Finding of No Significant Impact and Decision Notice

Animal and Plant Health Inspection Service

Issuance of permits to grow genetically engineer rice producing recombinant human lactoferrin, lysozyme or serum albumin

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has received permit applications (APHIS numbers 06-278-01r, 06-278-02r and 06-285-02r) from Ventria Bioscience to conduct field tests with genetically engineered rice lines producing recombinant human lactoferrin, lysozyme or serum albumin found exclusively within its seeds. A description of the field plantings may be found in the attached Environmental Assessment (EA) which was prepared pursuant to APHIS regulations at 7 CFR 372, promulgated under the National Environmental Policy Act. The field tests are scheduled to begin in May 2007 in Geary County, Kansas.

A draft EA was prepared and submitted for public comment published on February 28, 2007 (Docket No. APHIS-2007-0006, 72 FR 8959-8960). APHIS received 20,034 comments during the 30-day comment period. As the result of this comment period, APHIS has revised the EA to include additional analysis on the potential impacts from severe weather, from introduction of rice culture to Kansas, from cumulative impacts, to migratory birds, and to the U.S. commercial rice supply.

APHIS proposed three different actions to take in response to the permit application:

- Alternative 1, the no action alternative, under this alternative APHIS would deny the permit request,
- Alternative 2 the granting of the permit with Supplemental Permit Conditions containing additional environmental safety requirements and a requirement for the filing of field test reports with APHIS, and
- Alternative 3 granting of the permit (as in Alternative 2) with additional requirements for an emergency management plan, specific testing procedures for Ventria's rice lines and BRS auditing of Ventria records.

APHIS' preferred alternative is Alternative 3 to grant the permit with the supplemental permit conditions identified in Alternative 2 and the additional permit conditions described in Alternative 3.

Based upon analysis described in the EA and the three previous EAs on these rice plants, APHIS has determined that the preferred alternative, to grant the permit with conditions outlined under Alternative 3, should not have a significant impact on the quality of the human environment because:

1. Growing these genetically engineered rice plants according to the permit conditions described in alternative 3 are extremely unlikely to impact the commercial rice supply, including organic rice. The rice will be grown, harvested, and processed in ways to reduce the likelihood of this rice becoming commingled with the U.S. commercial rice supply. The field trial is isolated from commercial rice production by over 300 miles. Dedicated equipment will be used for production. Rice is primarily self-fertilizing. The combination of isolation distance, production practices, and rice biology make it extremely unlikely that this rice would impact the U.S. commercial rice supply.
2. Planting these GE rice lines is not likely to significantly impact non-target organisms, including endangered species. Planting rice may change the suitability of the fields for use by birds or small mammals from what it had been in the previous season. Choices such as which crops to plant and which management practices to apply can change the suitability of agricultural land for use by birds and small mammals. The area to be planted in rice is a very small portion of the agricultural land in the county. Planting rice will not significantly change the available corn, alfalfa, or grain sorghum acreage available to wild-life. Lysozyme, lactoferrin and human serum albumin producing rice are not likely to significantly affect wildlife that may feed on it. The proteins are only produced in the seed. The proteins are not toxic to animals. Possible exposure to small numbers of these seeds by non-target vertebrate, invertebrate or aquatic organisms, including birds, would pose no significant risks to these organisms. It may be expected that growing rice in these fields will result in changes in populations of soil micro- and macro-flora and fauna from increased water use.

These changes would not be unexpected as microbial community diversity changes in agricultural soils are commonly known. These local changes are not expected to significantly impact the environment.

3. Lists of TES and proposed TES, as well as an analysis of designated critical habitat and proposed designated habitat, were obtained from the U.S. Fish and Wildlife Service (USFWS). Upon review of the information obtained from USFWS, it was determined that there are seventeen TES in the state and no critical habitat in the proposed planting areas. BRS has reviewed this data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service (USFWS) to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS has reached a determination that release under these permits (06-278-01r, 06-278-02r and 06-285-02r) would have no effect on designated critical habitat or listed threatened or endangered species and consequently, a written concurrence or formal consultation with the USFWS is not required for this project. Therefore, under Alternatives 1, 2 or 3, there should be no effects on threatened and endangered species.
4. Extreme weather events are rare and unlikely to occur in the area of the field trial. It is unlikely that flooding or tornados would contribute to the dispersal of viable seed beyond the field trial area. The combination of the biology of rice and the climate of Kansas further decrease the likelihood that the rice would persist outside of the managed site should it be dispersed. Therefore, there are no significant impacts on the human environment from extreme weather events. However, should an unforeseen event occur, the permit conditions described in Alternative 3 will facilitate a rapid response should an extreme weather event occur.
5. Cultivating rice is new to this area. Water use, pesticide use, fertilizer use are not expected to significantly change due to these field trials. While the patterns in these fields may change, it is a small portion of the overall agriculture in the area and therefore not likely to have a significant impact on the human environment.

Based on the analysis documented in its EA, APHIS has selected the action proposed in Alternative 3. APHIS has determined that the proposed action will not have a significant impact, either individually or cumulatively, on the quality of the human environment and that no Environmental Impact Statement will be prepared regarding this decision.

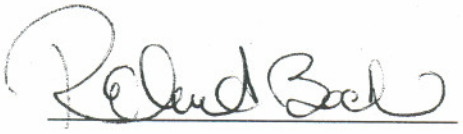
Pursuant to its regulations (7 CFR 340) promulgated under the Plant Protection Act of 2000, APHIS has determined that this field trial will not pose a risk of the introduction or dissemination of a plant pest for the following reasons:

1. Dedicated equipment will be used for planting and harvesting and will be labeled accordingly. This precaution ensures that the transgenic rice plants are not inadvertently removed from the field and therefore eliminates dispersal and gene flow of the transgenic rice plants. Dedicated storage space and equipment must be labeled NON-FOOD/NON-FEED USE ONLY.
2. A perimeter fallow zone of 50 feet will be maintained around the transgenic test site to ensure that transgenic rice are not inadvertently commingled with plants to be used for food or feed.
3. In addition to the large degree of self-pollination of rice plants, other mitigating measures are implemented to prevent gene flow through pollen dispersal to any compatible species or by seed dispersal. The field site will be isolated from sexually compatible species by at least 1/4 mile. The nearest commercial rice production is over 300 miles away. Additionally, the applicant presented a procedure to report to APHIS any unauthorized or accidental release of the transgenic material.
4. The test plots will be monitored weekly for weed, disease, and insect infestation.
5. Unless Ventria grows in the same fields next year, the fields will be monitored for rice volunteers for one growing season after harvest. In the growing season following the harvest, the test area will be left fallow.
6. Rice is a highly domesticated aquatic crop species which grows exclusively in highly managed aquatic ecosystems. Rice is unable to persist in the environment

without continuous human intervention and is not reported to be an agricultural weed outside of rice fields.

7. The proposed cultivation practices involved in growing these transgenic rice plants are similar to growing practices for normal commercial rice and as a result no "unusual" growing practices should be expected to increase weediness or volunteers.
8. Ventria will use a strict chain of custody and closed loop identity preservation system to isolate their product from commercial rice.
9. Ventria is required to have contingency/emergency/ mitigation management plans describing detailed procedures to be undertaken in the event of accidental or unauthorized release or commingling with any other non-PMP material.
10. Ventria is required to have available event specific testing procedures to identify their PMP lines.

For the reasons enumerated above, which are consistent with regulations implementing the Plant Protection Act, these plantings of rice containing recombinant human lactoferrin, lysozyme and serum albumin are hereby authorized.



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Animal and Plant Health Inspection Service
U.S. Department of Agriculture

Date: MAY 9 2007

Attachment
Finding of no significant impact
Response to comments
APHIS No. 06-278-01r, 06-278-02r and 06-285-02r

In response to a notice published in the Federal Register (Docket No. APHIS-2007-0006) on February 28, 2007, APHIS received 20,034 comments on permits 06-278-01r, 06-278-02r and 06-285-02r and environmental assessment during the 30-day comment period closing on March 30, 2007. There were 29 comments from groups or individuals that supported the Ventria's plantings in Kansas. There were approximately 1000 individuals and several rice grower organizations that were opposed to Ventria's proposed plantings but did not cite specific plant pest or environmental risk issues associated with this particular EA. Two public interest groups submitted approximately 18,910 nearly identical form letters from individuals opposed to growing food crops producing pharmaceutical or industrial compounds in general without addressing specific issues within the EA.

Comments supporting Ventria's proposed plantings in Kansas came from 2 farm industry organizations, several business organizations located in Kansas, 9 physicians or other scientific professionals, the Kansas Secretary of Agriculture, one scientific society public policy committee, the mayor of Junction City, KS, representatives from Kansas State University and Kansas University School of Medicine, the President and CEO of Ventria and 4 other individuals. Comments supporting Ventria's plantings focused on benefits from affordable healthcare products, value-added agriculture production, expansion of the bioscience industry in Kansas and economic benefits to farmers and the State. Several comments pointed to Ventria's closed loop production system. Additionally, several comments point to a study published in 2007 documenting the use of lactoferrin and lysozyme products to reduce the duration of childhood diarrhea (Zavaleta, N. et al, 2007). Ventria's comments pointed to financial benefits to farmers, creation of jobs, and other potential benefits to Kansans and rural communities.

Comments from those opposed to APHIS' permitting of Ventria's plantings in Kansas are addressed below.

Comment: The majority of general comments and a comment from one public interest group opposed to this field release expressed the opinion that genetically engineered plants producing pharmaceutical or industrial products are unwanted and are dangerous, potentially causing harm to Americans.

Response: APHIS disagrees with the statement that genetically engineered plants are dangerous and unwanted. First it must be noted that genetically engineered crops have a history of safe use. Over a billion acres have been planted with genetically engineered crops and there are no instances of any physical harm to humans and the environment (Graham Brookes and Peter Barfoot, ISAAA Briefs 36, 2006, http://www.isaaa.org/). Though genetically engineered crops have been adopted on a widespread basis in the U.S. and are accepted by much of the public, APHIS acknowledges that the acceptance is

not universal and that these types of crops are not wanted by some. There appears to be a higher level of concern on the use of food crops for production of pharmaceutical crops. APHIS' role does not entail taking positions on the need or value of such plantings, but rather fulfilling its obligations of addressing safety issues under the Plant Protection Act and other relevant statues. Ventria plantings include the following numerous redundant safeguards to mitigate the potential harm to humans or impacts to the environment and to assist APHIS in assessing Ventria compliance:

1. Surrounding the field with a 50 foot fallow zone;
2. Restrictions on the production of food and feed crops at the field test site and perimeter fallow zone in the following season;
3. Mandatory use of dedicated planters and harvesters in the permitted test sites;
4. Mandatory use of dedicated facilities for the storage of equipment and regulated articles for the duration of the field test. Facilities must be cleaned according to APHIS approved protocols prior to general use of the facilities;
5. Mandatory cleaning procedures to minimize the risk of seed movement by field operations or equipment (such as movement of seed on tires of tractors, clothing, etc.);
6. Mandatory training programs approved by APHIS to ensure that personnel are prepared to successfully implement and comply with permit conditions;
7. Multiple field and permit inspections to ensure permit compliance;
8. Use of low production geography. No rice production occurs in the state of Kansas. The nearest commercial rice production is over 300 miles away;
9. No weedy red rice or other sexually compatible relatives are currently found in Kansas.
10. Strict chain of custody and closed loop identity preservation systems.
11. APHIS will require contingency/emergency/ mitigation management plans describing detailed procedures that Ventria will undertake in the event of accidental or unauthorized release or commingling with any other non-PMP material.
12. APHIS will require that Ventria have available event specific testing procedures to identify their PMP lines.
13. APHIS will supply labels/placards to Ventria for use on dedicated storage/ dedicated use equipment indicating for NON-FOOD/ NON-FEED USE ONLY.

These numerous safeguards and compliance requirements are designed to exclude any commingling of pharma crops with food crops. In the unlikely event that all these redundant safeguards fail, very little of the plant material is expected to commingle with food crops because there is no other rice production in the entire state of Kansas and rice is poorly adapted to grow under the same cultivation conditions used for neighboring crops.

Comment: One comment was received that indicated some concern about red rice as a weed in Kansas.

Response: As noted in a previous EA (05-117-01r, response to comments), weedy/ red rice is a weed complex consisting of several *Oryza* species and biotypes. Red rice is not currently present in Kansas because it only occurs in areas where rice has previously been grown. Ventria vigorously controls its seed production to be free of red rice and scouts within ¼ mile of the field test site for red rice and will destroy red rice plants should any be found.

Comment: One commenter suggested that APHIS should have assessed the possibility of effects on whooping cranes, an endangered species. The commenter went on further to determine that sightings of whooping cranes are extremely rare in Geary County.

Response: As noted by the commenter, whooping cranes are extremely rare in Geary County, Kansas. Animal feeding work on chicks (Huang, et al., 2002) demonstrated a beneficial effect of long-term feeding of its lactoferrin and lysozyme rice on chick health. Serum albumin has no reported oral or dermal activities and would be extremely unlikely to have any effect on any animals if consumed. These points, coupled with Ventria's bird deterrence methods and the very short time when seed would be available for consumption (immediately after harvest) strongly suggests that the likelihood of any effect of these trials on whooping cranes is extremely remote.

Comment: Some comments were made that the FDA should never allow these sorts of field trials.

Response: As the regulations under which these trials might be allowed are strictly USDA-APHIS authority, the FDA is not directly involved in either approving or not approving such trials.

Comment: Some comments were received indicating general disapproval of allowing these trials in California.

Response: As noted in the EA, these permit applications were submitted for trials in Kansas.

Comment: One comment was received that claims that all open air field testing cannot be confined and that APHIS should remedy what they view as a contradiction between "confined field release" and "release into the environment."

