

NEPA Decision Summary for Permit 09-307-104r

Based on a review of Permit 09-307-104r, 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 previously grew rice in this area in Kansas in 2007, 2008, and 2009 and satisfactorily managed those plantings. The proposed plantings in 2010 are much smaller than those proposed in 2007, 2008, and 2009 (an Environmental Assessment has been prepared previously for pharmaceutical-producing rice in this county).
- There are no threatened and endangered species (TES) in the action area. There are two TES noted in Geary County, the Topeka shiner (a fish) and the Least Tern (a bird). Given the location of the trial sites, the fish would not be expected to be exposed to Ventria's rice. The Tern feeds primarily on small fish and insects and exposure to Ventria's planting sites would not be expected. Regardless, Ventria's primary products have not shown toxicity to birds in their testing work, although some of their newly developed products have not been evaluated for toxicity. The lack of exposure of these TES to Ventria's rice provides further assurance that there should be no effect on TES from growing these rice lines.
- Rice is highly self-pollinated (the pollen is heavy) 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 Kansas.
- Ventria has monitored for the presence of its engineered proteins (lactoferrin, lysozyme and serum albumin) in soils for several growing seasons and none has been 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. Ventria is using the same regulatory sequences in gene constructs for their newly developed products and it is likely that they would also not be found in soils.
- 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. One of Ventria's proposed uses is as an antimicrobial.
- 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. One of Ventria's proposed uses is as an antimicrobial.
- 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.

- The other gene products being developed (claimed as CBI) may also have pharmaceutical uses. None of these other gene products are commonly characterized as toxins or allergens.
- In previous field tests and applications, seed dormancy in rice has not been observed. Issues related to volunteer rice plants, therefore, are minimal.
- 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 2007, 2008 and 2009 and none was found. Ventria will be required to scout for and remove any weedy rice that is found within these plots and within the 1320 isolation zone.
- An EA was prepared for rice containing several of these gene products produced in rice in this location in 2007. 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, and those documented on the NEPA/ESA worksheet, APHIS has determined that (1) pursuant to 7 CFR 372, the field trials proposed under permit #09-307-104r 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 despite the protective and ameliorative measure specified above. Therefore, this field test is deemed confined within the meaning of 7 CFR 372.5.

Signed: _____/s/_____

Michael T. Watson, Ph.D.
Division Director ERAP

Division Director, Environmental Risk Analysis Program
Biotechnology Regulatory Services

Date: February 3, 2010

JMC_/s/_