

NEPA Decision Worksheet

Permit #
 Institution
 Organism
 Category
 Gene

06-061-01r
 Iowa State University
 corn
 OO- pharmaceutical
 LT-B enterotoxin subunit

1. Confinement	
Confinement and mitigation conditions have been reviewed and determined to be adequate	X
2. Threatened or Endangered Species or its habitat	
Resident or migratory in counties and harm to threatened or endangered species or habitat is likely	
Resident or migratory in counties and harm to threatened or endangered species is unlikely	X
None observed in area (no harm to threatened and endangered species)	
New or Novel	
3. New or Novel Crop	
Never used in a field trial	
Not new but no prior EA	
Not new and prior EA	X
4. New or Novel Trait (gene product)	
Never used in a field trial	
Not new but no prior EA	X
Not new and prior EA	
Raises new issues	
5. Cumulative Effects	
Cumulative effects likely	
Cumulative effects possible	
Cumulative effects unlikely	X
6. Plant Pollination	
Primarily bee or insect pollinated crop	
Primarily wind pollinated food or feed crop	X
Primarily self fertilized food or feed crop	
Non-food or feed crop	
7. Effects on Food/Feed Supply	
Known allergen, antinutritive, oral toxicant	
Food safety not established	X
GRAS status or approved food additive for native protein	
GRAS status or approved food additive for plant produced protein	
8. Isolation Distance	
AOSCA standard for crop	1/8 mile
Proposed isolation distance	1/2 mile*
9. Scale	
>100 acres/trait/crop/institution/year	
50-99 acres/trait/crop/institution/year	
10-49 acres/trait/crop/institution/year	
<10 acres/trait/crop/institution/year	X
10. Effects (positive or negative) on other species	
Significant effects expected/observed	
Minimal, non-cumulative effects expected/observed	
No effects expected/observed	X
11. Sexually Compatible Relatives	
Relatives within dispersal distance	
Relatives not within dispersal distance	X
12. Seed Dormancy	
>3 years	
3 years	
2 years	
<2 years	X
13. Persistence in environment	
Crop can naturalize	
Crop can persist 3-5 years without human intervention	
Crop does not persist without intervention	X
14. Comments	
*transgenic corn to be detasseled to prepare male sterile lines for future use	

Decision Document for Permit 06-061-01r

Based on my review of Permit 06-061-01r, I have made the following determinations:

- The threatened or endangered species known to be present in Marshal County, Iowa are not known to inhabit or forage in corn fields, and the gene product at issue in the proposed field trials has no known toxic effects on wildlife. Therefore these field trials will not have adverse or other significant effects on threatened or endangered species.
- Hundreds of field trials have been performed with transgenic corn plants under APHIS authority, and APHIS is familiar with corn biology and methods to manage confined corn field trials.
- Corn is not pollinated by bees. The applicant proposes a separation distance of over 1/2 mile or 4 times the distance recommended by AOSCA for the production of certified seed corn. Additionally, the applicant will be scouting the planting daily during the expected time of tassel emergence and will be detasseling transgenic plants (pages 3 and 4, parts 13.f and h of the permit application). This will be effective in preventing the release of transgenic pollen from this trial site. Non-transgenic pollen donors will be planted at the site to pollinate the transgenic lines to develop male sterile LT-B corn lines for future use.
- Because all transgenic plant material will be removed from the test site and destroyed, there will be no foreseeable cumulative impacts resulting from multi-year field trials of these same transgenic lines
- The gene product proposed for this field trial, LT-B enterotoxin subunit, has been shown to not have toxic effects when ingested. In fact, it is being developed as a possible oral booster vaccine.
- The proposed field trial is less than 1 acre. Trials of such small size are and have been easily monitored and confined to the permitted area, under environmental mitigation measures specified in the permit application.
- Corn is not observed to be capable of establishment in wild environments: it is reliant on continuous human intervention for its survival. In previous field tests and applications, seed dormancy in corn has not been observed. There are no sexually-compatible relatives of corn known to exist in the area where the trials will be performed.

For the above reasons, APHIS has determined that (1) pursuant to 7 C.F.R. 372, the field trials proposed under permit #06-061-01r will not significantly affect the physical environment and (2) there are no applicable, extraordinary, or other reasonably foreseeable circumstances under which significant environmental effects could occur despite the protective and ameliorative measures specified above. Therefore, this field test is deemed confined within the meaning of 7 C.F.R. § 372.5.

Signed: _____/s/_____

Neil E. Hoffman
Director, Environmental Risk Analysis Division
Biotechnology Regulatory Services

Date: 3.15.06