Response: APHIS disagrees that there is a contradiction. The following definition of "confined" has been agreed upon by the U.S. and Canada, has been accepted by the North American Plant Protection Organization (NAPPO):

> Describes a field test or other environmental release of a transgenic organism performed under terms and conditions intended to minimize establishment and spread into, and interaction with the environment of the transgenic organism and any progeny derived from it.

Comment: Two commenters made reference to alleged failure of USDA to inspect previous Ventria trials in 2005 and failure of Ventria to submit appropriate reports, as required, and cite a Union of Concerned Scientists (UCS) report as evidence of this. This report also alleges failure of either Ventria or APHIS to communicate about possible loss of trial confinement resulting from Hurricane Ophelia in September 2005.

Response: APHIS denies the accuracy of the UCS report based on Agency records. For most field trials of annual crops engineered to produce pharmaceutical and industrial compounds, APHIS conducts five inspections throughout the growing season and two in subsequent years as follows: 1) at pre-planting; 2) at planting; 3) during the growing season, usually around the time of flowering; 4) at harvest time; 5) post-harvest, to verify cleanup at the field site; and two inspections in a subsequent year(s) to monitor for volunteers.

The Freedom of Information Act (FOIA) request from UCS (upon which their report was based) was received before all of the growing season inspections were done and nearly a year before the last two inspections (which are done to ensure that no GE material persists after the end of the field trial). Only information that has been collected on or before the request date is provided.

APHIS provided UCS with reports of the four inspections for all three trials that had occurred before the date of their FOIA request: the pre-planting and planting inspections, which both occurred on the date of planting (two separate reports); the mid-season flowering report; and the harvest report. The remaining three inspections were completed after the date of the FOIA request: post-harvest (March 2006) and two volunteer monitoring reports (June and October 2006).

Regarding Ventria's required submissions; supplemental permit conditions require Ventria to submit five reports to APHIS: a pre-planting notification, a planting report, a pre-harvest notification (or termination report), a field test data report, and a volunteer monitoring report. A sixth report is only required in the event of an accidental unauthorized release.

Ventria submitted all required reports and is fully compliant with the reporting requirements specified in its supplemental permit conditions. APHIS misinterpreted UCS' original FOIA request and did not provide all of the applicant reports. Later, UCS clarified that they also wanted applicant reports and BRS provided those materials to FOIA. APHIS' FOIA office met with UCS to help prevent any future miscommunication.

Regarding communications about Hurricane Ophelia, BRS provided information to UCS showing that we inquired as to damage after the hurricane and found that the county where field tests were conducted was not affected. APHIS has regional biotechnologists available to assess such incidents in a timely manner.

BRS is committed to ensuring safety in the oversight of field tests and other activities involving GE plants. Since 1985, BRS has carried out an effective regulatory program for plants and plant products derived through genetic engineering. During this 20-year period, BRS has developed and refined risk-based regulatory requirements, performance standards and permit conditions. These requirements are based on the best available science and have a proven track record of effectiveness.

Comment: Several commenters pointed to recent court cases in which USDA-APHIS has received unfavorable judgments and these cases alone should be a basis for denying Ventria's permit applications until all issues associated with those cases are resolved.

Response: APHIS is aware of the issues associated with the cases noted relating to field trials in Hawaii and Oregon and a determination for nonregulated status for an herbicide tolerant alfalfa. APHIS has made a number of changes to its processes and procedures designed to address the findings in those cases. APHIS continues to improve its procedures to address all legal statutes in the most appropriate ways while continuing to protect U.S. agriculture and the environment. As most commenters are aware, APHIS has numerous redundant measures and procedures in place to prevent the introduction of PMPs into agricultural products or commodities. As noted from APHIS' website in a publication on permitting for pharmaceutical and industrial-producing plants (http://www.aphis.usda.gov/publications/biotechnology/index.shtml):

> APHIS imposes more stringent confinement measures than for field tests of conventional GE crops, such as increased isolation distances and fallow zones, and increased inspections and oversight.

The confinement measures are described in the permit and EAs and the extent of reporting requirements and APHIS inspections are described in the proposed supplemental permit conditions (Appendix 4 of the EA).

Comment: One commenter noted that the gene for each individual permit was not reported.

Response: APHIS acknowledges this oversight and has made this correction in the final EA as to which permit is for which gene product.

Comment: One commenter contends that a single EA is inadequate to address issues related to 3 different permits with 3 different proteins.

Response: APHIS disagrees with this comment. An EA needs to address the relevant issues and can be contained in one or multiple documents. APHIS has previously covered

issues related to similar field tests in prior EAs for permits 05-117-01r, 05-117-02r and 96-355-01r. Many of the primary issues focus on the biology of rice, the location of the plantings, and the measures employed to ensure confinement. These are common to the three permits and proteins. Protein specific issues are also addressed. APHIS therefore believes the current EA adequately addresses issues relevant to the current plantings which largely involve the new site location.

Comment: Two commenters indicate that without knowledge of the acres to be planted by Ventria, the public is unable to evaluate the risks of these plantings or confinement measures and that APHIS has misrepresented the size of the proposed plantings in Kansas.

Response: It is extremely common that permit applicants request larger acreages in their original permit applications than they intend to plant. Ventria's original applications were submitted on October 5 and October 12, 2006, more than 6 months ago. Subsequent to those submissions, Ventria indicated to APHIS-BRS that their plans had changed significantly and that they would only be able to plant a fraction of what they had originally planned. Ultimately, what is presented in the draft EA is accurate and the planned plantings for 2007 are similar in size and scope to previous and currently planned plantings in North Carolina, however, APHIS did consider the entire requested acreage when preparing this EA.

Comment: One commenter claims that APHIS has failed to evaluate the controversial nature of this permitting action.

Response: As noted in the introduction to our response to comments, over 18,000 nearly identical comments were received that indicated opposition to approval of these plantings. Additionally there were many other individual comments indicating general opposition to these trials. However, mere public opposition to or criticism of an APHIS action analyzed under NEPA is not the same thing as a "highly" controversial environmental impact. Controversy in the NEPA context refers to scientific controversy. Few of these comments indicated controversy surrounding the scientific issues relating to confinement and environmental effects of these trials and the ability of Ventria to manage their plantings. There are in fact numerous confinement methods that Ventria employs that will be effective; extreme isolation from commercial rice growing regions, the use of a crop which is highly self-pollinating, use of a 50-ft fallow area surrounding the fields, as well as use of water soaked fields which discourages casual intrusion into plots by many animals. While many commenters speculate on the hypothetical risks to human health and the environment, little evidence is provided that supports these claims. Ventria has, in fact, conducted an approved human clinical trial of its lysozyme and lactoferrin products to alleviate childhood diarrhea (Zavaleta, et al., 2007). Additionally, Ventria has been conducting similar field trials for several years and has not reported any adverse effects of their plantings on either animals or the environment surrounding their trials (as they are required to do if they occur). Twenty-nine comments were received in support of allowing Ventria's plantings. A number of these were from scientists and medical doctors at universities or medical schools as well as the Kansas Department of Agriculture. These

comments support conclusions reached by APHIS in the EA and support the ability of Ventria to successfully manage these trials.

Comment: Several comments suggested that the EA is inadequate because it does not adequately consider the socio-economic impacts that could be caused by permitting this field trial.

Response: APHIS understands the concerns of the commenters. However, analyzing the full socioeconomic impacts of an action goes well beyond the intent of an EA. CEQ's own guidelines suggest that:

> Since the EA is a concise document, it should not contain long descriptions or detailed data which the agency may have gathered. Rather, it should contain a brief discussion of the need for the proposal, alternatives to the proposal, the environmental impacts of the proposed action and alternatives, and a list of agencies and persons consulted. Section 1508.9(b). (http://ceq.eh.doe.gov/nepa/regs/40/30-40.HTM#36)

As has been noted in the referenced EAs, seed that may be picked up by birds or other animals and deposited in adjacent fields (which may contain corn, soybeans or wheat) is extremely unlikely to grow and produce seed in a field designed to grow these other crops. Because the cultural conditions in such fields are suboptimal for rice, any rice that would be deposited by animals would occur late in the season making a rice crop in the current year impossible, and as rice does not have dormancy or capability to overwinter in Kansas, rice distributed by animals would not produce a crop in the following year either. APHIS is charged with regulating based on scientific data. APHIS has reviewed the scientific literature, evaluated the applicant's permit, and considered the potential environmental impacts that may occur as the result of this action (granting a permit). APHIS has found there should be no significant impacts associated with this action, and therefore there should be no economic effects as a result of environmental impacts.

Comment: Several comments suggested that food and feed crops should not be used to produce PMPs and that the practice of growing these sorts of crops should be banned. Commenters focused on winds or severe weather events blowing rice seeds into neighboring fields of corn, soybeans or wheat.

Response: For genetically engineered crops which are not being developed for food and feed, APHIS relies on strict confinement and compliance measures to ensure that these crops do not enter the food and feed supply chain (see Appendix 4 of the EA outlining APHIS' proposed Supplemental Permit Conditions). APHIS does not restrict the type of crop that is used to produce a particular protein; however, APHIS does consider the biology of the crop chosen in devising confinement measures. Applicants are free to develop the plant that best suits their production needs but bear the responsibility for keeping their crop confined. Ventria has been growing rice under permit for several years and has adhered to the strictest confinement measures. Additionally, Ventria has moved its operations great distances away from commercial rice operations in order to ensure that their rice does not mix with commercial rice. The nearest commercial rice operations

to Ventria's location is well over 300 miles away (see map on page 18 at the end of this document). Historically, these measures have worked to ensure the segregation of this product from food and feed rice and it is reasonably foreseeable that they will continue to be effective in the future given current confinement and isolation measures in place. In all the trials that Ventria has conducted in the past, they have never noted escaped rice plants in fields adjacent to their plantings. The rice variety used by Ventria has specialized requirements for successful growth, namely a requirement for very wet soil which would be detrimental to corn, soybeans, or wheat. This striking difference in cultural requirements makes it unlikely that any rice would produce seed in neighboring fields of these crops under the remote chance that seeds were blown into such fields.

Comment: Several commenters argued that these plantings should not be allowed because the proteins produced in Ventria's rice have not been given a food safety assessment by FDA. They point to a Generally Recognized as Safe (GRAS) submission for recombinant human lactoferrin that Ventria ultimately withdrew from further FDA consideration.

Response: The safety and regulatory status of recombinant human lactoferrin for use in food and feed falls under the regulatory purview of the Food and Drug Administration. As incorporated by reference into the draft EA from permit 05-117-01r, any food or feed uses of rice containing recombinant human lactoferrin must comply with the requirements of the Federal Food, Drug and Cosmetic Act. Comments on the safety and regulatory status of recombinant human lactoferrin for use in food and feed are outside the scope of this permitting procedure; therefore, these comments do not change the outcome of APHIS' environmental assessment.

The permitted field plantings have strictly mandated measures to confine the crop and mitigate the possibility of commingling with food products. The chain of events suggested by commenters concerning Ventria rice traits entering the market place are remote and highly speculative and are therefore not reasonably foreseeable as an effect in connection with this action. Therefore an FDA assessment is not needed prior to permitting this action.

Moreover, in its draft environmental assessment, APHIS did consider measures to ensure that seeds grown under permit would not be mixed with seeds intended for human or animal consumption. Those measures are further described earlier in these responses to comments (pages 1-2).

Comment: One commenter claims that the EA is arbitrary and capricious because it fails to address environmental impacts of rice cultivation where no rice production ever existed. The commenter suggests that APHIS analyze aspects of rice production related to water use, pesticide use and an extended list of possible environmental impacts. The commenter lists at least 3 rice pesticides and suggests that APHIS analyze the possible environmental impacts of each.

Response: APHIS has included a section in its final EA (pp. 11-13) which addresses issues related to the environmental impacts of Ventria's rice production compared to other types of agricultural production. In summary, with the exception of increased water use, the cultivation of rice is fundamentally similar to the other types of agriculture production currently employed in Kansas.

As noted elsewhere in this response to comments, rice is grown on approximately 3 million acres in the U.S. and has been for many years. Rice growers apply water, pesticides and fertilizers to their fields on a regular basis, as do growers of other annual crops such as corn, soybeans and wheat. The land on which Ventria will be growing their rice is land that has historically been used and managed for agriculture for over 50 years; as such, it too has had applications of pesticides and fertilizers over a long period of time. This is traditional farming, using traditional methods, and is certainly not novel. The Kansas Department of Agriculture oversees water, pesticide, fertilizer and environment issues (http://www.ksda.gov/) and it can reasonably be expected that they will be appropriately consulted regarding aspects of these trials related to these issues. The Department has been in discussions with Ventria and has shown full support for Ventria's work in Kansas (comment 0140 on this docket from the KS Secretary of Agriculture). As Ventria has in the past, it can further be expected that they will follow all applicable state and federal regulations. Regarding the commenter's noted pesticides, Ventria has no current plans to use these in its Kansas operations. Even if it did, however, use of the pesticides is regulated and allowed by the Federal government and is further overseen by the Kansas Department of Agriculture (http://www.ksda.gov/pesticides%5Ffertilizer/).

Comment: One commenter claims that the EA is arbitrary and capricious because it fails to address issues related to climate change and rice production. The commenter focuses primarily on methane (a greenhouse gas) emissions from rice paddies.

Response: Ventria's original permit submissions for these plantings requested 3200 acres. The acreage of rice planted in the U.S. in the 10 years from 1997 to 2006 varied from a high of 3,384,000 acres in 2005 to a low of 2,838,000 acres in 2006, a difference of 546,000 acres in just that one year (http://www.nass.usda.gov/QuickStats/PullData_US.jsp). Averaged across those 10 years, yearly acreage amounts to approximately 3.2 million acres. In 2003, global rice acreage was 307 million acres (http://nue.okstate.edu/Crop_Information/World_Wheat_Production.htm). Ventria's request for up to 3200 acres amounts to approximately 0.1% of that U.S. yearly average rice production and only 0.001% of global rice production. In terms of the contribution to global warming from rice production, the Ventria field trial is inconsequential.

