United States
Department of
Agriculture

Marketing and
Regulatory
Programs

Animal and Plant
Health Inspection
Service

Proposal to permit the field release of genetically engineered diamondback moth in New York

Environmental Assessment, June 2017

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ACRONYMS AND ABBREVIATIONS

°F	Degrees Fahrenheit
APHIS	Animal and Plant Health Inspection Service
BRS	Biotechnology Regulatory Services
CAA	Clean Air Act
CFR	Code of Federal Regulations
CWA	Clean Water Act
CH_4	Methane
CO_2	Carbon Dioxide
EA	Environmental Assessments
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FR	Federal Register
FQPA	Food Quality Protection Act
GE	Genetically Engineered
GHG	Greenhouse Gas
N_2O	Nitrous Oxide
NAAQS	National Ambient Air Quality Standards
NEPA	National Environmental Policy Act
NPS	Non-Point Source
NY	New York
NYSAES	New York State Agricultural Experiment Station
OSHA	Occupational Safety and Health Administration
OSTP	Office of Science and Technology Policy
PDP	Pesticide Data Program
PIP	Plant Incorporated Protectant
PM	Particulate Matter
PPA	Plant Protection Act of 2000
ppb	Parts per Billion

ppm	Parts per Million
SIP	State Implementation Plan
SIT	Sterile Insect Technique
TSCA	Toxic Substances Control Act
US	United States
USC	United States Code
USDA	United States Department of Agriculture
WPA	Worker Protection Standard

1 OVERVIEW

United States Department of Agriculture (USDA), Animal Plant Health Inspection Service (APHIS) has prepared an environmental assessment (EA) in response to an environmental release permit application (APHIS Number 16-076-101r) received on March 16th, 2016 from Dr. Anthony Shelton of Cornell University[1] to allow the field release of genetically engineered (GE) diamondback moth (*Plutella xylostella*) strain OX4319L-Pxy on a release site within the grounds of the Cornell University New York State Agricultural Experiment Station (NYSAES). The release site for this EA consists of an experimental field, up to 10 acres in size, within which there will be a single point at which the open air release will occur[2]. The applicant would additionally be conducting caged field studies in the area defined as the release site, but outside of the *Brassica* plot containing the single release point. In subsequent years, the specific location of the release site within the NYSAES may change due to crop rotation practices; hence this EA considers locations covering the entire NYSAES as the action area.

The GE diamondback moth strain OX4319L-Pxy has been genetically engineered with a single construct to confer red fluorescence and repressible female lethality.The purpose of the requested field release is for the applicant to assess the efficacy of GE diamondback moth strain OX4319L-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.

APHIS has previously issued the applicant permits authorizing the importation of GE diamondback moth strains OX4319L-Pxy, OX4319N-Pxy, and OX4767A-Pxy from the United Kingdom to the NYSAES (APHIS Numbers 12-227-102m, 13-297-101m). Renewals were issued for OX4319L-Pxy only (15-098-101m and 16-098-101m). The applicant submitted an application for field release of GE diamondback moth (13-297-102r) that was approved and subsequently amended (13-297-102r-a1), but this permit was ultimately withdrawn due to administrative errors by APHIS.

In summary of this EA, APHIS has concluded that potential impacts of APHIS issuing a permit for the field release of GE diamondback moth strain OX4319L-Pxy, on the physical environment (e.g., soil resources, water resources, air quality, and climate change); the biological environment (e.g., wildlife, plant communities, and biological diversity); and the human health environment (e.g., farmworker health and health of the general public) are unlikely (Section 5). Additionally, APHIS has concluded that cumulative impacts are unlikely (Section 6), and that APHIS' action will have no effect on listed Threatened and Endangered species or species proposed for listing, and will not affect designated critical habitat or habitat proposed for critical habitat designation (Section 7).

[1] Referred to as the applicant, hereinafter

[2] The action area, release site, and release point are shown in figure 2.

2 PURPOSE AND NEED

2.1 Regulatory Authority

"Protecting American agriculture" is the basic charge of the United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS). APHIS provides leadership in ensuring the health and care of plants and animals. The agency improves agricultural productivity and competitiveness, and contributes to the national economy and the public health. USDA asserts that all methods of agricultural production (conventional, organic, or the use of genetically engineered varieties) can provide benefits to the environment, consumers, and farm income.

Since 1986, the United States (US) government has regulated genetically engineered (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 should define those transgenic organisms subject to review to the extent permitted by their respective statutory authorities; (2) agencies are required to focus on the characteristics and risks of the biotechnology product, not the process by which it is created; (3) agencies are mandated to exercise oversight of GE organisms only 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 Animal and Plant Health Inspection Service (APHIS), the US Food and Drug Administration (FDA), and the US Environmental Protection Agency (EPA).

APHIS is responsible for regulating GE organisms and plants under the plant pest authorities in the Plant Protection Act of 2000, as amended (7 USC § 7701 *et seq*.) to ensure that they do not pose a plant pest risk to the environment.

The regulation of GE organisms by FDA and EPA are further discussed in Section 2.5.

2.2 Regulated Organisms

The APHIS Biotechnology Regulatory Service’s (BRS) mission is to protect America’s agriculture and environment using a dynamic and science-based regulatory framework that allows for the safe development and use of GE organisms. APHIS regulations at 7 Code of Federal Regulations (CFR) part 340, which were promulgated pursuant to authority granted by the Plant Protection Act (PPA), as amended (7 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.

2.3 APHIS Response to a Permit Application for a Field Release

The PPA directs the USDA to facilitate imports and interstate commerce in agricultural products in ways that will reduce, to the extent practicable, the risk of dissemination of plant pests. Under APHIS regulations, the APHIS Administrator has authority to regulate any organism or product altered or produced through genetic engineering that the Administrator determines is a plant pest or has reason to believe is a plant pest. When APHIS receives an application for a permit for environmental release, the application is evaluated to determine whether the environmental release, 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 GE 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 (APHIS Number 16-076-101r). This information is summarized below in Section 2.4 of this EA. Additionally, this information has been reviewed and analyzed in this EA.

2.4 Description and Purpose of the Research

The following information is from the applicant's permit application, Number 16-076-101r.

The GE diamondback moth strain OX4319L-Pxy,[3] is genetically engineered to show a phenotype consisting of two introduced traits:

- Red fluorescence; and
- Tetracycline-repressible female lethality.

The red fluorescence trait is conferred by activity of an introduced red fluorescent protein, DsRed2. Activity of DsRed2 in GE diamondback moth is intended to facilitate identification of GE from non-GE diamondback moths during field trials.

Tetracycline-repressible female lethality, also known as female autocide, is conferred by activity of an expressed protein, tTAV. The female autocidal trait permits the selection of male diamondback moths during rearing, as all females incur mortality unless provided in their diet a

[3] Collectively referred to as GE diamondback moth, hereinafter

repressor compound[4]. Additionally, the female autocidal trait is anticipated to decrease the number of diamondback moth offspring following field release through elimination of female moths. Any female progeny produced from GE diamondback moth males and non-GE diamondback moth females is likely to die (Jin *et al.*, 2013).

The purpose of the requested permit is basic research to assess the feasibility and efficacy of this GE diamondback moth 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 release of these GE diamondback moths will allow the applicant to gauge the efficacy of this system in reducing pest diamondback moth populations.

This release of GE male diamondback moths is anticipated to oversaturate breeding populations of non-GE diamondback moths with GE males. In the absence of a dietary repressor (tetracycline or suitable analogues supplied in their artificial diet), successful mating between GE male and non-GE female diamondback moths produced only 9% female survival to pupation and no more than 1% female survival to adult (Jin et al. 2013). The study observed few dead or dying late-instar larvae, indicating that death occurs primarily during early larval stages.

Continued presence of either progeny males or introduced GE males that carry the female lethal gene will become a repeated cycle during the growing season of that planted field, and will result in a net reduction of the diamondback moth population (Figure 1).

Under the permit application submitted by the applicant, one site will be planted with a cruciferous crop (e.g., cabbage, broccoli) and subject to the release of male GE diamondback moths. During a permitted field trial, the applicant will release up to 10,000 male GE diamondback moths per release (up to 30,000 males per week). Some of these released GE diamondback moth males may be marked with Day-Glo fluorescent dusts[5] in order to distinguish released GE diamondback moth males from the male progeny of GE diamondback moth males. Monitoring of diamondback moths in the study sites will be undertaken using mating stations or sticky traps baited with a synthetic sex pheromone specific for diamondback moth. Mating stations will consist of confined, wild-type females that attract males. For each experiment, release and monitoring of GE and non-GE diamondback moths will take place for the duration of the cruciferous crop planting cycle (anticipated to range from 3 to 4 months). At the conclusion of each experiment, the release site will be devitalized of any remaining diamondback moths through the application of the EPA-registered insecticide, Coragen (chlorantraniliprole). Post-experiment monitoring of diamondback moths with the traps will continue until no GE diamondback moths are recaptured for 2 consecutive months. If this permit is issued by APHIS, the permitted field trial may not exceed two years in length.

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[4] i.e., tetracycline

[5] Day-Glo Color Corp., Cleveland, OH. http://www.dayglo.com/ Last accessed April, 2014

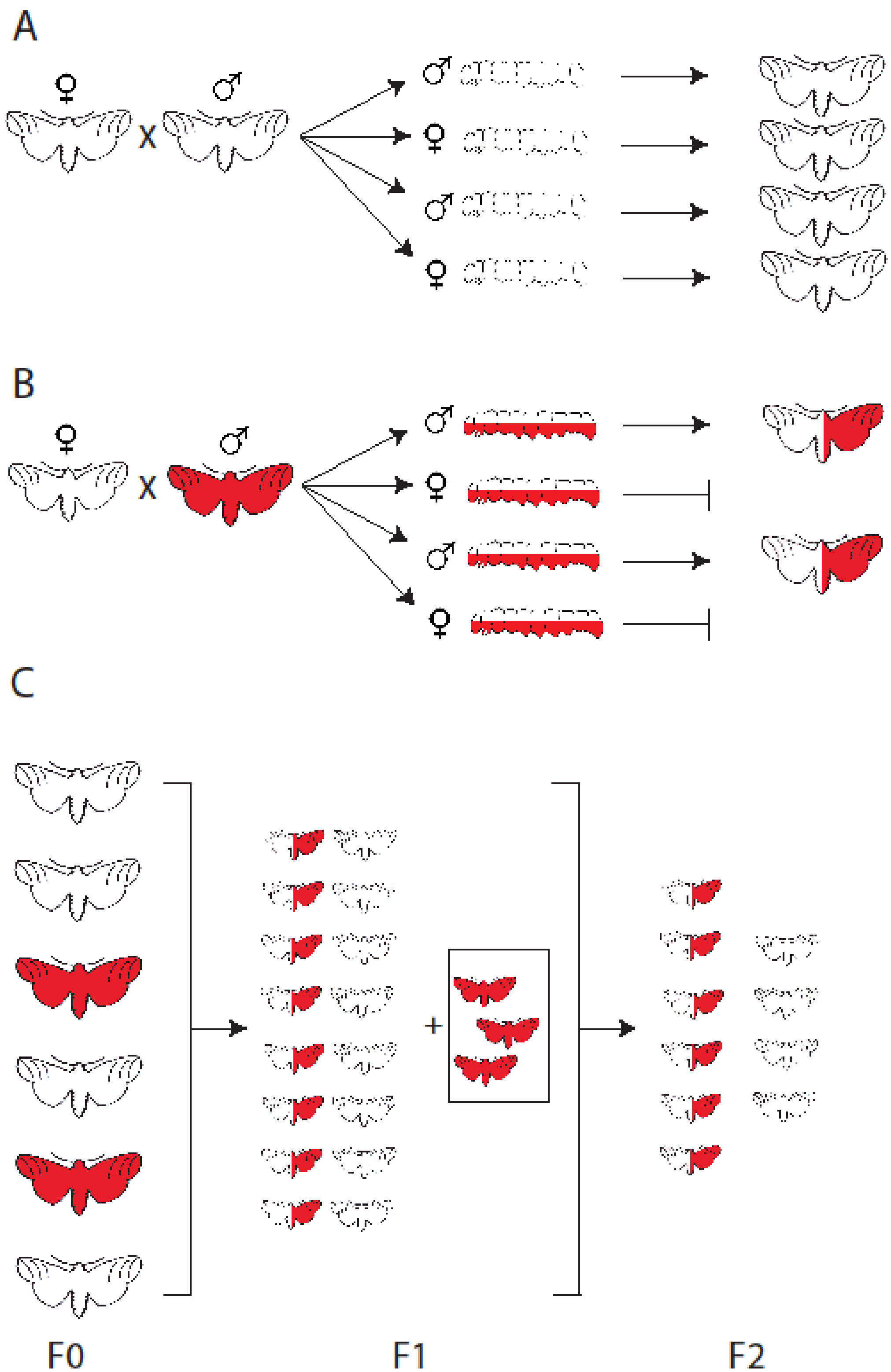

Figure 1. Diamondback moth reproductive cycle in the absence/presence of the female autocidal trait.

Caption for Figure 1 on the previous page. (A) non-GE [white moths] diamondback moth reproductive cycle. (B) non-GE [white females] and GE [red males] diamondback moth reproductive cycle. After mating between a GE male and a non-GE female, all progeny larvae carry the female autocidal trait [half white/red larvae]. As a result, all female larvae die and only male larvae mature into adult moths. (C) Simplified model showing the overall reduction in diamondback moth population as a result of GE diamondback moth introduction. At the start of a permitted field trial, there will be a combination of non-GE [white moths] and GE [red moths] diamondback moths following field release. In every successive generation [i.e., F_1, F_2, etc.], adult male moths containing the female autocidal trait are anticipated to be present, either as heterozygous progeny [half white/red moths] from the successful mating of a non-GE female and GE male or the continuous introduction of GE [boxed red moths] diamondback moths. Mating of either of these males with non-GE females causes the overall diamondback moth population to decrease over time. Furthermore, in every successive generation, male diamondback moths containing the female autocidal trait are anticipated to outnumber non-GE males, due to the weekly introduction of GE diamondback moth males and the resulting male diamondback moth progeny that also carry the female autocidal trait.

2.5 Coordinated Framework Review and Regulatory Review

The US government has regulated GE organisms since 1986 "The Coordinated Framework for the Regulation of Biotechnology" (henceforth referred to here as the Coordinated Framework) (51 FR 23302; 57 FR 22984).

The Coordinated Framework, published by the Office of Science and Technology Policy (OSTP), describes the comprehensive Federal regulatory policy for ensuring the safety of biotechnology research and products. It also explains how Federal agencies will use existing Federal statutes to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry.

Three central guiding principles form the basis for the Coordinated Framework:

1) Agencies should define those transgenic organisms subject to review to the extent permitted by their respective statutory authorities;
2) Agencies are required to focus on the characteristics and risks of a biotechnology product, not the process by which it was created;
3) Agencies are mandated to exercise oversight of GE organisms only 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-APHIS, the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). A summary of each role follows.

2.5.1 USDA-APHIS

As noted in Section 2.2, the PPA authorizes and mandates USDA-APHIS to regulate, manage and control plant pests. This directive includes regulatory authority over the introduction (i.e., 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 part 340.2) and is also considered a plant pest. A GE organism is also regulated under 7 CFR part 340, when USDA-APHIS has reason to believe that the GE organism may be a plant pest or USDA-APHIS does not have sufficient information to determine if the GE organism is unlikely to pose a plant pest risk. A GE organism is no longer subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340, when APHIS determines that it is unlikely to pose a plant pest risk.

An individual may petition the Agency for a determination that a particular regulated article is unlikely to pose a plant pest risk, and should not be regulated under the plant pest provisions of the PPA or the regulations at 7 CFR part 340. Under §340.6(c)(4), the petitioner must provide information related to plant pest risk that the Agency can use to determine whether or not a regulated article poses a plant pest risk. A GE organism or other regulated article is subject to the regulatory requirements of 7 CFR part 340 of the PPA until USDA-APHIS determines that it is unlikely to pose a plant pest risk.

2.5.2 FDA

The FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are genetically engineered. To help developers of food and feed derived from GE crops comply with their obligations under Federal food safety laws, FDA encourages them to participate in a voluntary consultation process. All food and feed derived from GE crops currently on the market in the US have successfully completed this consultation process. The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the *Federal Register* (FR) on May 29, 1992 (57 FR 22984-23005). Under this policy, FDA uses what is termed a consultation process to ensure that human food and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of bioengineered food.

The permit applicant did not undergo this voluntary consultation because GE diamondback moth is not anticipated to yield food or feed.

2.5.3 EPA

The EPA regulates plant-incorporated protectants (PIPs) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain biological control organisms under the Toxic Substances Control Act (TSCA).

The EPA is responsible for regulating the sale, distribution and use of pesticides, including pesticides that are produced by an organism through techniques of modern biotechnology. Such pesticides are regulated by EPA as PIPs under FIFRA (7 U.S.C. 136 *et seq.*). EPA also regulates certain biological control organisms under the Toxic Substances Control Act (15 U.S.C. 53 *et seq.*). Before planting a crop containing a PIP, an individual or company must seek an experimental use permit from EPA. Commercial production of crops containing PIPs for purposes of seed increase and sale requires a FIFRA Section 3 registration with EPA.

Any herbicide (or any other pesticide) in the United States must be registered by the EPA prior to any specific use in the United States. EPA regulates pesticide use under authority granted by FIFRA (see 21 U.S.C. § 301 et seq.). EPA defines pesticide registration as:

> … a scientific, legal, and administrative procedure through which EPA examines the ingredients of the pesticide; the particular site or crop on which it is to be used; the amount, frequency, and timing of its use; and store and disposal practices. In evaluating a pesticide registration application, EPA assesses a wide variety of potential human health and environmental effects associated with the use of the product (EPA, 2013c).

EPA requires a variety of pre-defined tests in a pesticide registration package. The potential pesticide registrant must provide this data, according to EPA guidelines (EPA, 2013c). The data resulting from these tests is used by the EPA to produce an ecological risk assessment and human health risk assessment in order to:

> …evaluate whether a pesticide has the potential to cause adverse effects on humans, wildlife, fish, and plants, including endangered species and non-target organisms, as well as possible contamination of surface water or ground water from leaching, runoff, and spray drift. Potential human risks range from short-term toxicity to long-term effects such as cancer and reproductive system disorders (EPA, 2013c).

Following submission of a complete pesticide registration package, EPA may decide to register or not register a pesticide. If EPA decides to register a pesticide, then the pesticide can only be used:

> …legally according to the directions on the labeling accompanying it at the time of sale. Following label instructions carefully and precisely is necessary to ensure safe use (EPA, 2013c).

As a result of this pesticide registration process by EPA, any EPA-registered pesticide used in the United States:

> …if used in accordance with specifications, they will not cause unreasonable harm to the environment (EPA, 2013c).

EPA did not review this GE diamondback moth strain because it neither contains PIPs nor does it require use of any new pesticides that otherwise would not be used on other non-GE diamondback moths.

2.6 Public Involvement

APHIS routinely seeks public comment on EAs prepared for permit requests for the field release of regulated GE organisms. APHIS does this through a notice published in the *Federal Register*. Prior to receiving the permit application that is the subject of this EA, a permit application was submitted to APHIS on October 24, 2013 (APHIS Permit Number 13– 297–102r) for a similar field release. Permit 13– 297–102r was issued in November 2014 and caged releases were made in 2015.

APHIS prepared an EA for the 2014 permit, and on August 28, 2014, published a notice in the *Federal Register* (79 FR 51299-51300, Docket No. APHIS–2014–0056) announcing the availability of the 2014 EA for public review and comment. APHIS issued a final EA and associated finding of no significant impact (FONSI) for permit 13– 297–102r, which were subsequently withdrawn on November 8, 2016 (discussed in more detail below in Section 3.1 – Introduction). Permit 13– 297–102r was withdrawn in 2016.

On March 16th, 2016, APHIS received a permit application seeking the permitted release of one GE diamondback moth strain OX4319L-Pxy, and began development of a new EA. While the EA for permit request 13– 297–102r was withdrawn, the public comments received on the 2014 EA informed the development of the 2016 draft EA.

