NOFA-NY
NORTHEAST ORGANIC FARMING ASSOCIATION OF NEW YORK

Docket No. APHIS–2014–0056,
Regulatory Analysis and Development, PPD,
APHIS, Station 3A–03.8,
4700 River Road Unit 118,
Riverdale, MD 20737–1238

NOFA-NY Comments on the December 2016 Environmental Assessment of the Proposal to permit the field release of genetically engineered diamondback moth in New York

Founded in 1983, the Northeast Organic Farming Association – New York (NOFA-NY) is the premier statewide organization growing a strong organic and sustainable agriculture movement in New York State and is part of a regional network of seven Northeast Organic Farming Associations. NOFA-NY provides education and assistance to local organic and sustainable farmers; connects consumers with organic and sustainable farmers; advocates policies that support a sustainable food and farm system at both the state and federal levels; and is the largest USDA-accredited organic certifier in New York certifying nearly 1,000 organic operations in the state.

NOFA-NY objects to the short 30-day comment period for this Environmental Assessment, especially since April and May are in the middle of the planting window for New York State farmers. On April 21, NOFA requested an extension, but never received a response. This is unfortunate for the farmers of the region who may be significantly affected by these trials.

NOFA-NY considers the first-in-the-world open air release of the Genetically Engineered Diamondback moth – a novel organism – to be a major activity with potentially significant and heretofore unknown health and environmental effects. We have expressed concern about the proposed trials of the Genetically Engineered Diamondback Moth (GDM) for many years, and continue to be significantly troubled at the prospect of an open-air release of a novel organism in New York State without comprehensive health, safety, and environmental review. If approved, the proposed experiments would likely be the first to utilize GE insects with a female-killing trait anywhere in the world. Yet, the owner of this technology (originally, Oxitec UK – now Intrexon) has not completed comprehensive, independent health, safety, and environmental review required by international protocols.

Most of this Environmental Assessment (EA) confines its review to the general impacts of the new technology, and neglects to adequately assess the impacts of the trials themselves on New York State farms and residences near the New York State Agricultural Experiment Station (NYSAES) in Geneva, NY and the state as a whole. While Diamondback moths are considered "weak flyers

incapable of long-distance dispersal" (EA, p. 12) they do not need to move far to broach the NYSAES boundary, and it is unreasonable to assume that they won't move off the 870-acre site.

NOFA-NY objects to the characterization of the Action Area as solely the NYSAES property, and therefore notes that the complete lack of discussion of impacts to significant populations and geographic areas outside of NYSAES is unacceptable. The Action Area should be broadened based on data that should be provided, including land use and climate modeling, detailed below.

Other issues which we have found lacking in this Environmental Assessment include:

1. Transparency: Access to the current permit application and supporting documents
2. Specific details and analysis of the 2015 Caged Trials which were performed at the NYSAES in Geneva, NY by Dr. Shelton.
3. Evaluation and Mapping of land use surrounding the NYSAES site including farms, residences, schools etc.
4. Evaluation and Modeling of climate and wind trends in the region throughout the season
5. Specific mapping and analysis of known agronomic or livestock antibiotic use on the NYSAES site
6. Identification and mapping of possible agronomic or livestock antibiotic use in areas around the NYSAES site
7. Comprehensive food safety assessment to establish that the anticipated or accidental consumption of GE moth adults or larvae is not harmful to humans.
8. Documentation of potential economic and social effects of the trials as well as the proposed technology
9. Analysis of cumulative impacts

In summary, NOFA-NY finds the Environmental Assessment of the Proposal to permit the field release of genetically engineered diamondback moth in New York to be inadequate in evaluating potential impacts of both the technology and the trials on New York State residents and farmers. It is dismissive of the possibility that there may be impacts beyond the NYSAES 870-acre site, and has therefore given inadequate review or analysis of the range of potential impacts to the region and the state. This does a disservice to the Geneva community which proudly hosts some of the most advanced agricultural research in the world.

