

NEPA Decision Worksheet

Permit #	06-055-01r
Institution	Chlorogen Inc.
Organism	tobacco
Category	OO
Gene	CBI

<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	X
Not new and prior EA	
<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
<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 ft
Proposed isolation distance	minimum 1320 ft**
<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
<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
<b>14. Comments</b>	
** chloroplast transformed plants--- do not pass genes through pollen.	

Decision Document for Permit 06-055-01r

Chlorogen has requested a permit to plant under 10 acres of genetically engineered tobacco lines producing traits claimed as CBI at sites in Fayette, Harrison and Woodford Counties, KY. The permit is for research and development activities aimed at breeding improved lines.

Based on a review of Permit 06-055-01r, the following determinations were made:

- The threatened or endangered species known to be present in the counties where these field trials will occur are not known to inhabit or forage in tobacco fields. Additionally, the gene products at issue in the proposed field trials have no known toxic effects on wildlife. Therefore these field trials will not have adverse or other significant effects on threatened or endangered species.
- Numerous field trials have been performed with transgenic tobacco plants under APHIS authority and APHIS is familiar with tobacco biology and methods to manage confined field trials.
- The technology of the transformation used on these plants prevents dissemination of the gene by pollen movement. Additionally, the plants will be manually topped throughout the trial period to remove flower buds prior to any pollen release. AOSCA standards for seed production of tobacco of ¼ mile will be maintained, nonetheless.
- Because all transgenic plant material will be either removed from the test site or destroyed, there will be no foreseeable cumulative impacts resulting from multi-year field trials of these same transgenic lines.
- Given that tobacco is not used for food or feed and that non-target species are unlikely to be feeding on these plants, issues with toxic and allergenic effects are unlikely.
- The proposed field trials are all less than 10 acres. Trials of such small size are and have been easily monitored and confined to the permitted area, under environmental mitigation measures specified in the permit application.
- Tobacco is not observed to be capable of establishment in wild environments. It is reliant on continuous human intervention for its survival. In previous field tests and applications, seed dormancy has not been observed. There are no sexually-compatible relatives known to exist in the area where the trials 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 #06-055-01r 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 despite 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, Environmental Risk Analysis Division

## Biotechnology Regulatory Services

Date: 3.14.06