

NEPA Decision Worksheet

Permit # 05-025-01r  
 Institution SemBioSys  
 Organism Safflower  
 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	
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	X
Not new and prior EA	
<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	X
Non-food or feed crop	
<b>7. Effects on Food/Feed Supply</b>	
Known allergen, antinutritive, oral toxicant	
Food safety not established	
GRAS status or approved food additive for native protein	X
GRAS status or approved food additive for plant produced protein	
<b>8. Isolation Distance</b>	
AOSCA standard for crop	
Proposed isolation distance	2 MILES
<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
<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	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>	

Additional supportin documentation is found in the summary risk assessment completed on

April 27, 2005

## NEPA Decision Summary for Permit 05-025-01r

SemBioSys has requested a permit to plant up to 10 acres of genetically modified safflower expressing a CBI enzyme with food applications and designated by SemBioSys as SPC. SPC is expressed as a fusion protein with oleosin. Oleosins are a unique class of structural proteins that maintain the integrity of the oil-containing vesicles and are present in all oilseeds and in fruits such as olives and avocados. The permit is strictly for research and development activities, specifically to test for food applications.

Based on a review of Permit 05-025-01r, the following determinations were made:

- According to the U.S. Fish and Wildlife Service [http://ecos.fws.gov/tess\\_public/TESSWebpageUsaLists?state=WA](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 and 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. The SPC native protein has GRAS status and is not known to be toxic to birds and 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 SPC protein 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.
- A PubMed/Medline literature search for toxicity of the SPC protein found only one match and this article indicated that the SPC native protein had no negative impact on rats in a 90-day trial. The full length SPC protein is identical to the enzyme commercially used for food applications and which has GRAS status. GRAS are substances that are **generally recognized as safe** among experts qualified by scientific training and experience to evaluate their safety ("qualified experts"), as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or through experience based on common use in food) to be safe under the conditions of their intended use by the FDA (<http://www.cfsan.fda.gov/~dms/opa-fsis.html>).
- Safflower is mainly (>80%) self-pollinated, and is occasionally pollinated (<20%) by insects. Other than the cultivated variety, there are no known sexually compatible species of safflower resident in the USA. According to the WA State Farm Service Agency office, no commercial fields of safflower were grown in Douglas County in 2004 and the nearest safflower grown in 2004 was approximately 120 miles from the proposed test site. 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.

For the above reasons, APHIS has determined that (1) pursuant to 7 C.F.R. 372, the field trials proposed under permit #05-025-01r 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 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 \_\_\_\_\_