

NEPA Decision Worksheet

Permit # 05-087-01r  
 Institution Planet Biotechnology  
 Organism Tobacco  
 Category Pharmaceutical-antibody  
 Gene Antibody that binds to *Streptococcus mutans* the bacteria that cause tooth decay.

Confinement and mitigation conditions have been reviewed and determined to be adequate	X
<b>2. Threatened or Endangered Species or its habitat</b>	
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
<b>New or Novel</b>	
<b>3. New or Novel Crop</b>	
Never used in a field trial	
Not new but no prior EA	
Not new and prior EA	X
<b>4. New or Novel Trait (gene product)</b>	
Never used in a field trial	
Not new but no prior EA	
Not new and prior EA	X <sup>4</sup>
<b>Raises new issues</b>	
<b>5. Cumulative Effects</b>	
Cumulative effects likely	
Cumulative effects possible	
Cumulative effects unlikely	X
<b>6. Plant Pollination</b>	
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 <sup>6</sup>
<b>7. Effects on Food/Feed Supply</b>	
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	
<b>8. Isolation Distance</b>	
AOSCA standard for crop	1320'
Proposed isolation distance	X <sup>8</sup>
<b>9. Scale</b>	
>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
<b>10. Effects (positive or negative) on other species</b>	
Significant effects expected/observed	
Minimal, non-cumulative effects expected/observed	
No effects expected/observed	X
<b>11. Sexually Compatible Relatives</b>	
Relatives within dispersal distance	
Relatives not within dispersal distance	X
<b>12. Seed Dormancy</b>	
>3 years	
3 years	
2 years	
<2 years	X <sup>12</sup>
<b>13. Persistence in environment</b>	
Crop can naturalize	
Crop can persist 3-5 years without human intervention	
Crop does not persist without intervention	X <sup>13</sup>
<b>14. Comments</b>	
<p><sup>4</sup> 88-333-02r, 01-121-01p</p> <p><sup>6</sup> 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).</p> <p><sup>8</sup> All plants will be topped prior to flowering to assure that no seed is produced. Isolation distance is 1320 feet from the nearest tobacco plant.</p> <p><sup>12</sup> Chaplin, J. F. &amp; Burk, L.G. 1979. Plant Propagation. In United States Department of Agriculture Technical Bulletin Number 1586. pp. 28-32.</p> <p><sup>13</sup> Shew, H. D., and Lucas, H.D. 1991. Compendium of Tobacco Diseases. p. 2. The American Phytopathological Society.</p>	
Additional supporting documentation is found in the summary risk assessment completed on 6/3/2005	

## NEPA Decision Summary

Based on a review of Permit 05-087-01r, 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 and 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, 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 10 acres. Trials of such size are easily monitored and will be 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 #05-087-01r 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: \_\_\_\_\_

06.03.05