On April 19, 2017, APHIS published a notice in the *Federal Register* (82 FR 18416-18417) announcing the availability of the 2016 draft EA for a 30-day public review and comment period. Comments were accepted from the public until May 19, 2017, 11:59 PM ET. APHIS received 673 individual comments during the 30-day comment period. An overview of the types of comments received is provided below.

Summary of Types of Comments Received from the Public for the Draft DBM EA

Classification of Comments	Number	Percent of Total
1 – General Support	36	5.3%
2 – General Oppose	525	78.0%
3 – Substantive- Support	32	4.8%
3 – Substantive- Oppose	40	5.9%
4 – Oppose-with Form Letter	27	4.0%
5 – Out of scope	9	1.3%
6 – Neutral	2	0.3%
7 – Extension Request	2	0.3%
Total	**673**	**100.0%**

APHIS evaluated all issues identified in comments received for the draft DBM EA. The substantive comments received addressed a broad range of topics relevant to the analysis of potential environmental, human health, and socioeconomic impacts. The comments received, however, did not require significant revision to the draft EA. APHIS provides detailed responses to the comments received in the FONSI for this EA.[6] A full record of each comment received for the draft EA is available for public review at: www.regualtions.gov, Docket ID: APHIS-2014-0056.[7]

2.7 Issues Considered

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 such as insect-resistant and glufosinate tolerant Pioneer corn (USDA-APHIS, 2013b); Genective glyphosate tolerant corn (USDA-APHIS, 2013a); insect-resistant DAS soybean (USDA-APHIS, 2014); and GE fruit fly and GE pink bollworm (USDA-APHIS, 2008). 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.

[6] See USDA-APHIS-BRS, Permits with Environmental Assessments, Permit No. 16-076-101r: https://www.aphis.usda.gov/brs/biotech_ea_permits.html

[7] http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0056

3 AFFECTED ENVIRONMENT

3.1 Introduction

The diamondback moth (*Plutella xylostella*) is an important pest of cruciferous crops[8] throughout New York State and the rest of the world (Talekar and Shelton, 1993; Shelton, 2001a). New York State is ranked as the third largest cabbage and cauliflower producer within the United States (NY Department of Agriculture and Markets, 2014). Though economic impact from the diamondback moth may vary from year to year, a severe outbreak of the pest is estimated to decrease 10-20% of New York crucifer crop values (Zalucki *et al.*, 2012). In the United States, management costs alone for DBM were estimated to be between $1.3 and $2.3 billion in 2012 (Zalucki *et al.*, 2012). However, when the costs of residual pest damage is added to management costs, the combined economic impact of this pest in 2012 was estimated to range from $4 to $5 billion (Zalucki *et al.*, 2012).

On October 24th, 2013, APHIS received a permit application from an applicant seeking the permitted field release of three GE diamondback moth strains, OX4319L-Pxy, OX4319N-Pxy, and OX4767A-Pxy, at the Cornell University New York State Agricultural Experiment Station[9]. These GE diamondback moth strains are genetically engineered to exhibit red fluorescence and repressible-female lethality (Section 2.4). Subsequent to receiving the permit application, on August 28, 2014, APHIS published in the Federal Register a notice (79 FR 51299-51300, Docket No. APHIS–2014–0056) in which we announced the availability, for public review and comment, of an EA that examined the potential environmental impacts associated with the proposed release of the GE DBMs. We received 287 comments.

Based upon analysis described in the EA and a thorough review of the comments we received, APHIS determined that release of the GE DBMs would not have a significant impact on the quality of the human environment. The FONSI was posted on the APHIS Web site. Based on this finding, in November 2014, APHIS issued Permit Number 13 297-102r, which allowed for open field release of the GE DBMs. No open field releases took place under this permit. In July 2015, the initial permit was amended to add caged releases to the list of allowable actions (APHIS Permit Number 13-297-102r-a1). Caged releases pursuant to the amended permit occurred between July 2015 and March 11, 2016, when the permit was voluntarily withdrawn.

The EA and associated FONSI were withdrawn on November 8, 2016 because APHIS did not formally advise the public of our FONSI regarding the release of GE DBMs via publication of a second notice in the Federal Register. On March 16th, 2016, APHIS received a revised permit application seeking the permitted release of one GE diamondback moth strain OX4319L-Pxy.

The purpose of the field release is basic research to assess the feasibility and efficacy of GE diamondback moth in reducing pest populations of non-GE diamondback moth under field conditions. According to the applicant, these GE diamondback moths may serve as an insecticide-

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[8] including but not limited to cabbage, broccoli, cauliflower, collards, rape, mustard, and Chinese cabbage

[9] Referred to as NYSAES hereinafter

free means of controlling non-GE diamondback moth in a species-specific manner (Section 2.4). The field release of these GE diamondback moths will allow the applicant to gauge the efficacy of this system in reducing pest diamondback moth populations.

The following sections describe the action area and aspects of the human environment[10] considered in this EA for evaluation of the release of OX4319L-Pxy GE diamondback moth strain. Collectively, the action area and considered aspects of the human environment will constitute the Affected Environment of this EA.

3.2 EA Action Area

The primary action area for this EA consists of the entire NYSAES in Geneva, NY that contains the release site. In subsequent years, the specific location of the release site within the NYAES may change due to crop rotation practices, hence locations covering the entire NYSAES are considered the action area for this EA. The NYSAES itself consists of 870 total acres and is located on the northwestern edge of Geneva, NY, approximately 2 miles from suburban/urban areas (Figure 2). Castle Creek, a forested riparian corridor, flows roughly eastward through the NYSAES, draining into Seneca Lake. 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 site.

The release site is an experimental field containing a *Brassica* plot with a single release point for GE diamondback moth[11] described within the permit application Number 16-076-101r (Section 2.4). The release site is bounded by six points. The applicant would additionally be conducting caged field studies in the area defined as the release site, but at a distance of at least 160 meters from the release point. Caged field studies are needed to examine mating behavior and competition in a controlled way. The cage studies are done separately from the field release so that they don't interfere with one another. Large cages across the release area will change local landscape, and therefore behavior, of open-released GE diamondback moth. Cage studies will start out with unmated females, which emit pheromones. Therefore, cage studies will be conducted non-concurrently from an active open-air release so as to avoid interfering with the behavior of the open-release GE diamondback moth.

Despite reports of diamondback moths moving long distances, (Talekar and Shelton, 1993; Hopkinson and Soroka, 2010), this EA will 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

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[10] The human environment, as defined by CEQ (40 CFR 1508.14), "shall be interpreted to comprehensively include the natural and physical environments and the relationship of people with that environment." See http://www.gpo.gov/fdsys/pkg/CFR-2012-title40-vol34/pdf/CFR-2012-title40-vol34-sec1508-14.pdf . Last accessed March, 2014

[11] Total acreage for this potential release site is not to exceed 10 acres

3.6), or the evaluation of Potential Environmental Consequences (Section 5). 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; Shelton, 2001a; USDA-APHIS, 2014b). Observations from the peer-reviewed literature that long-distance dispersal of diamondback moth, when and where it occurs, is typically facilitated by strong wind currents across geographic regions (Hopkinson and Soroka, 2010), and wind conditions at the area of origin during infestation (Dosdall et al. 2001; Fu et al. 2014).
- The proposed timeframe for the release of GE diamondback moth spans from May to December. Using regional climate data from NOAA-NCEI (2016), the predominant wind directionality in and around the proposed release site and across the New England region of the United States during this timeframe is predominantly from the south/southwest/west (American Meteorological Society, 2012; WeatherSpark, 2014; NOAA-NCEI, 2016).
- If long-distance dispersal of GE diamondback moth were to occur from the proposed release site, then the predominant winds in the region of the proposed release site would likely move it to regions of similar latitude or further north (i.e., to regions that experience winter months just as cold or colder than Geneva, NY). Windrose data for the closest city (Rochester) indicates predominant winds from between the south and the west; wind direction from the next closest city (Syracuse) is more mixed, but most often from the west and east (USDA-NRCS, 2016).
- Movement of GE diamondback moth to areas where it may overwinter is unlikely, due to these predominant wind directions and its inability to overwinter in regions similar to or colder than Geneva, NY (Talekar and Shelton, 1993; Hopkinson and Soroka, 2010; USDA-APHIS, 2014b). Dosdall *et al.* (2001) determined, over a 6-year period, that there is no evidence diamondback moth can overwinter in western Canada. These later findings support APHIS' conclusion that diamondback moth is unlikely to successfully overwinter in extreme northern regions, and there is no evidence that diamondback moth can overwinter in Ithaca, New York where the average winter temperature is at or below freezing. This conclusion is further supported by observations of Walker et al. (2011), who noted that diamondback moth "does not survive in areas where the ground is frozen over winter…," and the observation of other authors that noted a relationship between the ability of diamondback moth to overwinter and winter temperatures (Furlong et al. 2013; Wei et al. 2013; Fu et al. 2014; Yang et al. 2015).
- Given the ubiquity of diamondback moth in regions where cruciferous crops are grown, it is unlikely that any potential long-distance dispersal of GE diamondback moth would introduce it into crucifer-production regions where wild diamondback moth is not already present. Therefore, there is no increased plant pest risk solely from the presence of GE diamondback moth.
- The presence of a hurricane near the release site may temporarily shift the directionality of predominant winds in the region of the proposed release site, such that long-distance dispersal of GE diamondback moth may occur toward areas where it may overwinter. To mitigate this risk, the field trial must be terminated and the release site/surrounding isolation

area treated with insecticides to devitalize the GE diamondback moth at least two days in advance of a hurricane (or similar meteorological event) arriving at the release location.

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 reported 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. Taking into account these observations, the ubiquity of non-GE diamondback moth in North America during the growing season (Andaloro, 1983; Talekar and Shelton, 1993; Shelton, 2001a), and permit conditions imposed on the applicant by APHIS to facilitate confinement (Section 4.2), the long-distance dispersal of diamondback moth into areas where it may overwinter is not considered likely, and thus, will not be considered in the establishment of the action area (Section 3.2), the description of the relevant resource areas (Sections 3.3, 3.4, 3.5, and 3.6), or the evaluation of Potential Environmental Consequences (Section 5).

In the case that GE diamondback moth males move into regions where they can successfully overwinter, their establishment in the environment will be constrained by:

1. The space and time availability of suitable host plants. For the diamondback moth to succeed in an environment, suitable plant hosts should be present. Diamondback has a well-known association with Brassicaceae, and especially many crucifers in cultivation (Talekar and Shelton, 1993). Some diamondback moth strains may survive on alternate host plants, but these instances are unique cases or exhibit low survival rate in an artificial setting (Gupta and Thorsteinson, 1960; Loehr, 2001). Cultivated crucifers receive frequent insecticidal treatment to protect them against the diamondback moth and other pests (Hill and Foster, 2000).
2. Common agricultural practices in cruciferous crops aim to keep the populations of this insect below 0.3 larvae per plant, and in order to achieve this lower density, frequent applications of insecticides are necessary (Capinera, 2012). The use of other agronomic practices such as weed control outside agricultural fields, prevent the volunteer plants and weeds from being present as food for diamondback moth larvae (Dittmar and Stall, 2000).
3. The movement of GE diamondback moth outside its release area has to coincide with other actively-growing cruciferous crops and weeds elsewhere. These plants have different growing seasons in various parts of the country: a situation that obeys to weather patterns, land availability and market demands. Therefore crucifers are not available everywhere and all the time for diamondback moth establishment (Delahaut and Newenhouse, 1997; Cornell University, n.d.-b).
4. The sex ratio in the diamondback moths is nearly half males and half females (Talekar and Shelton, 1993). Thus, females are the sex that drives the population fluctuations (Carey, 1993) and having extra copulations with wild or GE males is not expected to enhance their reproductive capability. The tetracycline-repressible female lethality mechanism in the GE diamondback moth will produce nearly all males (Alphey *et al.*, 2008). If these males mate, only the male progeny will survive, and depending on the frequency with which GE males

versus wild males mate with wild females, the female population may actually decrease. If the male progeny subsequently mate with wild females, only half of the offspring will carry the inserted gene, and of those that do, only the males will survive. However, all progeny of mating between wild males and females will survive. This process will continue in subsequent generations. Thus, without repeated introductions of GE male moths to regions where they can overwinter, the GE moth population will gradually be eliminated.

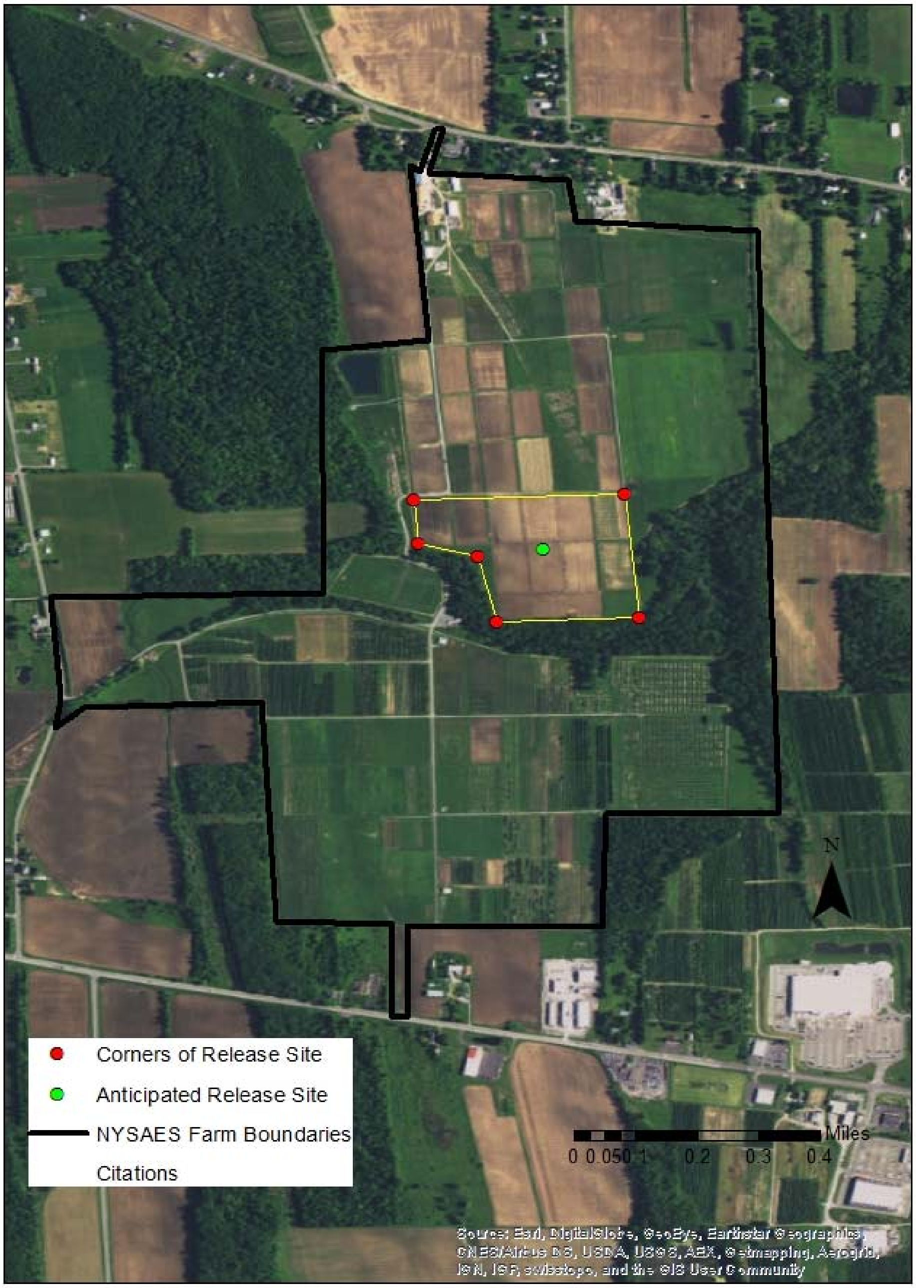

Figure 2. Action area of this Environmental Assessment.

The action area consists of a single release point, (green dot), and six boundaries (red dots), of the region on the farm within which the release will occur. The applicant would be conducting caged field studies within the six boundaries but at least 160 meters from the release point. In subsequent years, releases may occur in other locations on the NYSAES due to crop rotation practices. Hence locations covering the entire NYSAES farm boundaries are considered the action area.

3.3 Resource Areas

A resource area is a relevant component of the human environment. The human environment may include, but not be limited to, aspects of the natural (e.g., soil, water, wildlife, etc.) and human (e.g., economics, social values, etc.) environment. For meaningful environmental analysis of the proposed action, the range of resource areas analyzed in this EA are identified as those areas that have the potential to be impacted by an agency decision.

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, 2016ab), including NEPA documents for the release of GE insects (USDA-APHIS, 2005; 2008). 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: Soil resources;

- Soil resources;
- Water resources;
- Air quality;
- Climate change;
- Plant communities;
- Wildlife;
- Biological Diversity;
- Farm worker health; and
- Health of the general public.

In the following subsections, each specific resource area will be characterized as a component of Physical[12], Biological[13], or Human Health environments[14]. Additionally, brief descriptions will be provided for each specific resource area. Analyses of the potential impact on each specific resource area as a result of an Alternative will be undertaken in Section 4.

[12] i.e., land use and soil resources; water resources; and air quality and climate change

[13] i.e., plant communities; wildlife and insects; and biological diversity

[14] i.e., farm worker health and general population health

3.4 Physical Environment

The physical environment consists of abiotic[15] components within the action area. For the purposes of this EA, components of the physical environment include soil resources, water resources, air quality, and climate change.

3.4.1 Soil Resources

Soil consists of solids (minerals and organic matter), liquids, and gases. This aggregation of inorganic and organic matter is home to a wide variety of fungi, bacteria, and arthropods, as well as the growth medium for terrestrial plant life (USDA-NRCS, 2004). Soil is characterized by its layers that can be distinguished from the initial parent material due to additions, losses, transfers, and transformations of energy and matter (USDA-NRCS, 1999). It is further distinguished by its ability to support rooted plants in a natural environment. Soil plays a key role in determining the capacity of a site for biomass vigor and plant productivity by physical support, inclusion of air and water, ability to moderate temperature, protect from toxins, and make nutrients available. Soils also determine a site's susceptibility to erosion by wind and water, and a site's flood attenuation capacity.

Furthermore, soil properties change over time; temperature, pH, soluble salts, amount of organic matter, the carbon-nitrogen ratio, numbers of microorganisms and soil fauna all vary seasonally, as well as over extended periods of time (USDA-NRCS, 1999). Soil texture and organic matter levels directly influence its shear strength, nutrient holding capacity, and permeability. Soil taxonomy was established to classify soils according to the relationship between soils and the factors responsible for their character (USDA-NRCS, 1999).

Soils are classified taxonomically into soil orders based on observable properties such as organic matter content and degree of soil profile development (BCAP, 2010). Alfisols and Inceptisols are the primary soil types within the action area (EPA, 2012d). Alfisols result from a variety of weathering processes that leach constituents from the surface layer into the subsoil, while inceptisols are soils of semiarid environments that show a moderate level of soil weathering and development (BCAP, 2010). Both soil types function as good agricultural soils (USDA-NRCS, 2004). Further description of these two soil types may be found in USDA-NRCS (1999).

3.4.2 Water Resources

Water is essential for life and plays a vital role in the proper functioning of the Earth's ecosystems. Water pollution has a substantial impact on all living creatures, and can negatively affect the use of water for drinking, household needs, recreation, fishing, transportation and commerce. Water resources may be considered as either surface or groundwater (USGS, 2013; 2014).

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[15] i.e., non-living

Surface water[16] is water contained within rivers, streams, creeks, lakes, and reservoirs (USGS, 2014). Surface waters support everyday life through the provision of water for drinking and other public uses. Surface water quality is determined by the natural, physical, and chemical properties of the land that surrounds the water body (USGS, 2014). When land use affects one or more of these natural physical characteristics of the land, water quality is almost always impacted to some extent. These impacts may be positive or negative, depending on the type, duration, and extent of land use.

