

NEPA/ESA Decision Summary for Permit 10-025-107r

Based on a review of Permit #10-025-107r, the following determinations were made:

The genetically engineered corn lines proposed for confined field release are expected to result in corn seed that produce either brazzein or the hepatitis B virus surface antigen (HBsAg). Brazzein is a plant-derived protein that is being developed as a nutritive sweetener. HBsAg is the major coat protein of hepatitis B virus presently marketed for use in humans as a vaccine for the prevention of hepatitis B disease.

The transformed DNA consists of the brazzein gene from a plant (*Pentadiplandra brazzeana*) and the HBsAg gene from hepatitis B virus that may be fused to [] to improve HBsAg product efficacy; and non-expressed regulatory components which include: seed-specific promoters to target expression to the corn embryo (gamma zein from *Zea mays* or []), a transcription factor (alpha amylase signal sequence from *Hordeum vulgare*) and [] designed to increase production levels, and the proteinase inhibitor II terminator (from *Solanum tuberosum*).

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The transformed lines also include the selectable marker gene, phosphinothricin N-acetyltransferase (from *Streptomyces viridochromogenes*). The promoter and the terminator for the selectable marker is the 35S from cauliflower mosaic virus (CaMV). Based on *Agrobacterium* transformation, only the genetic construct that is designed to be expressed in the genetically engineered corn line is expected to be stably inserted into the corn genome.

HBsAg is currently used to make the commercial vaccine for hepatitis B, and millions of people have been injected with this protein. Oral administration of the hepatitis B coat protein antigen has shown no signs of toxicity (Thanavala 2005 PNAS 102:3378-3382, 2005). The HBsAg [] fusion protein is designed to increase the immunogenic response in animals. [] has no enzymatic or other toxic properties other than targeting the antigen to the appropriate cells to increase the immune response []. The gene conferring glufosinate resistance has been previously approved by APHIS for over 1000 applications in multiple plant species over a period of 15 years. The inserted gene construct contains non-coding regions derived from plant pests (the promoter and terminator from CaMV) that have been safely used to regulate the expression of transgenes in corn and other plants. None of the genes encoding the desired traits or the selectable marker, nor the regulatory elements controlling their expression, have any inherent plant pest characteristics, and they are not likely to pose a plant pest risk.

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Proposed Actions to Confine the Regulated Material to the Field Trial Site

The biology of corn is well known (Consensus Document on the Biology of *Zea mays* subsp. *Mays* (MAIZE), 2003. Available at [http://www.olis.oecd.org/olis/2003doc.nsf/LinkTo/env-jm-mono\(2003\)11](http://www.olis.oecd.org/olis/2003doc.nsf/LinkTo/env-jm-mono(2003)11).

Hundreds of field trials have been performed with transgenic corn plants under APHIS's authority; and APHIS is familiar with corn biology and methods to manage confined corn field trials. The field trial will contain a maximum of one acre (smaller than a football field).

The field trial site has adequate security:

The field trial site will be identified with a sign restricting access to authorized personnel only. All four corners of the site will be marked with a post suitable to permit identification of the site during the growing season and the period of post-harvest. Only authorized personnel will enter the field trial site.

The seed will be confined during transportation to the field trial site:

Seed for planting will be contained in a sealed bag in a second enclosed plastic container. Transportation will be by car or other enclosed vehicle that will be locked if unattended. The vehicle will be thoroughly cleaned at the field trial site.

The pollen will be confined:

The entire isolation area that includes from the edge of the field trial to the isolation distance as indicated below, will be monitored for corn plants at 2-4 week intervals beginning in May until flowering of the regulated corn is complete in August-September.

The isolation distance from the edge of the field trial site to reproductively compatible plants (corn, *Zea mays*) will be by one of two following methods:

1. No corn grown within 1.0 mile of the field or
2. Corn tassels will be bagged, or corn tassels will be removed and
 - i. there will be no corn grown within 0.5 mile of the field trial and
 - ii. and the transgenic corn will be planted no less than 28 days before or 28 days after any corn growing in a zone extending from 0.5 mile to 1 mile from the field trial and
 - iii. If tassels are bagged, plants will be checked weekly for intact bags.

The seed and other plant material will be confined at the field trial site:

- Dedicated equipment (seed jabber – to plant the seeds, seed sheller, any hand tools (knives, pruners, hoes) and backpack sprayer when not in use will be stored at a locked dedicated site at [] separately from equipment used for food or feed.
- Before removal from the field trial site, all field equipment (tractor and attachment –disk, ring roller and harrow) will be thoroughly cleaned to remove seed and plant parts that may adhere to the equipment according ABI submitted and APHIS approved SOPs.
- All equipment will be cleaned to remove plant parts. If cleaning occurs off-site, then the equipment will be placed in a secure plastic bag so that no regulated material will be released during transportation to the dedicated storage facility.

