.

Despite reports of diamondback moths moving long distances[3] (Talekar and Shelton, 1993; Hopkinson and Soroka, 2010), the EA did not consider the long-distance dispersal of GE diamondback moth in the description of the relevant resource areas (Sections 3.3, 3.4, 3.5, and 3.6 of the EA), or the evaluation of Potential Environmental Consequences (Section 5 of the EA). This exclusion of long-distance dispersal of GE diamondback moth is based on:

- The general characterization of diamondback moth as a weak flyer, a characteristic that strongly limits its ability to disperse long distances (Talekar and Shelton, 1993, Appendix A; Shelton, 2001a);
- Observations from the peer-reviewed literature that long-distance dispersal of diamondback moth, when and where it occurs, is facilitated by strong wind currents across geographic regions (Hopkinson and Soroka, 2010);
- Predominant wind currents across the New England region of the United States, and thereby, across the potential release sites, is primarily west to east (towards a destination which would not change the climatic zone) or south to north (American Meteorological Society, 2012; WeatherSpark, 2014) (which would further assure inability to overwinter) during cruciferous crop planting seasons; and
- The inability of diamondback moth to overwinter at similar latitudes or to the north of the potential release sites (Talekar and Shelton, 1993; Appendix A the EA; Hopkinson and Soroka, 2010).

In summary of the points listed directly above, diamondback moth is generally characterized as a weak flyer incapable of long-distance dispersal. Long-distance dispersal of diamondback moth observed in the peer-reviewed literature is generally regarded as the result of strong wind currents. Predominant wind patterns over New York State when release of GE diamondback moth may occur will generally preclude the movement of any diamondback moth, GE or non-GE, into regions where it may successfully overwinter. As a result of these observations and the ubiquity of non-GE diamondback moth in North America (Andaloro, 1983; Talekar and Shelton, 1993; Shelton, 2001a), the long-distance dispersal of diamondback moth into areas where it may overwinter is not considered likely, and thus, was not be considered in the establishment of the action area (see Section 3.2 of the EA), the description of the relevant resource areas (see Sections 3.3, 3.4, 3.5, and 3.6 of the EA), or the evaluation of Potential Environmental Consequences (see Section 5 of the EA).

[2] Total acreage for these potential release sites is not to exceed 60 acres
[3] Defined as greater than 100 km

The EA analyzes the potential environmental consequences of a proposal for APHIS to issue an environmental release permit with supplemental permit conditions to allow the field release of GE diamondback moth engineered to reduce pest populations of non-GE diamondback moths. Based upon the permit application submitted by Dr. Anthony Shelton of Cornell University, two alternatives are considered and analyzed in the EA: (1) no action - deny the permit and (2) preferred alternative - issue the APHIS permit.

Alternative A: No Action – Deny the Permit

Under the No Action Alternative APHIS would deny the permit application (APHIS Number 13-297-102r) submitted by the applicant. The applicant would not be authorized to release the GE diamondback moth strains OX4319L-Pxy, OX4319N-Pxy and OX4767A-Pxy. APHIS may choose this alternative if there were sufficient evidence to demonstrate that these GE diamondback moth strains would eitherpresent a plant pest risk or would not be a confined release.

Alternative B: Preferred Alternative – Issue the APHIS Permit

Under the Preferred Alternative, APHIS would issue an environmental release permit to the applicant in accordance with 7 CFR part 340 to allow the release of GE diamondback strains OX4319L-Pxy, OX4319N-Pxy and OX4767A-Pxy over a maximum field area of 60 acres. APHIS may choose this alternative if there were sufficient evidence to demonstrate that these GE diamondback moth strains would not increase the already existent plant pest risk or allow the establishment and persistence in the environment. If APHIS chooses this alternative, then the permit will be subject to the conditions described in 7 CFR part 340.4[4].

Under the Preferred Alternative, the permit would be valid for a three-year period. The permit will need to be renewed by the applicant and subsequently approved by APHIS to allow any additional release of GE diamondback moths beyond the three-year time period specified in the permit application. Additionally, under the Preferred Alternative, the applicant would be allowed to gather data on performance of GE diamondback moths in reducing populations of non-GE diamondback moths over a multi-year period.

Environmental Consequences of APHIS' Selected Action

The EA contains a full analysis of the alternatives to which we refer the reader for specific details. The following table briefly summarizes the results for each of the issues fully analyzed in the Environmental Consequences section of the EA.

Attribute / Measure	Alternative A: No Action Alternative Deny the permit request	Alternative B: Preferred Alternative Approve the permit request
Meets Purpose and Need and Objectives	**No**	**Yes**
Unlikely to pose a plant	No plant pest risk.	Satisfied through use of regulated field trials, including APHIS imposed permit conditions and monitoring for

[4] http://www.gpo.gov/fdsys/granule/CFR-2012-title7-vol5/CFR-2012-title7-vol5-sec340-4/content-detail.html Last accessed May, 2014

Attribute / Measure	Alternative A: No Action Alternative Deny the permit request	Alternative B: Preferred Alternative Approve the permit request
pest risk		compliance. Impacts would be similar to the no action alternative.
Physical Environment		
Soil Quality	Common agricultural activities related to field preparation/maintenance that impact soil (e.g., tillage, pesticide application, etc.) will continue under the No Action Alternative.	The permitted field release of GE diamondback moth is not anticipated to change common agricultural activities related to preparing and maintaining an agricultural field that is already occurring under the No Action Alternative. Transfer of non-native DNA from decomposing GE diamondback moth to other soil microflora is not likely under the Preferred Alternative. Thus, impact on soil resources would be similar to the no action alternative.
Water Resources	Agronomic practices that could impact water resources (e.g., irrigation, tillage practices, and the application of agronomic inputs) would be expected to continue under the No Action Alternative. The use of pesticides in accordance with EPA-approved label directions assure no unreasonable risks to water quality from their use	The permitted field release of GE diamondback moth is not anticipated to change common agricultural activities related to preparing and maintaining an agricultural field that is already occurring under the No Action Alternative. Thus, impact on water resources would be similar to the no action alternative.
Air Quality	Common agricultural activities having the potential to impact air quality such as tillage, the application of pesticides and fertilizer, and use of particulate- and pollutant -emitting agricultural equipment would continue under the No Action Alternative. The use of pesticides in accordance with EPA-approved labels minimizes drift and reduces environmental impacts.	The permitted field release of GE diamondback moth is not anticipated to change common agricultural activities related to preparing and maintaining an agricultural field that is already occurring under the No Action Alternative. Thus, impact on air quality would be similar to the no action alternative.
Climate Change	Common agricultural activities possess the potential to impact climate change, through the release of CO_2 to the atmosphere from tillage; machinery powered by fossil fuel; and NO_2 emissions associated with nitrogen fertilizers use. These activities are already occurring, and are likely to continue occurring, under the No Action Alternative.	The permitted field release of GE diamondback moth is not anticipated to change common agricultural activities related to preparing and maintaining an agricultural field that is already occurring under the No Action Alternative. Thus, the impact on GHG emissions and climate change would be similar to the no action alternative.
Biological Environment		

