

NEPA Decision Worksheet

Permit # 05-354-04r  
 Institution Planet Biotechnology  
 Organism Tobacco  
 Category Pharmaceutical antibody  
 Gene Antibody that binds to *Streptococcus mutans* the bacteria that may cause tooth decay, or to the virus that can cause the common cold

<b>1. Confinement</b>	
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>5</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 feet
Proposed isolation distance	1320 feet <sup>6</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>	
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 Interspecific hybrids exhibit very low fertility, refer to attached summary risk assessment for further information.	
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	6/16/2006
Biotechnology Regulatory Programs Animal and Plant Health Inspection Service	

## NEPA Decision Summary

Based on a review of Permit 05-354-04r, On the basis of our review of this application, we conclude that this is a confined environmental release of the genetically engineered tobacco plants described in this application and the field test will not present any risk of plant pest introduction or dissemination for the reasons cited below:

1. The location of the environmental release is in an area of light industry without tobacco that might be grown for commercial or seed production. Thus there is no likelihood that the transgenes would be transferred to tobacco grown for commercial production.
2. Greenhouse tests of *Nicotiana* interspecific hybrids from the same species as the parents of the hybrids used for this release, showed extremely low pollen viability (1 % viability or less) and no seed set even when manually crossed. The lines proposed for testing 06PBCarHG1 and 06PBRinoHG1 are expected to have at least as low fertility with any natural crossing mediated by insects (honey bees, sweat flies, bumblebees and hawkmoths), hummingbirds and bats as that which occurred in the greenhouse tests.
3. Gene flow can not occur as there is no chance for hybridization to wild relatives, because there are no wild relatives growing in the region.
4. No San Francisco marsh plants are known to cross with *Nicotiana* species. Additionally marsh plants are not located within 0.5 miles of the test site.
5. Commonly planted horticultural varieties of tobacco *N. alata*, *N. langsdorffii*, *N. x sanderae* and *N. sylvestris* if planted in the surrounding area, would not be expected to provide receptive species for any gene flow because of the disparity of the chromosome numbers. And even if crossing were to occur, it is unlikely to result in persistence because the seed from the these ornamentals is not likely to be saved and propagated and that any seed produced would not be viable.
6. Antibodies are not known to be toxic compounds. Because of the small scale of the environmental release, the exposure level of insects to the antibodies would be extremely low because the site of the release is an industrial area. This lack of exposure combined with the lack of toxicity of antibodies indicates this environmental release is not likely to harm any insects that might come into contact with the transgenic *Nicotiana* hybrid plants.
7. Butterflies are known to feed on nectar, that is reported to contain a very small amount of protein. Because of the small scale of the environmental release, the exposure level would be extremely low and this combined with the lack of toxicity of antibodies indicates this environmental release is not likely to harm insects that may frequent this industrial area.

8. Of the 129 animals and 179 plants in California that are recognized as threatened and endangered species (TES) by the U.S. Fish and Wildlife Services, are known consume tobacco (*Nicotiana tabacum*) and *Nicotiana* species hybrids or is considered part of the TES critical habit. Therefore these field trials will not harm or have adverse or other significant effects on threatened or endangered species.
9. The environmental release of 250 potted plants will occur behind a locked wire fence topped with barbed wire in an industrial area, thus animals are not likely to be exposed to the engineered plants.
10. Any maturing seed capsules will be bagged to prevent unintended seed dispersal.
11. The *Nicotiana* hybrid plants will be grown at an isolation distance of at least 1320 feet (AOSCA standard for production of foundation seed) from other *N. tabacum*.
12. Any resulting seed capsules will be bagged to prevent unintended dispersal.
13. Material will be disposed of by grinding or autoclaving as appropriate to devitalize.
14. 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.

For the above reasons, APHIS has determined that (1) pursuant to 7 C.F.R. §372, the field trials proposed under Permit 05-354-04r 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/ JC for NH\_\_\_\_

Neil E. Hoffman

Director of Regulatory Programs

Date: \_\_\_\_6/20/06\_\_\_\_