Groundwater is water that flows underground and is stored in natural geologic formations called aquifers (USGS, 2013). In the United States, approximately 47 percent of the population depends on groundwater for its drinking water supply (NGWA, 2010). Groundwater is ecologically important because it sustains ecosystems by releasing a constant supply of water into wetlands and contributes a sizeable amount of flow to permanent streams and rivers (USDA-FSA, 2010). Currently, the largest use of groundwater in the United States is irrigation, representing approximately 67 percent of all the groundwater pumped each day (McCray, 2012).

Agricultural practices have the potential to impact water use through irrigation practices. Additionally, agricultural practices have the potential to substantively impact water quality due to the vast amount of acreage devoted to farming nationwide and the physical and chemical demands that agricultural use imposes on the land. The most common types of agricultural pollutants include excess sediment, fertilizers, animal manure, pesticides and herbicides. Agricultural nonpoint source (NPS) pollution is the leading source of impacts to surveyed rivers and lakes, the third largest source of impairment to estuaries, and a major source of impairment to groundwater and wetlands (USDA-NRCS, 2011). The principal law governing pollution of the nation's water resources is the Federal Water Pollution Control Act of 1972, better known as the Clean Water Act (CWA).

3.4.3 Air Quality

Dry air consists of about 78% nitrogen, 21% oxygen, 0.9% argon and 0.03% carbon dioxide. It also contains small amounts of water vapor and particulate matter (Darley and Middleton, 1966). Air quality is the capability of the atmosphere to sustain life, enabling living organisms to respire, and to buffer life on earth from the extremes of temperature variations (BCAP, 2010).

As defined by the EPA pursuant to the Clean Air Act (CAA) and the National Ambient Air Quality Standards (NAAQS), air quality impairments may represent ozone (O_3); nitrogen dioxide (NO_2); carbon monoxide (CO); sulfur dioxide (SO_2), lead (Pb); or inhalable particulates (coarse particulate matter [PM] greater than 2.5 micrometers and less than 10 micrometers in diameter [PM_{10}] and fine particles less than 2.5 micrometers in diameter [$PM_{2.5}$]) (BCAP, 2010)

[16] i.e., freshwater surface water

3.4.4 Climate Change

The climate of the action area is broadly representative of the larger Northeastern United States and is characterized as humid continental type (NY State Climate Office, n.d.). Approximately 30 – 45 inches of precipitation falls every year, and temperatures range from 16 – 80°F (EPA, 2012d).

Climate and climate change are discrete, but related, concepts. Climate is defined as the average weather, or rigorously, as the statistical description in terms of the mean and variability of relevant measurable units over a period of time in both the short- and long-term scales(EPA, 2013b). Climate change is a statistical departure in regional climate patterns, including shifts in the frequency of extreme weather, compared to long term baseline conditions and resulting from warming at the global scale (Cook *et al.*, 2008; Karl *et al.*, 2008).

Climate change is a sustained, statistically significant change in average weather conditions over a broad region. EPA has identified CO_2, methane (CH_4), and nitrous oxide (N_2O) as the most important greenhouse gases (GHG) contributing to climate change. While each of these occurs naturally in the atmosphere, human activity has been a major contributor to the increase of their concentrations since the beginning of the industrial revolution. The level of human-produced gases has been accelerating since the end of World War II, when industrial and consumer consumption expanded greatly. Since the advent of the industrial age, the increase in the concentration of some important GHGs are as follows: CO_2, 36%[17]; CH_4, 148% and N_2O, 18% (EPA, 2011a).

3.5 Biological Environment

3.5.1 Wildlife

The biological environment consists of biotic[18] components within the action area. For the purposes of this EA, components of the biological environment include plant communities, wildlife and insects, and biological diversity.

Wildlife is the totality of all animals in a specific area, including those wildlife species that are native, introduced, desirable, and undesirable (BCAP, 2010). Wildlife species may be generally characterized as mammals, birds, reptiles, amphibians, fish, and molluscs (NatureServe, 2013). Descriptions of each wildlife type may be found in Cambell (1999).

Wildlife in the action area mainly reflects the historic and current use of much of the land as agricultural fields. Wildlife will also be present in the Castle Creek corridor, which flows through the site.

Agricultural fields may be host to a variety of wildlife species for the purposes of habitat or feed. Although agricultural fields are generally considered poor habitat for birds and mammals in

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[17] As of 2015, this was 43%.
https://www.epa.gov/climate-indicators/climate-change-indicators-atmospheric-concentrations-greenhouse-gases
[18] i.e., living

comparison with uncultivated land because of continual disturbances associted with typical cultivation activities, the use of these fields by some wildlife is not uncommon (Vercauteren and Hygnostrom, 1993; Patterson and Best, 1996; Palmer *et al.*, 2011) For example, some mammals that utilize cornfields are ground-feeding ominvores that feed on the corn remaining in the field following harvest (Vercauteren and Hygnostrom, 1993; Krapu *et al.*, 2004; Palmer *et al.*, 2011).

Additionally, a number of insects may be found within an agricultural field (NY State IPM Program, 2013). The most relevant of these insects, however, are those insect pests that feed upon the cultivated crop and the insects that prey upon these insect pests (Robertson *et al.*, 2012). In particular, a major cruciferous pest within the action area is diamondback moth (Andaloro, 1983; Talekar and Shelton, 1993; Shelton, 2001a) (Figure 3), due to the significant production of cruciferous crops in New York (NY Department of Agriculture and Markets, 2014). Additional information regarding diamondback moth within the action area may be found in Section 2.5.1.

Figure 3. Diamondback moth adult (A), larvae (B), and damage on a cruciferous crop from diamondback moth larvae.
Individual images derived from Cornell University (n.d.-a).

3.5.2 Plant Communities

The plant community within an area is the totality of plants in a particular area, including native, introduced, desirable, and undesirable plants (BCAP, 2010). The plant species in the action area may represent a diverse variety of plant species, including forbs, vines, succulents, ferns, grasses, shrubs, and trees (BONAP, 2013). Definitions for these plant types may be found in BONAP (2013). The proposed action area of the NYSAES consists mainly of agricultural fields, with crops that change with the shifts in experiments over time. In addition, the site is traversed by Castle Creek, and the plants associated with the riparian forest corridor. The release of experimental moths will occur in the agricultural fields, and the entire NYSAES action area will be monitored for two years. Hence, the discussion of plant communities in this EA will focus on the Brassicaceae[19], as this is the plant family most likely to be impacted by any decision by USDA-APHIS to deny or issue the applicant's permit application.

[19] Also known as the Cruciferae

The Brassicaceae is a large plant family, containing over 338 genera and 3709 species (Al-Shehbaz, 1984; OECD, 2012). The Brassicaceae constitute some of the world's most economically important plants, in addition to also containing significant agricultural weeds (OECD, 2012).

Domesticated Brassicaceae include vegetable and oilseed crops (OECD, 2012). New York produces many domesticated Brassicaceae (Cornell University Cooperative Extension, 2013). Of the domesticated Brassicaceae, New York is ranked as the third largest cabbage and cauliflower producer within the United States (NY Department of Agriculture and Markets, 2014).

There are numerous weedy Brassicaceae. However, those with the greatest interest to agriculture include *Sinapis arvensis* (wild mustard or charlock), *Raphanus raphanistrum* (wild radish), *Brassica rapus* (wild or bird rape), and *Hirschfeldia incana* (hoary mustard) due to their propensity to cross-pollinate with domesticated *B. napus* (OECD, 2012).

A detailed review of the biology and ecology of both domesticated and non-domesticated Brassicas can be found in OECD (2012).

3.5.3 Biological Diversity

Biological diversity generally refers to the variety and variability of living organisms and the ecosystems where they occur (BCAP, 2010). The degree of biodiversity in an agroecosystem depends on four primary characteristics: (1) diversity of vegetation within and around the agroecosystem; (2) permanence of various crops within the system; (3) intensity of management; and (4) extent of isolation of the agroecosystem from natural vegetation (Altieri, 1999).

The primary function of biological diversity is to contribute to ecosystem services. These ecosystem services may include: pollination, genetic introgression, biological control, nutrient recycling, competition against natural enemies, soil structure, soil and water conservation, disease suppression, control of local microclimate, control of local hydrological processes, and detoxification of noxious chemicals (Altieri, 1999). In general, the loss of biological diversity may result in a need for costly management practices in order to provide these functions (Altieri, 1999).

3.6 Human Health Environment

The human health environment consists primarily of farm worker health and health of the general public. Characterization of human health into these two components is primarily due to the route of exposure to the agricultural activities that are common within the action area and the rest of the NYSAES. Farmworkers are most often directly exposed to agricultural activities. In contrast, the general public is directly exposed to agricultural activities to a much lesser extent, with indirect exposure to the products of those agricultural activities occurring much more frequently.

3.6.1 Farmworker Health

Agriculture is one of the most hazardous industries for US workers. Approximately 3.1 million people in the United States are reported as farm workers, representing approximately 1 percent of the total US population (EPA, 2014a).

Farm workers are exposed to a variety of hazards as a result of common agricultural activities, such as accidents related to production machinery or agricultural inputs. As a result, Congress directed the National Institute of Occupational Safety and Health to develop a program to address high-risk issues related to occupational workers. In consideration of the risk of pesticide exposure to field workers, EPA's Worker Protection Standard (WPS) (40 CFR Part170) was published in 1992 to require actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS offers protections to more than two and a half million agricultural workers who work with pesticides at more than 560,000 workplaces on farms, forests, nurseries, and greenhouses. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance; furthermore, the Occupational Safety and Health Administration (OSHA[20]) require all employers to protect their employees from hazards associated with pesticides and herbicides.

Pesticides[21] are used on most agricultural acreage in the United States. Under FIFRA, all pesticides, sold or distributed in the United States must be registered by the EPA (EPA, 2005b). During the registration decision, the EPA must find that a pesticide does not cause unreasonable adverse effects to human health or the environment if used in accordance with the approved label instructions (OSTP, 2001).

EPA labels for pesticides include use restrictions and safety measures to mitigate exposure risks (EPA, 2014c). Growers are required to use registered pesticides consistent with the application instructions provided on the EPA-approved pesticide labels. Worker safety precautions and use restrictions are clearly noted on pesticide registration labels. EPA labels for registered herbicides have been designed to reduce the risks of illness or injury resulting from workers' and handlers' occupational exposures to pesticides used in the production of agricultural plants on farms (EPA, 2014c).

Adult moths do not purposely alight on and use vertebrates for dispersal, and are likely to fly off of/away from any human or wildlife that may come into physical contact with it in the proposed release site. Thus, the dispersal of GE diamondback moth adults through contact with humans or wildlife is unlikely. Furthermore, as an added precaution, permit conditions require staff to visually inspect themselves and their clothing for incidental hitchhiking moths before leaving the release area and field cages. With respect to GE diamondback moth larvae, there is no evidence to indicate that dispersal of diamondback moth larvae on human or wildlife is possible; at present, the

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[20] https://www.osha.gov/ Last accessed March 14, 2014

[21] i.e., herbicides, insecticides, and fungicides

movement of diamondback moth larvae is commonly associated with the human-mediated movement of cruciferous plants (Shelton, 2001). Permit conditions mandate that any crucifer planted at the proposed release site is intended for research purposes and are prohibited from entering food and feed product streams; furthermore, permit conditions mandate that the planted crucifers will not be harvested or moved.

3.6.2 Health of the General Public

Direct exposure of the general population to agricultural activities is limited to personal use of pesticides on personal property or public areas[22]. In scenarios such as this, safe use of pesticides is facilitated much in the same way as described directly above for farm workers (Section 2.6.1). The amount of pesticide residues that may remain on agricultural commodities is regulated by EPA and are called pesticide "tolerances" in the United States (EPA, 2014d). The proposed release site is on the grounds of the New York State Agricultural Experiment Station (NYSAES). The NYSAES is a secure facility enclosed with a fence that is locked during non-business hours (Personal Communication, A. Shelton). Thus, only appropriate personnel and small wildlife (e.g., mice, birds, etc.) are likely to move through the proposed release site.

Pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA must establish the tolerance value for pesticide residues that can remain on the crop or in foods processed from that crop (EPA, 2010b). In addition, the FDA and the USDA monitor foods for pesticide residues and enforce these tolerances (USDA-AMS, 2010). If pesticide residues are found to exceed the tolerance value, the food is considered adulterated and may be seized. The USDA has implemented the Pesticide Data Program (PDP) in order to collect data on pesticides residues on food (USDA-AMS, 2010). The EPA uses PDP data to prepare pesticide dietary exposure assessments pursuant to the 1996 Food Quality Protection Act (FQPA). Pesticide tolerance levels for various pesticides have been established for a wide variety of commodities, including soybean, and are published in the *Federal Register*, CFR, and the *Indexes to Part 180 Tolerance Information for Pesticide Chemicals in Food and Feed Commodities* (EPA, 2011b).

[22] e.g., state forests, county parks, etc.

4 ALTERNATIVES

This EA analyzes the potential environmental consequences of APHIS' response to an environmental release (APHIS Number 16-076-101r) received from an applicant to allow the release of GE diamondback moths at the Cornell University New York State Agricultural Research Station. A single release point at an experimental field, up to 10 acres in size, is being requested as a primary action area for this EA. These GE diamondback moth males possess the introduced traits of red fluorescence and repressible-female lethality. The purpose of the environmental release is for the applicant to assess the efficacy of GE diamondback moths in reducing the population of non-GE diamondback moths in a release site. See the APHIS permit 16-076-101r for more information about the proposed research and GE diamondback moths.

Under APHIS regulations, the Administrator must either deny or grant permits properly submitted under 7 CFR part 340. Based upon the permit application submitted by the applicant, two alternatives are considered and analyzed in this EA: (1) deny the permit and (2) approve permit application request and issue the APHIS permit.

4.1 No Action Alternative – Deny the Permit

Under the No Action Alternative APHIS would deny the permit application (APHIS Number 16-076-101r) submitted by the applicant. The applicant would not be authorized to release the GE diamondback moth strain OX4319L-Pxy. APHIS may choose this alternative if there is sufficient evidence to demonstrate that this GE diamondback moth strain would either increase the plant pest risk that is already present due to the ubiquity of wild diamondback moth, or allow the establishment and persistence of a new plant pest risk due to the GE diamondback moth in the environment.

4.2 Preferred Alternative – Issue the APHIS Permit

Under the Preferred Alternative, APHIS would issue an environmental release permit in conjunction with Permit Conditions (Section 4.2.1) to the applicant in accordance with 7 CFR part 340 to allow the release of GE diamondback strain OX4319L-Pxy, over a maximum field area of 10 acres. APHIS may choose this alternative if there is sufficient evidence to demonstrate that this GE diamondback moth strain would not increase the plant pest risk that is already present due to the ubiquity of wild diamondback moth or allow the establishment and persistence of a new plant pest risk due to the GE diamondback moth in the environment. If APHIS chooses this alternative, then the permit will be subject to the conditions described in 7 CFR part 340.4[23] and the Permit Conditions described below (Section 4.2.1).

Under the Preferred Alternative, the permit would be valid for a two-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 two-year period specified in the permit application.

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

Additionally, under the Preferred Alternative with a two-year permit, the applicant could better assess the potential use of GE diamondback moths as a pest management strategy that reduces populations of non-GE diamondback moths.

4.2.1 Standard and Supplemental Permit Conditions

Standard Permit Conditions

1. The regulated article shall be maintained and disposed of (when necessary) in a manner so as to prevent the dissemination and establishment of plant pests.

2. All packaging material, shipping containers, and any other material accompanying the regulated article shall be treated or disposed of in such a manner as to prevent the dissemination and establishment of plant pests.

3. The regulated article shall be kept separate from other organisms, except as specifically allowed in the permit.

4. The regulated article shall be maintained only in areas and premises specified in the permit.

5. An inspector shall be allowed access, during regular business hours, to the place where the regulated article is located and to any records relating to the introduction of a regulated article.

6. The regulated article shall, when possible, be kept identified with a label showing the name of the regulated article, and the date of importation.

7. The regulated article shall be subject to the application of measures determined by the Administrator to be necessary to prevent the accidental or unauthorized release of the regulated article.

8. The regulated article shall be subject to the application of remedial measures (including disposal) determined by the Administrator to be necessary to prevent the spread of plant pests.

9. A person who has been issued a permit shall submit to APHIS a field test report within 6 months after the termination of the field test. A field test report shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.

10. APHIS shall be notified within the time periods and manner specified below, in the event of the following occurrences:

    (i) Orally notified immediately upon discovery and notify in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article;

(ii) In writing as soon as possible but not later than within 5 working days if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application for a permit or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms).

11. A permittee or his/her agent and any person who seeks to import a regulated article into the United States shall:

    (i) Import or offer the regulated article for entry only through any USDA plant inspection station listed in 7 CFR 319.37-14;

    (ii)Notify APHIS promptly upon arrival of any regulated article at a port of entry, of its arrival by such means as a manifest, customs entry document, commercial invoice, waybill, a broker's document, or a notice form provided for such purpose; and

    (iii) Mark and identify the regulated article in accordance with 7 CFR 340.7.

    Rev. January 1, 2010

Supplemental Permit Conditions

1. All persons handling the genetically-engineered (GE) diamondback moth or entering the cruciferous field at any time from release of the GE diamondback moth until termination of the experiment with the genetically-engineered (GE) diamondback moth must be informed of these permit conditions. Anyone working with these insects must sign/ initial a document containing these conditions before beginning work. All personnel must visually inspect themselves and their clothing for potential hitchhiking moths before leaving the release area and field cages. These signed conditions must be readily accessible in the event of an APHIS inspection and presented upon request.

   The signed conditions may be copied and stored electronically for electronic signature and initialing and must include the permit number, authorized organisms and life stages, release locations, and authorization statement. The residency condition does not need to be signed. Signing these conditions only indicates that the person working under this permit has read and understands them; the permit holder is the sole responsible party under this permit.

2. Confinement and Reproductive Isolation

   A 10-meter buffer of bare ground, maintained by weekly disking, must be maintained around the perimeter of the open release site. The buffer must be surrounded by an additional 50 meters that, excepting cages, must not be planted with crops that can act as a host for diamondback moth and any substantial clusters of plants that could serve as hosts must be eliminated. Host plants may be planted in cages used for cage experiments located within the 50 meter area. No caged releases can occur within the 10 meter buffer or additional 50 meter zone at the same time that the open field release is being conducted.

Dispersal of regulated diamondback moths within and outside of the perimeter of the open release site must be monitored, at minimum, once per week using the mark/recapture methods described in the permit. Traps must be placed in at least 8 equidistant locations around the outside edge of the 10 meter buffer, and in at least four locations along the four compass points out to 1 km from the center of the release site. Passive traps (with no pheromone lure) will be placed on the outside edge of the 10 meter buffer; pheromone traps will be placed at all other locations outside the release area. Data from this monitoring must be analyzed within a week of collection to assess the number and frequency of dispersal of regulated moths to and beyond the perimeter and reported as part of the Field Test Report. At minimum, this mark/recapture data must include date/number of regulated diamondback moth release; date/number/distance of diamondback moth recapture; and date/number/proportion of regulated diamondback moth recapture.

If the weekly mark/recapture data suggests that a greater-than-anticipated number of regulated diamondback moths are dispersing to the outside edge of the 10 meter buffer, THIS EVENT MUST BE VERBALLY REPORTED IMMEDIATELY TO APHIS BRS COMPLIANCE AS AN UNUSUAL OCCURRENCE at 301-851-3935 and reported in writing within 24 hours at brscompliance@aphis.usda.gov. If staff are unavailable to answer the phone, leave a voice mail with details of the occurrence and contact information. A greater-than-anticipated number of regulated moths is defined as either of the following: >1% of the released number of regulated GE moths (calculated on a weekly basis), or any regulated GE moths captured in pheromone traps outside of the NYSAES.