Attribute / Measure	Alternative A: No Action Alternative Deny the permit request	Alternative B: Preferred Alternative Approve the permit request
Wildlife	Common agricultural activities such as such as tillage, cultivation, pesticide and fertilizer applications, and the use of agricultural equipment would continue to impact wildlife communities. The use of EPA-registered pesticides and herbicides in accordance with EPA-approved labels minimize potential impacts to animal communities.	The permitted field release of GE diamondback moth is not anticipated to change common agricultural activities related to preparing and maintaining an agricultural field that is already occurring under the No Action Alternative. The introduced traits in GE diamondback moth do not encode for any known allergen or toxin, and GE diamondback moth is not anticipated to persist within the action area due to its inability to overwinter. Additionally, horizontal gene transfer of DNA from GE diamondback moth to wildlife that may consume it is unlikely. Thus, impact to wildlife would be similar to the no action alternative.
Plant Communities	Under the No Action Alternative, the plant community within the action area will continue to generally consist of planted crops (cruciferous and non-cruciferous) and weeds of those planted crops. As a result of this simplified agricultural ecosystem, planted crops will continue to be potentially harmed by pests and weeds, and growers will continue to manage the population of pests and weeds.	The permitted field release of GE diamondback moth is not anticipated to change common agricultural activities related to preparing and maintaining an agricultural field that is already occurring under the No Action Alternative. Adult diamondback moths do not damage plant tissues and diamondback moth larvae only feed upon cruciferous plants. Damage from GE diamondback moth larvae on planted cruciferous plants is not anticipated to be substantial, because of the ubiquity of diamondback moth in the action area and its inability to persist within the action area. Damage from GE diamondback moth larvae on cruciferous weeds is also not anticipated to be substantial, because these cruciferous weeds are likely to be managed through cultural or chemical methods; the damage from GE diamondback moth larvae is unlikely to be more than the approaches land managers are likely taking to eradicate these cruciferous weeds from fields within the action area. Thus, impact to plant communities would be similar to the no action alternative.
Biological	Under the No Action Alternative, biological diversity within the action	The permitted field release of GE diamondback moth is not anticipated to

Attribute / Measure	Alternative A: No Action Alternative Deny the permit request	Alternative B: Preferred Alternative Approve the permit request
Diversity	area is reduced and will continue to be reduced when compared to environments that are less intensively managed.	change common agricultural activities related to preparing and maintaining an agricultural field that is already occurring under the No Action Alternative. Thus, impacts to biological diversity from common agricultural activities would be similar to the no action alternative. The release of GE diamondback moth is not anticipated to substantially affect biological diversity because non-GE diamondback moth is already targeted for management/control within the action area; and because GE diamondback moth is unlikely to persist within the action area after the end of the calendar year, similar to non-GE diamondback moth.
Human Health Environment		
Human Health	No changes are anticipated to currently-adopted agricultural activities under the No Action Alternative. As a result, human exposure (e.g., farmworkers or the general human population) to risks and hazards as a result of these common agricultural activities are also anticipated to continue occurring under the No Action Alternative. A variety of EPA-approved pesticides would continue to be used for pest management within the action area. Use of registered pesticides in accordance with EPA-approved labels protects human health and worker safety. EPA also establishes tolerances for pesticide residue that give a reasonable certainty of no harm to the general population and any subgroup from the use of pesticides at the approved levels and methods of application.	The permitted field release of GE diamondback moth is not anticipated to change common agricultural activities related to preparing and maintaining an agricultural field that is already occurring under the No Action Alternative. Thus, impacts to human health (e.g., farmworkers and the general human population) from common agricultural activities would be similar to the no action alternative. Previous NEPA documents have analyzed and concluded that there is no unreasonable risk to humans associated with the introduced traits in GE diamondback moth. Thus, GE diamondback moth itself is not anticipated to substantially affect human health under the Preferred Alternative. Additionally, GE diamondback moth is not a member of any lepidopteran family that may generally cause allergic reactions to humans from exposure to scales or hairs.

Attribute / Measure	Alternative A: No Action Alternative Deny the permit request	Alternative B: Preferred Alternative Approve the permit request
Compliance with Other Laws		
CWA, CAA, EOs	Fully compliant	Fully compliant

Finding of No Significant Impact

The analysis in the EA indicates that there will not be a significant impact, individually or cumulatively, on the quality of the human environment as a result of this proposed action. I agree with this conclusion and therefore find that an EIS need not be prepared. This NEPA determination is based on the following context and intensity factors (40 CFR 1508.27):

Context – The term "context" recognizes potentially affected resources, as well as the location and setting in which the environmental impact would occur. This action would be limited to the environmental release of a GE diamondback moth on six potential release sites[5] described within the permit application #13-297-102r (see Section 2.4 of the EA). The action area is contained within the NYSAES in Geneva, NY. The NYSAES itself consists of 870 total acres and is located on the north-western edge of Geneva, NY, approximately 2 miles from suburban/urban areas. The field release has limited potential to affect resources outside of field test sites. Permit conditions in 7 CFR part 340.4[6] will effectively mitigate any potentially adverse environmental impacts associated with the permitted field release of GE diamondback moth.

Intensity – Intensity is a measure of the degree or severity of an impact based upon the ten factors. The following factors were used as a basis for this decision:

1. *Impacts that may be both beneficial and adverse.*
   According to the applicant, GE diamondback moths may serve as an insecticide-free means of controlling field populations of diamondback moths in a species-specific manner. APHIS issuance of the field release permit would allow research to assess the reduction of pest populations of non-GE diamondback moths. The release of GE diamondback moth strains OX4319L-Pxy, OX4319N-Pxy, and OX4767A-Pxy on release sites within the grounds of the Cornell University NYSAES will allow the applicant to obtain data on performance of the GE moths. The field release will not have any impact on existing agricultural practices because they are solely for research purposes. Thus, current agricultural practices will essentially remain unchanged.

