

NEPA Decision Worksheet

Permit #	05-025-03r
Institution	SemBioSys
Organism	Safflower
Category	OO
Gene	Protein A

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	
None observed in area (no harm to threatened and endangered species)	X
New or Novel	
3. New or Novel Crop	
Never used in a field trial	
Not new but no prior EA	X
Not new and prior EA	
4. New or Novel Trait (gene product)	
Never used in a field trial	
Not new but no prior EA	X
Not new and prior EA	
Raises new issues	
5. Cumulative Effects	
Cumulative effects likely	
Cumulative effects possible	
Cumulative effects unlikely	X
6. Plant Pollination	
Primarily bee or insect pollinated crop	
Primarily wind pollinated food or feed crop	
Primarily self fertilized food or feed crop	X
Non-food or feed crop	
7. Effects on Food/Feed Supply	
Known allergen, antinutritive, oral toxicant	X
Food safety not established	
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	
Proposed isolation distance	2 MILES
9. Scale	
>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	1 acre
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	X
12. Seed Dormancy	
>3 years	
3 years	
2 years	
<2 years	X
13. Persistence in environment	
Crop can naturalize	
Crop can persist 3-5 years without human intervention	
Crop does not persist without intervention	X
14. Comments	

Additional supportin documentation is found in the summary risk assessment completed on April 27, 2005

NEPA Decision Summary for Permit 05-025-03r

SemBioSys has requested a permit to plant up to 1 acre of genetically modified safflower expressing the five IgG binding domains present in native Protein A expressed as a fusion protein to oleosin. Oleosins are a unique class of structural proteins that maintain the integrity of the oil-containing vesicles present in all oilseeds and in fruits such as olives and avocados. The permit is strictly for research and development activities.

Based on a review of Permit 05-025-03r, the following determinations were made:

- According to the U.S. Fish and Wildlife Service http://ecos.fws.gov/tess_public/TESSWebpageUsaLists?state=WA, <http://www.fostercreek.net/wildlife.html>, <http://www.fostercreek.net/plants.html>, there are only two threatened or endangered animals: Bald Eagle - *Haliaeetus leucocephalus* and Pygmy rabbit - *Brachylagus idahoensis* that live or once lived in Douglas County, WA. Bald eagles do not consume safflower. There is no known information to indicate that Protein A is toxic to birds or mammals (see below) that might consume the safflower seed and serve as prey for the Bald Eagle. The Pygmy rabbit is not known to eat safflower seed and since the Protein A is only expressed in the seed and not in any other parts of the safflower plant, the Pygmy rabbit will not be exposed to the transgene protein. Based on the above, APHIS is confident that these field trials will not harm or have adverse or other significant effects on threatened or endangered species either by direct or indirect exposure.
- Several field trials have been performed with transgenic safflower plants under APHIS authority, and APHIS is familiar with safflower biology and methods to manage confined safflower field trials.
- Safflower is mainly (>80%) self-pollinated, and is generally pollinated (<20%) by insects. Other than the cultivated variety, there are no known sexually compatible species of safflower resident in the USA and no commercial fields of safflower are grown in the county. The Association of Official Seed Certifying Agencies (AOSCA) certified seed regulations for safflower foundation seed require a minimum isolation distance from other safflower varieties of at least 1320 feet. The current permit conditions call for a 50 foot fallow zone and a separation distance of 2 miles (10,560 feet) from any other safflower (8 times the AOSCA standard). In the year following harvest, the test site will be left fallow with no food or feed crops harvested from the site. Safflower has no seed dormancy. Nonetheless the applicant will monitor for volunteers 2 years after harvest. A dedicated planter and harvester will be used for this test. These confinement procedures are noted in the Supplemental Permit Conditions under Item 2. These confinement procedures are sufficient to prevent outcrossing with other safflower and to prevent commingling with other food or feed crops.
- Because all transgenic plant material remaining after harvest will be tilled into the soil, there will be no foreseeable cumulative impacts resulting from field trials of these transgenic lines. No LD50 toxicological or other ingestion data could be found for Protein A. In Wernerus *et al*, 2002, (Engineering of staphylococcal surfaces for biotechnological applications. J. Biotechnol. **96**:67-78.), this team investigated the engineering of food grade *Staphylococcus carnosus* with surface proteins such as Protein A for use as “live bacterial vaccine delivery vehicles.” Research such as this suggests that the protein is not toxic at relatively small doses.

For the above reasons, APHIS has determined that (1) pursuant to 7 C.F.R. 372, the field trials proposed under permit #05-025-03r 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: _____4.27.05_____