If a hurricane is projected to affect the release site, no regulated moths may be released within one week prior to the event OR the release site must be treated with an insecticide (per EPA regulations) to kill any existing regulated moths no less than two days prior to the event. Additionally, THIS EVENT MUST BE VERBALLY REPORTED IMMEDIATELY TO APHIS BRS COMPLIANCE AS AN UNUSUAL OCCURRENCE at 301-851-3935 and reported in writing within 24 hours at brscompliance@aphis.usda.gov. If staff are unavailable to answer the phone, leave a voicemail with details of the wind event, the anticipated action, and contact information.

If any other unusual event occurs, THIS EVENT MUST BE VERBALLY REPORTED IMMEDIATELY TO APHIS BRS COMPLIANCE AS AN UNUSUAL OCCURRENCE at 301-851-3935 and reported in writing within 24 hours at brscompliance@aphis.usda.gov. If staff are unavailable to answer the phone, please leave a voice mail with details of the occurrence and contact information.

In the event of an unusual occurrence (e.g. greater than expected local dispersal of regulated diamondback moths), additional conditions may be required by APHIS on a case-by-case basis.

3. Field Test Termination and Post-termination Monitoring

   Field Test Termination

   This is a crop-destruct trial. The host material planted at the release site and in the cages will be treated as regulated material. No plants/plant materials that can function as hosts for diamondback moth can be moved from the proposed release site and isolation perimeter other than in double contained bags transported to the secure laboratory for examination and eventual destruction via freezing and/or autoclaving to render any insects non-viable. No plant/plant materials that can function as hosts for diamondback moth can be used for food or feed.

   On or before the expiration of the permit, the field test must be terminated by treating the release site out to the 10 m buffer and the caged areas with an insecticide to kill any existing diamondback moths. All plants within the release site and in the cages must be devitalized by disking into the ground. Cages must not be removed until after insecticide treatment and devitalization of host plants within the cages are completed.

   Post-termination Monitoring

   Following field test termination, and starting two weeks before temperatures are expected to be conducive to diamondback moth development, a pheromone trap must be placed at the location of each field cage and 50 spaced pheromone traps must be placed within the open release site and up to 60 meters beyond the perimeter of the release site. Traps must be monitored for the presence of regulated moths no less than once every 2 weeks until there are two consecutive months free of any regulated moths when temperatures are conducive to moth development. This post-termination monitoring data must be submitted as a part of the post-termination monitoring report (see Reports and Notices below) and at minimum must include date of monitoring activity; date/number/distance of diamondback moth capture; and date/number/proportion of GE diamondback moth recapture (if applicable).

   If the detection of GE diamondback moth occurs, THIS EVENT MUST BE VERBALLY REPORTED IMMEDIATELY TO APHIS BRS COMPLIANCE AS AN UNUSUAL OCCURRENCE at 301-851-3935 and reported in writing within 24 hours at brscompliance@aphis.usda.gov. If staff are unavailable to answer the phone, please leave a voice mail with details of the occurrence and contact information. In the event of an unusual occurrence, additional conditions may be required by APHIS on a case-by-case basis. The post-termination monitoring period will not be considered complete until two consecutive months conducive to diamondback moth development have passed without the detection of any GE diamondback moth.

4. Any regulated article introduced not in compliance with the requirements of 7 Code of Federal Regulation Part 340 or any standard or supplemental permit conditions, shall be subject to the immediate application of such remedial measures or safeguards as an inspector determines necessary, to prevent the introduction of such plant pests. The

responsible party may be subject to fines or penalties as authorized by the Plant Protection Act (7 U.S.C. 7701-7772).

5. This Permit does not eliminate the permittee's legal responsibility to obtain all necessary Federal and State approvals, including for the use of: (1) any non-genetically engineered plant pests or pathogens as challenge inoculum; (2) plants, plant parts or seeds which are under existing Federal or State quarantine or restricted use; and (3) experimental use of unregistered chemical or other approval as permitted under FIFRA.

6. Modifications to the containment of these organisms must be approved prior to making changes by applying for an amendment in ePermits.

7. The permit holder must maintain an official permanent work assignment at the address identified on this permit. If the permit holder ceases assignment/affiliation at the address identified on this permit, or personnel circumstances change in any way, then the BRS Compliance Staff must be notified within three business days by either (a) email to BRSCompliance@aphis.usda.gov, (b) verbal communication at 301-851-3935, or (c) conventional mail to BRS Compliance Staff, 4700 River Road, Riverdale, Unit 91, MD 20737. The permit holder must destroy all regulated organisms prior to departure unless the permit holder either (a) requests cancellation of this permit and complies with all permit-specific termination conditions, (b) applies for and receives a permit to move the organisms to a new facility, or (c) relinquishes control of the regulated organisms to a qualified individual who obtained a permit for the continued use of these regulated organisms prior to this permit holder's departure.

8. THIS AUTHORIZATION IS VALID FOR THE RELEASE INTO THE ENVIRONMENT OF THIS GENETICALLY ENGINEERED INSECT ONLY IN THE AREAS DESCRIBED IN THE APPLICATION.

9. Without prior notice and during reasonable hours authorized APHIS and State regulatory officials shall be allowed to inspect the locations where this genetically engineered insect is being released and all related records.

10. Reporting an Unauthorized or Accidental Release
    a. According to the regulation in 7 CFR § 340.4(f)(10)(i), APHIS shall be notified orally immediately upon discovery and notified in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article.

       - For immediate verbal notification, contact APHIS BRS Compliance Staff at (301) 851-3935 and ask to speak to a Compliance and Inspection staff member. Leave a verbal report on voicemail if the phone is not answered by a Compliance Officer.
       - In addition, in the event of an emergency in which you need to speak immediately to APHIS personnel regarding the situation, you may call:

       The APHIS/BRS Regional Biotechnologist assigned in the region where the field

test occurs:
- For Western Region, contact the Western Region Biotechnologist at (970) 494-7513 or e-mail: BRSWRBT@aphis.usda.gov
- For Eastern Region, contact the Eastern Region Biotechnologist at (919) 855-7622 or e-mail: BRSERBT@aphis.usda.gov Or

The APHIS State Plant Health Director for the state where the unauthorized release occurred. The list of APHIS State Plant Health Directors is available at: http://www.aphis.usda.gov/services/report_pest_disease/report_pest_disease.shtml. or http://pest.ceris.purdue.edu/stateselect.html

b. Written notification should be sent by one of the following means:

By e-mail:
BRSCompliance@aphis.usda.gov

By mail:
Biotechnology Regulatory Services (BRS)
Regulatory Operations Program
USDA/APHIS
4700 River Rd. Unit 91
Riverdale, MD 20737

Additional instructions for reporting compliance incidents may be found at http://www.aphis.usda.gov/biotechnology/compliance_incident.shtml

11. Reporting Unintended Effects

According to the regulation in 7 CFR § 340.4(f)(10)(ii), APHIS shall be notified in writing as soon as possible if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the permit application or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms).

Written notification should be sent by one of the following means:

By e-mail: BRSCompliance@aphis.usda.gov

By mail:

Biotechnology Regulatory Services (BRS)
Regulatory Operations Program
USDA/APHIS
4700 River Rd. Unit 91
Riverdale, MD 20737

12. Planting or Environmental Release Report

Submit all reports and notices via ePermits using the link under "My Reports and Notices." A link to instructions for submitting via ePermits is located here: https://epermits.aphis.usda.gov/epermits/xml_schema/BRS_Reports_and_Notices_User_Guide.pdf

Other options are to submit reports and notices via email or paper, however, we strongly encourage submission via ePermits. If submitting using any other method, both CBI and CBI-deleted or non-CBI copies should be submitted via:

BRS E-mail: BRSCompliance@aphis.usda.gov

BRS Mail:

Animal and Plant Health Inspection Service (APHIS)
Biotechnology Regulatory Services (BRS)
Regulatory Operations Program
4700 River Rd. Unit 91
Riverdale, MD 20737

THE FOLLOWING REPORTS ARE REQUIRED:

a. Planting and Environmental Release Reports
Planting and/or Environmental Release reports must be submitted to BRS by the 15th of the month following the month in which the environmental release was started, and must be submitted every 30 days thereafter until the 15th of the month following the final release. The reports must include the following data:
- Permit number
- Regulated article
- State
- County
- Location Name (Unique ID)
- GPS coordinates of the planting/release
- Planting/Release Unique ID
- Planting Start Date/Release Date
- Total acreage of the host material planted/total number of insects released over the period since the initial release or, for subsequent reports, the previous report
- List of all constructs released

NOTE: THESE REPORTS SHOULD BE SUBMITTED ON-LINE THROUGH ePermits.

b. Field Test Report

Within six months after the expiration date of the permit, the permittee is required to submit a Field Test Report. Field Test Reports provide the final status and observations at each location and must include:

- Permit number
- State
- County
- Location Name(s)
- Location Unique ID(s)
- Any release that occurred at each location
- GPS coordinates for each planting/release
- Size of the release (number of insects, area of host material planted in acres) at each location
- Phenotypic designations (all constructs that were release)
- Describe any other disposition methods that may be applicable
- Describe any deleterious effects on plants, non-target organisms, or the environment
- Describe methods of observations and resulting data and analyses
- Indicate if you have submitted any of the following:

1. A report on the accidental or unauthorized release of the regulated article;
2. A report that characteristics of the permitted species are substantially different from those listed in the application; or
3. A report of any unusual occurrence

Additionally, a report from the weekly mark/recapture monitoring of the regulated insects must be included as part of the Field Test Report. At minimum, this mark/recapture data must include date/number of regulated diamondback moth released; date/number/distance of diamondback moth recaptured; and date/number/proportion of regulated diamondback moth recaptured. Results from PCR validation of the identity of a subset of captured moths must also be included in this report.

APHIS considers these data reports as critical to our assessment of plant pest risk and development of regulatory policies based on the best scientific evidence. Failure by an applicant to provide data reports in a timely manner for a field trial may result in the withholding of permission by APHIS for future field trials.

NOTE: THESE REPORTS SHOULD BE SUBMITTED ON-LINE THROUGH ePermits.

c. Post-Termination Report

For the purposes of this permit, this report may be submitted via ePermits as a “volunteer monitoring report.” The report must include:

- Permit number
- State
- County

- Location Name(s)
- Location Unique ID(s)
- Dates when the field site and perimeter fallow zone were inspected for regulated diamondback moth and planted or volunteer host material
- Number/distance of diamondback moths observed
- Number/distance/proportion of regulated diamondback moth observed
- Any actions taken to remove or destroy regulated diamondback moths and planted or volunteer host material

The final monitoring report is due no later than three months from the end of the post-termination monitoring period.

NOTE: THESE REPORTS SHOULD BE SUBMITTED ON-LINE THROUGH ePermits.

13. ***Important***

Interstate movement, release/movement, and release permits may also be subject to PPQ domestic permit and/or quarantine requirements. Please call PPQ @ (877) 770-5990 for additional assistance in regards to their requirements.

4.3 Comparison of Alternatives

Table 1. Comparison of Alternatives

Attribute / Measure	Alternative A: No Action Alternative Deny the permit request	Alternative B: Preferred Alternative Grant the permit request
Meets Purpose and Need and Objectives	**No**	**Yes**
Unlikely to pose a plant pest risk	No plant pest risk.	Satisfied through use of regulated field trials, including APHIS-imposed permit conditions and monitoring for compliance. Impacts would be similar to the No Action Alternative.
Physical Environment		
Soil Quality	Common agricultural activities related to field preparation/maintenance that impact	The permitted field release of GE DBMs is not anticipated to change common agricultural activities

Attribute / Measure	Alternative A: No Action Alternative Deny the permit request	Alternative B: Preferred Alternative Grant the permit request
	soil (e.g., tillage, pesticide application, etc.) will continue unchanged under the No Action Alternative.	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 DBMs to other soil microflora is not likely under the Preferred Alternative. Therefore, impacts 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 unchanged under the No Action Alternative. The use of pesticides in accordance with EPA-approved label directions assures no unreasonable risks to water quality from their use.	The permitted field release of GE DBMs 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. Therefore, impacts on water resources would be similar to the No Action Alternative.
Air Quality	Common agricultural activities (e.g., tillage; use of mechanized equipment that emits exhaust pollutants, and applications of pesticides and fertilizers) would continue unchanged 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 DBMs is not anticipated to change common agricultural activities currently used for fields as described under the No Action Alternative. Therefore, impacts 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	The permitted field release of GE DBMs is not anticipated to change common agricultural activities related to preparing and maintaining an agricultural field as is already occurring under the No Action Alternative. Therefore, the impact

Attribute / Measure	Alternative A: No Action Alternative Deny the permit request	Alternative B: Preferred Alternative Grant the permit request
	activities are already occurring, and are likely to continue occurring, under the No Action Alternative.	on GHG emissions and climate change would be similar to the No Action Alternative.
Biological Environment		
Wildlife	Common agricultural activities such as such as tillage, cultivation, pesticide and fertilizer applications, and the use of agricultural equipment may impact wildlife communities. The use of EPA-registered pesticides and herbicides in accordance with EPA-approved labels minimizes potential impacts to animal communities.	The permitted field release of GE DBMs are not anticipated to change common agricultural activities related to preparing and maintaining agricultural fields that are currently occurring under the No Action Alternative. The introduced traits in GE DBMs do not encode for any known allergens or toxins, and GE DBMs are not anticipated to persist because they cannot overwinter in the action area. Horizontal gene transfer of DNA from GE DBMs to wildlife that may consume them is also unlikely. Therefore, impacts on 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 DBMs is not anticipated to change common agricultural practices currently used on fields as described for the No Action Alternative. Adult DBMs do not damage plant tissues and DBM larvae only feed on cruciferous plants. Damage from GE DBM larvae on planted cruciferous plants is not anticipated to be substantial because of the ubiquity of non-GE DBMs in the action area and their ability to persist within the action area. Damage from GE DBM larvae on cruciferous weeds is also not anticipated to be substantial because they are likely to be

Attribute / Measure	Alternative A: No Action Alternative Deny the permit request	Alternative B: Preferred Alternative Grant the permit request
		managed through cultural or chemical methods, so any damage from GE DBMs to cruciferous weeds is likely to be less than that from deliberate efforts to control them. Therefore, the impact to plant communities would be similar to the No Action Alternative. Cruciferous plants do not pose a risk of entering or contaminating the food supply because: no harvesting or movement of plants/plant materials that can function as hosts for DBMs can be moved from the proposed release site and isolation perimeter unless they are double bagged before transiting to a secure laboratory within a quarantine containment facility, where they will eventually be destroyed prior to disposal, and none of the plant parts or other derivatives of crucifers capable of supporting DBMs will be used for food or feed. In New York crucifer production, it is common practice to destroy crop debris following harvest by plowing it under to kill eggs and larvae of DBMs and other insect pests (Extension and Markets 2015). DBMs cannot develop at temperatures below 2.1°C. (35.8 °F) (Bahar et al. 2014). Since average annual low temperatures are below this threshold for Geneva, New York during the months of November-March (Data 2016), this indicates

Attribute / Measure	Alternative A: No Action Alternative Deny the permit request	Alternative B: Preferred Alternative Grant the permit request
		that DBMs are highly unlikely to overwinter in Geneva, New York.
Biological Diversity	Under the No Action Alternative, biological diversity within the action area is reduced and will continue to be reduced when compared to environments that are less intensively managed.	The permitted field release of GE DBMs is not anticipated to change common agricultural activities related to preparing and maintaining agricultural fields already used as described for the No Action Alternative. Therefore, impacts to biological diversity from common agricultural activities would be similar to the No Action Alternative. The release of GE DBMs is not anticipated to substantially affect biological diversity because non-GE DBMs are already targeted for management/control in the action area, so both non-GE and GE DBMs are unlikely to persist within the action area after the end of a growing season.
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., to farmworkers or the general human population) from 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	The permitted field release of GE DBMs is not anticipated to change common agricultural activities related to preparing and maintaining an agricultural field that is currently occurring under the No Action Alternative. Therefore, impacts to human health (e.g., farmworkers and the general human population) from common agricultural activities would be similar to the No Action Alternative.

Attribute / Measure	Alternative A: No Action Alternative Deny the permit request	Alternative B: Preferred Alternative Grant the permit request
	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.	Cruciferous plants do not pose a risk of entering or contaminating the food supply because no harvesting or movement of plants/plant materials that can serve as hosts for DBMs can be moved from the proposed release site and isolation perimeter unless double bagged for secure transiting to the laboratory within the APHIS-regulated quarantine containment facility for examination before eventual destruction and disposal in accordance with APHIS regulations; no plant/plant materials that can serve as hosts for DBMs can be used for food or feed. Previous NEPA documents,(USDA-APHIS 2008a, 2011a), have analyzed and concluded that there is no unreasonable risk to humans associated with the introduced traits in the GE DBMs described in the permit application. These GE DBMs also do not differ otherwise taxonomically from naturally occurring DBMs, which belong to the lepidopteran Family, Plutellidae, which is a group (taxon) that is not known to cause any allergic reactions in humans. Therefore, these GE DBMs are not anticipated to substantially affect human health differently from what may occur under the No Action Alternative.
Compliance with Other Laws		

Attribute / Measure	Alternative A: No Action Alternative Deny the permit request	Alternative B: Preferred Alternative Grant the permit request
CWA, CAA, EOs	Fully compliant	Fully compliant

5 POTENTIAL ENVIRONMENTAL CONSEQUENCES

This analysis of potential environmental consequences addresses the potential impact to the human environment from the alternatives analyzed in this EA, namely taking No Action (i.e., deny the permit) or the Preferred Alternative (i.e., issue the permit). The Alternatives presented in this EA are discussed further in Section 3. Potential environmental impacts within the action area from the No Action Alternative and the Preferred Alternative for GE diamondback moth are described in detail throughout this section.

5.1 Scope of the Analysis

Potential environmental impacts from the No Action Alternative and the Preferred Alternative for GE diamondback moth are described in detail throughout this section. These potential environmental impacts are described within the context of the resource areas described in the Affected Environment (Section 3).

An impact would be any change, positive or negative, from the existing (baseline) conditions of the affected environment. This baseline condition is described in the No Action Alternative analysis for each resource area. Impacts may be categorized as direct, indirect, or cumulative. A direct impact is an effect that results solely from a proposed action without intermediate steps or processes. Examples include soil disturbance, air emissions, and water use. An indirect impact may be an effect that is related to but removed from a proposed action by an intermediate step or process. Examples include surface water quality changes resulting from soil erosion due to increased tillage, and worker safety impacts resulting from an increase in herbicide use.

A cumulative effects analysis is also included for each environmental issue. A cumulative impact may be an effect on the environment which results from the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions. An example includes potential future field releases of GE diamondback moth. If there are no direct or indirect impacts identified for a resource area, then there can be no cumulative impacts. Cumulative impacts are discussed in Section 5.

Where it is not possible to quantify impacts, APHIS provides a qualitative assessment of potential impacts. Certain aspects of this permit may be no different between the alternatives; those are described below.

Because this is an analysis for a permitted field release, APHIS will limit the environmental analysis to those areas where the potential field release would occur. Additionally, APHIS will also consider those areas adjacent to the potential release site when appropriate. Collectively, the potential release site and areas adjacent to it are considered the action area. The action area is further described in the Affected Environment (Section 3).

5.2 Physical Environment

5.2.1 No Action Alternative: Soil Resources, Water resources, Air Quality, and Climate Change.

Summary of potential impacts

Under the No Action Alternative, common agricultural activities are currently occurring and will continue to occur within the action area. These common agricultural activities include practices related to field preparation (e.g., tillage) and field maintenance (e.g., tillage, irrigation, and the application of agricultural inputs). Irresponsible conduct regarding these common agricultural activities has the potential to negatively affect soil resources, water resources, air quality, and climate change. For example, irresponsible tillage practices may lead to soil erosion, which in turn not only impacts soil quality, but also contributes particles that can impact water (e.g., sedimentation) and air quality (e.g., air-borne dust). Furthermore, the irresponsible use of agricultural inputs can also negatively affect water resources and air quality through the off-site movement of these agricultural inputs.

However, common agricultural practices and regulations also exist to preserve soil resources, water resources, air quality, and the climate. Under the No Action Alternative, these practices and regulations currently and will continue to be in place to mitigate agricultural impacts to the each aspect of the physical environment.