2. *The degree to which the proposed action affects public health or safety.*
   The proposed action to issue the APHIS field release permit should not pose an unnecessary risk to human health and therefore would have no significant impacts on human health. GE diamondback moth is not used for food or feed purposes and does not contain any genetically engineered pesticides or tolerance to herbicides. However, at the conclusion of each experiment, the release sites will be devitalized of any remaining diamondback moths through the application of the EPA-registered insecticide, Coragen (chlorantraniliprole).

[5] Total acreage for these potential release sites is not to exceed 60 acres

[6] http://www.gpo.gov/fdsys/granule/CFR-2012-title7-vol5/CFR-2012-title7-vol5-sec340-4/content-detail.html Last accessed May, 2014

Post-experiment monitoring of diamondback moths with the traps will continue for 2 weeks after the conclusion of each experiment to monitor field longevity of GE diamondback moth. Adherence to EPA label instructions will ensure that negligible impacts are achieved as a result of pesticide use. Potential adverse impacts to public health or safety as a result of approving field release of GE diamondback moth are negligible.

3. *Unique characteristics of the geographic area such as proximity to historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas.*

This action would be limited to the environmental release of a GE diamondback moth on six potential release sites described within the permit application #13-297-102r (see Section 2.4 of the EA). The action area is contained within the NYSAES in Geneva, NY. The field release has limited potential to affect resources outside of field test sites. Issuing the permit for GE diamondback moth is not expected to impact unique characteristics of geographic areas such as park lands, prime farmlands, wetlands, wild and scenic areas, or ecologically critical areas. As discussed in the Environmental Consequences chapter of the EA, no different agronomic activities within the action area are anticipated as a result of the Preferred Alternative. If the permit is issued, the field release will occur on land already under agricultural management, and is not expected to alter land use patterns within the action area.

There are no proposed major ground disturbances; no new physical destruction or damage to property; no alterations of property, wildlife habitat, or landscapes; and no prescribed sale, lease, or transfer of ownership of any property. This action is limited to issuing a three-year permit for GE diamondback moth release. This action would not convert land use to non-agricultural use and, therefore, would have no adverse impact on prime farmland. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted under the Preferred Alternative, including the use of EPA-registered pesticides. The inability of diamondback moth to overwinter in the action area suggests that any remaining GE diamondback moth remaining at the conclusion of the calendar year will not persist into the following calendar year (see Section 3.2 of the EA).

Based on these findings, including the assumption that label use restrictions are in place to protect unique geographic areas and that those label use restrictions are adhered to, issuing a permit for the field release of GE diamondback moth is not expected to impact unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas.

4. *The degree to which the effects on the quality of the human environment are likely to be highly controversial.*

The effects on the quality of the human environment are not highly controversial. Although there is some opposition to APHIS issuing the field release permit, this action is not highly controversial in terms of size, nature or effect. This action would be limited to six potential release sites[7] described within the permit application #13-297-102r (see Section 2.4 of the EA). The action area is contained within the NYSAES in Geneva, NY. The public comments did not register any specific factual concerns with the data provided to APHIS for this permit application and which were presented in the EA.

[7] Total acreage for these potential release sites is not to exceed 60 acres

5. *The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.*
The effects of the proposed action to issue the APHIS field release permit are not highly uncertain and do not involve unique or unknown risks. Based on the analysis documented in the EA, the effects on the human environment would not be significant. APHIS has no evidence for any unknown risks of the GE diamondback moth strains OX4319L-Pxy, OX4319N-Pxy, and OX4767A-Pxy when released in the environment. The field release of GE diamondback moth does not present any unforeseen risks. Based on the analysis and information provided in the EA and supporting permit application, the new genes that are engineered into the specified GE diamondback moth strains should not pose significant risk associated with field release. Adherence to the permit conditions established for the permit by the applicant will effectively limit any potential adverse impacts to the human environment.

6. *The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.*
The proposed action would not establish a precedent for future actions with significant effects or represent a decision in principle about a future decision. Similar to past permit applications reviewed and approved by APHIS, the decision on whether or not to issue a permit for environmental release will be based upon information provided in the permit application. APHIS regulations at 7 CFR part 340 regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. In accordance with these regulations when APHIS receives an application for a permit for environmental release or movement, the application is evaluated to determine whether the environmental release or movement, with appropriate conditions imposed, can be carried out while preventing the dissemination and establishment of plant pests. The applicant has provided the information associated with this request in the permit application and APHIS now must make a determination to either approve or deny the permit. Each permit application that APHIS receives undergoes this independent review to determine if APHIS should approve or deny the individual permit.

7. *Whether the action is related to other actions with individually insignificant but cumulatively significant impacts.*
No significant cumulative effects were identified through this assessment. As discussed in the cumulative effects analysis presented in the EA, APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to create cumulative impacts or reduce the long-term productivity or sustainability of any of the resources (soil, water, ecosystem quality, biodiversity, etc.) associated with the release sites or the ecosystem in which they are situated. No resources will be significantly impacted due to cumulative impacts resulting from the proposed action.

8. *The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historical resources.*
This action would be limited to the environmental release of a GE diamondback moth on six potential release sites described within the permit application #13-297-102r (see Section 2.4 of the EA). The action area is contained within the NYSAES in Geneva, NY. The field

release has limited potential to affect resources outside of field test sites. APHIS' proposed action, issuing a permit for the three-year field release of GE diamondback moth, is not expected to adversely impact cultural resources on tribal properties. APHIS' Preferred Alternative would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would it likely cause any loss or destruction of significant scientific, cultural, or historical resources. This action is limited to issuing a three-year permit for the field release of GE diamondback moth.

APHIS' proposed action is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the National Historic Preservation Act (NHPA). In general, common agricultural activities associated with this action do not have the potential to introduce visual, atmospheric, or noise elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for increased noise on the use and enjoyment of a historic property during the operation of tractors and other mechanical equipment close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary effects on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition, with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the action area. The three-year field release of GE diamondback moth is not expected to change any of these agronomic practices that would result in an adverse impact under the NHPA.