Comment: Some comments noted concern that rice containing the lactoferrin gene would be more competitive, due to the protein's anti-microbial properties. The commenters assert that this character in weedy or red rice would result in a more competitive weedy strain by conferring disease resistance.

Response: This comment is highly speculative and requires a series of unlikely events that makes this possibility not reasonably foreseeable. First there are no weedy rice relatives in Kansas so gene flow will not occur. Second, Ventria has mandatory requirements to scout and destroy weedy/ red rice within 1320 feet of the field test and uses management practices such as irrigating fields in the off season to keep weedy rice from establishing. Third, the rice varieties containing the lactoferrin gene show no increase in competitiveness compared to conventional varieties after observations from 6 years of testing. Thus, there is no reason to believe lactoferrin will increase the competitiveness of weedy rice. Fourth, many rice diseases involve infection of the root and shoot tissue. As the lactoferrin gene is only expressed in the seed, there is no theoretical basis for why lactoferrin would confer disease resistance in other tissues. Fifth, there is no evidence that weedy rice populations are limited by disease susceptibility. Sixth, weedy rice is a poor competitor outside of cultivated rice fields because it requires specialized conditions for growth. That is even in the unlikely event weedy rice acquired the lactoferrin gene, there is no reason to believe that such rice would now be able to survive outside of rice cultivation.

Comment: Two commenters claim that APHIS has failed to make Ventria's permit application, including SOPs, publicly available and that they are therefore unable to assess the adequacy of either APHIS' analysis or Ventria's product control measures.

Response: While it is true that APHIS has not posted Ventria's application on its website, APHIS has never posted permit applications and SOPs, as the commenter implies. As is standard practice, such materials are available if requested, under the Freedom of Information Act (FOIA), which considers the possible Confidential Business Information (CBI) limitations in fulfilling requests.

Comment: One commenter claimed that relying on previous EAs for these trials is arbitrary and capricious.

Response: CEQ, in fact, strongly encourages incorporation by reference to avoid duplication and to keep environmental documents short. As noted in the EA, assessments for many of the issues covered in the referenced EAs are unchanged. None of the issues incorporated by reference (Section VI of the draft EA), persistence in the environment, potential for gene transfer, fate of transgenic DNA, etc., would be any different in Kansas than they would in NC or CA. The plants are basically identical and the environments where they will be grown in Kansas have been in agricultural production for over 50 years. Referenced materials have been readily available on the APHIS-BRS or Virginia Tech websites (http://www.aphis.usda.gov/brs/ph_permits.html, http://www.isb.vt.edu/cfdocs/fieldtests3.cfm).

Comment: One commenter suggested that EPA should also address environmental impacts based on the pesticidal properties of lactoferrin and lysozyme.

Response: Both lactoferrin and lysozyme proteins have been shown to have antimicrobial properties and some research has been done on the use of these to confer resistance to disease in plants

(http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=15864332&dopt=Abstract, http://news.ncsu.edu/releases/2007/march/046.html, http://cat.inist.fr/?aModele=afficheN&cpsidt=2750386, http://www.springerlink.com/content/60n23216370nr254/). While these studies indicate a potential for lactoferrin or lysozyme to confer some degree of bacterial, viral, or fungal resistance, Ventria makes no such claim their rice lines have any increased resistance. Ventria has submitted data to APHIS in its applications demonstrating that none of the recombinant proteins are secreted through the rice plant roots, therefore effects on rhizosphere soil microorganisms would not be expected. Production of all of these proteins is limited, by design, to the developing seed and seed husk (EA for 05-117-01r, p. 12 and EA for 05-117-02r, p. 12). None of the genetic changes in these plants is expected to alter the susceptibility of these plants to disease or insect damage. Under the terms of this and previous permits, Ventria is required to report any such unanticipated effects to APHIS and there have been no such notations to date.

The regulatory authority that EPA works within in dealing with pesticides is the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA applies when there is a claim or intended use of a material as a pesticide (http://www.epa.gov/pesticides/about/index.htm). As there is no claim or intended use of lactoferrin and lysozyme as pesticides, EPA has no authority to regulate these proteins under FIFRA, nor are these proteins subject to registration.

Comment: Some commenters were concerned with the possibility of movement of seeds by animals and birds.

Response: While it is a possibility that animals may move seeds, commenters provided no evidence that seed so moved could be reasonably expected to grow, persist, and produce more seeds. Only the seeds produce recombinant protein and unless more seeds are produced, contamination of the food supply via animals moving seeds is not reasonably foreseeable. Rats, including the Norway rat, may on occasion be a pest in rice fields however several unlikely events would need to occur in order for these rice lines to persist outside the field trial area. First and foremost, seed would need to remain undigested and viable after ingestion and defecation. The commenter has provided no citation that this occurs widely with rice. Second, seed would need to be deposited in an environment conducive to seed germination, growth and seed set; another set of unlikely events given that fields adjacent to Ventria's rice fields will be managed primarily for corn, soybean or wheat. While one commenter makes note of a 2-3 mile foraging distance for the Norway rat, its typical territory is much smaller, up to ~50 meters (Myers, P. and D. Armitage. 2004. "*Rattus norvegicus*" (On-line), Animal Diversity Web. Accessed April 02, 2007 at http://animaldiversity.ummz.umich.edu/site/accounts/information/Rattus_norvegicus.html.). This species of rat typically has a relatively short lifespan in the wild (http://www.ratbehavior.org/WildRats.htm) and it can be expected that both Ventria and adjacent growers have active pest/rodent control programs. Normal agronomic practices in surrounding fields (tilling, herbicide application, plowing, etc.), whether they are corn, soybeans or wheat, would be expected to remove any volunteer rice. If animals move any

rice, it would be the rice that remains in the field after harvest. As harvest occurs late in the season, such rice cannot reasonably be expected to grow into a crop because Ventria's rice varieties require at least 4 months of warm temperature for maturity and Kansas winter temperatures would destroy the crop prior to seed set. Similarly, Ventria's rice lines do not exhibit extended dormancy and exposure to moisture leads to germination so no rice can reasonably be expected to overwinter and grow the following season. Even if such rice did move into another field, overwinter, and germinate the following season, it would not reasonably be expected to survive the weed control practices applied to surrounding fields such as corn, soybean, or wheat. Ventria has not noted volunteer rice within their ¼ mile scouting distance over the course of several years of conducting similar plantings. Finally, in order for there to be a significant impact, these plants would need to persist in a favorable growing environment (i.e., a rice field). Given the location in Kansas, far away from commercial rice operations the likelihood of persistence of these rice lines outside the planting areas is not reasonably foreseeable and therefore movement of seeds by animals should not result in significant impacts.

Comment: There were several comments concerned with movement of grain by birds. Commenters speculate that birds may be sources of movement of viable seed well away from the planting sites. Possible mechanisms were by carrying grain on their feathers, on muddy feet and through defecation of undigested viable rice seed. Additionally commenters postulate that un-retrieved birds killed by hunters and predators can have undigested seed in their digestive tracts and this avenue would be a source of grain moving off the planting sites. As they further note, "…ability to disperse viable grains of rice, however, remains untested." Another paper cited by one commenter referenced a 2002 study on ducks and their potential to disperse wetland plant species seeds widely (Mueller and van der Valk, 2002)

Response: This issue was addressed in the 2005 Environmental Assessments (p. 9 and p. 18-19 of EA for 05-117-01r and p. 8-9 and p. 18 of EA for 05-117-02r) and referenced in this EA. Rice seed is a highly digestible grain that does not pass in a viable form through waterfowl, the most likely animals to consume grain in rice fields (Powers et al., 1978; Smith and Sullivan, 1980; Drobney, 2005). Powers et al. (1978); Smith and Sullivan, (1980) and Drobney (2005) checked the gut of 51 hunter killed waterfowl, and identified, counted and germinated the seed found. They found that the seeds of red rice, which are large and have a thin seed (similar to Ventria's rice lines) coat did not pass intact. Similarly, John Cummings of the APHIS Wildlife Services, National Wildlife Research Center performed a study where rice was fed to mallards, pheasants, blackbirds or pigeons and in no case did viable rice pass through the digestive tract (unpublished data) although viable seed was retained in the esophagus, crop, and gizzard. Based on these observations, APHIS concludes that it is not reasonably foreseeable that birds will spread viable rice seeds by defecation. The study cited by the commenter, (Mueller and van der Valk, 2002) where 1-16% of recovered seed remained viable did not examine rice and is therefore not a pertinent reference.

APHIS acknowledges that viable seed may be spread by birds that have fed on the Ventria field trial, are shot within 12-24 hours of feeding, and are not retrieved. APHIS

also acknowledges that some viable seed may move after attachment to bird's feet or feathers. Ventria proposes precautions to discourage birds feeding while the grain is mature and discourage waterfowl from entering the fields by keeping the fields dry in the fall and winter. After the grain is mature but before harvest, methods such as using timed air cannons, fluorescent flagging, chemical, electrical or mechanical repellents will be employed to discourage birds in the field. Furthermore, as soon as possible after harvest, the field will be tilled or burned to minimize the time animals can feed on the residual crop and to limit the amount of rice accessible to animals. More importantly, the likelihood that seeds within the carcasses of these birds, or seeds that have fallen from their feet or feathers would germinate and grow to seedset late in the season is not reasonably foreseeable because the most likely time for consumption of viable rice grains by birds would be close to harvest and any growing plants would be killed by winter temperatures. Additionally, because rice requires specialized cultural conditions for growth, it is unlikely that any plants would grow and persist in neighboring crop fields. The nearest commercial rice growing regions are over 300 miles away in southeast Missouri, central Arkansas and northeast Texas/southwest Arkansas (Livezey, J. and L. Foreman, 2004, see map following references). In the unlikely event these plants did get moved 300 miles to a rice field and did begin to grow, they would be out of synchronization with the plants in the cultivated rice operation and would be managed as weeds prior to the planting of the rice crop. Therefore APHIS concludes that movement of the seeds by birds, the subsequent transportation to an environment conducive to germination of those seeds, and persistence in the environment is of very low probability and not reasonably foreseeable.

Comment: Several commenters expressed concern about the possibility of dispersal of seed through incorrect handling to or from planting sites. Comments suggested that seed may be lost being transported either to or from the fields where plants will be grown. These commenters, as well as others, point to recent instances of commercial rice seed contamination with unapproved genetically engineered rice.

Response: As stated in the referenced Environmental Assessments from 2005 (EA for 05-117-01r, p. 9 and 19 and EA for 05-117-02r, p. 9 and 18), the most reliable means of preventing potential human errors is to maintain and reinforce stringent standard operating procedures. Ventria has submitted Standard Operating Procedures (SOPs) as a part of its permit submissions (06-278-01r, 06-278-02r, and 06-28502r) and these have been reviewed by APHIS. Ventria's current seed production work has occurred either in Ventria's contained facilities (not requiring permit by APHIS) or on APHIS-permitted sites in North Carolina. Neither location has commercial rice seed production in the vicinity so issues related to outcrossing are not foreseeable. Ventria has intentionally located operations far from commercial rice production (over 300 miles away for the KS location) in order to eliminate the possibility of such an occurrence. Ventria maintains a closed loop system for growing, harvest and transport of its rice products. They use dedicated storage facilities and equipment for production, as required by USDA/APHIS. Ventria describes movement of seed and the equipment used to transport seed in their SOPs for these permits. Ventria's procedures have been assessed by APHIS and have been found to be adequate to contain rice during transport to and from Ventria's facilities

and planting sites in NC, CA and KS, including both pre-and post-harvest transport within the state. Seeds are moved using different methods depending on the size of shipments. Seed may be transported in poly bulk bags in fully enclosed vehicles or in a fully enclosed hopper-bottom trailer (described in permit applications). In addition to having stringent SOPs, all the harvested seeds will be stored in dedicated storage areas and most seeds (except those retained for future plantings or analytical work) will be processed at their central processing facility in Junction City. During processing (in Ventria's enclosed facility), the seed will be dehusked using a dedicated dehusker and will be milled in a dedicated staging area (in Ventria's enclosed facility) using a dedicated mill owned by Ventria. Only Ventria personnel or employees assigned and trained by Ventria will be allowed to handle any seeds. Employing these methods along with following their SOPs will minimize the possibility of human error moving seed into other fields or losing seed during transport. USDA/APHIS has overseen Ventria's operations for several years in several states and has not noted significant issues related to their containment of materials in storage, transportation of materials to or from planting sites or confinement of materials in their plantings. Ventria has a valid movement permit (issued 2/2/2007) (06-319-101m), which describes how they will move regulated materials between their CA, NC and KS sites. Their release permit application describes movement of their materials from their dedicated storage site in Junction City to their planting sites and APHIS has determined that their procedures are adequate to maintain control of their materials.

Comment: Many commenters raised concerns about locating these trials in Kansas where high winds and tornadoes are considered common. One comment noted that Kansas averages 47 tornadoes per year. Several commenters made reference to "Tornado Alley." Several comments also indicated that floods were of concern and could wash away viable seed and/or plants leading to plant establishment outside the planted fields.

Response: APHIS has included a section in its final EA (pp.14-15) which addresses issues related to extreme weather events and the likelihood of persistence of rice in sites outside of Ventria's managed plantings. In summary, however, the likelihood of high wind or flood events spreading viable plants or seed is small and the likelihood of persistence of such viable plants or seed outside of the planting areas is extremely small because the catastrophic events leading to the distribution of the seed are likely to ruin the crops where the seed is deposited. As rice does not persist in the environment without human intervention, APHIS concluded that it is not reasonably foreseeable that rice would be blown out of the Ventria field trial by extreme weather and survive to flowering in proximity to other rice plants.