Background

The physical environment consists of soil resources, water resources, air quality, and climate change (Section 3). Each individual aspect of the physical environment may be substantially affected by the anthropogenic activities that occur on it.

As previously discussed in the Affected Environment (Section 2), the action area is located within the NYSAES in Geneva, NY. The action area, similar to rest of the NYSAES-owned land that surrounds it, is land that has been maintained under some form of agricultural management for much of its 134-year history (NYSAES, 2014). Consideration of historical land use patterns and the NYSAES mission[24] strongly suggests that present-day agricultural activities within the action area will continue under the No Action Alternative. Consequently, any current impact on the physical environment as a result of these agricultural activities will also continue under the No Action Alternative.

Common agricultural activities (Delahaut and Newenhouse, 1997; Seaman, 2013) are facilitated by the use of motorized farm equipment[25] and include tillage and the use of agricultural inputs

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[24] The NYSAES was established by the New York State Legislature for "…the purpose of promoting agriculture in its various branches by scientific investigation and experiment." See http://www.nysaes.cornell.edu/cals/nysaes/about/history.cfm. Last accessed March, 2014

[25] e.g., tractors, plows, etc.

(Personal Communication, A. Shelton). Tillage and the use of agricultural inputs possesses the potential to directly and indirectly affect the physical environment if not properly used (USDA-NRCS, 2001). For example, tillage and the use of motorized farm equipment may directly or indirectly affect components of the physical environment through the release of soil particles and the emission of various gases (EPA, 2012b). These potential impacts for each component of the physical environment are presented in the following subsections.

Additionally, the use of agricultural inputs may also directly or indirectly affect components of the physical environment (Leistra *et al.*, 2006; Tong, 2009). However, the use of any EPA-registered pesticide within the United States is unlikely to cause adverse effects on the environment if used according to the specifications on the label (See Section 2.5.3 and EPA, 2013c). Therefore, the use of any EPA-registered pesticide is unlikely to have a significant impact on individual components of the physical environment and will not be discussed further.

<u>Soil resources</u>

Modern agricultural activities possess the potential to modify soil quality. While practices such as tillage and the use of agricultural inputs can improve soil health, they can also cause substantial damage if not properly used (USDA-NRCS, 2001). Several concerns relating to common agricultural activities include concerns relating to soil structure[26] and soil composition[27] (USDA-NRCS, 2001).

Soil is generally characterized by the structure and composition of organic/inorganic materials (USDA-NRCS, 1999). Accordingly, any agricultural activity that modifies the structure or composition of soils may affect the quality of the soil (USDA-NRCS, 2001).

Conventional tillage is the intentional disturbance of the soil to achieve a variety of objectives, including weed control, incorporation of agricultural inputs into the soil, and modification of soil aeration/water drainage properties (Hoeft *et al.*, 2000). The intensity of soil disturbance during tillage is a primary factor affecting soil quality (Hoeft *et al.*, 2000; Smith and Conen, 2004), as conventional tillage generally exposes the upper layers of soil to the environment, making it more susceptible to degradation from wind- and water-mediated erosion (NCGA, 2007). Additionally, the use of machinery to till a field may potentially compact the soil (i.e., compaction) (Delahaut and Newenhouse, 1997). Compacted soil possesses a reduced number and size of air spaces in soil, ultimately leading to decreased aeration and water-holding capacity in that soil (USDA-NRCS, 2001). Conservation tillage practices manages the soil erosion and structural concerns of conventional tillage by leaving undisturbed plant residues in the field at the conclusion of the growing season, relying exclusively on herbicide application to control weeds following planting (Markus, 1997; O'Brien, 1998; Hoeft *et al.*, 2000) .

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[26] i.e., erosion and compaction

[27] i.e., nutrient imbalance or the presence of synthetic chemicals

The use of agricultural inputs is an important aspect of modern agriculture (Heiniger, 2000; Farnham, 2001; University of Arkansas, 2006; USDA-NASS, 2007; NSRL, n.d.). Two primary types of agricultural inputs used in modern agriculture are fertilization and pesticide application. Fertilization is generally used to compensate for deficiencies or imbalances of soil micro/macro nutrients (Delahaut and Newenhouse, 1997; USDA-NASS, 2007; Seaman, 2013; NSRL, n.d.), while pesticide application is used to manage agricultural pests[28] that decrease crop yields (Talekar and Shelton, 1993; Anonymous, 1999; Hoeft *et al.*, 2000; Farnham, 2001; USDA-ERS, 2005; USDA-NASS, 2007; Boucher, 2012). The use of both types of agricultural inputs may potentially impact soil quality by adding additional components to the soil, thereby potentially altering soil composition.

For example, growers may choose a variety of methods to control pests in an agricultural field, though the specific method will ultimately be dependent on the nature of the pest itself and grower want and need (USDA-ERS, 2005; 2010). Growers may choose certain pesticides based on weed, insect and disease pressures, cost of seed and other inputs, technology fees, human safety, potential for crop injury, and ease and flexibility of use (Heiniger, 2000; Farnham, 2001; University of Arkansas, 2006). The environmental risks of pesticide use on soil resources are assessed by EPA in the pesticide registration process and are regularly reevaluated by EPA for each pesticide to maintain its registered status under FIFRA (EPA, 2014c). When used according to label directions, pesticides can be used without posing unreasonable risk to the environment, including soil quality (EPA, 2014c).

Water resources

Water resources generally incudes the amount of water available for use and the quality of water available for use. Common agricultural activities possess the potential to affect water resources, either through direct use for irrigation or indirectly through the contribution of non-point source (NPS) pollutants.

Within the action area, agricultural use of water through irrigation is only used when needed; the source of the irrigation within the NYSAES is an irrigation pond found on the property of the NYSAES (Personal Communication, A. Shelton).

Tillage and the use of motorized farm equipment may result in soil disturbances (USDA-NRCS, 2001). The intensity and frequency of this disturbance is especially relevant for water quality, as any resulting erosion may facilitate the release of sediments in water bodies. At present, sediments represent the primary source of agricultural NPS pollution in the United States (EPA, 2005a; 2012e). Associated with the potential release of sediments into water bodies following the use of tillage or motorized farm equipment, is the release of agricultural inputs that may have adhered with soil particles into these same bodies of water (Whitney, 1997; EPA, 2005a; USDA-NASS, 2007; EPA, 2012e; NSRL, n.d.).

[28] i.e., weeds, insect pests, or microbial pests

While tillage or the use motorized farm equipment may facilitate the release of sediments or agricultural inputs adhered to sediments into water bodies, agricultural practices that reduce soil disturbances may also reduce the potential impact on water quality (Hoeft *et al.*, 2000; NCGA, 2007).

While sediments represent the most common cause of agricultural water quality impairments, it is not the only source (EPA, 2005a). The off-site movement[29] of agricultural inputs, such as fertilizer or pesticides, also represent common water quality impairments (EPA, 2012e). In the United States, nutrients and pesticides ranked as the 3rd and 16th most important causes of impairments in assessed water bodies, respectively (EPA, 2012e).

Water quality in the United States is overseen by the EPA under authority of the Clean Water Act (CWA). The CWA authorizes the establishment of water quality standards, permit requirements, and monitoring to establish a legal framework to protect and enhance domestic water quality. The EPA sets standards for water pollution abatement for all waters of the U.S. under the authority of this enabling legislation. In most cases, EPA extends to qualifying states the authority to issue and enforce permits. The CWA (33 U.S.C. 1251 et seq.) authorizes regulation of discharges of pollutants into the waters of the U.S. and the establishment of quality standards for surface waters. It is the principal US legislation for safeguarding surface water, but it does not directly address groundwater.

Accordingly, the EPA oversees groundwater and drinking water through the Safe Drinking Water Act (SDWA) of 1974 (Public Law 93-523, 42 U.S.C. 300 *et seq*.) and the Sole Source Aquifer (SSA) designation under the SDWA (US-EPA, 2011). Under the SDWA, the EPA sets national health-based standards for drinking water quality to protect against both naturally-occurring and man-made contaminants that may be found in drinking water.

Air quality

Air quality is the capability of the atmosphere to sustain and buffer life on earth from the extremes of temperature variations (BCAP, 2010). Common agricultural activities may generate each of the criteria pollutants for air quality established under the Clean Air Act (CAA) and the National Ambient Quality Standards (NAAQS) (BCAP, 2010), though in particular, common agricultural activities primarily possess the potential to generate inhalable particulates. Additionally, common agricultural activities may also contribute other air quality impairments, primarily due to the off-site movement/volatization of agricultural inputs.

Dust represents the primary form of particulate matter that may impair air quality in agriculture (EPA, 2013a). Dust, consisting of soil particles suspended in the air, may be generated directly or indirectly following tillage or any other agricultural activity that requires the use of motorized farm equipment (e.g., tractors, plows, etc.) (Fawcett and Towery, 2002). Wind-mediated erosion and the release of particulates into the air following the use of tillage or motorized farm equipment

[29] i.e., agricultural runoff

generally represents an indirect cause of air impairment from common agricultural activities (Fawcett and Towery, 2002).

As previously discussed for soil and water resources, the use of conservation tillage possesses the potential to decrease both direct and indirect causes of agricultural-derived dust, due to the lower intensity of intentional and direct soil disturbance (Fawcett and Towery, 2002).

Common agricultural activities, including the use of mechanized equipment and the application of agricultural inputs, may result in agricultural emissions that may consist of gases (e.g., carbon monoxide) or inhalable particulates (e.g., smoke). Agricultural emissions may derive from exhaust from the use of motorized farm equipment or the aerial movement/volatilization of agricultural inputs (Fawcett and Towery, 2002), such as fertilizers and pesticides (FOCUS, 2008; USDA-ARS, 2011).

There are, however, many options to improve air quality within an agricultural setting. These include conservation tillage, residue management, wind breaks, road treatments, burn management, prunings shredding, feed management, manure management, integrated pest management, chemical storage, nutrient management, fertilizer injection, chemigation and fertigation (inclusion in irrigation systems), conservation irrigation, scrubbers, and equipment calibration (USDA-NRCS, 2006).

Air quality within the United States is overseen by the EPA pursuant to the CAA and the NAAQS. Under the CAA, every state is required to achieve and maintain the NAAQS and to prepare a State Implementation Plan (SIP) identifying strategies to achieve and maintain the national standard of air quality within the state" (BCAP, 2010).

The environmental risks of pesticide applications are assessed by EPA in the pesticide registration process. Additionally, pesticides are regularly reevaluated by the EPA to maintain its registered status (EPA, 2014c). When used in accordance with registered uses and EPA-approved labels, glyphosate poses minimal risks to air quality (EPA, 2014c). With regard to pesticide movement (i.e., drift), the EPA is currently evaluating new regulations for pesticide drift labeling and the identification of best management practices to control such drift (EPA, 2009).

Climate change

Climate change represents a statistical change in global climate conditions, including shifts in the frequency of extreme weather, that may be measured across time and space (Cook *et al.*, 2008; Karl *et al.*, 2008). Agriculture is recognized as a direct (e.g., exhaust from equipment) and indirect (e.g., agricultural-related soil disturbance) source of greenhouse gas (GHG) emissions (Rosenzweig and Parry, 1994; Dale, 1997; Fargione *et al.*, 2008). GHGs, including CO_2, methane (CH_4), and N_2O, function as retainers of solar radiation (Aneja *et al.*, 2009). The US agricultural sector is second only to energy production as a contributor to GHG emissions (EPA, 2010a).

US agriculture may influence climate change through various facets of the production process and conversion of land to agriculture (Horowitz and Gottlieb, 2010). Additionally, tillage contributes to GHG production because it releases CO_2 sequestered in soil and promotes oxidation of soil organic matter (Baker *et al.*, 2005). CH_4 and N_2O are the primary GHGs emitted by agricultural activities, including emissions from the use of motorized equipment and soil N_2O emissions (Hoeft *et al.*, 2000; Robertson *et al.*, 2000; Del Grosso *et al.*, 2002; West and Marland, 2002; Aneja *et al.*, 2009; EPA, 2011a). The major sources of GHG emissions associated with crop production are soil N_2O emissions, soil CO_2 and CH_4 fluxes, and CO_2 emissions associated with farm equipment operation (Adler *et al.*, 2007).

The contribution of agriculture to climate change largely is dependent on the production practices employed to grow various commodities, the region in which the commodities are grown, and the individual choices made by growers. For example, emissions of nitrous oxide, produced naturally in soils through microbial nitrification and denitrification, can be influenced dramatically by fertilization, introduction of grazing animals, cultivation of nitrogen-fixing crops and forage (e.g., alfalfa), retention of crop residues (i.e., no-till conservation), irrigation, and fallowing of land (EPA, 2012a). These same agricultural practices can influence the decomposition of carbon-containing organic matter sequestered in soil, resulting in conversion to carbon dioxide and subsequent loss to the atmosphere (EPA, 2012a). Conversion of crop land to pasture results in an increase in carbon and nitrogen sequestration in soils (EPA, 2012a).

Additionally, one outcome of the potential effects of agricultural production on climate change is the potential effect of the climate change on agriculture itself. In response to climate change, the current range of weeds and pests of agriculture is expected to increase. Current agricultural practices will need to adapt in response to these changes in the ranges of weeds and pests of agriculture (Field *et al.*, 2007).

5.2.2 Preferred Alternative: Soil Resources, Water Resources, Air Quality, and Climate Change

Under the Preferred Alternative, impacts to the physical environment, including impacts to soil resources, water resources, air quality, and climate change would be similar to the no action alternative. The nature of the activities associated with the Preferred Alternative, the magnitude of these activities, and the size of the potential release fields all represent current agricultural activities that have occurred and will continue to occur within the action area. Under the Preferred Alternative, an experimental field up to 10 acres in size within the NYSAES action area will be planted with a cruciferous crop (e.g., broccoli or cabbage) (Section 3.4). The agricultural activities used to plant and maintain these cruciferous crop fields are the same as those agricultural activities (e.g., tillage or pesticide application) that are already occurring and described under the No Action Alternative (Section 4.2.1). Releases of the GE diamondback moth will likely utilize roadways and other access systems already present and utilized within the NYSAES. Consequently, the potential impacts on the physical environment, including soil resources, water resources, air quality, and climate change as a result of these agricultural activities are also the same as those potential impacts described under the No Action Alternative (Section 4.2.1).

The release of GE diamondback moth is not anticipated to substantially affect individual or multiple components of the physical environment, as non-GE diamondback moth is already ubiquitous in the action area (Shelton, 2001b). While the applicant will release GE diamondback moths, these GE diamondback moths are functionally equivalent to non-GE diamondback moth, with the exception of the introduced traits[30] and a slight decrease in lab-observed fitness (Jin *et al.*, 2013). These traits are not anticipated to have an effect on the physical environment, as these traits affect the biology of diamondback moth only (Jin *et al.*, 2013).

During public comment for the previous EA, concern had been raised about the potential transfer of DNA, particularly DNA of the introduced traits, from decomposing GE diamondback moth to individual soil microflora. While the transfer of DNA between soil microorganisms is common (Keese, 2008; McDaniel *et al.*, 2010), biodegradation of any organisms after death is likely to result in fragmentation of DNA strands into small pieces (Lerat *et al.*, 2007; Levy-Booth *et al.*, 2008; Hart *et al.*, 2009). The transfer of functioning DNA for these introduced traits from decomposing GE diamondback moth to water sources, air quality, or soil microorganisms is remote and unlikely.

5.3 Biological Environment

5.3.1 No Action Alternative: Wildlife, Plant Communities, and Biological Diversity

<u>Summary of potential impacts</u>

Under the No Action Alternative, common agricultural activities are currently and will continue to occur within the action area. These common agricultural practices include activities related to field preparation and maintenance (e.g., tillage, irrigation, and the application of agricultural inputs). As a result of the current and continued practice of these common agricultural activities, individual aspects of the biological environment, including wildlife, plant communities, and biological diversity will continue being impacted under the No Action Alternative.

In general, agricultural environments are not ideal habitats for wildlife and plant communities. As a result, biological diversity is generally lower in these agricultural environments when compared to more natural, less intensively-managed areas. This general impact on wildlife, plant communities, and biological diversity is currently on-going under the No Action Alternative. Additionally, given the likelihood of continued agricultural activities within the action area, it is likely that these general impacts will continue under the No Action Alternative.

<u>Background</u>

The biological environment of the action area consists of wildlife, plant communities in and around the potential release fields, and biological diversity (Section 3).

As previously discussed in the Affected Environment (Section 3), the action area is located within the NYSAES in Geneva, NY. The action area, similar to rest of the NYSAES-owned land that surrounds it, is land that has been maintained under some form of agricultural management for

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[30] i.e., red fluorescence and repressible-female lethality (i.e., female autocide)

much of its 134-year history (NYSAES, 2014). The site also includes the Castle Creek riparian corridor, which traverses the experimental station. Consideration of historical land use patterns and the NYSAES mission[31] strongly suggests that present-day agricultural activities within the action area will continue under the No Action Alternative.

Accordingly, the potential impacts to individual components of the biological environment under the No Action Alternative are those potential impacts that may result from the continuation of existing agricultural activities within the action area. A discussion of these potential impacts as a result of the No Action Alternative on individual components of the biological environment is presented below.

Additionally, the use of agricultural inputs may also directly or indirectly affect components of the biological environment (Leistra *et al.*, 2006; Tong, 2009). However, the use of any EPA-registered pesticide within the United States is unlikely to cause adverse effects on the environment if used according to the specifications on the label (See Section 2.5.3 and EPA, 2013c). Therefore, the use of any EPA-registered pesticide is unlikely to have a significant impact on individual components of the biological environment and will not be discussed further.

Wildlife

Wildlife in the action area would reflect the expanses of agricultural fields on the NYSAES, as well as the riparian corridor. In general, land that is under modern agricultural management provides less suitable habitat for wildlife uses than fallow fields or natural areas (Lovett *et al.*, 2003; Landis *et al.*, 2005). As such, the number and types of animal species found in fields under modern agricultural management are less diverse by comparison (Harlan, 1975). Additionally, deer (Curtis *et al.*, 1994) and red-winged blackbird may also be found in or around a cruciferous crop fields (Bollinger and Caslick, 1985; Curtis *et al.*, 1994).

Invertebrate organisms that feed on cruciferous crops within the action area include beneficial and pest insects. Beneficial insects include pollinators, such as honey bees and bumblebees (OECD, 2012). Other beneficial arthropods may also include predatory or parasitic insects that feed on other insects, particularly insect pests, within the agricultural field. Arthropods that feed on insect pests include spiders, lady beetles, hover flies, and various parasitoids (Table 2). Dietary assessments of predator/prey organisms consuming insectivore diets have shown that they are largely generalist organisms and only a small fraction of their diets is a single insect species (Blum *et al.*, 1997). Pest insects include cabbage root maggot (*Delia radicum*); flea beetle (*Phyllotreta striolata* and *P. cruciferae*); diamondback moth (*P. xystella*); imported cabbageworm (*Pieris rapae*); cabbage looper (*Trichoplusia ni*); cabbage and green peach aphids (*Brevicoryne brassicae* and *Myzus persicae*, respectively); onion thrips (*Thrips tabaci*); and Swede midge (*Contarinia nasturii*) (NY State IPM Program, 2013). In particular, diamondback moth is a major pest of

[31] The NYAES was established by the New York State Legislature for "…the purpose of promoting agriculture in its various branches by scientific investigation and experiment." See http://www.nysaes.cornell.edu/cals/nysaes/about/history.cfm. Last accessed March, 2014.

cruciferous crops, such as cabbage and broccoli (Andaloro, 1983; Talekar and Shelton, 1993), and will be further discussed directly below.

Table 2. Selected beneficial insects found in conjunction with cultivated *Brassica* species. Table derived from Root (1973).