9. *The degree to which the action may adversely affect an endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.*
APHIS evaluated the potential for negative effects on federal threatened and endangered species as listed by the U.S. Fish and Wildlife Service from the issuance of the field release permit and associated permit conditions and concluded that there would be no effect on federally listed threatened or endangered species or species proposed for listing, or on designated critical habitat or habitat proposed for designation *(see* section on Threatened and Endangered Species in the EA).

10. *Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.*
The proposed action would be in compliance with all federal, state, and local laws. The proposed action to issue the APHIS field release permit would be carried out in accordance with 7 CFR part 340. GE diamondback moth is not used for food or feed purposes and does not contain any genetically engineered pesticides or tolerance to herbicides, thus FDA and EPA consultation is not required. At the conclusion of each experiment, the release sites will be devitalized of any remaining diamondback moths through the application of the EPA-registered insecticide, Coragen (chlorantraniliprole) in accordance with EPA label instructions. There are no other Federal, state, or local permits that are needed prior to the implementation of this action.

NEPA Decision and Rationale

I have carefully reviewed the EA prepared for this NEPA determination and the input from the public involvement process. I believe that the issues identified in the EA are best addressed by selecting the preferred alternative - Issue the APHIS Permit.

As stated in the CEQ regulations, "the agency's preferred alternative is the alternative which the agency believes would fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors." The preferred alternative has been selected for implementation based on consideration of a number of environmental, regulatory, and social factors. Based upon our evaluation and analysis, Alternative B is selected because (1) it allows APHIS to fulfill its statutory mission to protect America's agriculture and environment using a dynamic and science-based regulatory framework that allows for the safe development and use of genetically engineered organisms; and (2) it allows APHIS to fulfill its regulatory obligations. Therefore, it is my decision to implement the preferred alternative as described in the EA. Based on all of the analysis and reasons above, I have determined that there would be no significant impact to the quality of the human environment from the implementation of the chosen alternative (the preferred alternative to issue the APHIS permit) and therefore, no EIS needs to be prepared. As such, APHIS will issue this permit to allow the field release of a GE diamondback moth engineered to reduce pest populations of non-GE diamondback moths within the grounds of the Cornell University New York State Agricultural Experiment Station.

Michael J. Firko, Ph.D.
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Biotechnology Regulatory Services
Animal and Plant Health Inspection Services
U.S. Department of Agriculture

Date

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USDA-APHIS (2008) "Use of Genetically Engineered Fruit Fly and Pink Bollworm in APHIS Plant Pest Control Programs: Final Environmental Impact Statement." Riverdale, MD.

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Response to public comments on USDA-APHIS's Proposal to permit the field release of genetically engineered diamondback moth in New York

On August 28th, 2014, APHIS published a notice in the Federal Register (79 FR 51299-51300, Docket no. APHIS-2014-0056) announcing the availability of the Simplot Innate™ potato petition (13-022-01p) for a 30-day public review and comment period. Comments were required to be received on or before September 29th, 2014. The docket folder containing the comments can be located[8] at http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0056.

A total of 286 individual comments were received, in addition to a single comment containing 19,869 signatures, during the 30-day comment period. APHIS evaluated all issues raised by the comments and the submitted documentation. Many of these comments were generically opposed to GE organisms and are outside of the scope of this EA. APHIS carefully reviewed the articles sent in by commenters. Many of them were included in the EA, and APHIS has responded below to the issues that were raised which relate to docket APHIS-2014-0056.

Issue 1:

Several commenters stated that an Environmental Impact Statement (EIS) is needed in lieu of an Environmental Assessment (EA).

APHIS Response:

APHIS disagrees with this comment that an EIS is needed. APHIS believes that the EA is comprehensive, and the appropriate environmental review document for this proposed action. Moreover, APHIS is confident that the EA has sound and reliable environmental and scientific analysis. APHIS carefully considered and analyzed the possible environmental impacts of the proposed action, and is satisfied that the EA developed for the proposal to permit the field release of genetically engineered diamondback moth is adequate and sufficient. APHIS used sound science to inform its regulatory decision regarding proposed permitted field release of genetically engineered diamondback moth, and has concluded that its permitted field release is unlikely to result in significant impacts to the human environment.

In the EA, APHIS fully considered and evaluated opposing and/or contrary views; it has reviewed data submitted by those who supported or opposed the proposed permitted field release, and has used objective, reliable environmental and scientific information. APHIS has included an analysis of each of the alternatives and evaluated and used the best available information from various sources, including peer-reviewed scientific literature that was reviewed and incorporated into APHIS' analysis. APHIS relied on a variety of credible sources to support its analysis of the potential impacts of permitted field release for genetically engineered diamondback moth. These sources include, but are not limited to scientific technical reports and peer-reviewed literature.

[8] Hyperlink cannot be directly opened. The hyperlink must be pasted in web browser address bar to be functional.

The EA has been prepared in order to specifically evaluate the potential effects on the quality of the human environment that may result from a permitted field release of genetically engineered diamondback moth. As described in the Chapter 4 of the EA, APHIS evaluated two alternatives; (1) no action and (2) issue the APHIS permit. The agency evaluated these alternatives, in light of the agency's statutory authority under the plant pest provisions of the Plant Protection Act, and the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be the appropriate ones to consider in reference to making a decision on whether to permit the field release of genetically engineered diamondback moth.

APHIS has prepared the EA to specifically evaluate the potential effects on the quality of the human environment that may result from the permitted field release of genetically engineered diamondback moth. The environmental analysis in the EA has not indicated that any significant impacts on the environment would result from issuing the APHIS permit and therefore, APHIS does not need to prepare an EIS for this proposed action.

Issue 2:

Several commenters stated that the public comment period for the EA should be extended.

APHIS Response:

APHIS deemed the 30-day comment period sufficient opportunity for the public to provide meaningful comments on this EA. Following the comment period, the Agency thoroughly reviewed the comments and carefully considered other inputs as it prepared APHIS' EA and FONSI in response to this proposal for a permitted field release of genetically engineered diamondback moth.

Issue 3:

Several commenters expressed concern over the lack of containment in this proposed permitted field release and the lack of consideration regarding the long-distance dispersal of genetically engineered diamondback moth. Additionally, other commenters also expressed concern about the movement of genetically engineered diamondback moth into other areas where it may overwinter.