Comment: One commenter claims that APHIS has failed to adequately analyze potential harm to wildlife from consuming Ventria's rice. The commenter particularly notes that lactoferrin can promote the growth of some human pathogens and speculates that the growth of some animal pathogens might be similarly promoted. The commenter further speculates that this may exacerbate a diseased animal's infection and lead to increased mortality. They have not provided citations or references to support this hypothesis. The

commenter also seems to believe that Ventria will be taking no steps to exclude animals from their planting sites.

Response: As has been noted in previous EAs, Ventria does employ both active and passive measures to exclude animals from their field plots (EA for 05-117-01r, pp. 18-19 and the attached response to comments noting use of air cannons and other repellants). As noted previously in the same response to comments, assessing pathogen populations in an animal infected with any number of disease-causing agents can be extremely difficult. There is uncertainty in knowing what populations of what animals may be infected with a pathogen that may increase in response to exposure to lactoferrin. APHIS will assume, however, that a small percentage of a population of animals may be infected with some disease-causing organism. As lactoferrin is also known to have anti-microbial properties, one can additionally assume that consumption of lactoferrin-containing rice would improve the health of a consuming animal (noted in EA for 05-117-01r, p. 45-46, Humphrey, et al, 2002). Ventria's data in fact demonstrated a reduced pathogen load in the intestines of the chicks over a 21-day feeding period (Humphrey, et al., 2002). Considering the speculative nature of the comment, the Humphrey, et al, 2002 study, the fact that only a small percentage of any animal population is likely to be diseased, and the fact that any consumption of Ventria rice would be of very short duration, APHIS has concluded that potential effects to wildlife, including TES (either harmful or beneficial) should be insignificant.

Comment: Several commenters pointed to the USDA Office of the Inspector General Audit Report (Audit 50601-8-Te, December 2005) and recent instances of the identification of both approved and unapproved genetically engineered rice varieties found in conventional rice as failures of APHIS-BRS to maintain proper oversight of GE plant field trials.

Response: BRS has made substantive changes to address the recommendations in the 2005 OIG report. Most of the recommendations in the report were in line with changes that BRS had already enacted. Many of these recommendations were procedural in nature or focused on documentation. APHIS has strong regulations in place and OIG suggestions were not focused on safety and confinement measures. Many of the auditor's recommendations focused strictly on plantings conducted under APHIS' notification system, not the system in place for managing pharmaceutical or industrial plants, which, considering the extensive supplemental permit conditions is demonstrably more stringent.

Comment: Several commenters were concerned that the EA failed to address possible negative economic impacts on growers of corn, soybeans or wheat in adjacent fields if Ventria's rice were to contaminate these crops.

Response: APHIS has considered this possibility and concluded that the likelihood of foreseeable economic impact is negligible because 1) there is no rice production in the state of Kansas; 2) rice plants are unlikely to survive the management regimes used for corn, soybean, or wheat, 3) multiple redundant confinement procedures are in place such as:

- The use of dedicated equipment
- Fallow zones
- Pre-selected contract distributors for shipping of seeds and harvested materials
- Secure distribution of seeds by developer to pre-selected contract growers
- Sealed containers shipped under permit in triple containment
- Continuous tracking of inventory
- Direct transport to the processing facility
- Point to point pre-determined chain of custody with sign off and release
- Strictly controlled processing of product in dedicated facilities outside of conventional food and feed channels

Comment: Several rice producer organizations submitted comments noting recent contamination incidents in commercial rice from field trials of engineered varieties and recommend strongly that Ventria permits should not be issued.

Response: APHIS understands the concerns of all those connected with the commercial rice supply chain and is continuing its investigation into the recent contamination incidents. While it is true that in two cases, barely detectable levels of unapproved genetically engineered rice varieties were found in conventional rice lines, these instances most likely resulted from the co-existence of GE field trials in close proximity to commercial rice and not from trials being conducted over 300 miles away from the nearest commercial rice. Additionally, those trials were conducted under APHIS notification procedures, not the more stringently controlled systems and procedures mandated for pharmaceutical and industrial product production (described earlier in this document). Further, and as noted on numerous occasions, Ventria uses a closed-loop system for maintaining strict control of its products. APHIS reasonably concludes that the conditions of the proposed Ventria field trial are vastly different from those where commingling occurred and therefore disagrees that these past instances of commingling can be generalized to the present case.

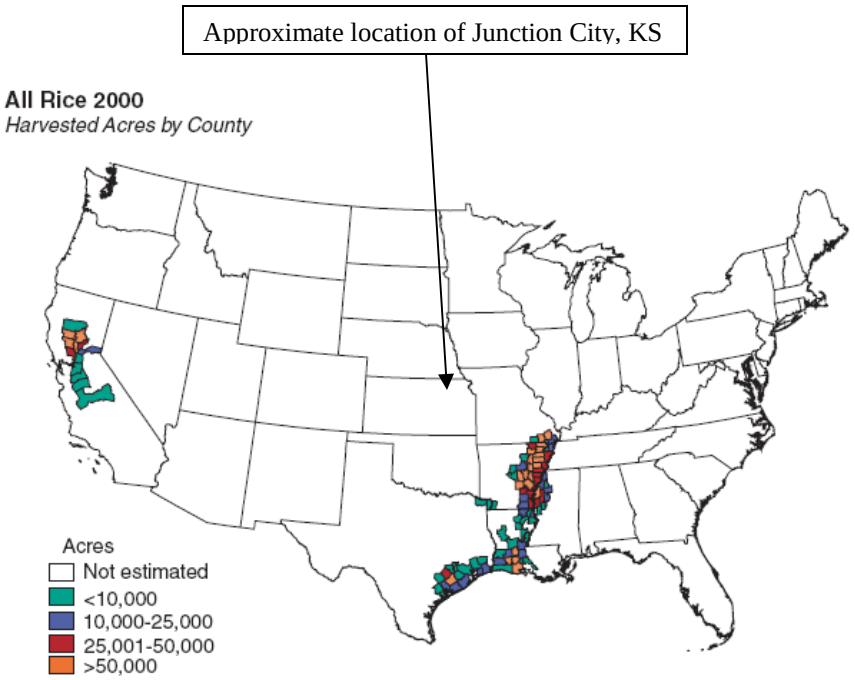
References:

Zavaleta N, Figueroa D, Rivera J, Sanchez J, Alfaro S, Lonnerdal B. Efficacy of rice-based oral rehydration solution containing recombinant human lactoferrin and lysozyme in Peruvian children with acute diarrhea. J. Pediatric Gastroenterology and Nutrition. 2007 Feb: 44(2): 258-64.

Drobney RD (2005) Personal Communication with Dr. Levis Handley (APHIS), Natural Biological Service, University of Missouri, Columbia, MO.

Powers KD, Noble RE, Chabreck RH (1978) Seed Distribution by Waterfowl in Southwestern Louisiana USA. Journal-of-Wildlife-Management 42: 598-605
Smith RJ, Sullivan JD (1980) Reduction of red rice grain in rice fields by winter feeding of ducks. Arkansas Farm Research 29: 3.

Humphrey BD, Huang N, Klasing KC (2002) Rice expressing lactoferrin and lysozyme has antibiotic-like properties when fed to chicks. J Nutr 132: 1214-1218



Location of Rice Acreage and Regions

Rice is grown in the United States in two distinct areas: (1) northern California and (2) an area in the southern United States that follows the Mississippi River from the boot heel of Missouri south to northeastern Louisiana and then continues along the Gulf Coast from southwestern Louisiana down through the lower Gulf Coast of Texas (see maps).

From Livezey, J. and L. Foreman, Characteristics and Production Costs of U.S. Rice Farms. 2004. Electronic Report from the Economic Research Service, Bulletin Number 974-7 (www.ers.usda.gov).

USDA/APHIS
Environmental Assessment

In response to Permit applications 06-278-01r, 06-278-02r and 06-285-02r
received from Ventria Bioscience
To conduct field plantings of rice (*Oryza sativa*) genetically engineered to
express recombinant human lysozyme, lactoferrin and serum albumin

U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services

Table of Contents

I. Summary

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service, Biotechnology Regulatory Services (APHIS/BRS) has prepared an environmental assessment (EA) in response to permit applications (APHIS numbers 06-278-01r, 06-278-02r and 06-285-02r) received from Ventria Bioscience, Sacramento, California, to grow genetically engineered rice (*Oryza sativa* L.) in Geary County, Kansas. These transgenic plants have been modified to express the recombinant human (*Homo sapiens*) proteins lysozyme, serum albumin, or lactoferrin. The plants expressing lysozyme and lactoferrin have also been engineered with the selectable marker gene *hpt*[1] which encodes for the enzyme hygromycin B phosphotransferase (Hpt). Hpt inactivates the antibiotic hygromycin. Plants containing serum albumin also contain either the *hpt* marker gene and/or the phosphinothricin acetyltransferase (*pat*) gene which allows laboratory selection of transformed tissues using bialaphos herbicide. None of the marker genes are expressed in mature plants due to the nature of the gene promoters.
This EA incorporates the material in the following EAs by reference.

- USDA/APHIS Environmental Assessment In response to permit applications (04-309-01r and 05-117-02r) received from Ventria Bioscience for field-testing of rice, *Oryza sativa*, genetically engineered to express human lysozyme[2]
- USDA/APHIS Permit 96–355–01r for Field Testing Genetically Engineered Rice Plants: Environmental Assessment and Finding of No Significant Impact[3]
- USDA/APHIS Environmental Assessment In response to permit applications (04-302-01r and 05-117-01r) received from Ventria Bioscience for field-testing of rice, *Oryza sativa*, genetically engineered to express human lactoferrin[4]

These documents describe the biology of rice, the function of the recombinant DNA, and the non-site-specific effects of planting these rice varieties. This document focuses on the potential impacts on the human environment that are specific to planting these crops in Geary County, Kansas.

The following issues are addressed:

- Effects caused by changes in land use/ agricultural practices
- Alteration in susceptibility to disease or insects
- Extreme weather events
- Effects on non-target organisms including migratory birds
- Effects on Federally listed Threatened or Endangered species
- Potential impacts on U.S. commercial rice supply, including organic rice

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[1] By convention, the gene is designated by small italic letters and the protein produced by that gene is designated by non-italicized letters, first letter capitalized.

[2] http://www.aphis.usda.gov/brs/aphisdocs/05_11702r_ea.pdf

[3] http://www.isb.vt.edu/cfdocs/fieldtests3.cfm

[4] http://www.aphis.usda.gov/brs/aphisdocs/05_11701r_ea.pdf

- Potential cumulative effects

II. Introduction

Ventria Biosciences and its predecessor Applied Phytologics have been issued 23 permits since 1997 to grow rice plants producing pharmaceutical or value added proteins in Hawaii, California and North Carolina. They have a history of good compliance with APHIS regulations and have been inspected regularly by APHIS.

APHIS has received three permit applications from Ventria to plant rice expressing recombinant proteins that will be used in research and nutritional supplements. In addition to extracting the recombinant proteins the company will use some of the harvested rice seed for future plantings.

A description of rice biology is incorporated here by reference to the Environmental Assessment (EA) completed for permit 05-117-01r (Section V, pp 7-9). This document is applicable to all three permit applications that are the subject of this EA and can be found here: http://www.aphis.usda.gov/brs/ph_permits.html. Topics covered in the referenced Environmental Assessment discuss rice systematics, genetic improvement, weediness, modes of gene escape, outcrossing, movement of seed by animals, movement of seed by water and movement by human error.

A. Intended uses for the developed rice lines

Ventria Bioscience (formerly Applied Phytologics) has been developing genetically engineered plants producing pharmaceutical and novel proteins since 1996. They intend to continue this work in 2007, growing several different rice lines containing three distinct novel proteins, recombinant lactoferrin, lysozyme, and human serum albumin, which will be extracted from rice seed.

Ventria intends to extract recombinant human lysozyme and lactoferrin from rice flour for clinical and diagnostic purposes. Ventria will also extract recombinant human serum albumin (HSA) protein to be used primarily for cell culture use. These plantings in Kansas should be harvested in the fall of 2007. Similar plantings are planned in future years.

B. Regulatory Authority

The authorities for regulation of genetically engineered rice are the Plant Protection Act of 2000, 7 U.S.C. 7701-7772, and USDA, APHIS regulations under 7 C.F.R. Part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests." A genetically engineered organism is considered a regulated article if the donor

organism, recipient organism, vector or vector agent[5] used in engineering the organism belongs to one of the taxonomic groups listed in the regulation and is also a plant pest[6], or if there is a reason to believe it is a plant pest. In this submission, rice lines have been genetically engineered using techniques of microprojectile bombardment or disarmed *Agrobacterium*-mediated transformation. Both of these techniques are commonly used to insert recombinant DNA molecules into the genome of the recipient organism. Each plant line that is the subject of this EA was made using genes from at least one plant pest listed in 7 C.F.R. 340.2. The introduced recombinant DNA contains human, bacterial and synthetic gene sequences that have been engineered for optimal protein expression in rice. Regulatory and selectable antibiotic or herbicide marker gene sequences from *E. coli*, *Agrobacterium tumefaciens*, rice, and/or *Streptomyces hygroscopicus* are also incorporated into these rice lines. The antibiotic resistance gene is used in the construction and purification of the recombinant DNA prior to transforming the plant. These sequences are not expressed in the plant. These herbicide resistance sequences are incorporated to facilitate the selection of plants containing the recombinant DNA sequences in the laboratory. The promoter sequence used to drive the expression of the selectable marker, Hygromycin Phosphotransferase, expresses in the callus (Huang, et al., 2001). The selectable marker is not expressed in the rice plants grown in the field. [7]

Generally, issuance of a permit for field trials of regulated articles is categorically excluded from requirements for an environmental assessment (EA) under APHIS NEPA implementing procedures (7 C.F.R. § 372.5(c)(3)(i)). However, when APHIS determines that a confined field release of genetically engineered organisms has the potential to significantly affect the quality of the human environment, as those terms are defined in 40 C.F.R. §§ 1508.27 and 1509.14, an environmental assessment or environmental impact statement will be prepared, pursuant to 7 C.F.R. § 372.5(d). This EA was prepared because the applicant intends to have plantings of these engineered plants in Geary County, Kansas for the next several years. The potential for cumulative impacts of these future plantings in the same area raises issues that this EA addresses. Future plantings are anticipated to increase in acreage and will be required to meet all the performance and mitigation measures described in the permit applications and all permit conditions.

