Worksheet for Determining Whether Field Trials are Categorically Excluded from NEPA

Permit #:	04-044-02r
Company:	Large Scale Biology
Organism	Tobacco Mosaic Virus
Transgene	Aprotinin
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	
Not new and prior EA	X
Raises new issues	
5. Cumulative Effects	
Cumulative Effects likely	
Cumulative effects possible	
Cumulative effects unlikely	X[5]
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, antinutrative, 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	NA[8]
Proposed isolation distance	100 ft[8]
9. Scale	
>100 acres/trait/crop/company/year	
50-99 acres/trait/crop/company/year	
10-49 acres/trait/crop/company/year	X
<10 acres/trait/crop/company/year	
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	NA[11]
12. Seed Dormancy	
>3 years	
3 years	
2 years	
<2 years	NA[12]
13. Persistence in environment	
Organism can naturalize	
Organism can persist 3-5 years without human intervention	
Organism does not persist without intervention	X[13]
14. Comments	

[6, 11, 12] Tobacco plant is not transgenic. The TMV is not transmitted by the pollen.

[8] Isolation distance is 100' from TMV-susceptible field crops.TMV is only spread by direct physical contact and not by biological vectors such as insects.

[5] Permittee is developing an assay for aprotinin level in the soil that must be used in future field test to assay for accumulation in the soil.

[13] TMV does not persist in fields when the following crop is planted to a TMV-resistant crop. Engineered TMV loses its transgene during viral replication.

Additional supporting documentation is found in the summary risk assessment completed on 4.23.04

NEPA Decision Summary

Based on a review of Permit 04-044-02r, 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 or could be infected by TMV. Therefore these field trials will not harm or have adverse or other significant effects on threatened or endangered species
- Many field trials have been performed with TMV infected tobacco plants under APHIS authority, and APHIS is familiar with TMV biology and methods to manage confined TMV infected tobacco field trials.
- TMV is not insect transmitted and no plants susceptible to TMV will be grown within 100 feet of the field test site. TMV is not seed-borne nor transmitted through pollen. TMV is only spread by physical contact. Employees entering and working in the field wear disposable gloves and protective clothing (boots). Protective wear that come into contact with the TMV such as gloves or boots are autoclaved and discarded or cleaned with bleach that inactivates the virus. Tools and equipment used in TMV fields are treated with bleach after each use. Engineered TMV is not stable and loses its transgene during replication of the virus. Vigorous weed control by herbicide treatment or hand roguing is used in the field test plot to eliminate any TMV compatible plants in the area.
- For more information on aprotinin, see the Environmental Assessment prepared by APHIS http://www.aphis.usda.gov/brs/aphisdocs/04_12101r_ea.pdf
- Aprotinin occurs in many bovine tissues and is consumed without adverse effects by humans and animals that eat beef. Aprotinin is not absorbed into the bloodstream when taken orally by mammals or birds. Insecticidal activity of aprotinin has been documented at higher concentrations of aprotinin than produced by the TMV-infected plants. Therefore no foreseeable effects on other organisms are expected. Nevertheless, the permittee will monitor daily for the presence and any mortality of bees during pollen shed.
- Any plant material left after harvest will be plowed under the soil surface. With the exception of insecticidal activity as noted above, the proteins have no known or toxic effects, so this method of disposal should have no negative impacts on the environment. To monitor for any cumulative impacts resulting from field trials of these transgenic lines, prior to any additional field tests under new permit at this site, permittee must develop an assay for aprotinin levels in the soil. Permittee must collect and preserve soil samples from these sites prior to and after harvesting for future assaying.

For the above reasons, APHIS has determined that (1) pursuant to 7 C.F.R. §372, the field trials proposed under permit #04-044-02r 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: _____
Neil E. Hoffman
Director of Regulatory Programs

Date: ____7.19.04_____