Worksheet for Determining Whether Field Trials are Categorically Excluded from NEPA

Permit #	03-365-01r
Company	Ventria Bioscience
Organism	Rice
Category	Value added protein for human consumption
Transgene	Lactoferrin

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	
Not new and prior EA	X
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, antinutrative, oral toxicant	
Food Safety not established	X[7]
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	10 feet
Proposed isolation distance	200 feet
9. Scale	
>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
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	
[7] There is a GRAS notice for bovine lactoferrin (GRN 000077)	

Additional supporting documentation is found in the summary risk assessment completed on April 21, 2004

Worksheet for Determining Whether Field Trials are Categorically Excluded from NEPA

Permit #	03-365-01r
Company	Ventria Bioscience
Organism	Rice
Category	Value added protein for human consumption
Transgene	Lysozyme

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	
Not new and prior EA	X
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, antinutrative, 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	10 feet
Proposed isolation distance	200 feet
9. Scale	
>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
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	
[4] EA exists for chicken lysozyme in potato (91-007-06r) and apple (94-039-03r)	
[/] There is a GRAS notice for egg white lysozyme (GRN 000064)	

Additional supporting documentation is found in the summary risk assessment completed on April 21, 2004

NEPA Decision Summary

Based on a review of Permit 03-365-01r, the following determinations were made:

- Four threatened or endangered animal species and one plant species exist or once existed in the county where the trial will be performed. With the exception of the giant garter snake, none of the species listed inhabits rice fields. This snake is carnivorous and thus does not consume rice so would not be expected to be impacted by this field test. Therefore these field trials will not harm or have adverse or other significant effects on threatened or endangered species.
- Hundreds of field trials have been performed with transgenic rice plants under APHIS authority, and APHIS is familiar with rice biology and methods to manage confined rice field trials.
- Rice is highly self-pollinated, and is not generally pollinated by insects. Association of Official Seed Certifying Agencies (AOSCA) certified seed regulations for foundation seed and rice seed certification standards in California mandated by the California Crop Improvement Association require a minimum isolation distance from other rice varieties of at least ten feet when hand- or machine-planted. A 50 foot fallow zone and a separation distance of 200 feet from any other rice (twenty times the AOSCA standard) as proposed by the applicant should be more than adequate to prevent unintended release of the transgenic rice into adjacent fields. This distance between rice fields 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.
- Both bovine lactoferrin and egg white lysozyme, related gene products, have been granted GRAS status by the FDA. Both lysozyme and lactoferrin are used as food additives and sold as nutritional supplements. 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 rice has not been observed.
- There are no sexually-compatible relatives of rice 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_____