APHIS Response:

APHIS acknowledges these comments and concerns. As described in Section 3.2, EA Action Area, and Section 4.2, Preferred Alternative – Issue the APHIS Permit, permit conditions imposed by APHIS will prevent released genetically engineered diamondback moth or its progeny from persisting in the environment. Additional conditions are required for confinement of this genetically engineered diamondback moth during production or the process leading to release (Section 3.2, EA Action Area), Persistence of the moth will be unlikely, either in the presence or absence of long-distance dispersal because the potential field release of genetically

engineered diamondback moth represents a confined field release. The permit to be issued is unlikely to result in any significant environmental impact.

Issue 4:

Some commenters stated that genetically engineered diamondback moth has been inadequately tested and expressed concern regarding this inadequacy.

APHIS Response:

APHIS disagrees that genetically engineered diamondback moth has been inadequately tested. In addition to the references cited throughout the EA and the technical report appended to the EA as Appendix A, the applicant's research group has recently submitted a manuscript entitled *Pest control and resistance management through release of insects carrying a male-selecting transgene* to the peer-reviewed journal Proceedings of the National Academy of Science (Personal Communication with A. Shelton).

Reference(s)

Shelton, A. to Blanco, C. Personal Communication, RE: PNAS paper. October, 2014.

Issue 5:

Several commenters stated that the EA "neglected to examine the impacts of animal and human consumption of the GMO moths." Additionally, a commenter expressed concern regarding the safety of tTAV protein consumption and provided several references to justify this concern.

APHIS Response:

APHIS disagrees that the EA neglected to examine the potential impacts of animal and human consumption of genetically engineered diamondback moths and its introduced gene products. As presented in Section 5.3.2 and Appendix A of the EA, no significant impacts to wildlife or humans are anticipated from the consumption of genetically engineered diamondback moths. APHIS' review of the peer-reviewed literature also support the conclusion that potential impacts to animal and human health from the consumption of genetically diamondback moth is unlikely (FDA, 2010; Goodman, 2013).

APHIS also disagrees that the references submitted by the commenter supports any concern over the safety of consumption of the tTAV protein. Both Sisson *et al.* (2006) and Whitsett and Perl (2006) describe the *in vivo* physiological responses of mammalian systems expressing tTAV systems in tissues and not responses of wildlife and humans responses to consumption of genetically engineered organisms containing introduced tTAV genes. As APHIS (2014) has repeatedly demonstrated in its EAs and EISs, and in this EA, the intentional or unintentional consumption of introduced gene and gene products is not likely to have any significant impact on wildlife or human health.

Reference(s)

FDA (2010) Re: NPC 00004: Agency Response Letter. United States Food and Drug Administration. http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/Submissions/ucm222920.htm Last accessed October, 2014.

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Sisson, TH; Hansen, JM; Shah, M; Hanson, KE; Du, M; Ling, T; Simon, R; and Christensen, P (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. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2644220/. Last accessed: October, 2014.

USDA-APHIS (2014) Biotechnology Environmental Documents for Permits and Petitions. United States Department of Agriculture - Animal and Plant Health Inspection Service. http://www.aphis.usda.gov/biotechnology/biotech/brs_environmental_assessments.shtml. Last Accessed: March, 2014

Whitsett, J and Perl, A-KT (2006) Conditional Control of Gene Expression in the Respiratory Epithelium: A Cautionary Note. *American Journal of Respiratory Cell and Molecular Biology*. 34(5):519–520. http://www.atsjournals.org/doi/pdf/10.1165/rcmb.F310. Last accessed: October, 2014.

Issue 6:

Several commenters noted that Oxitec[9] was unable to get approval for the field release of genetically engineered diamondback moth in the UK and expressed concern that APHIS is proposing to permit a field release of genetically engineered diamondback moths in spite of this.

APHIS Response:

APHIS acknowledges that Oxitec was unable to get approval for the field release of genetically engineered diamondback moth in the UK. Conditions for release in UK may be considerably different from release in North America, and acceptance of any such release may require difference circumstances for the UK public.

Additionally, the cited UK regulatory decision is outside the scope of this EA. The EA has been prepared in order to specifically evaluate the potential effects on the quality of the human environment that may result from a permitted field release of genetically engineered diamondback moth. As described in the Chapter 4 of the EA, APHIS evaluated two alternatives; (1) no action and (2) issue the APHIS permit with its permit conditions. The agency evaluated

[9] The company that produced the genetically engineered diamondback moths

these alternatives, in light of the agency's statutory authority under the plant pest provisions of the Plant Protection Act, and the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be the appropriate ones to consider in reference to making a decision on whether to permit the field release of genetically engineered diamondback moth.

APHIS has prepared the EA to specifically evaluate the potential effects on the quality of the human environment that may result from the permitted field release of genetically engineered diamondback moth. The environmental analysis in the EA has not indicated that any significant impacts on the environment from issuing the APHIS permit are unlikely. Such conclusions are within APHIS' regulatory authority in accordance with 7 CFR 340 and the Plant Protection Act.

Issue 7:

Several commenters expressed concern that the genetically engineered diamondback moth could be used to introduce viral and other biological diseases into the environment.

APHIS Response:

APHIS disagrees that this genetically engineered diamondback moth could be used to introduce viral and other biological diseases into the environment. As described in the EA at Section 2.4, Description and Purpose of the Research, the purpose of this proposed permitted field release is to assess the feasibility and efficacy of genetically engineered diamondback moth strains in reducing ubiquitous pest populations of non-genetically engineered diamondback moths.

This release of GE male-sterile diamondback moths is anticipated to oversaturate breeding populations of non-GE diamondback moths with GE males. Successful mating between GE male diamondback moths and non-GE female diamondback moths will not produce viable female larvae because females would all bear the autocidal trait. Continued presence of either progeny males or introduced GE males with the sterility gene will become a repeated cycle during the growing season of that planted field, and will result in a net reduction of the feral diamondback moth population (see Figure 1 in the EA).

While it is true that this particular genetically engineered diamondback moth contains viral sequences, the viral sequences used are short and incomplete. Consequently, this genetically engineered diamondback moth is incapable of producing a fully-functioning infectious entity upon confined release into the environment.

