

Worksheet for Determining Whether Field Trials are Categorically Excluded from NEPA

Permit #	04-104-01r
Company	Ventria Bioscience
Organism Lactoferrin	Barley
Transgene	Lactoferrin
<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	
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	X
Non-food or feed crop	
<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	0 feet*
Proposed isolation distance	1320 feet
<b>9. Scale</b>	
>100 acres/trait/crop/company/year	
50-99 acres/trait/crop/company/year	
10-49 acres/trait/crop/company/year	
<10 acres/trait/crop/company/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>	
<p><sup>7</sup> There is a GRAS notice for bovine lactoferrin (GRN 000077)</p> <p><sup>8</sup> Non-hybrid barley is used in this field trial. Non-hybrid requires a minimum isolation distance from other barley varieties of zero feet. Isolation distance for hybrid seed production is 660 feet.</p>	

## NEPA Decision Summary

Based on a review of Permit 04-104-01r, the following determinations were made:

- Only one threatened or endangered animal species is listed as occurring in the county where the trial will be performed. It is a fish that does not occur in the location of the field test site. Therefore these field trials will not harm or have adverse or other significant effects on threatened or endangered species.
- Over fifty field trials have been performed with transgenic barley plants under APHIS authority, and APHIS is familiar with barley biology and methods to manage confined barley field trials.
- Barley is 99% self-pollinated, and is not generally pollinated by insects. Association of Official Seed Certifying Agencies (AOSCA) isolation distances for certification of foundation, registered or certified nonhybrid barley seed is zero feet. Therefore a 50 foot fallow zone and a distance of one-quarter mile from any other barley as proposed by the applicant should be more than adequate to prevent unintended release of the transgenic barley into adjacent fields. This distance is sufficient to reduce outcrossing to insignificant levels.
- Any plant material left after harvest, containing only insignificant amounts of the proteins, will be plowed under the soil surface. The proteins have no known or foreseeable toxic effects, so this method of disposal should have no negative impacts on the environment.
- Bovine lactoferrin, a related gene product, has been granted GRAS status by the FDA. Lactoferrin is also used as a food additive and is sold as a nutritional supplement. No foreseeable effects on other organisms are expected
- The proposed field trial is less than 10 acres. Trials of such small size are and have been easily monitored and confined to permitted areas, under environmental mitigation measures similar to those specified in the permit application and in the standard and supplemental permit conditions.
- In previous field tests and applications, seed dormancy in barley has not been observed.
- There are no sexually-compatible relatives of barley known to exist in the area where the trial 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 #03-365-01r 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 of Regulatory Programs

Date: \_\_\_\_7.19.04\_\_\_\_\_