In addition, it is incomprehensible that this 'new' Environmental Assessment does not contain vital documents pertinent to this permit – including the permit itself. For the previous permit, granted in 2014, it took many months for the Center for Food Safety to obtain copies of the 2014 permit, application and supporting documentation through the Freedom of Information Act. This is unacceptable for such an important issue as the release of an entirely new organism into our environment.

Without adequate review, we must conclude that the proposed experiments pose unnecessary risks to public health and the environment. Thus the application should be denied.

NOFA-NY acknowledges and supports the work of the following organizations whose comments should be considered as further basis for withdrawal of this EA, and the completion of a comprehensive Environmental Impact Statement: GeneWatch UK, Food & Water Watch, Center for Food Safety, Friends of the Earth, and Consumers Union.

Below is further detail on the points enumerated above.

1. Transparency: Access to the current permit application and supporting documents

The permit application should be publicly available as part of the Environmental Assessment. Primary documents such as this are crucial for citizens to access in order to make their evaluations of such a major proposed activity with such major potential personal impacts. In addition to the permit and application, all other supporting documents such as relevant studies must be included. While confidential business information (CBI) may be redacted, documents should be readable. It should not take months of FOIA requests to USDA/APHIS or Cornell University to receive this information, as happened with the 2014 permit. It is an incomplete submittal without these documents.

2. Specific details and analysis of the 2015 Caged Trials

In the summer of 2015, Dr. Anthony Shelton performed caged trials of the GE Diamondback moths at the NYSAES at Geneva, NY. While he has given a cursory overview of the trials and results on his webpage[1], these trials should be comprehensively documented in a peer-reviewed journal. In any case, data and results of a quality appropriate for peer review should be included in this phase permit application/Environmental Assessment – available to all. In April 2017, NOFA-NY wrote to Dr. Shelton[2] requesting that information, including:

- When are the results of the caged trial experiments expected to be published in a peer reviewed journal?
- When is the population modeling referred to on the website expected to be published in a scientific journal?
- How many GE moths were released?
- How many GE moths escaped? (Did you set up traps baited with female pheromone to attract GE males outside of the field cages to detect if any GE moths escaped the field cage?)
- How many female GE larvae of the GE moths survived to adulthood?
- What is the exact longevity of GE and non-GE moths?

[1] https://shelton.entomology.cornell.edu/2016/10/06/2015-diamondback-moth-field-cage-trials/

[2] https://www.nofany.org/files/Genetically_Engineered_Diamondback_Moth_GDM_Apr_2017.pdf

- What is the exact value of the GE male moth mating competitiveness?
- How long did any population suppression effect take to be observed? Additional details about timing of the population levels; i.e., in addition to the initial observation of the suppressive effect were there dips and/or resurgences of populations?
- What was the release ratio (of GE males to wild males) during the experiments?
- What damage to the cabbage was observed due to larvae eating them?
- Were the cabbage in the cages replaced at any point during the trials?

3. Evaluation and Mapping of land use surrounding the NYSAES site including farms, residences, schools etc.

NOFA-NY does not agree that the primary action area – generally used throughout the EA as the only area that impacts will occur – consists solely of the NYSAES 870 acres. It is unrealistic to believe that all released moths will confine themselves to the NYSAES property. Barriers to 'dispersal' noted in the EA include the fact that diamondback moths are not good flyers, they are unable to over-winter due to temperature, or that there will be a proposed permit condition that will cease the release if there are reports of an imminent hurricane. We disagree: the action area *does* include a larger radius, and therefore requires significant attention to what activities (human and otherwise) occur outside of the NYSAES property.

As a beginning to this significant area of investigation that is absent in this EA, land use in the entire region surrounding NYSAES must be delineated and mapped. This includes the City of Geneva, and should demarcate residences, schools, and farms, including the specific production nature of these farms. We note that this region of New York is not only a significant brassica-growing region, but that there are brassica seed production operations in the Geneva area. There are also certified organic vegetable growers who grow broccoli, cabbage, and/or cauliflower. These farms must be mapped.