Issue 8:

Several commenters expressed concern that the genetically engineered diamondback moth could become invasive in the proposed area of release.

APHIS Response:

APHIS disagrees that the proposed permitted field release of genetically engineered diamondback moth could become invasive in the proposed area of release. As described in the EA in Section 3.2, EA Action Area, this genetically engineered diamondback moth is unlikely to become established in the action area of any other area where it may inadvertently disperse to. Additionally, as described in the EA in Section 5.3.2, Preferred Alternative: Wildlife, Plant Communities, and Biological Diversity and in Jin *et al.* (2013), this genetically engineered diamondback moth demonstrates reduced fitness. While the reduced fitness was observed in contained studies, it lends further credence to the notion that this genetically engineered diamond moth is unlikely to become invasive upon confined field release. Additionally, this reduced fitness is not anticipated to interfere with the repression effect on local non-genetically engineered diamondback moth populations, so long as a constant supply of genetically engineered diamondback moths are supplied during the experiment (Harvey-Samuel *et al.*, submitted for publication).

Furthermore, the persistence of any diamondback moth strain, genetically engineered or non-genetically engineered, is largely dependent on the commercial planting of cruciferous crops by farmers. It is likely that any cruciferous crop outside the potential field release area would be actively managed, utilizing a variety of best management practices, for the purposes of diamondback moth control. Any genetically engineered diamondback moth or its progeny that potentially disperses to these cruciferous crop fields outside the potential field release area will be subject to these best management practices, thereby encountering a substantial obstacle to the development of further genetically engineered diamondback moths and its establishment/invasiveness.

Reference(s)

Harvey-Samuel, *et al.* Pest control and resistance management through releases of insects carrying a male-selecting transgene. Submitted for publication to PNAS.

Jin, L; Walker, AS; Fu, G; Harvey-Samuel, T; Dafa'alla, T; Miles, A; Marubbi, T; Granville, D; Humphrey-Jones, N; O'Connell, S; Morrison, NI; and Alphey, L (2013) Engineered Female-Specific Lethality for Control of Pest Lepidoptera. *ACS Synthetic Biology*, 2(3), 160-166. http://pubs.acs.org/doi/abs/10.1021/sb300123m. Last accessed: October, 2014.

Issue 9:

Several commenters expressed concern that no contingency plan to destroy the genetically engineered diamondback moths in case of any emergency.

APHIS Response

APHIS acknowledges that there is no contingency plan to destroy the genetically engineered diamondback moths. However, APHIS does not believe a contingency plan is required, as this genetically engineered diamondback moth is not anticipated to persist in the environment

following its proposed field release due to factors related to the environment and APHIS permit conditions (see in Section 3.2, EA Action Area, and Section 4.2, Preferred Alternative – Issue the APHIS Permit).

Furthermore, at the termination of this proposed field trial the applicant will spray a 100m (305') radius around the release site with a diamondback moth-active insecticide, reducing the population of non-genetically engineered and genetically engineered diamondback moths to extremely low numbers. This action, combined with the discussion already presented in the EA in Section 3.2, EA Action Area and the APHIS Response to Issue 8 (directly above), strongly suggests that the genetically engineered diamondback moth is unlikely to persist in the environment.

Issue 10:

Several commenters expressed concern that the EA did not sufficiently examine impacts on non-target organisms.

APHIS Response:

APHIS disagrees that the EA did not sufficiently examine potential impacts on non-target organisms. Substantial discussion on the potential impact on non-target organisms was presented in the EA in Section 5.3.2, Preferred Alternative: Wildlife, Plant Communities, and Biological Diversity; and Section 6, Cumulative Impacts; and Section 7, Threatened and Endangered Species. These comments were general in nature and did not specify which analyses in APHIS's EA did not sufficiently examine potential impacts on non-target organisms.

Issue 11:

Several commenters expressed concern regarding the tetracycline-repressible female lethality trait in this genetically engineered diamondback moth. Specifically, some commenters noted: a) that tetracycline may occur in the environment; and b) that other chemicals in the same chemical class as tetracycline may have the same effect. As a result of these potential issues, commenters expressed concern that the female lethality trait in this genetically engineered diamondback moth may be repressed if APHIS authorizes its permitted field release.

APHIS Response

APHIS disagrees that tetracycline (or any other similar chemical) in the environment may lead to repression of the tetracycline-repressible female lethality trait in this genetically engineered diamondback moth.

APHIS acknowledges that tetracycline or other similar chemicals may be present in agricultural soil samples, as observed by Ho *et al.* (2012) and Kyselkova *et al.* (2013), though concentrations are unlikely to be as high as described by Kyselkova *et al.* (2013) due to that publication's use of cow excrement and not the manure that more likely to be used in fields of agricultural crops (the mechanism of processing manure is likely to result in degradation of chemicals like tetracycline,

see text directly below). However, in order for tetracycline (or any other similar chemical) to repress the female-lethality phenotype in this genetically engineered diamondback moth, larval progeny resulting from the mating between genetically engineered diamondback moth males and non-genetically engineered diamondback moth females must consume tetracycline in order for the repression to occur. The references provided during the public comment period (e.g., Ho *et al.,* 2012 and Kyselkova *et al.,* 2013) demonstrate the presence of antibiotics in agricultural soil samples, but does not demonstrate the presence of antibiotics in cruciferous plants growing on these soils. The tetracycline-repressible female lethality trait in this genetically engineered diamondback moth only occurs after direct consumption of tetracycline in the larval diet (Jin *et al.*, 2013), and not simply by being near tetracycline.

Within the agricultural environment, tetracycline (and other related chemicals) is rapidly degraded by a variety of mechanisms, whether it is directly in the soil (Bautiz and Nogueira, 2006; and Reyes *et al.*, 2006) or during the production of manure sometimes used to fertilize agricultural soils (Kim *et al.*, 2011; and Sarmah *et al.*, 2006). During uptake by cruciferous plants, concentrations of tetracycline (or any other similar chemical) would likely be lower concentration of tetracycline (or any other similar chemical) than that of the soil. In laboratory experiments growing cabbage on soil artificially contaminated with chlortetracycline and manure from chlortetracycline-fed pigs, the concentration of tetracycline in the cabbage foliage was less than the dose required to repress the female-lethality trait (Kumar *et al.*, 2005; and Harvey-Samuel *et al.*, submitted for publication).