Species	Family
Order Mesostigmata	
Cheiroseius sp.	Ascidae
Order Araneidae	
Araniella displicata	Araneidae
Chiracanthium inclusum	Clubionidae
Clubiona obsea	Clubionidae
Dictyna hentzi	Dictynidae
Dictyna volucripes	Dictynidae
Ceraticelus emertoni	Linyphiidae
Erigone atra	Linyphiidae
Hypselistes florens	Linyphiidae
Microlinyphia mandibulata	Linyphiidae
Metaphidippus protervus	Salticidae
Tetragnatha laboriosa	Tetragnathidae
Theridion albidum	Theridiidae
Theridion murarium	Theridiidae
Tibellus oblongus	Thomisidae
Order Opiliones	
Phalangium opilio	Phalangida
Order Coleoptera	
Anthicus cervinus	Anthicidae
Ceratomegilla maculata	Coccinellidae
Coccinella novemnotata	Coccinellidae
Hippodamia convergens	Coccinellidae
Photinus sp.	Lampyridae
Collops quadrimaculatus	Melyridae
Orthoperus glaber	Orthoperidae
Stilbus apicalis	Phalacridae
Deleaster sp.	Staphylinidae
Heterothops sp.	Staphylinidae
Order Diptera	
Mesograpta marginata	Syrphidae
Metasyrphus americanus	Syrphidae
Sphaerophoria cylindrica	Syrphidae
Syrphus rectus	Syrphidae
Order Hemiptera	
Orius insidiosus	Anthocoridae
Nabis spp.	Nabidae
Order Hymenoptera	
Vespula sp.	Vespidae
Apanteles sp.	Braconidae
Aspilota sp.	Braconidae
Dacnusa sp.	Braconidae
Diaeretiella rapae	Braconidae
Microctonus vittatae	Braconidae
Synaldis sp.	Braconidae
Ceraphron sp.	Ceraphronidae
Alloxysta sp.	Figitidae
Alloxysta brassicae	Figitidae
Hexacola websteri	Figitidae
Copidosoma truncatellum	Encyrtidae
Tetrastichus sinope	Eulophidae
Polynema sp.	Mymaridae
Leptacis sp.	Platygastridae
Asaphes sp.	Pteromalidae
Macroglenes penetrans	Pteromalidae

Diamondback moth biology and ecology within the action area

Diamondback moth, originally introduced from Europe in 1854, only feeds on cruciferous plants in its larval form; its host plants include commercial cruciferous crops such as canola (*Brassica napus* L.), cabbage (*Brassica oleracea* L.), broccoli (*Brassica oleracea* var. *italica* L.), cauliflower (*Brassica oleracea* var. *botrytis* L.), Chinese cabbage (*Brassica pekinensis* Lour.), and Indian mustard (*Brassica juncea* L.). The current range of diamondback moth in the United States includes all states where cruciferous crops are produced, though damage is most severe in Hawaii and Southern US States where yearly temperatures permit it be present throughout the calendar year. In general, diamondback moths are weak flyers unable to travel long distances by spontaneous flight (Talekar and Shelton 1993; Shelton 2001). Mo et al. (2003) studied the local dispersal distance of diamondback moth and determined that its average dispersal distance is 14 – 35 m, and they estimated that less than one percent are expected to fly farther than 200 m from a release site. This study by Mo et al. (2003) represents the first statistical estimate of diamondback moth dispersal ranges and is widely cited in the scientific literature (e.g., see Furlong et al. 2013; Schellhorn et al. 2008; Phillips et al. 2014; Yang et al. 2015). Diamondback moths are also known to be transported long distances[32] by wind currents, but long-distance dispersal is not considered in this EA for the reasons stated in Section 3.2 above.

In general, the lifespan of adult diamondback moths ranges between of 12-16 days[33]. Adult diamondback moths do not cause any herbivory damage on cruciferous plants, subsisting on dew and/or water droplets. It is during this time period that adult diamondback moths mate and reproducs. Within the action area and all of the United States, diamondback moth is only able to reproduce with other diamondback moths, indicating an absence of sexually-compatible relatives. After mating, female diamondback moths can lay on average 160 eggs over about 10 days on a selected cruciferous plant.

After a pair of diamondback moths mate and reproduce, the eggs are laid individually or in groups of 2-8 on the upper leaf surface and hatch within 4-8 days. After hatching, diamondback moth larvae go through four instars[34] before pupation. The diamondback moth pupal stage can last between 5-15 days, depending on environmental conditions.

As a result of this lifecycle, multiple generations of diamondback moth can overlap and all life stages of diamondback moth can be present in the cruciferous crop field at the same time.

Plant communities

Plants associated with plant agricultural production, particularly those plants associated with cruciferous crop production, include within-field and adjacent-field plant communities. Within-

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[32] i.e., hundreds of kilometers

[33] Dependent on sex of the diamondback moth

[34] A developmental stage between larval molts

field plant communities generally consist of the planted crop and any weeds associated with the planted crop. Adjacent-field plant communities within the action area are also anticipated to consist of planted crops and any weeds[35] associated with planted crops, due to its use as agriculturally-managed land by the NYSAES (Figure 2). Plant communities in the Castle Creek corridor will mainly reflect riparian woodland associated plants, including trees and aquatic plants.

Due to the location and use of the potential release fields and its adjacent land in this EA, within-field and adjacent-field plant communities are anticipated to be similar within the action area, in that it will be a mixture of cultivated crops and weeds of those cultivated crops[36].

Domesticated crops that may be found within the action area include fruits, field crops, and vegetables (NYSAES, 2014). In particular, a variety of domesticated cruciferous crops may be planted in the action area, such as cabbage or broccoli (Table 3). Surrounding domesticated crops around the potential release fields generally consists of field corn.

Non-domesticated plants within an agricultural setting are generally regarded as potential weeds. There may be numerous non-domesticated plants within the action area; however, the most relevant, given the proposed action in this No Action analysis, are those non-domesticated plants that are also in the Crucifer family (Brassicaceae). These non-domesticated cruciferous plants span 50 species in 25 genera (Table 4). If present within an agricultural field, it is likely that these 50 species of crucifers would be intentionally managed, like any other weed present in that agricultural field, through the use of common agricultural activities (e.g., herbicide spraying).

In general, all individuals within the plant community may be subject to herbivory. In particular, cruciferous plants, whether domesticated or non-domesticated, may be subject to herbivory from diamondback moth larvae (Andaloro, 1983; Talekar and Shelton, 1993; Shelton, 2001a). Within an agricultural setting, damage from diamondback moth larvae is generally not noted if it occurs on non-domesticated cruciferous plants (i.e., weeds that are crucifers). However, damage on cultivated cruciferous plants may be noted by the manager of that field. If certain thresholds[37] are met, the manager of that agricultural field may choose to manage the diamondback moth population causing damage to the cultivated cruciferous plant. In general, if the population of larval diamondback moth exceeds a pre-determined threshold, then insecticide spraying is generally the only viable option (Andaloro, 1983; Talekar and Shelton, 1993).

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[35] Weeds may consist of non-cultivated and non-domesticated field plants and volunteer plants from the previous planting

[36] The potential release fields are adjacent to lands/fields already subjected to agricultural management, because of the location and use of the land by the NYSAES

[37] For example, the Canadian Canola Council website (www.canolacouncil.org/canola-encyclopedia/insects/diamondback-moth/) provides advice on detecting the DBM in the growing season. Farmers are advised to scout their fields early on in the growing season and checking throughout July and August, monitoring crops at least twice a week. Farmers need to take crop samples from a $0.1m^2$ area, beat them onto a clean surface and count the number of larvae dislodged. When 20-30 larvae/$0.1m^2$ are present at the advanced pod stage it is recommended to spray an approved insecticide.

Plant communities within agroecosystems are generally less diverse than plant communities within other ecosystems. This lack of diversity is attributable to ecological selection that is imposed by crop production practices, such as tillage and herbicide use (Gianessi and Reigner, 2007; Owen, 2008), that aims to maximize crop production (Green and Owen, 2011). Beyond the crop plant that is intentionally planted and cultivated, agricultural practices affect plant communities by exerting selection pressures that influence the type and composition of plants present in a community. For example, natural selection in frequently disturbed environments enables colonization by plants exhibiting early germination and rapid growth from seedling to sexual maturity, and the ability to reproduce sexually and asexually (Baucom and Holt, 2009). These weedy characteristics enable such plants to spread rapidly into areas undesired by humans.

Table 3. Domesticated cruciferous crops.
Table derived from OECD (2012).

Common Domesticated Brassica Species	
Horseradish	*Armoracia rusticana*
Brown and oriental mustard	*Brassica juncea*
Rutabaga	*Brassica napobrassica*
Oilseed rape/Canola	*Brassica napa*
Black mustard	*Brassica nigra*
Cabbage, broccoli, cauliflower, Brussel sprouts, kohlrabi, collards, and kale	*Brassica oleracea*
Chinese cabbage, Chinese mustard, broccoli raab, and turnip	*Brassica rapa*
Wasabi	*Eutrena japonica*
Garden cress	*Lepidium sativum*
Watercress	*Nasturtium officinale*
Radish	*Raphanus sativus*
Yellow mustard	*Sinapis alba*

Table 4. Non-domesticated brassicas in Ontario County, New York.
Table derived from BONAP (2014).

Brassica Species in Ontario County, New York	
Alliaria	***Descurainia***
Alliaria petiolata (Garlic mustard)	*Descurainia pinnata* (Western tansymustard)
Alyssum	***Draba***
Alyssum alyssoides (Pale madwort)	*Draba arabisans* (Rock draba)
Arabidopsis	*Draba verna* (Spring draba)
Arabidopsis lyrata (Lyre-leaved rock-cress)	***Erucastrum***
Arabidopsis thaliana (Thale cress)	*Erucastrum gallicum* (Common dogmustard)
Arabis	***Erysimum***
Arabis pycnocarpa (Creamflower rockcress)	*Erysimum cheiranthoides* (Wormseed wallflower)
Armoracia	***Hesperis***
Armoracia rusticana (Horseradish)	*Hesperis matronalis* (Dames rocket)

Barbarea	***Lepidium***
Barbarea vulgaris (Garden yellowrocket)	*Lepidium campestre* (Field pepperweed)
Berteroa	*Lepidium densiflorum* (Common pepperweed)
Berteroa incana (Hoary alyssum)	*Lepidium draba* (Heart-pod Hoarycress)
Boechera	*Lepidium virginicum* (Virginia pepperweed)
Boechera canadensis (Sicklepod)	***Microthlaspi***
Boechera grahamii (Spreadingpod rock-cress)	*Microthlaspi perfoliatum* (Claspleaf pennycress)
Boechera laevigata (Smooth rockcress)	***Nasturtium***
Boechera stricta (Drummond's rockcress)	*Nasturtium officinale* (Watercress)
Brassica	***Rorippa***
Brassica juncea (Brown mustard)	*Rorippa aquatica* (Lakecress)
Brassica nigra (Black mustard)	*Rorippa palustris* (Bog yellowcress)
Brassica rapa (Field mustard)	*Rorippa sylvestris* (Creeping yellowcress)
Camelina	***Sinapis***
Camelina microcarpa (Littlepod false flax)	*Sinapis alba* (White mustard)
Camelina sativa (Gold-of-pleasure)	*Sinapis arvensis* (Wild mustard)
Capsella	***Sisymbrium***
Capsella bursa-pastoris (Shepherd's purse)	*Sisymbrium altissimum* (Tall tumblemustard)
Cardamine	*Sisymbrium loeselii* (Small tumbleweed mustard)
Cardamine bulbosa (Bulbous bittercress)	*Sisymbrium officinale* (Hedgemustard)
Cardamine concatenata (Cutleaf toothwort)	***Thlaspi***
Cardamine diphylla (Crinkleroot)	*Thlaspi arvense* (Field pennycress)
Cardamine douglassii (Limestone bittercress)	***Turritis***
Cardamine hirsuta (Hairy bittercress)	*Turritis glabra* (Tower mustard)
Cardamine impatiens (Narrowleaf bittercress)	
Cardamine parviflora (Sand bittercress)	
Cardamine pensylvanica (Pennsylvania bittercress)	
Cardamine pratensis (Cuckoo flower)	
Cardamine rotundifolia (American bittercress)	

Biological diversity

Biodiversity refers to all plants, animals, and microorganisms interacting in an ecosystem (Wilson, 1988). Biodiversity provides valuable genetic resources for crop improvement (Harlan, 1975) and also provides other functions beyond food, fiber, fuel, and income. These include pollination, genetic introgression, biological control, nutrient recycling, competition against natural enemies, soil structure, soil and water conservation, disease suppression, control of local microclimate, control of local hydrological processes, and detoxification of noxious chemicals (Altieri, 1999). The loss of biodiversity can result in a need for costly management practices in order to provide these functions to the crop (Altieri, 1999).

The degree of biodiversity in an agroecosystem depends on four primary characteristics: 1) diversity of vegetation within and around the agroecosystem; 2) permanence of various crops within the system; 3) intensity of management; and 4) extent of isolation of the agroecosystem from natural vegetation (Harlan, 1975).

The action area, similar to any land subject to common agricultural management practices, generally has low levels of biodiversity compared with natural areas. Modern agriculture generally impacts biodiversity because its establishment represents conversion of natural habitats to monocultures (Ammann, 2005). Common agricultural practices related to field establishment and maintenance of that agricultural field, such as tillage, seed bed preparation, planting of a monoculture crop, pesticide use, fertilizer use, and harvesting all simplify the landscape and limit the diversity of plants and animals (Lovett *et al.*, 2003; Landis *et al.*, 2005).

Biodiversity can be maintained or reintroduced into agro-ecosystems through the targeted management of field edges/land adjacent to the field or the use of contour-strip cropping (Altieri and Letourneau, 1982; Landis *et al.*, 2005; Sharpe, 2010).

For example, field edges are often the least productive areas in a farm field and in some cases and the cost of producing crop areas along field edges exceeds the value of the crop produced (Sharpe, 2010). While allowing these field edges to be colonized by non-domesticated vegetation will contribute to weed seeds in the agricultural field, they may also facilitate its use by birds or beneficial arthropods (Altieri and Letourneau, 1982; Altieri, 1999; Sharpe, 2010). Additionally, the management of land adjacent to the field, such as drainage ditches, hedgerows, riparian areas, or woodlands may provide cover, nesting sites, and forage areas for wildlife populations (Sharpe, 2010; Palmer *et al.*, 2011).

Additionally, contour-strip cropping is another management practice that can be used to promote wildlife habitat. This practice alternates strips of row crops with strips of solid stand crops (i.e., grasses, legumes, or small grains) with the strips following the contour of the land (Sharpe, 2010). The primary purpose of contour-strip cropping is to reduce soil erosion and water runoff, but the solid stand crop also provides nesting and roosting cover for wildlife (Sharpe, 2010).

5.3.2 Preferred Alternative: Wildlife, Plant Communities, and Biological Diversity

The nature of the activities associated with the Preferred Alternative, the magnitude of these activities, and the size of the potential release fields all represents current agricultural activities that have and will continue within the action area. As a result, the only difference between the Preferred and No Action Alternatives is exposure of other organisms to GE diamondback moth, and any resulting potential impact this exposure may have on the wildlife, plant communities, and biological diversity within the action area. The dissemination and establishment of GE diamondback moth (or its progeny) in the environment beyond the action area is unlikely due to the biology of the organism, environmental conditions at the proposed release site, and permit conditions imposed by APHIS.

In the following subsections, potential impacts on each aspect of the biological environment as a result of the Preferred Alternative will be described.

Wildlife

Under the Preferred Alternative, the common agricultural activities used to prepare and maintain the potential release fields are the same common agricultural activities that are already occurring within the action area under the No Action Alternative. Consequently, the potential impact to wildlife, such as mammals, birds, and beneficial insects, from field preparation and management under the Preferred Alternative is the same as the No Action Alternative, as these potential impacts to wildlife are moderated by agricultural activities. Accordingly, the only difference between the Preferred and No Action Alternative, with respect to wildlife, is the potential exposure to GE diamondback moth.Two types of wildlife are most likely to be exposed to GE diamondback moth: 1) Sexually-compatible insects that may mate with GE diamondback moth; and 2) Vertebrate or invertebrate insectivores that may consume GE diamondback moth. These two distinct types of wildlife will be discussed below, along with any potential impact under the Preferred Alternative.

Within the action area, the only sexually-compatible insects that can mate with the released GE diamondback moth males are non-GE diamondback moth females (Section 2.4). Diamondback moths may only mate with other diamondback moths, thus indicating that vertical gene transfer[38] will occur only within the diamondback moth species.

As a result of the Preferred Alternative, GE diamondback moth males are likely to mate with non-GE diamondback moth females. Assuming stability of the female autocidal trait, the overall diamondback moth population is anticipated to decrease over time due to an anticipated reduction in reproductive potential of the diamondback moth population (Jin *et al.*, 2013 and Section 2.4). However, if functionality of the female autocidal trait were to deteriorate in subsequent diamondback moth generations during the growing season, the overall diamondback moth population may not experience an overall decrease (Jin *et al.*, 2013). Each scenario is anticipated to have a transient effect on diamondback moth populations within the action area. However, each scenario is not anticipated to have a long-term and significant impact on diamondback moth populations within the action area due to the ubiquitous nature of non-GE diamondback moth in the action area, facilitated by the continual yearly introduction of non-GE diamondback moth into the action area through diamondback moth-infested seedlings (Shelton, 2001b); the inability of diamondback moth to overwinter in the action area (Shelton, 2001b; Nguyen *et al.*, 2014); and the devitalization of all diamondback moths in the potential release fields at the conclusion of each growing season by the applicant (Section 2.4) These three factors strongly suggest that the local diamondback moth population (GE and non-GE) will be significantly reduced at the end of the growing season or calendar year and that a new population of non-GE diamondback moths will be present the following spring before release of GE diamondback moth begins again. This diamondback moth population pattern is already observed in the No Action Alternative.

Additionally, it is important to keep in mind that local populations of diamondback moth in fields adjacent to the potential release fields may potentially experience fluctuations in population size as

[38] i.e., movement of genes through sexual reproduction

a result of the released GE diamondback moth[39]. However, this potential impact on overall diamondback moth populations within these adjacent fields is no different from the No Action Alternative, as land managers are likely already using control methods (e.g., insecticide spraying) to manage diamondback moths and other insect pests in adjacent cruciferous crop fields.

Insectivores within the action area may generally include lower-order invertebrates (e.g., spiders, lady beetles, hover flies, and various parasitoids[Table 1]). Insectivores that consume GE diamondback moth under the Preferred Alternative are not likely to be impacted by the introduced gene or gene products. As previously discussed in the Purpose and Need (Section 1), the GE diamondback moth contains two introduced genes/gene products, DsRed2 and tTAV. The presence of these gene/gene products is a fundamental difference between GE and wild-type diamondback moths.

DsRed2 is a reporter gene/gene product that was previously examined in a prior APHIS EA (i.e., APHIS, 2011); furthermore, the similar DsRed gene/gene product (DsRed2 is derived from DsRed; see Zeiss, n.d.) was examined by APHIS in a prior EIS (USDA-APHIS, 2008). From these examinations, APHIS determined that the DsRed2 gene/gene product (and its parent sequence, DsRed) did not resemble an allergen or toxin, and that it posed little risk to animal and human health. This conclusion is supported by the FDA; following an evaluation of DsRed2, FDA (2010) determined that the DsRed2 gene/gene product posed no food or feed risk.

tTAV is the gene/gene product responsible for the female-specific lethality present in this GE diamondback moth. Like DsRed2, tTAV was previously examined by APHIS in a prior EIS (USDA-APHIS, 2008) and found to neither resemble an allergen or toxin, nor pose an unreasonable risk to animal and human health.

The wildlife that is most likely to be exposed to DsRed2 and tTAV genes/gene products are potential insect predators of diamondback moths. Nordin et al. (2013) examined the effect of DsRed2 and tTAV genes/gene products on two insect predators, *Toxorhynchites splendens* and *Tx. amboinensis*, following the consumption of mosquito larva transformed with DsRed2 and tTAV. No significant negative effect was observed in either insect predator in this study (Nordin et al., 2013). This study strongly suggests that diamondback moth insect predator exposure to DsRed2 and tTAV genes/gene products through the potential consumption of GE diamondback moth is unlikely to have an adverse effect.