III. Purpose and Need

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[5] Donor organism. The organism from which genetic material is obtained for transfer to the recipient organism. (7 C.F.R. 340.1)
Recipient organism. The organism which receives genetic material from a donor organism. (7 C.F.R. 340.1)
Vector or vector agent. Organisms or objects used to transfer genetic material from the donor organism to the recipient organism. (7 C.F.R. 340.1)

[6] Plant pest. Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants.

[7] See page 32 of permit 06-285-02r

A. Proposed Action

APHIS proposes to grant permits to allow the planting of genetically engineered rice. Permit number 06-278-01r is for up to 3000 acres of rice expressing recombinant human lysozyme[8]. Permit number 06-278-02r is for up to 100 acres of rice expressing recombinant human serum albumin[9]. Permit number 06-285-02r is for up to 100 acres of rice expressing recombinant human lactoferrin[10]. All three permits have identical field plot design and will use the same permit conditions.

Field Plot Design, Breeding Procedures and Agricultural Practices

Plot Design and Location

Ventria's plantings are proposed in Geary County, Kansas. There are no known commercial rice fields in Geary County, neighboring counties or the State. The area has a history of farming; soybean, corn, milo (grain sorghum) and alfalfa have been planted in the area for many years. Ventria will monitor for commercial rice production and scout for red/ weedy rice within ¼ mile of its plantings.

Rice is highly self-pollinating and is not generally pollinated by insects. 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 ¼ mile 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. To prevent erosion, the fallow zone may be planted with a low-growing crop that will not be used for food or feed. The rice will be grown in water soaked fields.

Agricultural Practices

The rice will be allowed to self pollinate to produce seed. No breeding operations are planned under this permit. Agricultural practices consistent with growing healthy rice plants will be used. Weeds will be controlled by herbicide applications. If necessary,

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[8] A description of this rice line can be found in "USDA/APHIS Environmental Assessment In response to permit applications (04-309-01r and 05-117-02r) received from Ventria Bioscience for field-testing of rice, *Oryza sativa*, genetically engineered to express human lysozyme." Section VI. Description of the Regulated Rice Plant. http://www.aphis.usda.gov/brs/aphisdocs/05_11702r_ea.pdf

[9] A description of this rice line can be found in "USDA/APHIS Permit 96–355–01r for Field Testing Genetically Engineered Rice Plants Environmental Assessment and Finding of No Significant Impact." IV. Description of the Regulated Article. http://www.isb.vt.edu/biomon/releapdf/9635501r.ea.pdf

[10] A description of this rice line can be found in "USDA/APHIS Environmental Assessment In response to permit applications (04-302-01r and 05-117-01r) received from Ventria Bioscience for field-testing of rice, *Oryza sativa*, genetically engineered to express human lactoferrin." Section VI. Description of the Regulated Rice Plant. http://www.aphis.usda.gov/brs/aphisdocs/05_11701r_ea.pdf

pesticides such as insecticides and/or fungicides will be used to control insect pests and disease. Any pesticides used will be applied by appropriately trained personnel. If necessary, EPA-registered pesticides will be used to control insect pests. Fields will be monitored for noxious weeds and other plant pests during the growing season. Three times during the growing season the plants will be inspected for traits such as weediness, resistance/susceptibility to insects or disease, or unusual differences in plant growth or morphology. The plot will be visually inspected weekly while personnel also conduct agricultural practices. Nearby fields will likely have crops such as corn, soybeans and milo (grain sorghum).

Field Observation and Monitoring

Termination of the field test and final disposition of the test plants

Seed will be machine-harvested using a dedicated combine and dried and cleaned in a designated/dedicated staging area in the same county using a dedicated dryer and cleaner. The seeds will be stored in dedicated storage bins until processed. During the process, the seed will be dehusked using a dedicated dehusker and will be milled in a dedicated staging area using a dedicated mill. Milled rice flour will be shipped to designated locations for subsequent processing. Any devitalized waste material from the milling operation will be returned to the field test site and incorporated into the soil or otherwise properly disposed of by an alternate, APHIS-approved method. All the operations up to milling will be performed in an APHIS-inspected dedicated area using dedicated equipment. Most material will be shipped only after milling. Some viable seed may be stored in APHIS-inspected locations and/or shipped to other locations for analysis or planting in subsequent seasons. All interstate shipments will be done under APHIS permits. Ventria's protocols call for intrastate movement of materials to be handled similarly such that all viable materials are moved under the same containment conditions.

After harvest, as soon as the weather allows, Ventria will burn and disk the fields to encourage rapid decomposition of all plant and seed materials that may remain. Off-season irrigation may also be used to accelerate the germination of any remaining viable seed prior to winter. Ventria plans to grow these rice varieties in the same locations in subsequent years. However, if a change to a different crop is anticipated, the field will be fallowed for one cropping season after the harvest of the transgenic lines. During this 18 month period (the period between harvest year 1 to planting year 3), the field will be monitored at least three times in the following growing season and managed to induce germination and/or decomposition of any viable seed. Ventria employs a "pureland" procedure to control volunteers. This includes irrigating the field with water during the growing season to induce germination of weed and rice seed, drying the field to kill seedlings, and then disking to dry and kill seedlings. This process is repeated three times.

B. Purpose

The purpose of this proposed introduction is multi-fold:

- For continued testing of gene stability over several generations of seed production,
- For further molecular and protein testing,
- To develop seed stock for product development and breeding, and
- For scale-up.

The regulated introduction is proposed for planting between March and May 2007 and would grow in the field until harvest (estimated September-November 2007). Ventria has proposed to plant acreages comparable in size and scope to those grown in North Carolina in 2006 (http://www.aphis.usda.gov/brs/ph_permits.html. See permit numbers 05-293-01r, 05-332-01r, and 05-332-02r). One noted change is the addition of rice lines developed to produce human serum albumin.

APHIS has reviewed and approved protocols that are proposed by Ventria to prevent the escape and dissemination of these plants, submitted on APHIS Form 2000. In addition, Standard Operating Procedures (SOPs) submitted by Ventria identify more detailed instructions and provide additional guidance.

This EA assesses potential environmental effects resulting from confined field plantings of the engineered rice lines in Geary County, Kansas. Permit applications were submitted by Ventria Bioscience to USDA/APHIS/BRS on October 5 and October 12, 2006.

Identical or nearly identical rice lines have been the subject of previous Environmental Assessments by APHIS and portions of those assessments, when appropriate, will be incorporated in this EA or appendices by reference.

C. Need for This Action

The Plant Protection Act directs the USDA to facilitate imports and interstate commerce in agricultural products in ways that will reduce, to the extent practicable, the risk of dissemination of plant pests. Under APHIS regulations, the APHIS Administrator has authority to regulate any organism or product altered or produced through genetic engineering that the Administrator determines is a plant pest or has reason to believe is a plant pest. When APHIS receives an application for a permit for environmental release, the application is evaluated to determine whether the environmental release, with appropriate conditions imposed, can be carried out while preventing the dissemination and establishment of plant pests. The receipt of a permit application to introduce a genetically engineered organism requires a response from the Administrator:

Administrative action on applications. After receipt and review by APHIS of the application and the data submitted pursuant to paragraph (a) of this section, including any additional information requested by APHIS, a permit shall be granted or denied. 7 CFR 340.4(e)

D. Public Involvement

APHIS-BRS routinely seeks public comment on draft environmental assessments. APHIS-BRS does this through a notice published in the Federal Register. In response to this notice (Docket No. APHIS-2007-0006, 72 FR 8959-8960 published on February 28, 2007) APHIS received 20,034 comments during the 30-day comment period.

Comments were received from corn grower's and grain sorghum producer's associations, a public policy committee for in vitro biology, academia, corporations, a state government agency, consumer groups, environmental groups, academic professionals, an organic food producer's and consumer's alliance, rice growers, millers, or from related industries, rice industry groups, and individuals. Issues raised include the volatility of the rice market in relation to adventitious presence, potential adverse health effects, molecular disparity of plant-produced lactoferrin and bovine lactoferrin, the lack of independent research, the lack of FDA approval, APHIS' objectivity in the environmental assessment, flaws in the regulatory process, and those opposed to biotechnology in general. Additional issues raised in comments that are included in this EA include the following: potential impacts on changes in land use, extreme weather events, effects on non-target organisms, impacts on the U.S. commercial rice supply (including organic rice) and potential cumulative impacts.

IV. Alternatives

APHIS has considered the following three alternatives in response to the applicant's request for a permit:

Alternative 1:

No action/deny the permit applications. Under this alternative, field releases of the engineered rice plants would not be authorized. APHIS might chose this alternative if it is determined that granting this permit would result in the dissemination or establishment of a plant pest.

Alternative 2:

Issue the permits for growing under the conditions proposed by the applicant. Under this alternative APHIS would grant permits (APHIS numbers 06-278-01r, 06-278-02r and 06-285-02r) received from Ventria Bioscience, Sacramento, California, to grow genetically engineered rice (*Oryza sativa* L.) in Geary County, Kansas. Standard permit conditions under 7 CFR § 340.4 would apply (See Appendix 1). Supplemental permit conditions as described in Appendix 4 (Sections I.-X.) would also apply. Under this alternative, field release of the engineered rice plants would be authorized at the specified locations with the following additional conditions.

- The plantings shall be at least ¼ mile from any commercial rice plantings.
- The applicant shall provide APHIS and State regulatory officials information on the location of the nearest commercial rice plants that are not part of the field test.

- The applicant shall provide APHIS and State regulatory officials a detailed map of the proposed plantings. One month after planting, the applicant will submit a detailed map of the planted sites.
- The applicant shall use screens on irrigation outlets to prevent movement of seeds/seedlings out of the field with water used to flood the field. They shall also employ methods which create a closed system so that ungerminated seeds cannot leave the field site.
- A zone of 50 feet shall be maintained surrounding the field test site. A non-food or non-feed cover crop may be planted in this zone to prevent erosion or this area may remain fallow.
- In the subsequent growing season, the production sites and the 50 foot fallow zone may not be planted with rice unless similar transgenic rice is repeated. If the same crop does not follow in subsequent years, the site shall be monitored for volunteer rice plants at least 3 times during the following growing season. Any volunteer rice plants shall be destroyed before flowering.
- Ventria shall use equipment dedicated to these plantings as outlined in their SOPs. This equipment shall not be used for any other purposes during the course of the field test. After the field test is completed, all equipment shall be thoroughly cleaned and inspected to ensure that all genetically engineered seed and other plant material has been removed and destroyed.
- Ventria shall scout for red rice during the entire growing season both within the growing plots and for ¼ mile from the production fields. Any red rice found shall be destroyed and shall not be allowed to flower. Ventria shall also inform APHIS if any red rice is found within the ¼ mile zone or in their production plots.

Alternative 3:

Issue the permits with additional conditions for carrying out the field plantings. This alternative incorporates all of the conditions of Alternative 2 and the following additional conditions (Appendix 4, Sections I. – XI.).

- APHIS will require contingency/emergency/ mitigation management plans describing detailed procedures that a permit holder will undertake in the event of accidental or unauthorized release or commingling with any other non-PMP/PMI material (including reporting requirements to APHIS/BRS).
- APHIS will require that applicants have available event specific testing procedures to identify PMP/PMI lines being grown.
- APHIS will require chain of custody documentation or accounting for large quantities of PMP/PMI viable materials. Documentation will be subject to inspection/auditing during scheduled inspections.
- APHIS will supply labels/placards to all applicants for use on dedicated storage/ dedicated use equipment indicating for NON-FOOD/ NON-FEED USE ONLY.

Preferred Alternative:

APHIS has chosen Alternative 3 as its preferred Alternative. This Alternative provides oversight as described in APHIS' March 10, 2003 Federal Register Notice with additional requirements for an applicant emergency management plan as well as other items to mitigate potential impacts as well as provide greater trial oversight by APHIS/BRS.

V. Affected Environment

Ventria's plantings are proposed in several fields in Geary County, Kansas. There are no known commercial rice fields in Geary County or neighboring counties. The area has a history of farming soybean, corn, milo (grain sorghum) and alfalfa for many years. Ventria will monitor for commercial rice production and scout for weedy red rice within ¼ mile of its plantings. Therefore, the affected environment for these permit applications includes the fields where these rice lines will be grown plus a 50-foot fallow area plus the area where Ventria will be required to monitor for the presence of red/weedy rice.

VI. Potential Environmental Impacts

Other than location-specific references, descriptions of the potential environmental impacts to Alternatives 1, 2 and 3 are incorporated here by reference to Environmental Assessments (EA) completed for permits 05-117-01r (lactoferrin, Section VIII, pp 16-24), 05-117-02r (lysozyme, Section VIII, pp 16-24) and 96-355-01r (human serum albumin, Section V, pp 5-7). These documents can be found at the following links: http://www.aphis.usda.gov/brs/ph_permits.html and http://www.isb.vt.edu/cfdocs/fieldtests3.cfm. Issues addressed included the potential for persistence in the environment, the potential for gene transfer, potential impacts from use of the marker genes, potential impact on native floral and faunal communities, potential alteration in susceptibility to disease or insects, potential impacts on existing agricultural practices, potential impact on adjacent row crops, fate of transgenic DNA, potential impacts on human health, and special considerations regarding other environmental statutes. Considering Kansas planting sites versus either North Carolina or Missouri planting locations, none of these issues are significantly different from the original analyses. The plant lines being used are essentially identical; the analyses done on soils where the plants have been grown are identical; confinement of the trials is essentially identical; and confinement processes and procedures to be used by Ventria will be essentially identical. Although native floral and faunal communities may be somewhat different in KS than other locations, the rice plants are still the same and APHIS' conclusions of no significant effects on such communities are still valid. These plantings are confined and the land being used has been under constant agricultural use (and as such highly disturbed and managed) for over 50 years.

