

NEPA Decision Summary for Permit 07-341-103r

Based on a review of Permit 07-341-103r, the following determinations were made:

- Thirty-six animals and twenty-seven plant species are listed as threatened or endangered in North Carolina (http://ecos.fws.gov/tess_public/StateListing.do?state=NC&status=listed). 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, 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 this location in North Carolina in 2005, 2006 and 2007 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. This distance between these rice fields and any potential commercial fields or 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.
- Human serum albumin (HSA) is a soluble, monomeric protein which comprises about one-half of the blood serum protein. The protein is encoded by the *alb* gene and is produced in the liver. It functions primarily as a carrier protein for steroids, fatty acids, and thyroid hormones and plays a role in stabilizing extracellular fluid volume. It is used in medical practice to replace blood volume in burn victims, patients suffering acute traumatic shock, and those undergoing certain types of surgery. It has no reported oral or dermal activities.
- Ventria is growing rice with several new proteins (claimed as CBI) this year in NC. None are listed as toxins in a database search (SWISS-PROT). Additionally, using generally accepted criteria for homology assessment (6 amino acids or greater), none of their proteins share significant sequence homology with known toxins.
- 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, 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 isolation zone.

- An EA was prepared for some of these gene products produced in rice in this location in 2005. A review of the application submitted by Ventria Bioscience, given the small size of this planting (~10 acres) 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 #07-341-103r 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: _____/s/_____

Neil E. Hoffman

Director, Environmental Risk Analysis Division

Date: _____

JMC /s/