NEPA Decision Worksheet

Permit #	05-053-01r
Institution	Planet Biotechnology
Organism	Tobacco
Category	Pharmaceutical-antibody
Gene	Antibody that binds to *Streptococcus mutans* the bacteria that cause tooth decay, or the virus that can cause the common cold.

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	
Not new and prior EA	X[4]
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[6]
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	1320'
Proposed isolation distance	X[8]
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[12]
13. Persistence in environment	
Crop can naturalize	
Crop can persist 3-5 years without human intervention	
Crop does not persist without intervention	X[13]

14. Comments

[4] 88-333-02r, 01-121-01p

[6] Primarily selfed (95%). Hummingbirds, bees and other insects may pollinate at 0.5 - 4 % frequency (Free, J.B. 1970. Insect Pollination of Crops. Pp. 355-356 Academic Press, New York).

[8] All plants will be topped prior to flowering to assure that no seed is produced. Isolation distance is 1320 feet from the nearest regulated tobacco and any non-regulated tobacco and at least 2,640 feet from any flowering tobacco. All tobacco between the 1,320 and the 2,640 foot distance will be topped and will not be used for seed production. The closest tobacco that will be allowed to openly flower and produce seed is over 1 mile from the field test. One field that is 0.9 miles from the field test will be allowed to flower, the only seed that will be saved will come from plants that are bagged to prevent outcrossing.

[12] Chaplin, J. F. & Burk, L.G. 1979. Plant Propagation. In United States Department of Agriculture Technical Bulletin Number 1586. pp. 28-32.

[13] Shew, H. D., and Lucas, H.D. 1991. Compendium of Tobacco Diseases. p. 2. The American Phytopathological Society.

Additional supporting documentation is found in the summary risk assessment completed on 5/16/2005

NEPA Decision Summary

Based on a review of Permit 05-053-01r, the following determinations were made:

- Due to the presence of nicotine in the tobacco plant, few organisms consume tobacco. The only reported consumption of field tobacco is occasional foraging by skunks and insects that are plant pests. Of the 38 animals and 9 plants in Kentucky that are recognized as threatened and endangered species by the U.S. Fish and Wildlife Services, none consume tobacco. Therefore these field trials will not harm or have adverse or other significant effects on threatened or endangered species.
- Over two hundred and fifty field trials have been performed with transgenic tobacco plants under APHIS authority, and APHIS is familiar with tobacco biology and methods to manage confined tobacco field trials.
- All plants will be topped prior to flowering to assure that no seed is produced. Because the plants will not be allowed to flower, will be grown at an isolation distance of at least 1320 feet (the AOSCA standard for production of foundation tobacco seed when flowers are not bagged or removed) from any flowering tobacco. All tobacco between the 1,320 and the 2,640 foot distance will be topped and will not be used for seed production. The closest tobacco that will be allowed to openly flower and produce seed is over 1 mile from the field test. One field that is 0.9 miles from the field test will be allowed to flower, the only seed that will be saved will come from plants that are bagged to prevent outcrossing. This distance is sufficient to reduce outcrossing to insignificant levels even if flowering were to occur.
- 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 proposed field trial is less than 10 acres. 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. Furthermore, flowers will be removed to eliminate seed production.
- There are no sexually-compatible relatives of tobacco known to exist in the area where the trial 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 #05-053-01r 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 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: _____/s/_____
Neil E. Hoffman
Director of Regulatory Programs
Date: _____
05.20.05