

NEPA Decision Summary for Permit 09-196-101r

Based on a review of Permit 09-196-101r, the following determinations were made:

- 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 has previously grown rice in North Carolina in 2005, 2006, 2007 and 2008 and in Kansas in 2007, 2008, and 2009 and has satisfactorily maintained confined plantings. They also grew PMP rice in this location in St. Croix in 2008-2009.
- 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.
- Federally listed threatened or endangered animal species in St. Croix include two types of coral, four species of sea turtle, two species of whale, the St. Croix ground lizard, the brown pelican, the Caribbean monk seal, and the roseate tern. Plant species in St. Croix include Vahl's boxwood and *Catesbaea melanocarpa*. The nearest critical habitat to the trial site in St. Croix is over 1 mile away in the ocean. 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 and no consultation with Fish and Wildlife Service is required prior to issuing this permit.
- Ventria has monitored for the presence of lactoferrin and lysozyme in soils during several growing seasons and none has ever been found. Given the similarity of all the gene constructs in all these rice lines, it is likely that none of the transgenic proteins produced in these rice lines are exuded through the root systems of these plants. 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 in typically consumed quantities.
- 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 typically consumed quantities.
- 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.
- Ventria's proposed planting will be conducted mostly outside of what is typically considered "hurricane season" (June 1- November 30) so dispersal of plant materials outside the trial site is unlikely. Even if plant material were dispersed beyond the trial site by extreme weather events, given the requirement of highly managed fields for growth and persistence of rice plants, it is unlikely that seed or plants would grow or persist.
- There is no weedy red rice in the immediate area since rice has not been grown in the area in the past. 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.
- Environmental assessment (EA) documents have been prepared for some of these gene products produced in rice for locations in NC and KS. A review of the application submitted by Ventria Bioscience, given the small size of this planting (less than 10 acres) raised no new issues, so previous EAs are applicable.

For the above reasons, and those documented on the NEPA/ESA worksheet, APHIS has determined that this permit involves a confined field trial of genetically engineered organisms that do not involve a new species or organism or novel modifications that raise new issues. APHIS has determined that the actions authorized under this permit do not have the potential to significantly affect the quality of the human environment. Therefore, approval of this permit is categorically excluded from the need to prepare an EA (or EIS) pursuant to 7 CFR 372.5., and none of the exceptions to this categorical exclusion apply.

Signed: _____

Michael T. Watson

Chief, Plant pests and protectants branch

Date:

JMC /s/ 7/20/09