

Worksheet for Determining Whether Field Trials are Categorically Excluded from NEPA

Permit#	04-061-01r
Company:	Edenspace
Organism	Tobacco (Nicotiana tabacum)
Category	Phytoremediation
Transgene	Citrate synthase
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	
none observed in area (no harm to threatened and endangered species)	X
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	
Primarily Self fertilized food or feed crop	
Non-food or feed crop	X
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	1/4 mile
Proposed isolation distance	3 miles
9. Scale	
>100 acres/trait/crop/company/year	
50-99 acres/trait/crop/company/year	
10-49 acres/trait/crop/company/year	
<10 acres/trait/crop/company/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	
^{8 & 12} All plants will be topped prior to flowering to assure that no seed or pollen is produced. Isolation distance is 1320 feet from other tobacco	

Additional supporting documentation is found in the summary risk assessment completed on April 30, 2004.

NEPA Decision Summary

Based on a review of Permit 04-061-01r, the following determinations were made:

- Threatened and endangered species recognized by the U.S. Fish and Wildlife Services as occurring in Maryland will not be affected by this field release. The species listed either do not exist within the county where the field trial will be performed or do not inhabit tobacco fields.
- Numerous field trials have been performed with transgenic tobacco (*Nicotiana tabacum*) plants under APHIS authority, and APHIS is familiar with tobacco biology and methods to manage confined tobacco field trials.
- Tobacco is known to be highly self pollinating. The Association of Official Seed Certifying Agencies (AOSCA) recommends a quarter mile isolation distance for foundation seed. The applicant proposes an isolation distance of three miles, 12 x the AOSCA standard for foundation seed.
- Any plant material left after harvest, containing only insignificant amounts of the proteins, will be plowed under the soil surface. The proteins have no known or foreseeable toxic effects, so this method of disposal should have no negative impacts on the environment.
- The gene products proposed for these field trials do not have characteristics of known toxins or allergens. No foreseeable effects on other organisms are expected.
- The actual area to be planted with transgenic plants is 0.006 acre. Trials of such small size are and have been easily monitored and confined to permitted areas, under environmental mitigation measures similar to those specified in the permit application and in the standard and supplemental permit conditions.
- Tobacco is not observed to be capable of establishment in unmanaged environments: it is reliant on continuous human intervention for its survival. In previous field tests and applications, seed dormancy in tobacco has not been observed.
- There are no known sexually compatible species in the area and the crop will not be allowed to flower.

For the above reasons, APHIS has determined that (1) pursuant to 7 C.F.R. §372, the field trials proposed under permit #04-061-02r 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 given 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: _____

Susan Koehler

Branch Chief, Environmental and Ecological Analysis

Date: ____7.19.04_____