NEPA Decision Summary for Permit **#11-256-103r**

Ventria Bioscience (Nathan Fortner) has requested a permit (#11-256-103r) to plant two sites in Geary and Riley Counties, KS, with rice (*Oryza sativa*) plants genetically engineered to produce one of four pharmaceutical proteins.

Based on a review of Permit #11-256-103r, the following determinations were made:

1. **Familiarity of the Crop and the Traits**: 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 Kansas from 2007 through 2011 and satisfactorily managed those plantings. The proposed plantings in 2012 are within the same size range as those grown in previous years, and include the same previous field locations in Geary County approved since 2008 and in Riley County approved since 2011. An Environmental Assessment (EA) has been prepared previously for pharmaceutical-producing rice in Geary County.

   Ventria has monitored for the presence of three 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 newer product (transferrin) and it is likely that it 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. 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. Serum albumin 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. Transferrin is an iron binding protein similar to lactoferrin, although found predominantly in blood serum as opposed to milk. Beginning in 2007, all four of these pharmaceutical proteins have been field tested in KS by Ventria. None of these four gene products are commonly characterized as allergens, nor do they share any amino acid homology with known toxic peptides. A selectable marker gene with a safe history of use, either phosphinothricin acetyltransferase or hygromycin phosphotransferase, was also used in each of the four constructs.

   An EA was prepared in 2007 for rice producing lactoferrin, lysozyme and serum

albumen in this ecoregion. A review of this application submitted by Ventria Bioscience raised no new issues, so the previous EA is applicable to this application.

2. **Method of Transformation**: All transformations were performed with the biolisitc method except for one genotype which was transformed with disarmed *Agrobacterium tumefaciens*. The regulatory elements controlling expression of the four introduced genes originate from rice and *A. tumefaciens*. The target molecules undergo post-translational transport to the rice endosperm and are free of potential contaminants from either human or transgenic animal or plant systems. No other plant tissue/part expresses any of the target molecules at detectable levels. The constructs and their transgenic lines have been grown for several years under greenhouse and field conditions, and have demonstrated gene expression and yield stability. There has been no observable phenotypic difference between these transgenic lines and either their untransformed antecedent rice lines or conventional cultivars. Also, Southern analysis has shown stable chromosomal integration/inheritance of the codon optimized synthetic target genes within the rice genome.

3. **Purpose and Design of the Field Trial:** The purpose of this introduction is for
   - production of rice for product extraction,
   - production of seed for future release permits, and
   - testing and evaluation of agronomic practices.

   None of this rice is used as food or feed. Ventria does not distribute or offer any of its proprietary rice lines to anyone.

4. **Crop Biology and Adequacy of Confinement:** 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.

   There are no commercial rice fields in Kansas. There is no weedy red rice in the immediate area of these field sites since rice has not been grown in the area in the past. Ventria scouted for weedy rice in this area from 2007 through 2011 and none was found.

   The proposed confinement protocols are adequate to ensure that the field test is confined. A 50 foot fallow zone (maintained with a mowed ground cover) surrounding each release site 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 gene flow.

   The 50 foot fallow zone is levied and has no outlet for the irrigation water, therefore any seed that is moved by the recirculated irrigation water will settle within this zone. Measures are in place to keep water from leaving the fields during managed flood

periods. Movement of seed off-field by waterfowl and establishment in other fields is unlikely because: (1) Ventria manages its rice fields to discourage waterfowl from landing during seed set and maturation; and (2) studies as summarized in the permit have shown that viable rice does not pass through the gut of waterfowl (Powers et. al, 1978; Smith and Sullivan, 1980). A more extensive bird digestion study was conducted by Cummings et al. (2008) that concluded that rice seeds, whether free-fed or force-fed, were digested and did not pass viable through the digestive tract of mallard ducks, ring-necked pheasants, red-winged blackbirds and rock pigeons. In previous field tests, seed dormancy in rice has not been observed. Following harvest, the fields will be mowed, burned, and disked, and off-season flushing will be used to accelerate germination of any remaining seed. After harvest the field will be fallowed for one full cropping season, about 18 months. Monthly scouting for 1 year from the date of harvest and removal of any weedy or volunteer rice before it flowers within the field plot and the 1320 isolation zone, particularly the 50 ft. fallow zone, will ensure that there are no issues related to volunteer rice plants.