Reference(s)

Bautitz, IR and Nogueira, RFP (2007) Degradation of tetracycline by photo-Fenton process—Solar irradiation and matrix effects. *Journal of Photochemistry and Photobiology Chemistry,* 187 (1), p 33-39. http://www.sciencedirect.com/science/article/pii/S1010603006005053. Last accessed: October, 2014.

Harvey-Samuel, *et al.* Pest control and resistance management through releases of insects carrying a male-selecting transgene. Submitted for publication to PNAS.

Ho, YB; Zakaria, MP; Latif, PA; and Saari, N (2012) Simultaneous determination of veterinary antibiotics and hormone in broiler manure, soil and manure compost by liquid chromatography–tandem mass spectrometry. *Journal of Chromatography*, 1262 (0), 160-68. http://www.sciencedirect.com/science/article/pii/S0021967312014094. Last accessed: October, 2014.

Jin, L; Walker, AS; Fu, G; Harvey-Samuel, T; Dafa'alla, T; Miles, A; Marubbi, T; Granville, D; Humphrey-Jones, N; O'Connell, S; Morrison, NI; and Alphey, L (2013) Engineered Female-Specific Lethality for Control of Pest Lepidoptera. *ACS Synthetic Biology*, 2(3), 160-166. http://pubs.acs.org/doi/abs/10.1021/sb300123m. Last accessed: October, 2014.

Kim, K-R; Owens, G; Kwon, S-I; So, K-H; Lee, D-B; and Ok, Y (2011) Occurrence and Environmental Fate of Veterinary Antibiotics in the Terrestrial Environment. *Water, Air, & Soil*

Pollution, 214 (1-4), 163-174. http://dx.doi.org/10.1007/s11270-010-0412-2. Last accessed: October, 2014.

Kumar, K; Gupta, S; Baidoo, S; Chander, Y; and Rosen, C (2005) Antibiotic Uptake by Plants from Soil Fertilized with Animal Manure. *Journal of Environmental Quality*, 34(6), 2082-2085. http://www.ncbi.nlm.nih.gov/pubmed/16221828. Last accessed: October, 2014.

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Reyes, C; Fernández, J; Freer, J; Mondaca, MA; Zaror, C; Malato, S; and Mansilla, HD (2006) Degradation and inactivation of tetracycline by TiO2 photocatalysis. *Journal of Photochemistry and Photobiology Chemistry,* 184 (1–2), 141-146. http://www.sciencedirect.com/science/article/pii/S1010603006001985. Last accessed: October, 2014.

Sarmah, AK; Meyer, MT; and Boxall, AB (2006) A global perspective on the use, sales, exposure pathways, occurrence, fate and effects of veterinary antibiotics (VAs) in the environment. *Chemosphere,* 65 (5), 725-759.

Issue 12

Several commenters expressed concern regarding horizontal gene transfer from this genetically engineered diamondback moth to microorganisms, and its implications for antibiotic resistance in microorganisms (e.g., microorganisms in the gut of insectivores).

APHIS Response

APHIS disagrees that horizontal gene transfer between this genetically engineered diamondback moth and microorganisms is likely, and that there are any implications for antibiotic resistance in microorganisms during the proposed duration of this potential field release.

First and foremost, there are no antibiotic resistances genes present in this genetically engineered diamondback moth. Secondly, while there is evidence for gene transfer from parasitic insects to vertebrates (Gilbert et al. 2014), it is clear that these events take place over evolutionary timescales (millions of years), rather than the duration of this trial. This conclusion regarding horizontal gene transfer is also supported by other APHIS EAs (USDA-APHIS, 2014). Moreover, the transgenes contained in this genetically engineered diamondback moths carry non-autonomous transposon sequences (i.e. the transposase-encoding sequence is not present), strongly indicating that autonomous movement of these transposon sequences is not likely (USDA-APHIS, 2008).

Reference(s)

Gilbert, C; Chateigner, A; Ernewein, L; Barbe, V; Bezier, A; Hernious, EA; and Cordaux, R (2014) Population genomics supports baculoviruses as vectors of horizontal transfer of insect transposons. *Nature Communications*, 5. http://dx.doi.org/10.1038/ncomms4348. Last accessed: October, 2014.

USDA-APHIS (2008) Use of Genetically Engineered Fruit Fly and Pink Bollworm in APHIS Plant Pest Control Programs: Final Environmental Impact Statement. Riverdale, MD. http://www.aphis.usda.gov/plant_health/ea/downloads/eis-gen-pbw-ff.pdf. Last accessed: October, 2014.

USDA-APHIS (2014) Biotechnology Environmental Documents for Permits and Petitions. United States Department of Agriculture - Animal and Plant Health Inspection Service. http://www.aphis.usda.gov/biotechnology/biotech/brs_environmental_assessments.shtml. Last Accessed: March, 2014.

Issue 13

Several commenters expressed concern that the fluorescent markers contained in or applied to this genetically engineered diamondback moth may fade within a few days, and as a result, make it more difficult to monitor the potentially-released genetically engineered diamondback moths.

APHIS Response

APHIS acknowledges this concern, though previous APHIS EAs have demonstrated that the inheritance and long-term stability of the DsRed2 transgene (USDA-APHIS, 2014). Furthermore, even if the applied fluorescent dusts were to fade in a few days, this would not preclude all types of monitoring. Genetically engineered diamondback moths or its progeny would still identifiable through activity of the DsRed2 transgene or molecular detection methods (e.g., polymerase chain reaction genotyping).

Reference(s)

USDA-APHIS (2014) Biotechnology Environmental Documents for Permits and Petitions. United States Department of Agriculture - Animal and Plant Health Inspection Service. http://www.aphis.usda.gov/biotechnology/biotech/brs_environmental_assessments.shtml. Last Accessed: March, 2014.

Issue 14

Sever commenters expressed concern that the 100m kill zone around the potential release site for pesticide application upon the termination of the potential field trial is not great enough and should be greater in order to prevent establishment of this genetically engineered diamondback moth.

APHIS Response

APHIS disagrees that the potential area around the potential release site should be greater than 100m. Firstly, the local dispersal of diamondback moth is less than 100m (Mo *et al.*, 2003). This action, combined with the discussion already presented in the EA in Section 3.2, EA Action Area and the APHIS Response to Issue 8 (directly above), strongly suggests that this genetically engineered diamondback moth is unlikely to persist in the environment.