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

Additionally, insectivores may also consume Day-Glo fluorescent dusts as a result of the Preferred Alternative (Section 2.4). Day-Glo fluorescent dusts are the most common commercial dust used to mark insects and has been used in a variety of other insect monitoring studies (Hagler and Jackson, 2001; Reeve and Cronin, 2010). No potential impact to insectivores is anticipated as a

[39] Fluctuations that are dependent on stability or instability of the female autocidal trait.

result of potentially consuming Day-Glo fluorescent dusts on GE diamondback moths, primarily due to the history and widespread use of Day-Glo fluorescent dusts in a variety of insect and wildlife field studies (Burns *et al.*, 1990; Werner and Holsten, 1997; Hagler and Jackson, 2001; Tupper *et al.*, 2009; Reeve and Cronin, 2010; Dickens and Brant, 2014).

Concern has also been noted about the horizontal transfer of introduced genetic elements into other organisms (CFC, 2007). The concern primarily focuses on the genetic elements[40] used to introduce the DsRed2 and tTAV traits into the GE diamondback moth strain. However, as noted by APHIS (2008) in an EIS for GE pink bollworm and GE fruit fly, movement of the *piggyBac*-derived transposable elements used to genetically engineer insects is not likely. This unlikely movement of the *piggyBac*-derived transposable element is caused by the inactivation of the transposase enzymes required for movement; thus, these transposable elements are incapable of moving themselves or any other introduced gene into other organisms (Thibault *et al.*, 1999; Peloquin *et al.*, 2000; Gomulski *et al.*, 2004; USDA-APHIS, 2005).

Assuming the female autocidal trait is stable, there is likely to be a transient increase in the availability of prey items[41] for insectivores upon release of GE diamondback moth (Section 2.4). This transient increase is anticipated to be followed by a reduction of the overall diamondback moth population within the action area as GE diamondback moth males mate with non-GE diamondback moth females (Section 2.4). This transient increase and subsequent decrease in prey availability is not anticipated to substantially affect insectivores, due to the relative safety of the introduced traits to insectivores (USDA-APHIS, 2005; 2008; 2011b) and non-specialist nature of the insectivores within the action area that may feed upon diamondback moths (Blum *et al.*, 1997; Nagel and Peveling, 2005; USDA-APHIS, 2014b). Furthermore, because of the inability of diamondback moth to overwinter within the action area (American Meteorological Society, 2012; WeatherSpark, 2014); the continual introduction of diamondback moth into the action area each growing season (Shelton, 2001a); and the unlikely complete extinction of diamondback moth as a result of GE SIT (Nagel and Peveling, 2005), generalist insectivores are unlikely to be deprived of diamondback moths prey entirely from year to year.

In the case that the female autocidal trait is not stable, there is also likely to be a transient increase in the availability of prey items upon release of GE diamondback moth (Section 2.4). However, following the mating of GE diamondback moth males with non-GE diamondback moth females, overall diamondback moth populations may stay the same or increase, dependent on the number of non-GE diamondback moth females already present. This potential transient increase in overall diamondback moth prey availability is not anticipated to substantially affect insectivores due to the relative safety of the introduced traits to insectivores (USDA-APHIS, 2005; 2008; 2011b) and may provide a transient increase in prey items during the course of the growing season. This transient increase, however, is not anticipated to result in a significant impact in the action area because of field devitalization by the applicant (Section 2.4), and the inability of diamondback moth to

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[40] i.e., transposable elements

[41] This transient increase of prey items is due to the release of the GE diamondback moth itself and the observation that adult diamondback moths only possess a lifespan of several days before dying

overwinter and the continual introduction of diamondback moth into the action area each growing season (Shelton, 2001b; Nguyen *et al.*, 2014; USDA-APHIS, 2014b). Thus, generalist insectivores are likely to continually encounter diamondback moth as prey items in a temporal pattern similar to that pattern that is already occurring under the No Action Alternative.

Two additional concerns related to wildlife arise under the Preferred Alternative. These are discussed directly below.

First, concern has been raised regarding the development of resistance to the autocidal trait[42] of GE RIDL insects (USDA-APHIS, 2008). This scenario could potentially occur in one of two ways. The first is through non-random mating, whereby non-GE females practice selective mating with non-GE males. The second is through "leakiness" of the autocidal trait, where the up to 1% of GE females that may survive to adulthood (Jin et al. 2013) gain a selective advantage and increase their numbers in the population. The development of resistance to the autocidal trait is unlikely to occur under the Preferred Alternative because of two main factors: 1) the devitalization of the field after each growing season (USDA-APHIS, 2014a)(USDA-APHIS, 2014); and 2) the inability of diamondback moth to overwinter in the action area (Shelton, 2001b; Nguyen *et al.*, 2014; USDA-APHIS, 2014b). Both of these two factors present a genetic dead-end to the local diamondback population. Furthermore, there is a , slight decrease in fitness of the GE diamondback moth strain when reared in permissive conditions in the lab (ie. with tetracycline) (Jin *et al.*, 2013). This fitness cost further decreases the risk of any resistance evolution.

Second, the permit calls for field monitoring of GE and non-GE diamondback moth populations using traps baited with a synthetic pheromone lure specific for diamondback moth. Deployment of these diamondback moth traps is likely to use already-existing road infrastructure within the NYSAES, meaning that new road construction and subsequent wildlife disturbances will not occur under the Preferred Alternative. The deployment and use of these traps is not anticipated to produce a significant impact that rises above of other more substantial agricultural activities, such as field preparation and harvest using motorized machinery (Nagel and Peveling, 2005). Additionally, because of the specificity of insect traps baited with synthetic pheromone lures, inadvertent capturing of non-target insects is much less likely than with other insect trap types (Nagel and Peveling, 2005).

Plant communities

Under the Preferred Alternative, the common agricultural activities used to prepare and maintain the potential release fields are the same common agricultural activities that are already occurring within the action area under the No Action Alternative. Consequently, the potential impact to plant communities from field preparation and management under the Preferred Alternative is the same as the No Action Alternative, as these potential impacts to plant communities are moderated by agricultural activities. Accordingly, the only difference between the Preferred and No Action Alternative, with respect to plant communities, is the potential exposure to GE diamondback moth.

[42] In this EA, repressible-female lethality and female autocidal traits are used interchangeably

Diamondback moth larvae only feed upon cruciferous plants, including domesticated and non-domesticated cruciferous plants (Talekar and Shelton, 1993). Consequently, the only members of the plant communities that may be potentially impacted by exposure to GE diamondback moth larvae under the Preferred Alternative are domesticated and non-domesticated cruciferous plants.

Adult diamondback moths do not cause herbivory damage on plants (Talekar and Shelton, 1993). Accordingly, adult male offspring resulting from mating between GE diamondback moth males and non-GE diamondback moth females are not anticipated to have any significant effect on any member of the plant community[43], because adult diamondback moths do not feed on plant tissue nor function as a significant pollinators of any other plant (Andaloro, 1983; Talekar and Shelton, 1993).

Domesticated cruciferous crops, such as cabbage or broccoli, will be planted on the potential release fields as a result of the Preferred Alternative (Section 2.4). Any damage to these cruciferous plants from GE diamondback larvae is not anticipated to yield a significant impact because these cruciferous plants will be explicitly planted for the sole purpose of incurring diamondback moth damage and providing a food source for the local population of diamondback moth during the duration of the permitted field study.

Assuming stability of the autocidal trait in the released GE diamondback moths, cruciferous crops planted on adjacent fields may experience some herbivory damage from the larval offspring of a GE diamondback moth male and a non-GE diamondback moth female. This potential impact on planted cruciferous crops in adjacent fields is not likely to be significant due to the anticipated reduction of the local diamondback moth population through a reduction in reproductive capacity (Jin *et al.*, 2013), the ubiquity of diamondback moth within the action area (i.e., those cruciferous plants are likely already incurring diamondback moth herbivory damage) (Andaloro, 1983; Shelton, 2001a; 2001b), nor is there likely to be a future impact because of the inability of that local diamondback moth to overwinter (Talekar and Shelton, 1993; Shelton, 2001b; Nguyen *et al.*, 2014) within the action area.

With regard to planted cruciferous crops on adjacent fields, this potential overall increase in diamondback moth damage is also not anticipated to be significant, due to the likelihood of existing grower management of insect pests in these adjacent fields (Andaloro, 1983; Shelton, 2001a), the ubiquity of diamondback moth in the action area (Andaloro, 1983; Shelton, 2001a; 2001b), and the inability of diamondback moth to overwinter within the action area (Talekar and Shelton, 1993; Shelton, 2001b; Nguyen *et al.*, 2014).

Non-domesticated cruciferous plants can also act as hosts of diamondback moth and may also incur some level of injury from diamondback moth larvae resulting from the mating of GE diamondback moth males and non-GE diamondback moth females. These potential non-domesticated cruciferous plants are listed in Table 4. However, because the potential release fields and adjacent fields all represent agricultural land (NYSAES, 2014 and Figure 2), it is likely that these non-domesticated cruciferous plants would be considered weeds and would likely be

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[43] Including cruciferous and non-cruciferous plants

targeted for management by the land manager. Any potential damage from diamondback moth larvae resulting from the mating of GE diamondback moth males and non-GE diamondback moth females is not anticipated to be significant when compared to the management activities (e.g., herbicide application) intended to eliminate these weeds that would likely occur under both the Preferred and No Action Alternatives.

Biological diversity

As described in the No Action Alternative analysis on biological diversity (Section 4.3.1), biological diversity within an agroecosystem is lower relative to natural ecosystems, primarily due to simplification of the landscape and the frequent cycles of disturbances associated with common agricultural activities. This continued simplification of the landscape (i.e., preparation of the field to plant crops primarily in monoculture), in conjunction with the continuity of common agricultural activities (e.g., tillage and pesticide use) under the Preferred Alternative, strongly suggests that those activities that already limit biological diversity within the agroecosystem under the No Action Alternative will continue under the Preferred Alternative. No significant impact to biological diversity is anticipated to occur as a result of releasing GE diamondback moth because the introduced traits are not likely allergenic/toxic to insectivores that may consume GE diamondback moth; GE diamondback moth is not an obligate prey of any insectivore ; and the inability of GE diamondback moth to overwinter and establish within the action area (Talekar and Shelton, 1993).

Furthermore, because the Preferred Alternative represents the continuity of common agricultural practices already occurring under the No Action Alternative, practices designed to increase biological diversity within an agroecosystem, such as the directed management of land adjacent to the agricultural field or contour stripping (Altieri and Letourneau, 1982; Altieri, 1999; Landis *et al.*, 2005; Sharpe, 2010; Palmer *et al.*, 2011), may also function to increase biological diversity under the Preferred Alternative.

The release of GE diamondback moth may actually benefit biological diversity, due to the absence of insecticide application during the growing season in potential release fields. In general, the application of broad-spectrum insecticides is more harmful to non-target wildlife than targeted efforts, such as GE SIT (Nagel and Peveling, 2005). With respect to the availability of diamondback moth as prey items for generalist insectivores, it is prudent to recall that control of this pest is likely to occur under both the No Action and Preferred Alternatives, with similar subsequent impacts on diamondback moth populations and its function as prey items for generalist insectivores.

5.4 Human Health Environment

5.4.1 No Action Alternative: Farmworker Health and Health of the General Public

Summary of potential impacts

Under the No Action Alternative, farmworkers are currently and will continue to be exposed to hazards generally associated with farm work, including hazards associated with the use of typical farm equipment/machinery (e.g., physical injury, noise, etc.) and the application of agricultural inputs. Current measures to mitigate exposure to these hazards includes Section 5(a)(1) of the Occupational Safety and Health Act, EPA's pesticide registration process, and EPA's Worker Protection Standards. Under the No Action Alternative, these measures will continue to protect farmworker health.

Additionally, under the No Action Alternative, the general public is currently and will continue to be indirectly exposed to pesticides used in agricultural production. This indirect exposure of pesticides generally occurs in the form of pesticidal residues. EPA regulates the exposure of the general population to these pesticidal residues through the establishment of pesticide tolerances and its pesticide registration process. For the health of the general population, establishment of pesticidal tolerances by the EPA ensures that there is a certainty of no unreasonable harm to the general population from exposure to these pesticidal residues commonly encountered on agricultural commodities.

Background

The human health environment consists of farmworker health and health of the general public (Section 3). Potential agricultural impacts to farmworker health and health of the general public are generally related to route of exposure and magnitude of exposure.

As previously discussed in the Affected Environment (Section 3), the action area is located within the NYSAES in Geneva, NY. The action area, similar to rest of the NYSAES-owned land that surrounds it, is land that has been maintained under some form of agricultural management for much of its 134-year history (NYSAES, 2014). Consideration of historical land use patterns and the NYSAES mission[44] strongly suggests that present-day agricultural activities within the action area will continue under the No Action Alternative.

Accordingly, the agricultural hazards will be different for farmworkers and the general public, because of differences in route and magnitude of exposure. The route and magnitude of exposure for farmworkers and the general public is described directly below, along with an examination of potential impacts under the No Action Alternative.

Farmworker health

Agriculture is one of the most hazardous industries in the Nation (Farmworker Justice, 2014). About 3.1 million people in the United States are reported as farmworkers, while double of that number live in farms in 2014 (EPA, 2014a). Agricultural workers are exposed to a variety of hazards on a farm; in general, these hazards are related to the use of equipment/farm machinery and agricultural inputs (OSHA, 2014b).

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[44] The NYAES was established by the New York State Legislature for "…the purpose of promoting agriculture in its various branches by scientific investigation and experiment." See http://www.nysaes.cornell.edu/cals/nysaes/about /history.cfm. Last accessed March, 2014.

Farmworkers use farm-related equipment such as tractors, combines, and sprayers for field cultivation, irrigation, harvest, and pesticide application. Besides the dangers associated with the movement of parts in mechanical equipment and the operation of such devices, farm workers are also exposed to electricity, falls, traffic on highways, livestock handling, toxic gases, slips / trips, pesticides, etc. (OSHA, 2005; Ministry of Labour Canada, 2006). Additionally, the use of agricultural inputs is common practice on many farms. Pesticide use in farms is based on weed, insect and disease pressures, cost of seed and other inputs, technology fees, human safety, potential for crop injury, and ease and flexibility of the production system (Heiniger, 2000; Farnham, 2001; University of Arkansas, 2006). As a result, farmworkers also come into constant and close contact with fertilizers and pesticides during and after application.

There are several ways to mitigate exposure to common agricultural hazards encountered by the typical farmworker.

Section 5(a)(1) of the Occupational Safety and Health Act requires employers to "furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees". Particularly for agricultural workers (29 CFR 1928), OSHA provides guidelines to prevent accidents and protect agricultural workers from hazards (OSHA, 2014b). The occupational safety and health standards for agriculture (OSHA, 2014a) provide specific guidelines (e.g., employee operating instruction, safety for agricultural equipment, and general environmental controls) in order to prevent accidents and hazards in farms.

The use of pesticides[45] on a farm is regulated by the EPA under FIFRA as part of the pesticide registration process. As part of the registration process, the EPA considers human health effects from the use of pesticides and must determine that the pesticide will not cause unreasonable adverse effects on human health. If needed, the EPA will establish label restrictions to mitigate or alleviate potential impacts on human health and the environment. Pesticide registration labels provide the guidelines, application restrictions, and precautions necessary to protect human health. These label restrictions carry the weight of law and are enforced by EPA and the states (Federal Insecticide, Fungicide, and Rodenticide Act 7 USC 136j (a)(2)(G) Unlawful Acts).

Additionally, EPA’s Worker Protection Standard (WPS) is regulation aimed at reducing the risk of pesticide poisoning and injury among agricultural workers and pesticide handlers. The current WPS offers occupational protections to over 2 million agricultural workers and pesticide handlers, requiring that owners and employers on agricultural establishments provide protections to workers and handlers from potential pesticide exposure, by pesticide safety training, access to information in pesticide labels and other specific material, measures to keep workers from treated areas and information about the restricted-entry interval, provide applicators and handlers with personal protective equipment, decontamination supplies, monitor handlers that handle certain pesticides, and emergency assistance (EPA, 2014b).

[45] e.g., herbicides, insecticides, and fungicides

Health of the general public

In contrast to farmworkers, the general public is not likely to encounter the same hazards that farmworkers encounter, primarily due to an absence of direct exposure to agricultural equipment/machinery and the application of agricultural inputs. However, due to the common practice of pesticide use in modern agricultural production, pesticidal residues[46] may remain on agricultural commodities. Consequently, the general population may be indirectly exposed to agricultural pesticides through these pesticidal residues on agricultural commodities.

To ensure the safety of the food supply, EPA regulates the amount of each pesticide that may remain in and on foods (EPA, 2012c). Some of the measures that EPA establishes to ensure that pesticides residues are within the acceptable levels include the mandatory pesticide registration; the establishment of tolerances to ensure food safety; and collaboration with other Agencies such as the Food and Drug Administration and the U.S. Department of Agriculture to enforce the pesticide tolerances in food (EPA, 2012c).

Of particular relevance for the general population are pesticide tolerances, as the general population often reflects an endpoint in the production of an agricultural commodity. These pesticide tolerances are also referred to as maximum residue limits (EPA, 2014d). EPA establishes tolerances for each pesticide based on the potential risks to human health posed by that pesticide. The data is established from field trials, food processing and monitoring studies, and surveillance programs. Pesticide tolerances' risk assessments are based on the assumption that residues will always be present in food at the maximum level permitted by the tolerance, or on the actual or anticipated use residue data, to reflect real-world consumer exposure as closely as possible (EPA, 2014d). Establishment of pesticidal tolerances ensures that there is a reasonable certainty of no harm from the pesticide, as obligated under the Federal Food, Drug, and Cosmetics Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

5.4.2 Preferred Alternative: Farmworker Health and Health of the General Public

With respect to the common agricultural activities related to the establishment and cultivation of crops on a managed field, there are no substantial differences between the No Action and Preferred Alternatives. Accordingly, if there are no substantial differences between agricultural activities under the No Action or Preferred Alternative, there can be no substantial differences in potential impacts on farmworker health or health of the general population, as these potential human health impacts are facilitated by agricultural activities within the action area.

With respect to the human health environment, the only true difference between the two Alternatives is potential exposure to GE diamondback moth under the Preferred Alternative. Accordingly, the release of GE diamondback moth is not anticipated to significantly affect farmworker health or the health of the general population.

[46] Pesticides that may remain on agricultural commodities in small amounts

Both farmworkers and the general population may be exposed to live GE diamondback moth. While the GE diamondback moth would not be consumed by humans, some allergic responses have been noted in human exposure to moth hairs and scales (Goddard, 1993). However, these allergic responses have been noted primarily in moths within Notodontidae, Saturniidae, and Lymantriidae (Goddard, 1993), insect families of which diamondback moth is not a member (UF-IFAS, 2012). Additionally, because the only difference between GE and non-GE diamondback moth is the phenotype associated with the GE traits (Jin *et al.*, 2013), exposure to scales of GE diamondback moth under the Preferred Alternative is not anticipated to yield any different effect than exposure to scales of non-GE diamondback moth under the No Action Alternative.

GE diamondback moth is genetically engineered to display red fluorescent and female autocidal traits (Section 2.4). The GE trait that causes red fluorescence, DsRed2, has previously been examined in a previous APHIS environmental analysis. These previous environmental analyses demonstrate the inheritance and long-term stability of the DsRed2 transgene, (USDA-APHIS, 2008), and was found to not resemble an allergen or toxin (USDA-APHIS, 2011b). Furthermore, DsRed2 was not found to be any unreasonable risk to human health (USDA-APHIS, 2011b). The GE trait that causes female autocide, tTAV, has also been examined in a previous APHIS EIS and was not found to resemble an allergen, toxin, or pose any unreasonable risk to human health (USDA-APHIS, 2008). In the unlikely event that GE diamondback moth or larvae is inadvertently consumed through the consumption of a cruciferous crop, no adverse impacts are anticipated due to the characteristics of these two introduced genes and production of their respective proteins.

