

Ventria NC permit 2008

NEPA Decision Summary for Permit 08-093-108r

This permit submission is essentially identical to permits submitted in 2006 and 2007 for these locations, growing these rice lines, in Washington County, NC.

Based on a review of Permit 08-093-108r, the following determinations were made:

- Ventria is proposing to grow rice lines producing lactoferrin, lysozyme and serum albumin in fields in Washington County, NC.
- 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 requires significant human intervention in order to grow, produce seed and persist in the environment.
- Ventria previously grew rice in these same locations in North Carolina in 2005, 2006 and 2007 and satisfactorily maintained confined plantings. The acreage requested for this permit is essentially identical to that requested in both 2006 and 2007.
- Rice is a highly self-pollinated crop species 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. The nearest commercial rice plantings are several hundred miles away.
- Ventria monitored for the presence of lactoferrin, lysozyme and serum albumin in soils during the 2005 and 2006 growing seasons and none was found. They have previously submitted data verifying that these proteins are only produced in rice seed. 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. Lactoferrin is ubiquitous in the human body and occurs in breast milk, tears, nasal secretions, saliva and other fluids. Lactoferrin is known to have antimicrobial effects but is not known to be toxic to humans or other animals.
- 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. Lysozyme is found in mammalian breast milk, tears, saliva and other secretions. Lysozyme is known to have antimicrobial effects but is not known to be toxic to humans or other animals.
- Human serum albumin is a soluble, monomeric protein which comprises about one-half of human blood serum protein. It is used in medicine to replace blood volume in burn victims, patients suffering acute traumatic shock and those undergoing certain types of surgery. It has no known toxic properties and no reported oral or dermal activities.
- Thirty-six animals and twenty-seven plant species are listed as threatened or endangered in North Carolina (http://ecos.fws.gov/tess_public/pub/stateListingAndOccurrence.jsp?state=NC). These include bats, whales, various mollusks, the eastern cougar, several fish, turtle and bird species, and others. Plant species include a lichen, pitcher-plants, a sedge, sunflower,

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coneflower and numerous others. Most have not been noted in Washington County where the plantings will occur. Only one threatened or endangered species is currently noted for Washington County (<http://www.fws.gov/nc-es/es/countyfr.html>); the Red Wolf (*Canis rufus*). None of the other species listed in NC 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.

- In previous field tests and applications, seed dormancy in rice has not been observed. Volunteer rice has not been noted outside the planted field sites. Volunteer rice has been noted inside planted sites but is managed/destroyed during normal field preparation prior to planting the subsequent rice crop.
- As required, Ventria has monitored for unusual occurrences and deleterious effects on plants, non-target organisms or the environment. None have been noted in several years of conducting these trials.
- There is no known 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, 2006 and 2007 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 foot isolation distance.
- Environmental Assessments have been prepared for these gene products produced in rice in 1996, 2005 and 2007 (permits 96-355-01r, 05-117-01r, 05-117-02r, and 06-278-01r). A review of this permit application submitted by Ventria Bioscience raised no new issues, so the previous EAs are 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 #08-093-108r 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, Environmental Risk Analysis Division

Date: _____