Changes in land use/ agricultural practices

Commercial rice production is not known to occur in Kansas. The areas that are proposed for these field plantings have most recently been planted in corn, alfalfa, grain

sorghum, and soybean. The fields have been grown under irrigation. In 2005, 22,711,000 acres of crops were grown in Kansas including 3,650,000 acres of corn, 2,900,000 acres of soybeans, 10,000,000 acres of wheat, 2,750,000 acres of sorghum, and 950,000 acres of alfalfa (http://usda.mannlib.cornell.edu/usda/current/CropProdSu/CropProdSu-01-12-2007.pdf.). These five crops represent 88% of the total crops grown in the state.

Under Alternative 1, the fields would likely be planted in a crop suitable for the area. Approved (EPA and KSDA) pesticides, fertilizers and irrigation water would be applied to all fields as determined by the grower. There would be no environmental impacts outside of those associated with conventional cultivation of irrigated crops in Kansas.

Under Alternative 2, potential environmental impacts would be similar to those associated with conventional agriculture currently occurring in Kansas. The Ventria request to plant approximately 3,000 acres of rice represents a miniscule fraction of Kansas cropland (0.01%). Approved pesticides (EPA and Kansas Department of Agriculture-approved), fertilizers and irrigation water would be applied to all fields as needed. Chemical inputs such as fertilizers and pesticides would be similar to those used for conventional crops grown in the area. For example, Ventria typically applies around 100 pounds of nitrogen fertilizer/acre which is less than the average of 132 pounds of nitrogen/acre added to corn in Kansas (http://usda.mannlib.cornell.edu/usda/nass/AgriChemUsFC//2000s/2006/AgriChemUsFC-05-17-2006.pdf.) Ventria has not needed to apply herbicides and insecticides to their rice in North Carolina and does not expect to need these chemicals the first season in Kansas. It is expected that pesticides will be needed in subsequent seasons, however the amounts are not likely to exceed pesticides applied to other crops in Kansas. For example, in Louisiana, where rice has been grown for many years, average herbicide use is 2.16 pounds/acre (Gianessi, L. P. et al., 2002). In comparison 2005 average herbicide use on corn in Kansas was similar at 2.04 pounds acre. As rice requires more water than crops that have typically been grown in this area, more water will be applied in order to keep fields very wet or muddy. Ventria has assessed rice growing practices that do not require totally flooded fields and are water-saving by comparison. As such, they will use pivot and rill irrigation systems that are currently in place. Farmers in Kansas harvest crops from both irrigated and non-irrigated fields. Irrigated acres amount to approximately 15% of total acreage (over 3 million of about 22 million acres total) and return approximately 25% of the total crop production value (http://www.oznet.k-state.edu/irrigate/Reports/ITrends.pdf). In total, approximately 4 million acre-feet (>1.6 trillion gallons) of water are diverted yearly for all uses (http://www.ksda.gov/appropriation/content/116). About 90% of this water comes from groundwater sources (i.e., not from surface water). Eighty to 85% of this water is used for agricultural crops. In 2000, the total volume of irrigation water pumped in the state was approximately 3,860,000 acre-feet, mostly in western and southwestern KS. If Ventria were to plant 3000 acres, which they may in future years (but not in 2007), this amounts to approximately 0.1% of the total KS irrigated acreage. Geary County rainfall averages just over 30” yearly (http://www.oznet.ksu.edu/wdl/KSPCP.htm). Across the state, yearly averages range from a low of 14.6” in Stanton County in the southwest to 45.6” in Crawford in the southeast. APHIS has consulted with the KS Department of

Agriculture's (KDA) Division of Water Resources and the Kansas Water Authority (KWA) and received information about irrigation water use in Geary County (Lane Letourneau, 2007; Earl Lewis, 2007). Water use and water rights are regulated and managed by KDA and KWA. In Geary County, total authorized (KDA/ Division of Water Resources) water rights amount to approximately 27,500 acre-ft of which approximately 7,000 acre-ft are authorized for irrigation (approximately 2/3 from groundwater and 1/3 from surface sources). The latest available data (2004) indicate that just over 1,500 acre-ft of those authorized were actually used (Lane Letourneau, 2007). The oversight board of the KWA also manages water use in KS and makes decisions about water use allocations by applicants. One such supply available in Geary County is the Milford Reservoir where there is approximately 80,000 acre-ft of water available for different uses on a yearly basis (Earl Lewis, 2007). In terms of authorized and available water versus actual use, there appears to be an adequate supply of water for Ventria's use without significantly impacting other potential users in the county. One likely impact on water use, which can be extremely variable and difficult to predict, is the annual rainfall received on planted acres. Between the years 2000 and 2006, rainfall in Geary County varied from a low of about 24 inches (2002) to a high of almost 39 inches (2001). Considering information from 2004 (about 28 inches rainfall), use of just over 20% of authorized water (KDA permitted 1500 acre-ft used/ 7000 authorized), and other water resources available in the area through the KWA, this further supports the indication that water is not a limiting resource in Geary County. Ventria will install levees around fields to manage water and potential run-off from fields. Ventria has also proposed to burn or till fields post-harvest to control volunteers and manage crop residue. Neither practice diverges from practices currently used in Kansas where tilling is common in many row crops and burning is used to manage grass pasture land and wheat stubble in fields. The State of Kansas Department of Health and Environment regulates air quality and Ventria is expected to abide by those regulations (http://www.kdheks.gov/bar/regs.html). As noted in a following section on Potential Cumulative Effects, the Kansas Department of Agriculture and Kansas Water Authority provide significant oversight and regulation of issues relating to pesticide use, water use and the environment (http://www.ksda.gov). Ventria has been working closely with the Department of Agriculture to ensure that all their practices are in compliance with State Regulations. Thus with respect to impacts on air quality, water, and soil, the practices Ventria intends to employ for rice cultivation are not fundamentally different from those used for the major crops grown in Kansas. Therefore there should be no significant environmental impacts expected from the introduction of limited rice culture into Kansas.

Under Alternative 3, potential environmental impacts associated with Alternative 2 should be mitigated in the event of accidental or unauthorized release of regulated materials. Additionally, APHIS will be able to provide closer oversight of larger trials such as this.

Alteration in susceptibility to disease or insects

Since Ventria first began planting these rice lines, they have not noted increased susceptibility to disease or insect pests. There has been no intentional genetic change in these plants to affect their susceptibility to disease or insect damage. Neither the

selectable marker genes, *hpt* and *pat*, nor the lysozyme, lactoferrin or *hsa* genes are expected to alter the susceptibility of the transgenic rice plants to disease or insect damage. Execution of the prescribed periodic monitoring of the field plots will allow the detection of any unexpected infestation by plant disease organisms or animal pests. Ventria is required to report any such unanticipated effects to APHIS.

Therefore, under Alternatives 1, 2 or 3, there should be no environmental impacts.

Extreme Weather Events

Parts of Kansas are subject to both high winds and tornadoes on a yearly basis and some commenters were concerned about the possibility that tornadoes or high winds might move viable plant material and seeds away from the planting sites.
APHIS/BRS contacted 2 departments within NOAA and was able to gather information about both the likelihood of extreme weather events occurring in the area in and around Geary County and historical data on how many extreme weather events have been documented in Geary County, KS between 1950 and 2006. In terms of the likelihood of occurrence of a tornado in any given year, the National Severe Storms Laboratory at NOAA has used data from a 20 year period (1980-1999) to generate a map (See Appendix 5) (http://www.nssl.noaa.gov/hazard/img/ttor8099.gif) that describes in contour style the number of "tornado days per year" for given areas across the U.S. For comparison, the highest numbers of "tornado days per year" occur in central Florida and eastern Colorado and are in the range of 1.6 to 1.8. Much of the western third of the U.S. is rated at 0. Most of the rest of the continental U.S. has ratings between 0.2 and 1.4. Eastern Kansas, including Geary County, has a rating of 1.0-1.2 (i.e., on average, it could be expected that there would be a tornado one day per year within 25 miles of any given point in this area). The National Climactic Data Center (NCDC) within NOAA also has historical data on extreme weather (e.g., high wind, tornado, flood, hail, etc) events occurring (by state and county) (http://www4.ncdc.noaa.gov/cgi-win/wwcgi.dll?wwEvent~Storms). In the >100 counties in the Kansas, Geary County ranks in the bottom 5 in terms of the number of tornadoes recorded between 1950 and 1995 (http://www.tornadoproject.com/alltorns/kstorn1.htm). Fifteen (15) tornadoes were recorded in Geary County in the years between 1950 and late 2006. Seventy-seven (77) thunderstorm/high wind events and 19 flood events occurred in the same time period in Geary County. One hundred nineteen (119) hail events were recorded during this same time period. In terms of the seasonality of occurrences of tornadoes, the highest probability of occurrence of tornadoes in this region in KS is late March/ early April and late July/ early August (See Appendix 5) (http://www.nssl.noaa.gov/hazard/hazardmap.html). Nineteen flood events have been documented in Geary County between 1950 and December 2006 (http://www4.ncdc.noaa.gov/cgi-win/wwcgi.dll?wwevent~storms). The occurrence of late season floods (when seeds would be mature and viable) is rare. APHIS notes none in September or October months when rice seed would most likely be mature and viable. From that same website, APHIS also notes only 3 of those 19 floods occurring in May when seed may have been recently planted and subject to being carried out of the planting sites. Once rice plants are established, flooding would be unlikely to wash away stands of rice with their developed root systems. The applicant has indicated to APHIS

that their current planting sites are in a 100-year flood plain. They have also indicated that parts of 1 of their proposed planting sites were covered with 1-2 feet of water in a July 1993 flood event in the Junction City area. This gives some indication as to the rarity of flood events in this area. It is impossible to predict when floods might occur and the severity of floods, but the probability appears low that flooding in the proposed growing areas would carry the rice downstream from this field site where it would subsequently germinate and persist in the environment. Taken together, all this information on tornado/ wind and flood events in the Geary County area lead APHIS to conclude that the likelihood of tornadoes, strong winds or flood events spreading viable seeds or plant material outside the field trial area and having a significant effect is extremely small.

Under alternative 1, there would be no environmental impacts outside of those that would occur to alternate crops planted in these same locations.
Under alternative 2, potential environmental impacts due to extreme weather events are unlikely as discussed below.

Ultimately, even if seeds were to be carried outside the trial area, the likelihood of persistence in the environment is extremely low. As noted in the EA for 05-117-01r;

> Rice is a highly domesticated aquatic crop species, which grows exclusively in highly managed aquatic ecosystems. It is non-competitive with weed species and is self-pollinated; errant seed does not pose a threat to wild or managed non-flooded ecosystems. Taipei 309 is a *Japonica* type rice which germinates very quickly and has no dormancy period (FAO, Accessed 2005). Japonica rice seed loses viability quickly under ambient conditions. Therefore the likelihood of persistence of seed in the environment is minimal (EA for 05-117-01r, p. 17).

Additionally;

> If there is grain on the plant, or enough of a flag leaf and immature panicle to give some weight to the top of the plant, the wind will knock over and lodge the plant. The grain is effectively driven to the ground, into the standing mud and water, where it usually rots under the vegetative material of the rice plant. This is a significant problem where high winds occur prior to harvest in rice growing regions like Louisiana. Therefore it is highly unlikely that the grain will be blown off the plant or plants uprooted in high winds (EA for 05-117-01r, pp. 55-56).

Under Alternative 3, potential environmental impacts associated with Alternative 2 should be mitigated in the event of accidental or unauthorized release of regulated materials. Additionally, APHIS will be able to provide closer oversight of larger trials such as this.

Effects on non-target organisms including migratory birds

Planting rice in this new area may serve to attract or repel birds that use the Central Flyway. Rice planting may also attract or repel small mammals, insects or other organisms that forage for food in agricultural areas. Migratory waterfowl can be found in Kansas as it is about half way down the Central Flyway's eastern tier of states.

According to the Kansas Department of Wildlife and Parks, 27 species of ducks migrate through Kansas (http://www.kdwp.state.ks.us/news/hunting/migratory_birds/ducks). Other migratory birds such as doves, geese, swans, cranes, rails, woodcock, and snipe are also found in Kansas (http://www.kdwp.state.ks.us/news/hunting/migratory_birds). The fields proposed for planting are typical to Kansas agriculture. Any future plants are expected to be in similar sites.

Under Alternative 1 there would be no effect on non-target organisms or migratory birds. These organisms would continue to use the cropland as they have in the past. The crop the grower chooses to plant and the management practices that the grower employs will determine the suitability of the sites for various organisms.

Under Alternative 2, Ventria would conduct plantings with conditions as described. As noted previously, data has been submitted and reviewed by APHIS demonstrating that recombinant proteins are only produced in developing seeds. APHIS has previously assessed potential animal exposure levels to lactoferrin (EA for 05-117-01r, pp. 12-14 and pp. 20-21) and lysozyme (EA for 05-117-02r, pp. 12-13 and pp. 19-20) and concluded that possible exposure to small numbers of these seeds by non-target vertebrate, invertebrate or aquatic organisms, including birds, would pose no significant risks to these organisms. A similar conclusion was reached for serum albumin (EA for 96-355-01r, p. 7). It can be expected that growing rice in these fields will result in changes in populations of soil micro- and macro-flora and fauna from increased water use. These changes would not be unexpected as microbial community diversity changes in agricultural soils are commonly known (Lundquist, et al., 1999, Dunfield, et al., 2004, Smit, et al., 2001). Similarly, changes in earthworm populations would also be expected on the acres under cultivation (http://www.wormdigest.org/content/view/305/2/). None of these changes should have significant environmental impacts.