4. Evaluation and Modeling of climate and wind trends in the region throughout the season

Dispersal through wind is noted as the major mechanism for diamondback moths to travel. Yet, without any data or documentation, the only winds actually discussed in this EA are hurricanes (or similar meteorological events):

> 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. (p.12)

In any case, climate, meteorological, and wind modeling are necessary data that need to be addressed in the EA. Central New York is known for strong summer storms (that are not hurricanes), and winds along the lake plains can be significant. More work evaluating the possibility of wind dispersal

off the NYSAES site throughout the release season is necessary.

Evaluation of climate and wind data may also serve to change the EA conclusions that the project:

> "…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.", or
>
> "…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." (EA p. 70)

Both tribal lands and unique geographic areas exist north and east (prevailing winds) of the NYSAES, including the Montezuma National Wildlife Refuge less than 20 miles away.

5. Specific mapping and analysis of known agronomic or livestock antibiotic use on the NYSAES site

Because the GDM technology includes the use of the common antibiotic tetracycline as a chemical switch to turn off the killing mechanism and allow breeding of its GE insects in the lab, the existence of background levels of antibiotics in the environment is significant for at least two specific reasons:

1) Contamination with tetracycline and related antibiotics in the environment could lead to significantly increased survival rates of the female diamondback moths, and

2) Due to the fact that insect guts are reservoirs for antibiotic resistant genes which can spread in the environment, the use of tetracycline could pose a major risk to human and animal health. There is significant concern about the dead GE larvae on the crop spreading antibiotic resistant bacteria into the environment.

NOFA-NY echos the remarks of GeneWatch UK in their submitted comments to this EA:

> "No public information is available about the proposed use of tetracyclines to feed the GE diamondback moths at Cornell, or the proposed method of disposal. It is unclear how the proposed use of tetracycline for a non-veterinary purpose can be regarded as consistent with FDA Guidance on this issue. The EA does not consider this issue at all, nor is it mentioned in the 2014 EA or FONSI.
>
> "The EA should be withdrawn and not reissued until the issue of the use of tetracycline in breeding the GE moths has been addressed. This must include assessment of the cumulative impacts of "reasonably foreseeable future actions", such as the removal of the crop destruct requirement and future trials or commercialisation on a larger scale."

Further, the NYSAES performs major agricultural research on both livestock and fruit trees – both of which are potential users of antibiotics, including tetracycline. It is unknown whether livestock are kept on the site, but the Geneva experiment station is widely known for its significant work on Apple and Pear trees and diseases which use tetracycline or streptomycin aerial sprays. Specific mapping of all agricultural uses on the entire 870 acres of the NYSAES Geneva experiment station is necessary to evaluate this. In addition, specific use patterns and dates of use should be

documented and analyzed for potential unintended effects.

Increased survival rates of female diamondback moths could cause the significant increase in numbers of GDM needed for release, which could increase the potential for dispersal beyond the NYSAES as well as interaction with non-target species including humans.

6. Identification and mapping of possible agronomic or livestock antibiotic use in areas around the NYSAES site

For the reasons noted in #5, above, the EA should additionally map farms in areas around, but outside of the boundaries of the NYSAES and specifically denote their type of production, carefully identifying those with brassica, livestock or tree fruit production. This information should be used to additionally evaluate the possibility of lower mortality of female diamondback moths and the affect on the research.

7. Comprehensive food safety assessment

The FDA is responsible for "ensuring the safety and proper labeling of all plant-derived foods and feeds", yet the permit applicant did not undergo FDA voluntary consultation process because "GE diamondback moth is not anticipated to yield food or feed." (EA p. 7).

However, we believe that it is likely that dead GE larvae may indeed be ingested by various non-target organisms, including humans.