- There will be a 50 foot fallow zone surrounding the field trial. Incursion by livestock or other large animals will be prevented by a fence with a locked gate. All personnel departing the field trial site will inspect shoes and clothing for regulated material for removal prior to departing the site.

The harvested seed will be confined during transportation from the field trial site and subsequent storage:

- Ears will be hand harvested at maturity and the seeds will be removed from the ears at the field trial site. Harvested seed will be transferred directly into the containers in which it will be stored at the dedicated storage facility at [].
- A chain of custody document will accompany all seed harvested from the field trial site. Harvested seed will be stored at a locked dedicated site.

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The regulated material that is not harvested for processing will be rendered non-viable:

- Seed, ears, and ear fragments not bagged and transported to the storage location will be buried at the site at a depth of at least 36 inches with markings to identify the precise location. Following harvest, all remaining material will be in contact with the soil (not left standing or left intact) to facilitate natural decay of plant material.
- All plant material (regulated and non-regulated plant material) will be treated as regulated and disposed of by cultivation into the soil by a tractor after harvest. No recovered plant material (including seeds) will be used for food or feed. The field site will be thoroughly tilled to incorporate the plant material into the soil.

Volunteers will be controlled before any pollen is produced from the volunteer plants:

- The field trial site and the perimeter fallow zone will be monitored for the presence of volunteers for 12 months after completion of the harvest. Monitoring will occur after the first rain (approximately Nov 1st) until the end of the rainy season (approximately May 1), every 2 weeks during the time when conditions are conducive to germination.
 - Any growth from germinated seeds from the previous year's field trial will be destroyed before flowering. Volunteers will be destroyed by one or more of the following methods:
 - Thorough mowing of the entire site.
 - Herbicide application (must be a product that will devitalize ABI's transgenic corn).
 - Plowing down the entire site and incorporation of any plant material into the soil.
 - Hand removal of the volunteer and incorporating it into the soil

Following harvest, APHIS restricts the production of food and feed crops at the field trial site and the perimeter fallow zone during the field trial and the growing season following harvest of the field trial.

- In the following growing season, the field trial site and the perimeter fallow zone will not be used for crops that are used for food or feed.
- Planting of cover crops that will not be harvested is allowed.
- No plants will be grown on the field trial site that will interfere with the identification and destruction of volunteers.

Staff carrying out all activities associated with the field trial will be adequately trained:

All field operations personnel are trained by the Field Test supervisor according to APHIS approved training to know their specific job responsibilities. The field trial size will be inspected by an internal auditor throughout the duration of the field trial to verify compliance with site security. An internal auditor will inspect records to verify compliance.

For the above reasons, and those documented in the NEPA/ESA decision worksheet, APHIS has determined that this permit involves a confined field trial of genetically engineered organisms or products that do NOT involve a new species or organism or novel modification that raises new issues. Issuance of this permit qualifies for categorical exclusion status under 7 CFR § 372.5(c)(3)(ii), and none of the exceptions for categorically excluded actions under 7 CFR § 372.5(d) apply to this action because APHIS has determined that all environmental impacts resulting from the issuance of this permit will be insignificant. APHIS has determined that this action does NOT have the potential to significantly affect the quality of the human environment, and neither an environmental assessment nor an environmental impact statement is required.

Endangered Species Act Analysis for Permit 10-025-107r

Action area

The action area is defined as the 1.0 acre release site in [] and the 660 feet surrounding the field trial site where pollen could be dispersed. A species list for [] was obtained from the U.S. Fish & Wildlife Services (http://ecos.fws.gov/tess_public/ searched on 3-19-2010). [] The scope of this analyses includes USFWS listed and proposed threatened and endangered species.

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In summary, the ESA analysis considered the effects of the release on appropriate federally listed threatened and endangered species, species proposed for listing, designated critical habitat, and habitat proposed for designation (i.e., those that might be near the area of this release). The final result is a no effect determination on all of these

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for the reasons articulated above. Most of the species would not find the release site suitable habitat. Others would not be expected to use the field site during the time of year the release will take place. The activities associated with the field release will not have any effect on the primary constituent elements of any designated critical habitat or habitat proposed for designation.

References

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Attachment 1

*****Field Trial Location Is CBI*****

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