

NEPA Decision Worksheet

Permit # 06-305-04r
 Institution Ventria
 Organism rice
 Category OO- value added proteins produced
 Gene synthetic lactoferrin, 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	
Not new and prior EA	X*
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	
GRAS status or approved food additive for native protein	X
GRAS status or approved food additive for plant produced protein	
8. Isolation Distance	
AOSCA standard for crop	10 ft
Proposed isolation distance	1320 ft
9. Scale	
>100 acres/tract/crop/institution/year	X
50-99 acres/tract/crop/institution/year	
10-49 acres/tract/crop/institution/year	
<10 acres/tract/crop/institution/year	
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	

*Previous Environmental Assessments completed for permits 04-302-01r, 04-309-01r, 05-117-01r and 05-117-02r

Additional supporting documentation is found in the summary NEPA assessment completed on November 15, 2006

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NEPA Decision Summary for Permit 06-305-04r

Based on a review of Permit 06-305-04r, the following determinations were made:

- Thirty-six animals and twenty-seven plant species are listed as threatened or endangered in North Carolina. These include bats, whales, various mollusks, the Bald eagle, the eastern cougar, several fish, turtle and bird species, and others. Plant species include a lichen, pitcher-plants, a sedge, sunflower, coneflower and numerous others. Most have not been noted in Washington County where the plantings will occur. None of the species listed grow in or inhabit rice fields or consume rice so would not be expected to be impacted by this planting. 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. Ventria previously grew rice in these same locations in North Carolina in 2005 and 2006 and satisfactorily maintained confined plantings.
- Rice is highly self-pollinated and is not generally pollinated by insects. Association of Official Seed Certifying Agencies (AOSCA) certified seed regulations for foundation rice seed 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 1320 feet from any other rice (one hundred thirty two 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. There are no commercial rice fields in NC and the distance to any research plots is sufficient to prevent outcrossing.
- Ventria monitored for the presence of lactoferrin and lysozyme in soils during the 2005 and 2006 growing seasons and none was found. Because all viable transgenic plant material will be removed from the test site and/or destroyed, there will be no foreseeable cumulative impacts resulting from field trials of these transgenic lines.
- Lactoferrin from cow's milk and related products have been granted GRAS status by the FDA. Lactoferrin is used as a food additive and is sold as a nutritional supplement. It has no known toxic effects.
- Egg white lysozyme and related gene products have been granted GRAS status by the FDA. Lysozyme is used as a food additive and is sold as a nutritional supplement. It has no known toxic effects.
- In previous field tests and applications, seed dormancy in rice has not been observed.
- There is no weedy red rice in the immediate area since rice has not been grown in the area in the past. Ventria scouted for weedy rice in this location in 2005 and 2006 and none was found. Ventria will be required to scout for and removed any weedy rice that is found within the nursery plots and within the 1320 isolation zone.
- An EA was prepared for this gene product produced in rice in this location in 2005. A review of the application submitted by Ventria Bioscience raised no new issues, so the previous EA is applicable to this location.

For the above reasons, APHIS has determined that (1) pursuant to 7 C.F.R. 372, the field trials proposed under permit #06-305-04r 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.

NEPA Decision Summary for Permit 06-305-04r continued..

Signed: _____/s/_____

Neil E. Hoffman
Director, Environmental Risk Analysis Division

Date: 19 Dec 2006