

**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 340.4¹. 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

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.

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 either present 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 340.4⁴.

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
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
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 sites⁵ 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 340.4⁶ 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

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.

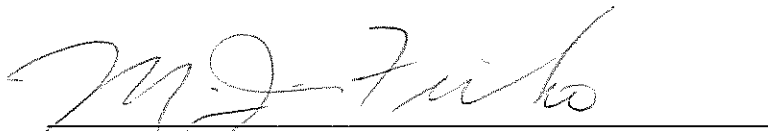
8. *The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historical resources.*

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

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.
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Services
U.S. Department of Agriculture

11/27/2014
Date

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 located⁸ 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.

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.

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:

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,

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.

Kyselkova, M; Jirout, J; Chronakova, A; Vrchotova, N; Bradley, R; Schmitt, H; and Elhottova, D (2013) Cow excrements enhance the occurrence of tetracycline resistance genes in soil regardless of their oxytetracycline content. *Chemosphere*, 93 (10), 2413-2418. <http://www.sciencedirect.com/science/article/pii/S0045653513011740>. Last accessed: October, 2014.

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 resistance 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)

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 adaptation 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

1265. <http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2664.2008.01498.x/abstract>. Last accessed: October, 2014.

Issue 16

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.