Under Alternative 3, potential impacts would be essentially the same as those associated with Alternative 2.

Effects of field plantings on Threatened and Endangered Species

APHIS evaluated the potential effects of these field plantings at sites in Geary County, Kansas on threatened and endangered species (TES).

The proposed field plantings are confined releases of the regulated articles into the environment in Geary County, Kansas. The updated proposed planting sites are within 5 miles of Ventria's storage and processing facility in Junction City, KS. Lists of TES and proposed TES, as well as an analysis of designated critical habitat and proposed designated habitat, were obtained from the U.S. Fish and Wildlife Service (USFWS). Upon review of the information obtained from USFWS, it was determined that there are seventeen TES in the state and no critical habitat in the proposed planting areas. These documents can be found at the following links: http://ecos.fws.gov/tess_public/StateListing.do?state=KS&status=listed and http://crithab.fws.gov/

The TES listed include the Indiana bat (*Myotis sodalis*), gray bat (*Myotis grisescens*), American burying beetle (*Nicrophorus americanus*), gray wolf (*Canis lupus*); 6 bird species: whooping crane (*Grus americana*), Eskimo curlew (*Numenius borealis*), bald eagle (*Haliaeetus leucocephalus*), Least tern (*Sterna antillarum)*, black-capped Vireo (*Vireo atricapilla*), piping plover (*Charadrius melodus*); 4 fish species: Neosho madtom (*Noturus placidus*), Pallid sturgeon (*Scaphirhynchus albus*), Arkansas River shiner (*Notropis girardi*), Topeka shiner (*Notropis topeka*); and three endangered plants: running buffalo clover (*Trifolium stolonifera*), Mead's milkweed (*Asclepias meadii*) and the western prairie fringed orchid (*Platanthera praeclara*) as existing or once existing in Kansas. Only 2 of these species have been recorded as identified in Geary County: the Topeka shiner and the Least tern. Neither of these would likely be exposed to or consume material from these plantings. The Topeka shiner is a small minnow, occurring typically in quiet, clear, open pools of river headwaters and creeks. It primarily consumes midge larvae and aquatic invertebrates. The Least tern is considered a shore bird and primarily consumes insects and fish. Several of the other species listed are presumed absent from Kansas. Given the non-toxic nature of the rice and proteins produced, other species, even if exposed, would not be expected to be affected.

BRS has reviewed this data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service (USFWS) to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS has reached a determination that release under these permits (06-278-01r, 06-278-02r and 06-285-02r) would have no effect on designated critical habitat or listed threatened or endangered species and consequently, a written concurrence or formal consultation with the USFWS is not required for this project.

Therefore, under Alternatives 1, 2 or 3, there should be no effects on threatened and endangered species.

Potential Impacts on U.S. Commercial Rice Supply, including Organic Rice

APHIS evaluated the potential effects of permitting these trials in Kansas on the U.S. commercial rice supply, including organic rice.

The planting sites are expected to provide adequate physical security. The contract farmers own the fields to be planted with the transgenic rice. The surrounding fields outside the food/feed crop fallow zone will be planted to soybean, corn or other crops. The sites are not prone to flooding although a part of one of their proposed planting sites was covered with 1-2 feet of water in a July 1993 flood in the Junction City area. The closest body of water is the Smokey Hill River which is located approximately 1 mile to the south of the two proposed plots. In both locations, the river is separated from fields by a steep embankment and these two particular locations do not have a significant history of flooding.

There is no commercial rice production in Kansas (Appendix 6). There is no indication that viable rice seeds or plants are likely to be physically moved hundreds of miles by extreme weather events or animals to the nearest organic rice fields in Missouri, Texas, Arkansas or any other state where organic rice is grown. Many redundant measures are in place to prevent this rice from entering the U.S. rice supply: (1) Plantings are located over 300 miles from the nearest commercial rice in Missouri and central Arkansas, (2) Plantings are confined to minimize loss of viable seed and plants from planting sites, (3) Rice is primarily self-pollinating so viable pollen will be unable to pollinate other rice, (4) Ventria has numerous processes and procedures in place to confine plants in plantings and contain seeds when in transit or storage, (5) APHIS inspects sites, equipment and facilities to verify compliance.

Given all these effective measures in place, there should be no significant effects on the U.S. commercial rice supply, including organic rice, under Alternatives 1, 2 or 3.

Potential Cumulative Environmental Effects

Under Alternative 1, there would be no cumulative environmental effects.

These will be the first field tests of the engineered rice plants at these locations. Ventria has assayed for lactoferrin, lysozyme and serum albumin in the soil surrounding the roots of the engineered plants, and has supplied data indicating that no recombinant protein has been detected. Given the specificity of the gene promoters used in these plants (specific for production of protein in seed), it is expected that no engineered protein will be secreted into soils; therefore, no accumulation in soil would be expected. Therefore, there is little likelihood that lactoferrin, lysozyme or serum albumin will accumulate in the soil. However, any as yet unidentified cumulative effects should be found in the subsequent monitoring periods required by APHIS in the same field sites in following years.

The land on which Ventria will be growing their rice is land that has historically been used and managed for agriculture for over 50 years; as such, it has had applications of pesticides and fertilizers over a long period of time. The Kansas Department of Agriculture and the Kansas Water Authority oversee and regulate water, pesticide, fertilizer and environment issues (http://www.ksda.gov/) and it can reasonably be expected that they will be appropriately consulted regarding aspects of these trials related to these issues. Ventria has been in discussions with the Kansas Department of Agriculture (KDA) and KDA has shown support for Ventria's work (comment 0140 on this docket from the KS Secretary of Agriculture). As Ventria has in the past, it can further be expected that they will follow all applicable state and federal regulations. Significant effects on the environment, outside of those associated with conventional farming practices in the areas of these plantings, are therefore unlikely.
Under Alternative 2, potential environmental impacts associated with long term growing of these rice lines on fields in Geary County, KS are unlikely and not reasonably foreseeable.

Under Alternative 3, potential cumulative environmental impacts associated with Alternative 2 should be mitigated in the event of accidental or unauthorized release of regulated materials. Additionally, APHIS will be able to provide closer oversight of larger trials such as this.

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Appendix 1: Standard Permit Conditions

7 CFR § 340.4(f) Permit conditions.

A person who is issued a permit and his/her employees or agents shall comply with the following conditions, and any supplemental conditions which shall be listed on the permit, as deemed by the Administrator to be necessary to prevent the dissemination and establishment of plant pests:

(1) The regulated article shall be maintained and disposed of (when necessary) in a manner so as to prevent the dissemination and establishment of plant pests.

(2) All packing material, shipping containers, and any other material accompanying the regulated article shall be treated or disposed of in such a manner so as to prevent the dissemination and establishment of plant pests.

(3) The regulated article shall be kept separate from other organisms, except as specifically allowed in the permit;

(4) The regulated article shall be maintained only in areas and premises specified in the permit;

(5) An inspector shall be allowed access, during regular business hours, to the place where the regulated article is located and to any records relating to the introduction of a regulated article;

(6) The regulated article shall, when possible, be kept identified with a label showing the name of the regulated article, and the date of importation;

(7) The regulated article shall be subject to the application of measures determined by the Administrator to be necessary to prevent the accidental or unauthorized release of the regulated article;

(8) The regulated article shall be subject to the application of remedial measures (including disposal) determined by the Administrator to be necessary to prevent the spread of plant pests;

(9) A person who has been issued a permit shall submit to APHIS a field test report within 6 months after the termination of the field test. A field test report shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.

(10) APHIS shall be notified within the time periods and manner specified below, in the event of the following occurrences:

(i) Orally notified immediately upon discovery and notify in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article;

(ii) In writing as soon as possible but not later than within 5 working days if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application for a permit or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms);

(11) A permittee or his/her agent and any person who seeks to import a regulated article into the United States shall:

(i) Import or offer the regulated article for entry only at a port of entry which is designated by an asterisk in 7 CFR 319.37-14(b);

(ii) Notify APHIS promptly upon arrival of any regulated article at a port of entry, of its arrival by such means as a manifest, customs entry document, commercial invoice, waybill, a broker's document, or a notice form provided for such purpose; and

(iii) Mark and identify the regulated article in accordance with Sec. 340.5 of this part.

Appendix 2: Description of the Regulated Rice Plants

Ventria has engineered these rice plants to produce human lysozyme, lactoferrin or human serum albumin in the seeds. The engineered rice (*Oryza sativa* ssp *japonica* var Taipei 309, M202 or M103) varieties are medium grain, Japonica types. They are not grown widely in the U.S. In each case, gene expression is targeted to the developing seed so the different proteins are not produced in other parts of the plant.

Detailed descriptions of the lactoferrin and lysozyme producing rice plants are incorporated here by reference to Environmental Assessments (EA) completed for permits 05-117-01r (lactoferrin, Section VI, pp 9-13) and 05-117-02r (lysozyme, Section VI, pp 9-13). These documents can be found here: http://www.aphis.usda.gov/brs/ph_permits.html. Topics covered in the referenced EAs discussed gene vectors, selectable markers, the genes of interest, characterization of the engineered plants, molecular characterization, protein characterization, assessments of protein toxicity and allergenicity, thermal and gastric stability and potential environmental exposure levels.

Ventria has made minor changes to its gene constructs and method of transformation for its HSA-containing rice lines. The plants developed for current use (permit application 06-278-02r) were generated using *Agrobacterium*-mediated transformation and the use of two selectable marker genes. The marker genes hygromycin phosphotransferase and phosphinothricin acetyltransferase (*hpt* and *pat*) are included to allow selection of transgenic tissues in the laboratory using the antibiotic hygromycin and/or the herbicide bialaphos. Neither selectable marker gene is expressed in mature rice tissues. In many years of testing, these rice plants have not exhibited plant pest characteristics when modified by the introduction of these genes and their associated regulatory sequences. These sequences do not have any inherent plant pest characteristics and are not known to enhance gene transfer from plants to other organisms.

Brief descriptions of the proteins to be produced in the engineered rice plants are included here.

Lysozyme is ubiquitous in the human body where it acts as a protective barrier against environmental agents and, in doing so, helps prevent infection. Lysozyme is a small enzyme that attacks the protective cell walls of bacteria. It breaks the carbohydrate chains in bacterial cell walls, destroys the structural integrity, and causes the bacteria to burst under their own internal pressure. Lysozyme plays a role in antibacterial disease defense, particularly against gram-positive bacteria. Both antiviral (O'Neil et al., 2001) and antifungal (Samaranayake et al., 2001) activity has been reported. Lysozyme in

cattle plays a role in gastric digestion and in chicken egg whites functions as an antibiotic. Lysozyme occurs in tears, nasal mucus, milk, saliva, blood serum, many types of tissues and secretions of different animals, including vertebrates and invertebrates, and in plant latex (O'Neil et al., 2001).

Lactoferrin is an iron-binding glycoprotein (~80 kDa) consisting of approximately 700 amino acids and is found in milk, tears, saliva and other mammalian body secretions (Ekstrand, 1994). In human milk, it is a major component of whey protein with 6-8 grams/liter in colostrum (foremilk) and 2-4 grams/liter in "mature" milk (Harper, accessed 2006). Bovine (cow) milk contains 5-20 times less by weight. Lactoferrin is reported to have broad antimicrobial properties (against bacteria, fungi, and viruses), an immune system regulatory function, anti-inflammatory properties, antioxidant activity, toxin binding properties and anti-cancer activity (Harper, accessed 2006). Lactoferrin may exist in several forms: iron deficient (apo-form), iron sufficient (holo-form), and an "activated" form (Naidu, 2002). The form it takes depends primarily upon pH, the citrate/bicarbonate ion ratios, and the iron content of the medium. Treatment of lactoferrin under specific chemical conditions results in "activation" of lactoferrin. The iron deficient (apo-) and activated forms, due primarily to their ability to sequester iron, are most active in their antimicrobial properties (Naidu, 2002).

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.

References

Ekstrand B, Dillon VM and Board RG (1994) Lactoperoxidase and lactoferrin. Natural Antimicrobial Systems and Food Preservation. Pp15-63.

Harper, accessed 12/2006. http://www-fst.ag.ohio-state.edu/People/HARPER/Functional-foods/Milk%20Components/LACTOFERRIN.html.

Naidu, AS. 2002. Activated Lactoferrin - A New Approach to Meat Safety. Food Technol. 56: (3) 40-46.

O'Neil MJ, Smith A, Heckelman PE (2001) Lysozyme *In*: The Merck Index. 13th edition, Vol 13th edition. Merck & Co., Inc., Rahway, NJ. p. 1011.

Samaranayake YH, Samaranayake LP, Pow EH, Beena VT, Yeung KW (2001) Antifungal effects of lysozyme and lactoferrin against genetically similar sequential *Candida albicans* isolates from a human immunodeficiency virus-infected southern Chinese cohort. J. Clin. Microbiol. **39:** 3296-3302.

