

NEPA Decision Worksheet

Permit # 04-309-02r  
 Institution Large Scale Biology  
 Organism TMV  
 Category Pharmaceutical  
 Gene Aprotinin

<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	X
None observed in area (no harm to threatened and endangered species)	
<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
<b>Raises new issues</b>	
<b>5. Cumulative Effects</b>	
Cumulative effects likely	
Cumulative effects possible	
Cumulative effects unlikely	X <sup>5</sup>
<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	NA <sup>8</sup>
Proposed isolation distance	100 ft <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	X
<10 acres/trait/crop/institution/year	
<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	NA <sup>11</sup>
<b>12. Seed Dormancy</b>	
>3 years	
3 years	
2 years	
<2 years	NA <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>	

<sup>5</sup> 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.

<sup>6, 11, 12</sup> Tobacco plant is not transgenic. The TMV is not transmitted by the pollen.

<sup>8</sup> 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.

<sup>13</sup> 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.

NEPA Decision Summary for Permit 04-309-02r

"Based on a review of Permit 04-309-02r, the following determinations were made:"

- Threatened and endangered species recognized by the U.S. Fish and Wildlife Services as occurring in Florida will not be affected by this field release because of lack of exposure and lack of toxicity of the transgenes and their products; Therefore these field trials **will not harm or have adverse or other significant** effects on threatened or endangered species.
- Because TMV is not seed-borne and the genetically-engineered TMV is unstable, the non-transgenic tobacco volunteers are not expected to contain genetically-engineered TMV. Nonetheless the field will be monitored for any Solanaceous plants which will be destroyed on site.
- Aprotinin occurs in many bovine tissues. Aprotinin is not absorbed into the bloodstream when taken orally by mammals or birds.
- An Environmental Assessment has been conducted by APHIS on the production of aprotinin in a genetically engineered corn plant [http://www.aphis.usda.gov/brs/aphisdocs/04\\_12101r\\_ea.pdf](http://www.aphis.usda.gov/brs/aphisdocs/04_12101r_ea.pdf)
- Insecticidal activity of aprotinin has been documented at higher concentrations of aprotinin than produced by the TMV-infected plants. Nevertheless, the permittee will monitor daily for the presence and any mortality of bees during pollen shed.
- 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.
- Previous confined field trials indicate the transgenic TMV is **confined to permitted areas when the release is conducted under environmental mitigation measures specified in the permit** application and in the standard and supplemental permit conditions.
- TMV is not insect transmitted and no plants susceptible to TMV will be grown within 100 feet of the field test site.
- Weeds in the field test plot will be controlled by herbicide treatment or by hand roughing.

For the above reasons, APHIS has determined that (1) **pursuant to 7 C.F.R. 372**, the field trials proposed under permit #04-309-02r **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, Environmental Risk Analysis Division

Date: 12/24/04