Reference(s)

Mo, J; Baker, G; Keller, M; and Roush, R. (2003) Local Dispersal of the Diamondback Moth (*Plutella xylostella* (L.)) (Lepidoptera: Plutellidae). *Population Ecology*, 32(1), 71-79. http://www.bioone.org/doi/pdf/10.1603/0046-225X-32.1.71. Last accessed: October, 2014.

Issue 15

Several commenters expressed concern regarding the penetrance of the female lethality trait, and that the potential failure of the RIDL system could be a favorable adaption and may produce unexpected changes in diamondback moth population dynamics.

APHIS Response

APHIS disagrees that there is substantial concern regarding the penetrance of the female lethality trait, as there are facts associated with this potential permitted field release that are likely to prevent the establishment of this genetically engineered diamondback moth.

As indicated in the EA (Appendix A) and the peer-reviewed literature (Jin *et al.*, 2013), the penetrance of the female lethality trait is greater than 95 percent. If the applicant chooses to use the most effective genetically engineered group of genetically engineered diamondback moth, then the penetrance increases to approximately 99 percent or greater (Jin *et al.*, 2013). However, APHIS acknowledges that these studies regarding the penetrance of the female lethality trait were conducted in the laboratory and may not accurately reflect field conditions. Given the likely confinement of genetically engineered diamondback moth within the action area as a result of the environment and permitted conditions (EA at Section 3.2), coupled with the decrease in fitness observed with these genetically engineered diamondback moth strains (Jim *et al.*, 2013 and Appendix A of the EA), establishment and persistence is not likely even if the penetrance of the female lethality trait were to decrease over time in the field.

Additionally, APHIS acknowledges the potential field failure of the RIDL (Release of Insects with Dominant Lethality) system in the EA (e.g., Section 5.3.2, Preferred Alternative: Wildlife, Plant Communities, and Biological Diversity), despite contained greenhouse studies showing the efficacy of the system in diamondback moth systems (Harvey-Samuel *et al.*, manuscript submitted). However, based on the analyses presented in Section 3.2, Section 5.3.2 of the EA, and elsewhere in the EA, any change in diamondback moth population dynamics will be transient, and thus, not likely to persist and result in a significant environmental impact following its potential confined field release. Furthermore, it is prudent to mention that any mutation that occurs releasing the genetically engineered diamondback moths from the RIDL system need not

be advantageous to fitness, and is just as likely, if not more, to be detrimental to fitness. The journal article submitted during the public comment period purports to support the notion that unexpected changes in diamondback moth populations can occur following the potential confined field release of genetically engineered diamondback moth (Yokab, *et al.*, 2008). However, APHIS disagrees that this peer-reviewed article provides sufficient evidence to contradict the analyses contained within APHIS' EA. Firstly, as mentioned above, APHIS acknowledges that failure of the RIDL system can lead to changes in diamondback moth populations, though these changes are anticipated to be transient and not result in significant environmental impacts. Secondly, the publication simulates population dynamics of *Aeges aegypti* and does not take into account a yearly collapse of all considered *Aeges aegypti* populations, as is likely to occur with this confined field release of genetically engineered diamondback moth (Section 3.2, EA Action Area). Thirdly, the publication itself actually demonstrates through simulation that use of RIDL technology (like the system employed in genetically engineered diamondback moth) is more effective than use of typical SIT (sterile insect technique, typically with sterility induced through radiation), and results in more predictable and expected changes in target insect population dynamics. And lastly, the publication demonstrated through simulation that undesirable effects on target insect population dynamics, both on and adjacent to the simulated release sites, were restricted to SIT *A. aegypti* and not RIDL *A. aegypti* (again, RIDL is the technology used in the production of these genetically engineered diamondback moths). In fact, field studies of SIT have observed that there is actually little impact on target moth insect populations in adjacent areas (Grefensette *et al.*, 2009; and Pierce *et al.*, 2013).

Reference(s)

Grefenstette, B; El-Lissy, O; and Staten, RT. (2009) Pink Bollworm eradication plan in the U.S. http://www.aphis.usda.gov/plant_health/plant_pest_info/cotton_pests/downloads/pbw-erad-plan2-09.pdf. Last accessed: October, 2014.

Harvey-Samuel, *et al.* Pest control and resistance management through releases of insects carrying a male-selecting transgene. Submitted for publication to PNAS.

Jin, L; Walker, AS; Fu, G; Harvey-Samuel, T; Dafa'alla, T; Miles, A; Marubbi, T; Granville, D;Humphrey-Jones, N; O'Connell, S; Morrison, NI; and Alphey, L (2013) Engineered Female-Specific Lethality for Control of Pest Lepidoptera. *ACS Synthetic Biology*, 2(3), 160-166. http://pubs.acs.org/doi/abs/10.1021/sb300123m. Last accessed: October, 2014.

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Several commenters noted that the APHIS EIS (2008) referenced throughout the EA was described as inadequate by the USDA Inspector General at the time and expressed concern that citation of this APHIS EIS (2008) is not appropriate, due to scientific deficiencies.

APHIS Response

APHIS acknowledges these comments and concerns. However, APHIS did not rely solely on that EIS for the analyses contained within this EA. Throughout the analyses in the EA, APHIS also relied on peer-reviewed literature and the weight of scientific evidence based on a survey of the peer-reviewed literature, which are cited in Section 10, References.

Additionally, the APHIS EIS (2008) described the use of genetically engineered pink bollworm and medfly in plant pest control programs, and thus, did not incorporate these as precedents for confinement conditions into its analysis. As described in Section 3.2, EA Action Area, and Section 4.2, Preferred Alternative – Issue the APHIS Permit, permit conditions imposed by APHIS onto the applicant, coupled with additional factors that facilitate confinement of this potential field release of genetically engineered diamondback moth (Section 3.2, EA Action Area), help ensure that any released genetically engineered diamondback moth or its progeny will not persist in the environment and cause a significant environmental impact.

Reference(s)

USDA-APHIS (2008) Use of Genetically Engineered Fruit Fly and Pink Bollworm in APHIS Plant Pest Control Programs: Final Environmental Impact Statement. Riverdale, MD. http://www.aphis.usda.gov/plant_health/ea/downloads/eis-gen-pbw-ff.pdf. Last accessed: October, 2014.