According to GeneWatch UK:

(i) The GE moth (particularly its larvae) may accidentally contaminate food crops (as highlighted above);
(ii) If contamination does occur (as anticipated via the reporting requirements for unexpected and anticipated events, included in the conditions), regulators will be unable to reassure consumers or markets (including overseas markets) that consumption of contaminated brassicas is safe;
(iii) The EA should have considered cumulative impacts, including the need for the crop to enter the market should this technology ever be commercialised (as outlined above).

As citizens of New York who will be the unwitting guinea pigs in this experiment of the open release of this novel technology, we object to the possibility of eating dead GE larvae without the acknowledgement of any potential harm, without studies which establish that the anticipated or accidental consumption of GE moth adults or larvae is not harmful to humans or wildlife, and without our knowledge or consent.

8. Documentation of potential economic and social effects of the trials as well as the proposed technology

Despite acknowledging the fact that economic and social values are a part of the human environment, and that these "effects" are a part of the legislative mandate under The National Environmental Policy Act of 1969 (NEPA), and other regulations, this EA did not address either economic or social impacts.

The EA notes that New York's cabbage and cauliflower production is ranked third in the United States, and evaluates the potential economic damage of the diamondback moth, but ignores the potential impacts of excessive dead larval remains on the final product and the damage to New York's reputation if these products are associated with contamination from genetically engineered insects. These effects would apply to both organic and conventional growers.

Organic Farming. Of most alarm to NOFA-NY and its members, is that no attention is paid to the economic or social impact to **organic** farmers who rely on systems approaches to plant pests and are unable to use repeated pesticide sprays to knock down the diamondback moth numbers. There may be serious economic impacts if organic product is found to have remains of GE organisms either in U.S. markets or abroad where attention and testing of GE organisms is heightened.

In addition, if genetically engineered organisms are found to have been used on an organic farm (with or without the farmer's consent), the federal organic certification of that farm may be at risk. Finally, the social stigma to an organic farm as well as the region from the potential for large numbers of dead GE larvae on food plants could be devastating to the reputation of organic cabbage, cauliflower and broccoli growing in New York State.

Without an acknowledgement of these potential impacts, there is no reference to the role that public information and local consultations could serve to advise farmers of potential economic harm, in order for them to prepare, as well as to feel that their economic needs have been taken into account. New York farmers and their economic as well as social contribution to our state have been entirely left out of the EA.

The role of the consumer expectations is similarly not mentioned, but is clearly a serious potential impact from consumers who have chosen to not eat foods containing or made from genetically engineered organisms.

It does not appear that any local/regional public consultations are planned, and impacts to the region are not addressed anywhere in the EA.

Economic and social impacts from the advancement of the technology itself are also ignored. How will this technology proceed as an answer to the diamondback moth as a plant pest? Will the technology be offered to individual farmers, or will it need to be a region-wide release program? Will the buyer of this technology need to purchase and release GE moths annually? – for a period of how many years? Unanswered questions abound.

This short overview is in no way a comprehensive review and analysis of the potential social and economic impacts of both the trials and of the technology. This EA is woefully remiss in this mandated area, and should be withdrawn and re-written to address social and economic impacts.

9. Analysis of cumulative impacts

This EA focuses on the general impacts from the technology, and a cursory look at impacts during the trials, but never fully evaluates:

1. All of the potential impacts of the new technology,

2. Potential impacts of these specific trials of the new technology, or

3. The trial's effect on the local and statewide environment.

This Environmental Assessment should include a cumulative assessment of risk, environmental and health impacts at each level.

CONCLUSION

For the reasons outlined above as well as in comments submitted by GeneWatch UK, Food & Water Watch, Center for Food Safety, Friends of the Earth, and Consumers Union, this Environmental Assessment for the Proposal to permit the field release of genetically engineered diamondback moth in New York is wholly inadequate. Without adequate review, we must conclude that the proposed experiments pose unnecessary risks to public health and the environment. Thus the application should be denied.

Submitted,

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