

NEPA Decision Worksheet

Permit # 05-355-02r
 Institution Novoplant GmbH
 Organism Field Pea (*Pisum sativum*)
 Category OO - Pharmaceutical
 Gene CBI

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	X
Not new and prior EA	
4. New or Novel Trait (gene product)	
Never used in a field trial	X
Not new but no prior EA	
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	
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	
Proposed isolation distance	X
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	X
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	

Decision Document for Permit 05-355-02r

MacIntosh and Associates on behalf of Novoplant GmbH has requested a permit to plant two 0.5 acres plots of genetically engineered field pea in Minot County, ND. The purpose of the field release is to grow materials for proof of concept testing, measuring the level of protein in plant tissues and increasing seed for regulatory testing needs for subsequent growing seasons. The genetically engineered field peas will ultimately be incorporated into pig feed in order to protect pigs from bacterial gastrointestinal infections.

Based on a review of Permit 05-355-02r, the following determinations were made:

- The threatened or endangered species known to be present in the county where these field trials will occur are not known to inhabit or forage in field 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.
- This research will be conducted on very small, isolated test plots. The total area of each field plot is predicted to be 106 ft x 171 ft, or less than or equal to 0.50 acres, which includes a 33 ft border of non-transgenic field pea. Total acreage for the two field plots will be less than 1 acre. There will be an additional 50 ft fallow border around each of the field test plots. Test plots will be located approximately 10 to 15 miles apart. Trials of such small size are easily monitored and confined to the permitted area, under environmental mitigation measures specified in the permit application.
- The transgenic field pea lines will produce viable pollen. However, field pea is a self-pollinating crop that produces heavy pollen that does not move far from plant and is not generally insect pollinated. Although there is no isolation distance required by AOSCA for Foundation, Registered or Certified field/feed pea seed crops, these experimental plots will be separated from other feed pea plants in adjacent fields by at least 660 ft.
- The plants to be field tested were transformed by the use of *Agrobacterium tumefaciens*, a plant pest that causes crown gall disease. Since the *A. tumefaciens* strain used was disarmed and eliminated from the tissue following transformation, the plants will not develop crown gall disease. Both of these transformation methods are well characterized, and results in the stable and irreversible integration of the donor genes into the chromosome of the recipient plant cell. These donor sequences are then maintained and inherited as any other genes of the plant cell.
- None of the genes encoding the desired traits or the selectable marker, nor the regulatory elements controlling their expression, have any inherent plant pest characteristics, and they are not likely to pose a plant pest risk.
- The seeds will be transported in a sealed container to and from the field plot in a truck. Planting and harvesting will be done by hand and a bundle thrasher will be used to manipulate the plant. Equipment will be thoroughly cleaned prior to leaving the field test plot. Non-transgenic feed pea plant materials will be

collected prior to transgenic feed pea to avoid any cross contamination. Harvested material will be stored in a locked box or locked freezer within a secured location. All plant material collected for laboratory analysis will be frozen or in some way devitalized (e.g., ground seed) and shipped on dry ice. Plant material not sent to the laboratory will be disposed of by autoclave, composting or buried at the planting site.

- Volunteers will be destroyed by hand or with herbicide treatment. Field pea does not survive the harsh North Dakota winter; therefore, volunteers in the subsequent season are unlikely but are possible in the early fall of the same planting season – one or two months after harvest. The fallow field will be monitored every two weeks after harvest until the first frost and monitoring will continue on a monthly basis for one year after trial termination.
- 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.
- There is no expected impact on non-target organisms since the expression of the protein is only found in seeds and not in any other part of the plant that might be fed upon by insects, mammals or birds. In addition, the gene product proposed for this field trial has not been shown to have toxic effects when ingested. In fact, it is being developed as a possible feed for pigs as a protection against gastrointestinal infections.
- Feed pea is grown for commercial production in North Dakota. In 2002, for example, 157,000 acres of feed pea were planted in North Dakota which constitutes approximately 0.4% of the total farm acreage. There are no wild pea relatives indigenous or introduced into North Dakota that could cross-pollinate with feed peas.
- The described monitoring protocols should be sufficient to allow for the detection and destruction of volunteer field pea before flowering occurs.
- Regulated materials in this field trial are not intended for food and/or feed. Any use of these products for food or feed must be in compliance with the guidelines published in the Federal Register by the United States Food and Drug Administration [57 FR 22984, May 29, 1992].

For the above reasons, APHIS has determined that (1) pursuant to 7 C.F.R. 372, the field trials proposed under permit #05-355-02r 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 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: _____4/10/06_____