

NEPA Decision Worksheet

Permit # 05-340-01r
 Institution
 Organism
 Category
 Gene

05-340-01r
 Dittier von Wettstein
 Horedum vulgare
 OO
 human lactoferrin and lysozyme

1. Confinement	
Confinement and mitigation conditions have been reviewed and determined to be adequate	yes
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)	yes
New or Novel	
3. New or Novel Crop	
Never used in a field trial	
Not new but no prior EA	
Not new and prior EA	yes
4. New or Novel Trait (gene product)	
Never used in a field trial	
Not new but no prior EA	
Not new and prior EA	yes
Raises new issues	
5. Cumulative Effects	
Cumulative effects likely	
Cumulative effects possible	
Cumulative effects unlikely	yes
6. Plant Pollination	
Primarily bee or insect pollinated crop	
Primarily wind pollinated food or feed crop	
Primarily self fertilized food or feed crop	yes
Non-food or feed crop	
7. Effects on Food/Feed Supply	
Known allergen, antinutritive, oral toxicant	
Food safety not established	
GRAS status or approved food additive for native protein	yes
GRAS status or approved food additive for plant produced protein	
8. Isolation Distance	
AOSCA standard for crop	
Proposed isolation distance	yes
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	yes
10. Effects (positive or negative) on other species	
Significant effects expected/observed	
Minimal, non-cumulative effects expected/observed	
No effects expected/observed	
11. Sexually Compatible Relatives	
Relatives within dispersal distance	
Relatives not within dispersal distance	yes
12. Seed Dormancy	
>3 years	
3 years	
2 years	
<2 years	yes
13. Persistence in environment	
Crop can naturalize	
Crop can persist 3-5 years without human intervention	
Crop does not persist without intervention	yes
14. Comments	

Additional supporting documentation is found in the summary risk assessment completed on 9 March 2006.

Signature

Lena C Soileau
 Biotechnologist
 Biotechnology Regulatory Programs
 Animal and Plant Health Inspection Service

NEPA Decision Summary for Permit 05-340-01r

Washington State University has requested a permit to field test genetically engineered barley (*Horedum vulgare*) plants that have been engineered to express either human lactoferrin or lysozyme. The purposes of these field tests are (1) to select for barley lines producing plants that express the human genes while not expressing the herbicide marker gene and (2) to select agronomically suitable plants for subsequent testing in future years.

Based on a review of Permit 05-340-01r, the following determinations were made:

- Confinement and mitigation measures are adequate to contain the transgenic crop to the field test site. Field trials of transgenic barley have been conducted under APHIS authority since 1993. APHIS is familiar with barley biology and methodology to manage confined barley field trials.
- No Federally listed threatened or endangered animal or plant species occur in Whitman County, Washington. Therefore, these field trials will not harm or have adverse or other significant effects on any threatened or endangered species.
- APHIS has prepared environmental assessments on transgenic barley as well as for rice expressing lactoferrin and lysozyme. All these environmental documents are publicly available.
- Barley is self-pollinating and is not generally pollinated by insects. Therefore there is negligible risk of gene flow via pollen. Barley does not hybridize with any other species growing in the United States or elsewhere. Therefore there is no risk of gene flow to wild and weedy species.
- Human lactoferrin and lysozyme are abundant proteins in saliva and human milk. They have no known toxic effects.
- The transgenic barley will be planted and seeds harvested by hand. Therefore there is no chance that seeds will be dispersed via mechanical equipment. Harvested seeds will be threshed and processed inside a designated laboratory. Therefore, viable seeds will not have the potential to be dispersed into the area outside of the test site during processing.
- The size of the proposed field test is very small, only 0.08 acres. Consequently environmental exposure will be negligible.
- Seed dormancy has not been demonstrated with this barley cultivar; therefore, emergence of volunteers will be limited to the following season.
- Cultivated barley does not have the ability to establish itself permanently in natural plant communities. Any accidental movement of seeds will not result in plants from this test becoming established outside of the field test area.

For the above reasons, APHIS has determined that (1) pursuant to 7 CFR 372, the field trials proposed under permit 05-340-01r 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 give the protective and ameliorative measures specified above. Therefore, this field test is deemed confined within the meaning of 7 CFR 372.5.

Signed: __/s/_____

Neil E. Hoffman
Director, Environmental Risk Analysis Division
Biotechnology Regulatory Services

Date: __3.09.06_____