5.4.3 Preferred Alternative: Socioeconomic Impact

The DBM is considered the most universally distributed of all Lepidoptera and the main insect pest of organic and conventional crucifers farms worldwide. DBM can reduce the marketability of organic and conventional cruciferous crops (i.e., broccoli, cabbage, kale) due to the heavy damage larvae can inflict on leaves, buds, and flowers. Over the last several decades, the importance of cruciferous vegetables in the human diet has increased, resulting in increased production and changing management practices. As demand for damage-free produce has intensified, farmers have relied on the intensive use of insecticides for control of DBM, which, in turn, has contributed to development (evolution) of insecticide resistance, can reduce popualtions of natural enemies (biological controls), frequent control failures, and some environmental and human health concerns (Jin *et al.*, 2013).

The use of synthetic pesticides may eliminate the natural enemies of DBM, creating the need for more pesticides, increasing production costs, and the development of insecticide resistance. The applicant for the permit subject of this EA has indicated that the DBM strain OX4319L-Pxy has a tetracycline-repressible female-lethal phenotype, which could serve as an insecticide-free means of controlling pest populations of DBM in the field in a species-specific manner.

Considering the permit conditions APHIS will impose on the field test (Section 4.2 of this EA); that it is probable that all, or at least the vast majority, of released GE DBM will remain in the 10 acre test site; that most organic and conventional farmers will already be implementing controls for various extant cruciferous plant pests (e.g., cabbage looper, cabbageworm, flea beetles); and that there are a variety of options for control of diamback moth; adverse economic impacts to conventional and organic crop producers in the area as a result of the proposed field test are not likely to occur. In the unlikley event of dispersal of GE DBM beyond the authorized field site; the required monitoring and reporting requirements, APHIS' ability to respond appropriately to any unusual occurrence reported during field testing, as well as available control methods for diamondback moth, are all expected to preclude or, at a miminum, mitigate any potential adverse economics impacts on conventional or organic crop producers in the area of the field test.

6 CUMULATIVE IMPACTS

Cumulative impacts are defined as those effects that result when added to past, present, and reasonably foreseeable future actions.

The purpose of the research associated with the proposed action is to determine the feasibility/efficacy of GE RIDL (release of insects carrying a [conditional] dominant lethal, Black et al. 2011) as a pest management strategy for diamondback moth (Section 2.4). If positive data is produced from this proposed action, it is reasonably foreseeable that the applicant may request an extension of the permit to further study the feasibility/efficacy of GE diamondback moth in a RIDL program within the action area (Personal Communication, C.Beech). Upon receipt of a request to extend the permit from the applicant, potential environmental impacts will be assessed in a separate NEPA document. Consequently, no cumulative impacts are anticipated at this time from the proposed action and future requests to extend the permit from the applicant.

As noted in the applicant's permit application, a single field up to 10 acres in size will be utilized for two years during this permitted field release of GE diamondback moth (Section 2.4). Based on past and current land use patterns of land managed by the NYSAES, it is reasonably foreseeable that those lands will return back to currently employed agricultural activities after expiration of the permit[47] (NYSAES, 2014). Use of these field for this permitted field release is not anticipated to result in any potential impact to any described aspect of the physical[48], biological[49], and human health[50] environments (Section 5) that would preclude return of those fields back to other agricultural activities that are already performed at the NYSAES.

Analysis of cumulative impacts for the release of other GE RIDL insects suggests an absence of significant cumulative effects when considering factors such as chemical control, insect resistance, human health, and environmental impacts (USDA-APHIS, 2008; 2009; 2011a). The proposed action may lead to additional management activities that may complement current control measures of diamondback moth. The proposed action may reduce the need for insecticide treatments if diamondback moths are detected in fields of cruciferous crops in the future. The release of GE diamondback moth may reduce non-GE diamondback moth populations from increasing to a level that would require insecticide treatment, similar to potential outcomes of SIT insect introductions (Klassen, 2005).

Collectively, the absence of direct and indirect impacts on the physical environment, biological environment, and human health environments from the proposed action (Section 4); the past, current, and reasonably foreseeable use of land managed by the NYSAES (NYSAES, 2014); previous APHIS experience with GE insect introductions (USDA-APHIS, 2008; 2009; 2011a)

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[47] Assuming a permit extension is not requested by the applicant

[48] i.e., soil resources, water resources, air quality, and climate change

[49] i.e., plant communities, wildlife and insects, and biological diversity

[50] i.e., farmworker health and health of the general population

strongly suggests that no cumulative impacts would occur that reduce the long-term productivity or sustainability of the human environment associated with the action area.

7 THREATENED AND ENDANGERED SPECIES

The Endangered Species Act (ESA) of 1973, as amended, is one of the most far-reaching wildlife conservation laws ever enacted by any nation. Congress passed the ESA to prevent extinctions facing many species of fish, wildlife and plants. The purpose of the ESA is to conserve endangered and threatened species and the ecosystems on which they depend as key components of America's heritage. To implement the ESA, the U.S. Fish & Wildlife Service (USFWS) works in cooperation with the National Marine Fisheries Service (NMFS), other Federal, State, and local agencies, Tribes, non-governmental organizations, and private citizens. Before a plant or animal species can receive the protection provided by the ESA, it must first be added to the Federal list of threatened and endangered wildlife and plants.

A species is added to the list when it is determined by the USFWS/NMFS to be endangered or threatened because of any of the following factors:

- The present or threatened destruction, modification, or curtailment of its habitat or range;
- Overutilization for commercial, recreational, scientific, or educational purposes;
- Disease or predation;
- The inadequacy of existing regulatory mechanisms; and
- The natural or manmade factors affecting its survival.

Once an animal or plant is added to the list, protective measures apply to the species and its habitat. These measures include protection from adverse effects of federal activities.

Section 7 (a)(2) of the ESA requires that federal agencies, in consultation with USFWS and/or the NMFS, ensure that any action they authorize, fund, or carry out is "not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat." It is the responsibility of the federal agency taking the action to assess the effects of their action and to consult with the USFWS and NMFS if it is determined that the action "may affect" listed species or designated critical habitat. The request before APHIS is an application for a permit, and the issuance of a permit is considered an agency action whose effects must be assessed.

APHIS met with USFWS officials on June 15, 2011, to discuss whether APHIS has any obligations under the ESA regarding analyzing the effects of pesticide use associated with field trials and production of GE organisms. As a result of these joint discussions, USFWS and APHIS have agreed that it is not necessary for APHIS to perform an ESA effects analysis on pesticide use because EPA has both regulatory authority over the labeling of pesticides and the necessary technical expertise to assess pesticide effects on the environment under FIFRA. APHIS has no statutory authority to authorize or regulate the use of pesticides by any party, including applications under permitted field trials. Under 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.

With respect to the pesticide application required by the permit conditions, APHIS would note that the field release site is an agricultural field that is already subject to various EPA registered pesticide treatments. EPA registered pesticides are required to be used in accordance with label specifications, which are designed to mitigate adverse impacts to the environment. Use of the EPA registered insecticide specified in supplemental permit conditions is unlikely to cause harm to endangered and threatened species when used in accordance with EPA label restrictions. As discussed elsewhere in this EA, the use of sterile insect technology in the GE diamondback moth strain, OX4319L-Pxy, mitigates many of the possible theoretical hazards and risks associated with insect genetic engineering. However, APHIS considered the following potential threats in its effects analysis:

- the transfer of transgenes to other insects, especially listed insects;
- the effect on availability of food to insectivores;
- the potential for toxicity and allergenicity of genetically engineered diamondback moth strain, OX4319L-Pxy as a result of the transformation; and
- the potential for the genetically engineered insects to attack/feed on listed plants.

APHIS considered the potential for the movement of the transgenes to other insects, especially listed insects. As discussed in section 5.3 Biological Environment, and the applicant's Environmental Risk Assessment, transfer of genes from the GE moths to other species of moths, including listed species, is not possible. This is because reproduction of diamondback moth is specific to diamondback moth. There are no related species which are sexually compatible.

As discussed in the Affected Environment Section of the EA, APHIS defined the action area for the ESA analysis to be within the boundaries of Ontario County, NY. The area is limited by the confinement measures of the permit conditions and biology of the organism, preventing overwintering in the northeast. APHIS reviewed the USFWS list of TES species (listed and proposed) in Ontario County. The search found that there are no listed species in Ontario County, NY but there is one proposed species. The northern long-eared bat (*Myotis septentrionalis*) is proposed as endangered without critical habitat (USFWS, 2013). During summer, northern long-eared bats roost singly or in colonies underneath bark, in cavities, or in crevices of both live and dead trees. It is opportunistic in selecting roosts, using tree species based on suitability to retain bark or provide cavities or crevices. It may also roost in cooler places, like caves and mines, and rarely, in structures like barns and sheds (USFWS, 2014b). Northern long-eared bats emerge at dusk to fly through the understory of forested hillsides and ridges feeding on moths, flies, leafhoppers, caddisflies, and beetles, which they catch while in flight using echolocation. It also feeds by gleaning motionless insects from vegetation and water surfaces (USFWS, 2014b). Although the release site is not primary habitat for the bat, it is possible that the GE diamondback moths could enter wooded areas in the vicinity and be consumed by a northern long eared bat.

APHIS considered the possibility that the inserted genetic material could adversely affect insectivores, like the northern long-eared bat, that may feed on the moths. As previously discussed in the Purpose and Need (Section 1), the GE diamondback moth contains two introduced genes/gene products, DsRed2 resulting in display to red fluorescence, and tTAV resulting in female autocidal traits in the absence of tetracycline. The GE trait that causes red fluorescence, DsRed2, has been examined in a previous APHIS EA and was found to not resemble an allergen or toxin (USDA-APHIS, 2011b). Furthermore, DsRed2 was not found to pose any unreasonable risk to human health (Richards *et al.*, 2003; USDA-APHIS, 2011b). The GE trait that causes female autocide, tTAV, has also been examined in a previous APHIS EIS and was not found to resemble an allergen, toxin, or pose any unreasonable risk to human health (USDA-APHIS, 2008). In the event that GE diamondback moth or larvae are consumed purposefully by insectivores, like the northern big-eared bat, or incidentally through the consumption of a cruciferous crop, no adverse impacts are anticipated as a result of the two introduced genes and production of their respective proteins.

As discussed in Section 5.3.2 Preferred Alternative: Wildlife, Plant Communities, and Biological Diversity, the numbers of diamondback moth adults available to insectivores will fluctuate as a result of the release. Initially there will be more available as the GE male moths are released (Section 2.4). Later, there will be a reduction in the overall diamondback moth population within the action area as GE diamondback moth males mate with non-GE diamondback moth females (Section 2.4). In addition, at the conclusion of the experimental release, the release site will be treated with a pesticide in accordance with EPA label requirements in order to eliminate any remaining diamondback moths. This transient increase and subsequent decrease in prey availability is not anticipated to significantly affect generalist insectivores (USDA-APHIS, 2005; 2008; 2009) like the northern long-eared bat. It is important to realize that consumption of diamondback moth by the northern long eared bat is likely uncommon, given the preferred habitat of the bat, and that control of this pest is likely to occur under both the No Action and Preferred Alternatives, with similar reduction in diamondback moth populations. In addition, the application of broad-spectrum insecticides is more harmful to non-target wildlife, especially insects, than targeted efforts such as GE SIT (Nagel and Peveling, 2005). Therefore, it is reasonable to assume that the fluctuation in diamondback moth prey resulting from release of the transgenic moths would have no effect on the northern long-eared bat. Further, because of the lack of any effects expected from consumption, there are no effects anticipated by the proposed action on the northern long-eared bat.

APHIS considered the possibility that the transgenic insects could be attracted to, and feed on, listed plants. The diamondback moth may feed on many species from the family Brassicaceae (Dosdall *et al.*, 2011). A search of the USFWS database of listed plant species indicates that there are 29 listed species and 1 species proposed for listing that are in the family Brassicaceae (USFWS, 2014a; 2014c). Table 5 lists these species along with the states where they are found:

Table 5. Listed and species proposed for listing in the Brassicaceae family.
Table derived from USFWS (2014a; 2014c)

Common Name	Scientific Name	Where Found	Listing Status
`anaunau	*Lepidium arbuscula*	HI	Endangered
Small-Anthered bittercress	*Cardamine micranthera*	NC, VA	Endangered
Missouri bladderpod	*Physaria filiformis*	AR, MO	Threatened
White Bluffs bladderpod	*Physaria douglasii* ssp. *tuplashensis*	WA	Threatened

Santa Cruz Island fringepod	*Thysanocarpus conchuliferus*	CA	Endangered
Texas Golden Gladecress	*Leavenworthia texana*	TX	Endangered
California jewelflower	*Caulanthus californicus*	CA	Endangered
Metcalf Canyon jewelflower	*Streptanthus albidus* ssp. *albidus*	CA	Endangered
Tiburon jewelflower	*Streptanthus niger*	CA	Endangered
Carter's mustard	*Warea carteri*	FL	Endangered
Penland alpine fen mustard	*Eutrema penlandii*	CO	Threatened
Slender-Petaled mustard	*Thelypodium stenopetalum*	CA	Endangered
Barneby reed-mustard	*Schoenocrambe barnebyi*	UT	Endangered
Clay reed-mustard	*Schoenocrambe argillacea*	UT	Threatened
Shrubby reed-mustard	*Schoenocrambe suffrutescens*	UT	Endangered
Barneby ridge-cress	*Lepidium barnebyanum*	UT	Endangered
Braun's rock-cress	*Arabis perstellata*	KY, TN	Endangered
Hoffmann's rock-cress	*Arabis hoffmannii*	CA	Endangered
McDonald's rock-cress	*Arabis macdonaldiana*	CA	Endangered
Santa Cruz Island rockcress	*Sibara filifolia*	CA	Endangered
Shale barren rock cress	*Arabis serotina*	VA, WV	Endangered
Howell's spectacular thelypody	*Thelypodium howellii spectabilis*	OR	Threatened
Dudley Bluffs twinpod	*Physaria obcordata*	CO	Threatened
Wide-Leaf warea	*Warea amplexifolia*	FL	Endangered
Gambel's watercress	*Rorippa gambellii*	FL	Endangered
Short's bladderpod	*Physaria globosa*	IN, KY, TN	Endangered
Kentucky glade cress	*Leavenworthia exigua laciniata*	KY	Threatened
[Unnamed] gladecress	*Leavenworthia crassa*	AL	Endangered
Slickspot peppergrass	*Lepidium papilliferum*	ID	Proposed Endangered
Georgia rockcress	*Arabis georgiana*	AL, GA	Threatened

As can be seen from the table, none of the Brassicaceae species, either listed or proposed for listing, are found in the northeast region of the United States. All are hundreds of miles away, and are upwind from the prevailing west to east weather pattern of the region (American Meteorological Society, 2012; WeatherSpark, 2014). In addition, the permit conditions described in Section 3.2 and Section 4.2 are designed to ensure that the moths will be confined to the region of the release. This, combined with the biology of the diamondback moth that prevents overwintering in the northeast makes it unlikely that release of the GE diamondback moths will result in any exposure to a Brassicaceae species that is listed or proposed for listing. Even if such exposure were to occur, the effects of feeding on the plant would not be expected to be any different than from non-transgenic diamondback moths that are already widespread throughout most of the United States.

Conclusion

After reviewing the possible effects of allowing the environmental release of the GE diamondback moth strain, OX4319L-Pxy, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. APHIS also considered the potential effect on designated critical habitat or habitat proposed for designation, and could identify no scenario where release of these insects would affect habitat in any way. The diamondback moth adults and larvae are safe for consumption by wildlife, and the female autocidal trait will prevent the inserted genetic material from passing on further than one generation. Based on these factors, APHIS has concluded that the experimental field release of diamondback moth strain, OX4319L-Pxy will have no effect on listed species or species proposed for listing, and will not affect designated habitat or habitat proposed for designation. Because of this no-effect determination, consultation under Section 7(a)(2) of the Act or the concurrences of the USFWS or NMFS is not required.

8 CONSIDERATION OF EXECUTIVE ORDERS, STANDARDS, AND TREATIES RELATING TO ENVIRONMENTAL IMPACTS

8.1 Executive Orders with Domestic Implications

The following EOs require consideration of the potential impacts of the Federal action to various segments of the population.

- **EO 12898 (US-NARA, 2010), "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,"** requires Federal agencies to conduct their programs, policies, and activities that substantially affect human health or the environment in a manner so as not to exclude persons and populations from participation in or benefiting from such programs. It also enforces existing statutes to prevent minority and low-income communities from being subjected to disproportionately high and adverse human health or environmental effects.

- **EO 13045, "Protection of Children from Environmental Health Risks and Safety Risks,"** acknowledges that children may suffer disproportionately from environmental health and safety risks because of their developmental stage, greater metabolic activity levels, and behavior patterns, as compared to adults. The EO (to the extent permitted by law and consistent with the agency's mission) requires each Federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children.

The No Action and Preferred Alternatives were analyzed with respect to EO 12898 and EO 13045. The environmental and human health impacts are presented in Section 4 of this EA. Neither alternative is expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

The following EO addresses Federal responsibilities regarding the introduction and effects of invasive species:

- **EO 1311 (US-NARA, 2010), "Invasive Species,"** states that Federal agencies take action to prevent the introduction of invasive species, to provide for their control, and to minimize the economic, ecological, and human health impacts that invasive species cause.

Diamondback moth is not listed in the United States as an invasive species by the Federal government but it is listed as an invasive species that is currently present in all U.S. States (CABI, 2014). While diamondback moth is a ubiquitous pest of cruciferous plants, domesticated and non-domesticated, within the action area, it does not persist from year to year. Rather, diamondback moth populations within the action area are primarily the result of repetitive introductions from year to year. The two GE traits engineered in the GE diamondback are not expected to contribute to increased fitness. Any reduced fitness that may occur in the GE moths is not anticipated to interfere with the repression effect on local non-GE diamondback moth populations, so long as a constant supply of GE diamondback moths are supplied during the experiment (Harvey-Samuel *et al.*, 2015).

Furthermore, the persistence of any diamondback moth strain, GE or non-GE, 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, using a variety of best management practices, for the purposes of diamondback moth control. Any GE 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.

The following executive order requires the protection of migratory bird populations:

- **EO 13186 (US-NARA, 2010), "Responsibilities of Federal Agencies to Protect Migratory Birds,"** states that federal agencies taking actions that have, or are likely to have, a measurable negative effect on migratory bird populations are directed to develop and implement, within two years, a Memorandum of Understanding with the Fish and Wildlife Service that shall promote the conservation of migratory bird populations.

Migratory birds may be found in fields containing cruciferous crops, where they may forage for insects and weed seeds found in and adjacent to the field. As discussed in the Preferred Alternative analysis of Wildlife communities (Section 5.3.2), the introduced proteins in GE diamondback moth are similar to other proteins assessed in APHIS NEPA documents and is not expected to be allergenic, toxic, or pathogenic in animals (USDA-APHIS, 2008). Therefore, there is no reason to believe that the release of GE DBM would have any effect on migratory birds.

8.2 Consultation and Coordination with Indian Tribal Governments

- **EO 13175 (US-NARA, 2010), "Consultation and Coordination with Indian Tribal Governments"** was issued to ensure that there would be "meaningful consultation and collaboration with tribal officials in the development of Federal policies that have tribal implications…"

APHIS has given this EO careful consideration and does not expect a significant environmental impact on tribal lands because the action area is not on any land maintained by an Indian Tribal Government.

8.3 Impacts on Unique Characteristics of Geographic Areas

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 (Section 5), 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 two-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 (Section 3.2).

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.

8.4 National Historic Preservation Act (NHPA) of 1966 as Amended

The NHPA of 1966 and its implementing regulations (36 CFR 800) require Federal agencies to: (1) determine whether activities they propose constitute "undertakings" that have the potential to cause effects on historic properties, and (2) if so, to evaluate the effects of such undertakings on such historic resources and consult with the Advisory Council on Historic Preservation (i.e., State Historic Preservation Office, Tribal Historic Preservation Officers), as appropriate.

APHIS' proposed action, issuing a permit for the two-year field release of GE diamondback moth, is not expected to adversely impact cultural resources on tribal properties. This is because any farming activity that may be taken by farmers on tribal lands would only be conducted at the tribe's request; thus, the tribes would have control over any potential conflict with 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 two-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 NHPA. In general, common agricultural activities conducted under 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 production area. The two-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.

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