

**NEPA/ESA Decision Summary for Permit #13-030-104r**

Applied Biotechnology Institute has requested a permit to plant up to [ ] acres of genetically engineered corn within one site in [ ] County, CA.

Based on a review of Permit #13-030-104r, the following determinations were made:

The gene constructs proposed for the environmental release are expected to result in the production of products intended for various purposes: pharmaceutical (hepatitis B virus surface antigen used in vaccine production, [ ]), industrial ([ ] and non-pharmaceutical and non-industrial (Brazzein for use as a nutritive sweetener and [ ] and the selectable marker PAT. 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, have any known toxicity, and they are not likely to pose a plant pest risk.

- The biology of corn is well known (OECD (2003) Consensus Document on the Biology of *Zea mays* subsp. *Mays* (MAIZE)).
- 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 less than [ ] acres.
- The field trial site will be fence with a locked gate and identified with a sign restricting access to authorized personnel only. Only authorized personnel will enter the field trial site. 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.
- 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.
- There will be a 50 foot fallow zone surrounding the field trial. 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:
  - No corn grown within 1.0 mile of the field or
  - Corn tassels will be bagged, or corn tassels will be removed and
    - there will be no corn grown within 0.5 mile of the field trial and
    - 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
    - Plants will be checked weekly for intact bags.
- The entire isolation distance to sexually compatible plants will be monitored for corn plants at 2-4 week intervals beginning in May until flowering is complete in August-September.
- Dedicated equipment (seed jabber, seed sheller, any hand tools (knives, pruners, hoes) and backpack sprayer when not in use will be stored at a locked dedicated sites 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 to 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.

- Ears will be hand harvested at maturity and transferred into containers and stored at locked dedicated storage facilities. A chain of custody document will accompany the seed harvested from the field trial site. Seed, ears, and ear fragments not bagged and transported to the storage location will be buried at the site to a depth of at least 36 inches with markings to identify the location. No recovered plant material (including seeds) will be used for food or feed.
- 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 1<sup>st</sup>) 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
  - Plowing under the entire site and incorporation of any plant material into the soil
  - Hand removal of the volunteer and incorporating it into the soil
- 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.
- All field operations personnel are trained by the Field Test supervisor according to APHIS approved training related to 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.

### **Endangered Species Act Analysis**

The action area is defined as the [ ] acre release site in [ ] county and the 660 feet surrounding the field trial site where pollen could be dispersed. The release site location has been used for managed production of annual agricultural crops. The scope of this analysis includes USFWS listed and proposed threatened and endangered species.

[ ]

For the above reasons, and those documented on the NEPA-ESA worksheet, APHIS has determined that permit application **13-030-104r** involves a confined field trial of genetically engineered organisms or products that do NOT involve a new species or organism or novel modifications that raise new issues. APHIS has determined that the actions authorized under this permit do NOT have the potential to significantly affect the quality of the human environment.

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Therefore, approval of this permit is properly categorically excluded from the need to prepare an EA (or EIS) pursuant to 7 CFR 372.5., and none of the exceptions to this categorical exclusion apply.