NEPA Decision Summary for Permit #07-052-106r

Dr. Kan Wang of Iowa State University has requested a permit for a confined field release of 0.25 acres of genetically engineered corn plants at a site in Des Moines County, Iowa.

Based on a review of Permit #07-052-106r, the following determinations were made:

1. The gene construct (one in a male corn line and one in a female corn line) proposed for the confined field release is expected to result in corn that produces heat labile *E. coli* enterotoxin (LT-B) in the endosperm of transgenic corn. The construct consists of the gamma zein (seed-specific) promoter from *Zea mays*, the LT-B gene (B unit of the *E. coli* enterotoxin) and the vegetative storage protein terminator from *Glycine max*. The construct also includes the selectable marker gene, *bar*, which codes the enzyme phosphinothricin acetyl transferase, from *Streptomyces hygroscopicus*. The promoter for the selectable marker is the ubiquitin promoter from *Zea mays* and the nos terminator from *Agrobacterium tumefaciens*. This construct containing the LT-B gene has been previously used under permits 06-061-01r, 05-069-01r, and 04-131-01r. The gene conferring Basta resistance (*bar*) has been previously approved by APHIS for 2500+ applications in multiple plant species over a period of 15 years. The gene construct contains non-coding regions derived from plant pests (the terminator from *Agrobacterium tumefaciens*) 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.

2. Based on biolistic transformation, only the genetic construct that is designed to be expressed in the genetically engineered corn lines is expected to be efficiently and stably inserted into the corn genome. No plant pest vectors are expected to be associated with the transformed corn lines as a result of the transformation process.

3. The intent of this field release is to further develop a male-sterile (pollenless) corn line as a proof-of-concept project to express desired pharmaceutical proteins. The applicant has no intention of commercializing future production of the LT-B protein. The resulting seeds from this permit will be used for breeding purposes, and for biochemical and immunological analyses of the LT-B protein under laboratory conditions.

4. The LT-B protein produced is non-toxic and is responsible for the immunological recognition of the toxin by the Gm1 receptors underlying the epithelium cells of the gastrointestinal tract of a host. LT-A, the subunit responsible for the toxic effects of the *E. coli* enterotoxin, is not produced in the transgenic corn. Thus, the protein produced during this pharmaceutical field trial is not toxic.

5. The proposed field site is on a military installation that has a fully fenced perimeter. Access is restricted to entry via a guarded gate that is locked when a guard is not present. The field site itself is also surrounded by a 6’ tall fence. A 24 inch tall electric mesh

fence will be installed outside the 6' tall fence. A gate to the plot will also include electric fence hardware. Thus, adequate security is in place for this field trial.

6. The proposed 0.25 acre field release site is limited to 2400 corn plants, of which due to the breeding scheme, only 1450 will be transgenic and reproductively viable during the field trial. The remnant 950 plants are not transgenic and will be eliminated from the field test by herbicidal (Basta) application. Given the small size of the field trial, it is anticipated that adequate resources will be available to manage the trial effectively.

7. The isolation distance between the transgenic corn and the nearest non-transgenic corn is greater than 1 mile (approximately 1.25 miles). This isolation distance is meets the APHIS guidelines for a pharmaceutical trial for open-pollinated corn.

8. The female transgenic population is a male sterile inbred line and no viable pollen is expected from this line. The male transgenic population is a fertile inbred. The tassels of this population will be bagged, pollen collected and hand pollinated to the female plants. Thus, the field test protocols will also control pollination for all corn plants in the field trial, further reduce the probability of pollen escaping the field trial and reaching corn fields greater than 1 mile away.

9. There is a 50 foot buffer surround the field test site. No food or feed will be harvested from the buffer zone and the plants within the buffer zone are not sexually compatible with corn.

10. All pollinated ears will be bagged and hand harvested for maturity with the husks on to further minimize any accidental spillage of seed. After hand harvesting the ears, stalks will be tilled or mixed with the soil at the site, buried at the site or removed from the site and incinerated or autoclaved.

11. The field plots and isolation distance (1 mile) will be monitored for volunteers every 4 weeks during the following (2008) growing season (May to August). All volunteer corn plants found will be removed chemically, manually, or mechanically.

12. During the 2008 growing season, if the field is not used again for another pharmaceutical field trial, a cover crop that is morphologically distinct from corn may be planted but will not be harvested for food or feed.

13. The confinement measures described in the application and supplemental permit conditions should be sufficient to prevent any unplanned releases of the transgenic plant material or transgenic seed; or the persistence of the transgenic material or its progeny in the environment.

14. According to the Fish and Wildlife Service (http://ecos.fws.gov/tess_public/StateListingAndOccurrence.do?state=IA, accessed 03/13/07) there are 15 federally listed threatened and endangered animals and 5 threatened and endangered plant species in the state of Iowa. Of the 15 listed animals,

none are known to use corn as a food plant. According to http://www.agriculture.state.ia.us/livingontheedge/endangeredanimals.htm, accessed on 3/13/07, the only threatened or endangered animal or plant species that is found in Des Moines County, IA is the Bald Eagle. Bald Eagles do not directly feed on corn or corn plants. No indirect effects on Bald Eagle prey are expected. Only the grain produced during this field trial expresses the LT-B protein, and the grain will be collected and not available for other species as a food resource. Furthermore, in the unlikely event of accidental consumption, the pharmaceutical protein produced during this field trial is non-toxic and is not expected to harm animals feeding on this grain. Therefore these field trials will have no effect on threatened or endangered species.

15. According to http://crithab.fws.gov/, accessed 04/06/07, there is no designated critical habitat or proposed designated critical habitat found in this county.

16. The gene products used in this field trial are not known to be toxic. Based on the above, APHIS is confident that these field trials will not harm or have adverse or other significant effects on threatened or endangered species either by direct or indirect exposure.

17. Regulated materials in this field trial are not intended for food and/or feed. Any use of these products for food or feed must be in compliance with the guidelines published in the Federal Register by the United States Food and Drug Administration [57 FR 22984, May 29, 1992].

For the above reasons, and those documented on the NEPA/ESA decision document, APHIS has determined that permit application 07-052-106r involves contained movement and confined field trails of genetically engineered organisms or products that do NOT involve a new species or organism or novel modification that raises 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. 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.

Signed: _____/s/_____
Michael T. Watson, Ph.D.
Branch Chief, Plant Pests and Protectants
Biotechnology Regulatory Services

Date:___4.12.07__
AFH_/s/_