The rice seed will be ground seeded (not aerially seeded) with a drill seeder or a ground-scale spreader so as not to encroach on the 50 foot fallow zone. Ventria has a closed-loop growing system using dedicated equipment for all planting, harvesting, seed cleaning, seed handling, drying and storage exclusively for its proprietary rice lines. Cleanout and storage of this equipment is described in their Standard Operating Procedures which have been reviewed by APHIS. An APHIS inspection will be required before such equipment can be returned to general use. All production personnel are trained in these methods.

5. **ESA Assessment:** APHIS has reached a determination that this action would have no effect on federally listed threatened or endangered species and designated critical habitat, and is unlikely to jeopardize the continued existence of a proposed species or adversely modify proposed critical habitat; therefore, conference, written concurrence, or formal consultation with either the United States Fish and Wildlife Service, or National Marine Fisheries Service is not required. There are no threatened and endangered species (TES) in the action areas and no critical habitat. There are two TES birds noted in Riley County (the Interior Least Tern and Piping Plover) and a TES fish (Topeka shiner) in both Counties. Given the location of the trial sites, the fish would not be expected to be exposed to Ventria's rice. The Tern and Plover feed 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. Some of the new products in development have not been assessed for food safety. Ventria assessed all for similarity to known toxins and found no protein sequence similarity that would indicate toxicity of any of these proteins. 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.

6. **Cumulative Impacts Assessment:** The incremental impact of the proposed release when added to other past, present, and reasonably foreseeable future actions (regardless of which agency or person undertakes such actions) is not expected to

have a potential for significant environmental impacts. The only past, present, and reasonably foreseeable actions specifically associated with the locations for the proposed releases are those related to agricultural production. The proposed release sites have been used for crop production for over 50 years, and the proposed release will not result in a change in agricultural practices. The size of the present environmental release comprises one-time plantings of up to four genotypes planted on two sites (one in Geary County and one in Riley County) (acreage CBI) for a period not to exceed one year without issuance of a new permit or deregulation, both of which would involve a separate NEPA assessment. The introduced traits, with their lack of toxicity, should not impact biological or physical resources. The location of the trial, the confinement methods and methods for termination of the trial should be adequate to confine the regulated article to the release sites and areas being monitored, should prevent its persistence in the environment, and should prevent gene flow that could impact sensitive markets. APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to create cumulative impacts or reduce the long-term productivity or sustainability of any of the resources (soil, water, ecosystem quality, biodiversity, etc.) associated with the release sites or the ecosystem in which they are situated. No resources will be significantly impacted due to cumulative impacts resulting from the proposed action.

For the above reasons, APHIS has determined that this permit involves a confined field trial of genetically engineered organisms or products that do not involve a new species or organism or novel modification that raises new issues. Issuance of this permit qualifies for categorical exclusion status under 7 CFR § 372.5(c)(3)(ii), and none of the exceptions for categorically excluded actions under 7 CFR § 372.5(d) apply to this action because APHIS has determined that all environmental impacts resulting from the issuance of this permit will be insignificant. APHIS has determined that this action does not have the potential to significantly affect the quality of the human environment, and neither an environmental assessment nor an environmental impact statement is required.

References

Powers, K. D., Noble, R. E., & Chabreck, R. H. 1978. Seed distribution by waterfowl in Southwestern Louisiana. *J. Wildlife Management* 42:598-605.

Smith, R. J., & Sullivan, J. D. 1980. Reduction of red rice grain in rice fields by winter feeding of ducks. *Arkansas Farm Research* 29, 4:3.

Cummings, J.L., Handley, L.W., MacBryde, B., Tupper, S.K., Werner, S.J., & Byram, Z.J. 2008. Dispersal of viable row-crop seeds of commercial agriculture by farmland birds: implication for genetically modified crops. *Environ. Biosafety Res.*7:241-252.

See also the supporting document in the ePermits folder entitled ‘2012 KS References’.

Signed: _____/s/_____

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Date:___2/14/12_____

Prepared by CMCV