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NEPA/ESA Decision Summary for Permit 11-024-102r

The National Environmental Policy Act of 1969 (NEPA) is the mandate of any federal agency or department for the protection of the environment. NEPA requires all federal agencies to consider the values of environmental preservation for all significant actions and prescribes procedural measures to ensure that those values are in fact fully respected.

The Council on Environmental Quality (CEQ) developed the categorical exclusion process to reduce the amount of unnecessary paperwork and delay associated with NEPA compliance.

The categorically excluded actions for APHIS Biotechnology Regulatory Service (BRS) processes are listed in 7 CFR 372.5(c)(2)(ii):

"Permitting, or acknowledgment of notifications for, confined field releases of genetically engineered organisms and products"

However, the CEQ acknowledged that, from time to time, exceptions to a categorical exclusion may arise. As a result, the CEQ requires all agencies to develop procedures to determine whether a normally excluded action may have a significant environmental effect. Exceptions to categorically excluded actions for APHIS BRS are determined by the following criteria found in 7 CFR 372.5(d)(4):

"When a confined field release of genetically engineered organisms or products involves new species or organisms or novel modifications that raise new issues."

ABI has requested a permit to plant up to 1.0 acre of genetically engineered corn within one site in [ ], CA.

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*).

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.

APHIS BRS has reviewed the permit application and has set permit conditions for the activities to be authorized under this permit. These conditions can be found in the e-permits file associated with this application. APHIS BRS has concluded that issuing Permit number 11-024-102r is categorically excluded action under section 7 CFR 372.5(c)(ii) because it is a confined field release of genetically engineered organisms.

The field release is confined for the following reasons:

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.
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 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 the **[ ]**.
- 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.

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.

APHIS has determined that the exception for categorically excluded actions (7 CFR 372.5(d)(4)) Do not apply to this action for the following reasons:

1) This GE corn is not a new species to APHIS. APHIS has granted over 8000 permits and notifications for this species since 1992.
2) The introduced traits do not raise new issues because brazzein is ubiquitous in nature and part of human and animal diet. Hepatitis B antigen is not an allergen and is readily digested if this GE corn is ingested by wild animals.
3) APHIS BRS has issued prior permits for this GE corn with the same traits and have found no significant impacts to the human environment.

In addition to determining that the field trial is confined and that the exclusions do not apply to this action, APHIS has also concluded that there are unlikely to be any significant impacts from the authorization of this field trial because:

1) The field release is limited in time and space. The plants will be in the field for less than one year in an area equal to or less than 1.0 acre
2) The genes do not code for toxins or any other substance that is likely to harm any animals or humans that may encounter the plants.
3) The GE plants do not encode any substances that will persist in the soil, water or air. Most of the genes alter the expression levels of naturally occurring compounds. The marker gene codes for a protein that will degrade in the environment like other proteins native to the plant.
4) The genetically engineered GE corn will not be used for food or feed.

APHIS analyzed the potential for effects to federally-listed threatened or endangered species and their critical habitat. Based on the analysis below APHIS has determined that there is no effect to any of these species or that the activities authorized in this permit would result in the alteration of any designated critical habitat.

Applicant and APHIS searched the US FWS web site (http://crithab.fws.gov) and relevant Federal Register Notices relating to listed endangered and threatened species. The endangered species analysis can be found at the end of this document. This GE corn field trial will occur on land that has been cultivated for agricultural purposes for over three years and therefore will not eliminate habitat that may contain a threatened, endangered or candidate species.

Signed: ____/s/_____
John M. Cordts, M.S.

Chief, Plant Pests and Protectants Branch
Environmental Risk Analysis Division
Biotechnology Regulatory Services

Date: _2-9-2011___

Endangered Species Act Analysis for Permit 11-024-102r

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 02/08/2010). **[ ]** The scope of this analyses includes USFWS listed and proposed threatened and endangered species.

[ ]

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 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

[ ]

Attachment 1
******Field Trial Location Is CBI*****

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