Appendix 3: Threatened or Endangered Species for Kansas (17 species)
(http://ecos.fws.gov/tess_public/StateListingAndOccurrence.do?state=KS)

Animals

- Bat, gray (*Myotis grisescens*)
- Bat, Indiana (*Myotis sodalis*)
- Beetle, American burying (*Nicrophorus americanus*)
- Crane, whooping (*Grus americana*)
- Curlew, Eskimo (*Numenius borealis*) (shorebird)
- Eagle, bald (*Haliaeetus leucocephalus*)
- Madtom, Neosho (*Noturus placidus*)(fish)
- Plover, piping (*Charadrius melodus*)(shorebird)
- Shiner, Arkansas (*Notropis girardi*)(fish)
- Shiner, Topeka (*Notropis topeka* (=*tristis*))
- Sturgeon, pallid (Scaphirhynchus albus)
- Tern, least (*Sterna antillarum*)
- Vireo, black-capped (*Vireo atricapilla*)
- Wolf, gray (*Canis lupus*)

Plants

- Clover, running buffalo (*Trifolium stoloniferum*)
- Milkweed, Mead's (*Asclepias meadii*)
- Orchid, western prairie fringed (*Platanthera praeclara*)

SUPPLEMENTAL PERMIT CONDITIONS

For Release of rice containing genes for lactoferrin, lysozyme or serum albumin

USDA-APHIS-BRS Permits **06-278-01r, 06-278-02r and 06-285-02r**

I. Compliance with Regulations

1. Any regulated article introduced not in compliance with the requirements of 7 Code of Federal Regulation Part 340 or any standard or supplemental permit conditions, shall be subject to the immediate application of such remedial measures or safeguards as an inspector determines necessary, to prevent the introduction of such plant pests. The responsible party may be subject to fines or penalties as authorized by the Plant Protection Act (7 U.S.C. 7701-7772).

2. This Permit (APHIS form 2000) does not eliminate the permittee's legal responsibility to obtain all necessary Federal and State approvals, including: (A) for the use of any non-genetically engineered plant pest or pathogens as challenge inoculum; (B) plants, plant parts or seeds which are under existing Federal or State quarantine or restricted use; (C) experimental use of unregistered chemicals; and (D) food, feed, pharmacological, biologic, or industrial use of regulated articles or their products and co-mingled plant material. In the latter case, depending on the use, reviews by APHIS, the U.S. Food and Drug Administration, or the U.S. Environmental Protection Agency may be necessary.

3. The procedures, processes, and safeguards used to prevent escape, dissemination, and persistence of the regulated article as described in the permit application, in APHIS-approved Standard Operating Procedures (SOPs) and, in the supplemental permit conditions must be strictly followed. The permittee must maintain records sufficient to verify compliance with these procedures, including information regarding who performed the activity. Persons performing such activities shall have received training as described in a training program submitted to and approved by APHIS. These records are subject to examination by APHIS. APHIS must be notified of any proposed changes to the protocol referenced in the permit application.

II. Reporting Unauthorized Releases and Unintended Effects

1. According to the regulation in 7 CFR § 340.4(f)(10)(i), APHIS shall be notified orally immediately upon discovery and notified in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article.

    - For immediate oral notification, contact APHIS/BRS Compliance Staff at (301) 734-5690 and ask to speak to a Compliance and Inspection staff member.
    - In the event of an emergency and you are unable to reach APHIS/BRS Compliance Staff at the above number, you may call:

The APHIS/BRS Regional Biotechnology Coordinator assigned to the state, where the field test occurs

For Western Region, contact Ralph Stoaks by phone at (970) 494-7573 or e-mail Ralph.D.Stoaks@aphis.usda.gov

Or

The APHIS/PPQ Regional Biotechnology Coordinator assigned to the state where the field test occurs

For Western Region, contact Stacy Scott by phone at 970-494-7577 or e-mail Stacy.E.Scott@aphis.usda.gov

Or

The APHIS State Plant Health Director for the state where the field tests occur.
Mr. Russell McKinney
Phone: 785-270-1381
Fax: 785-235-1464
Russell.A.McKinney@aphis.usda.gov

2. According to the regulation in 7 CFR § 340.4(f)(10)(ii), APHIS shall be notified in writing as soon as possible but within 5 working days if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the permit application or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms).

3. Written notification should be sent by one of the following means:

By e-mail:
BRSCompliance@aphis.usda.gov

By mail:
Biotechnology Regulatory Services (BRS)
Compliance and Inspection Branch
USDA/APHIS
4700 River Rd. Unit 147
Riverdale, MD 20737

III. Perimeter Fallow Zone

1. To ensure that transgenic plants are not inadvertently commingled with plants to be used for food or feed, a perimeter fallow zone of at least 50 ft. must be maintained around the transgenic test site in which no crops are grown to be harvested or used for food or feed.

2. The perimeter fallow zone shall be managed in a way that allows detection and destruction of volunteer plants that are the same as, or sexually compatible with, the transgenic plants.

IV. Dedicated Planting and Harvesting

1. To ensure that the regulated article is not inadvertently removed from the site, planting and harvesting equipment must be dedicated for use in the permitted test site(s) from the time of planting through the end of harvest.

2. After harvest, you will not be required to obtain APHIS authorization to use this equipment on APHIS -permitted sites (same sites or different sites) planted with same transgenic crop, with the target protein(s) authorized under this permit, in subsequent growing seasons under an extension of this permit or a different permit.

3. Authorization is required from APHIS before this planting and harvesting equipment can be used on sites planted to crops not included under this permit. Ventria must notify APHIS/BRS and the State Regulatory Official at least 21 calendar days in advance of cleaning this equipment for this purpose so that APHIS may schedule an inspection to ensure that the equipment has been cleaned appropriately.

V. Cleaning of Equipment

1. To minimize the risk of seed movement and commingling, equipment used for planting and harvesting, as well as other field equipment (e.g. tractors and tillage attachments, such as disks, plows, harrows, and subsoilers) used at any time from the time of planting through the post-harvest monitoring period must be cleaned in accordance with procedures submitted to and approved by APHIS before they are moved off of the test site.

2. Equipment used to transport seeds or harvested material must be cleaned prior to loading and after transportation to the authorized site in accordance with procedures submitted to and approved by APHIS.

3. Seed cleaning and drying must be performed in accordance with the procedures submitted to and approved by APHIS to confine the plant material and minimize the risk of seed loss, spillage, or commingling.

VI. Use of Dedicated Storage Facilities

1. Dedicated facilities (locked or secured buildings, bins, or areas, posted as restricted to authorized personnel only) must be used for storage of equipment and regulated articles for the duration of the field test.

2. Before returning these facilities to general use, they must be cleaned in accordance with procedures submitted to and approved by APHIS. **Ventria must notify** APHIS/BRS and the State Regulatory Official at least 21 calendar days in advance to allow for APHIS to schedule an inspection to ensure that the facilities have been cleaned appropriately. APHIS authorization should be received before facilities are returned to general use.

VII. Post Harvest Monitoring

The field test site including the perimeter fallow zone must be monitored for the presence of volunteer rice plants for 1 year after termination of the field test. Viable plant material should not remain at the test site following termination.

VIII. Post Harvest Land Use Restrictions

1. Production of food and feed crops at the field test site and the perimeter fallow zone is restricted during the growing season that follows harvest or termination of the field test.

2. Permission must be obtained from APHIS/BRS prior to planting any food or feed crop at the field test site and perimeter fallow zone during the post-harvest monitoring period. Requests for such permission are not encouraged and will not be granted in cases where there is a reasonable potential for plant material derived from, or originating from, the regulated articles to become mixed with the proposed food or feed crop during harvesting.

IX. Inspections

1. APHIS Biotechnology Regulatory Services (BRS) and/or an APHIS/PPQ Regional Biotechnologist, APHIS/BRS Regional Biotechnology Coordinator or APHIS State Plant Health Director may conduct inspections of the test site, facilities, and/or records at any time.

2. APHIS may invite the FDA or State Regulatory Officials to participate in these inspections.

3. Inspections will likely correspond to the beginning of the field test, mid-season or during flowering, at and/or following harvest, and during the post-harvest monitoring period.

4. Inspections will include examination of records that verify compliance with regulations and SOPs.

X. Reports and Notices

Send notices and all reports (CBI and CBI-deleted or non-CBI copies) to BRS by e-mail, mail, or fax.

BRS E-mail:
BRSCompliance@aphis.usda.gov

BRS Mail:
Biotechnology Regulatory Services (BRS)
Compliance and Inspection Branch
USDA/APHIS
4700 River Rd. Unit 147
Riverdale, MD 20737

BRS Fax:
Compliance and Inspection Branch
(301) 734-8669

In addition, fax the CBI deleted or non CBI version of the pre-planting and pre-harvest (termination) notices to the State Regulatory Official(s)

Contact information for State Officials
http://www.nationalplantboard.org/member/index.html

1. **Pre-Planting Notice**
   At least 7 calendar days before planting, submit a Pre-Planting notice that includes the following information for each field test site:
   i. Provide APHIS/BRS with the contact information for each field test site.
   ii. Indicate if planting and harvesting equipment will be moved between authorized field test sites.
   iii. A map that clearly identifies the site location to facilitate any inspections by USDA personnel.
   iv. The planned number of acres for each gene construct.
   v. The planned planting date

2. **Planting Report**
   Within 28 calendar days after planting, submit a planting report that includes the following information for each field test site:
   i. A map of the site, with sufficient information to locate it, that includes: the state, county, address, GPS coordinates for each corner of the plot;
   ii. The location and the approximate number and/or acres of transgenic plants which were actually planted at the test site for each of the target proteins;
   iii. The total acreage of the test plot (exclude border rows, if any);
   iv. The distance from the genetically engineered plants to the nearest plants of the same crop which will be used for food, feed, or seed production. A survey should be done within the distance specified in the permit.
   v. The actual planting date.

3. **Pre-Harvest/ Termination Notice**
   At least 21 calendar days prior to the anticipated harvest or termination, submit a Notice indicating the planned date of harvest **or** termination and the contact information for each field test site. For multiple harvests, submit the notice prior to the initial harvest.

4. **Field Test Report**
   Within 6 months after the end of the field test (final harvest or crop destruct), the permittee is required to submit a field test report. Field test reports shall include:
   i. APHIS reference number
   ii. Methods of observation.
   iii. Resulting data.
   iv. Analysis of all deleterious effects on plants, non-target organisms, or the environment.
   v. A list of the lines planted at each site
   vi. Disposition table
   The disposition table should contain the following information: site name (or GPS), crop, gene, harvest date, and disposition of harvested material.
   The disposition table is a formal record of how the regulated material was removed from the environment. An accounting of the harvested material should be provided with regards to what material is harvested, how much material is harvested per site, what is done to devitalize residual and harvested

material at the site, where the harvested material is transported, stored and further processed up to the time it is taken to a contained facility.

5. **Monitoring Report**

Within 3 months after the end of the monitoring period, submit a volunteer monitoring report. The report must include:

i. Dates when the field site and perimeter fallow zone were inspected for volunteers.
ii. Number of volunteers observed.
iii. Any actions taken to remove or destroy volunteers.

XI. Additional Requirements

1. Ventria will submit contingency/emergency/ mitigation management plans describing detailed procedures that Ventria will undertake in the event of accidental or unauthorized release or commingling with any other non-PMP/PMI material (including reporting requirements to APHIS/BRS).

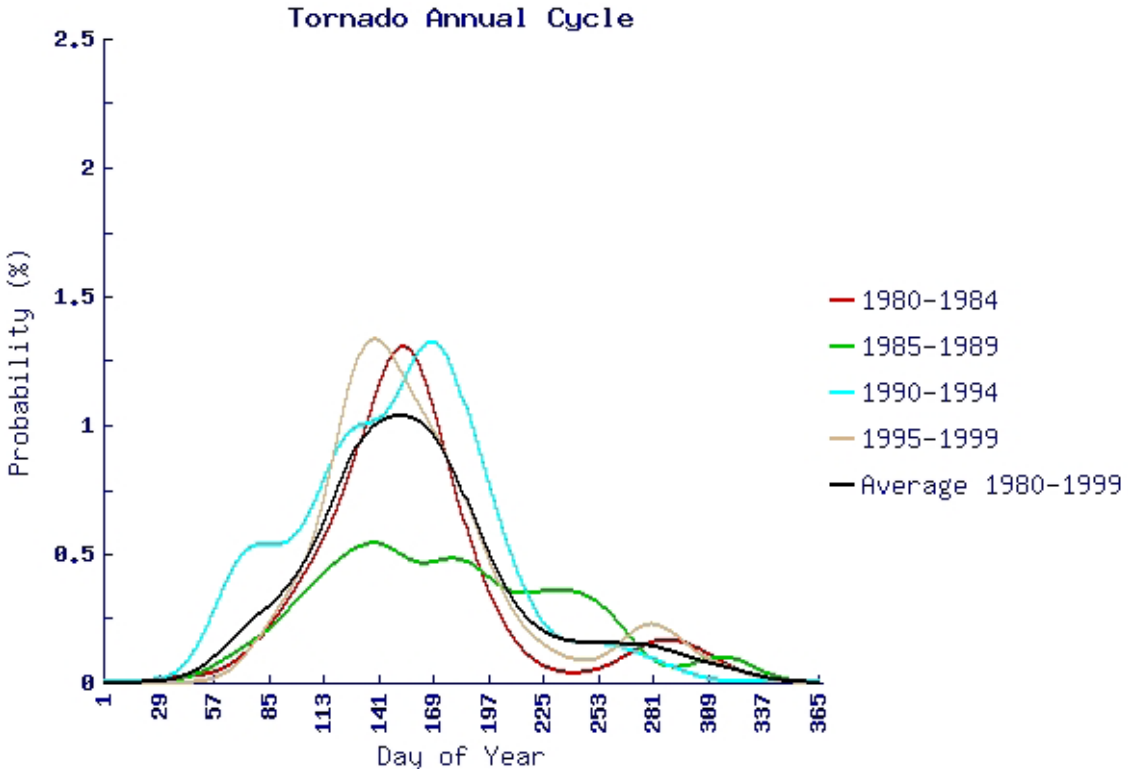
2. Ventria will make available to APHIS gene specific testing procedures to identify PMP/PMI lines being grown.

3. Ventria will maintain chain of custody documentation or accounting for large quantities of PMP/PMI viable materials. Documentation will be subject to inspection/auditing during scheduled inspections.

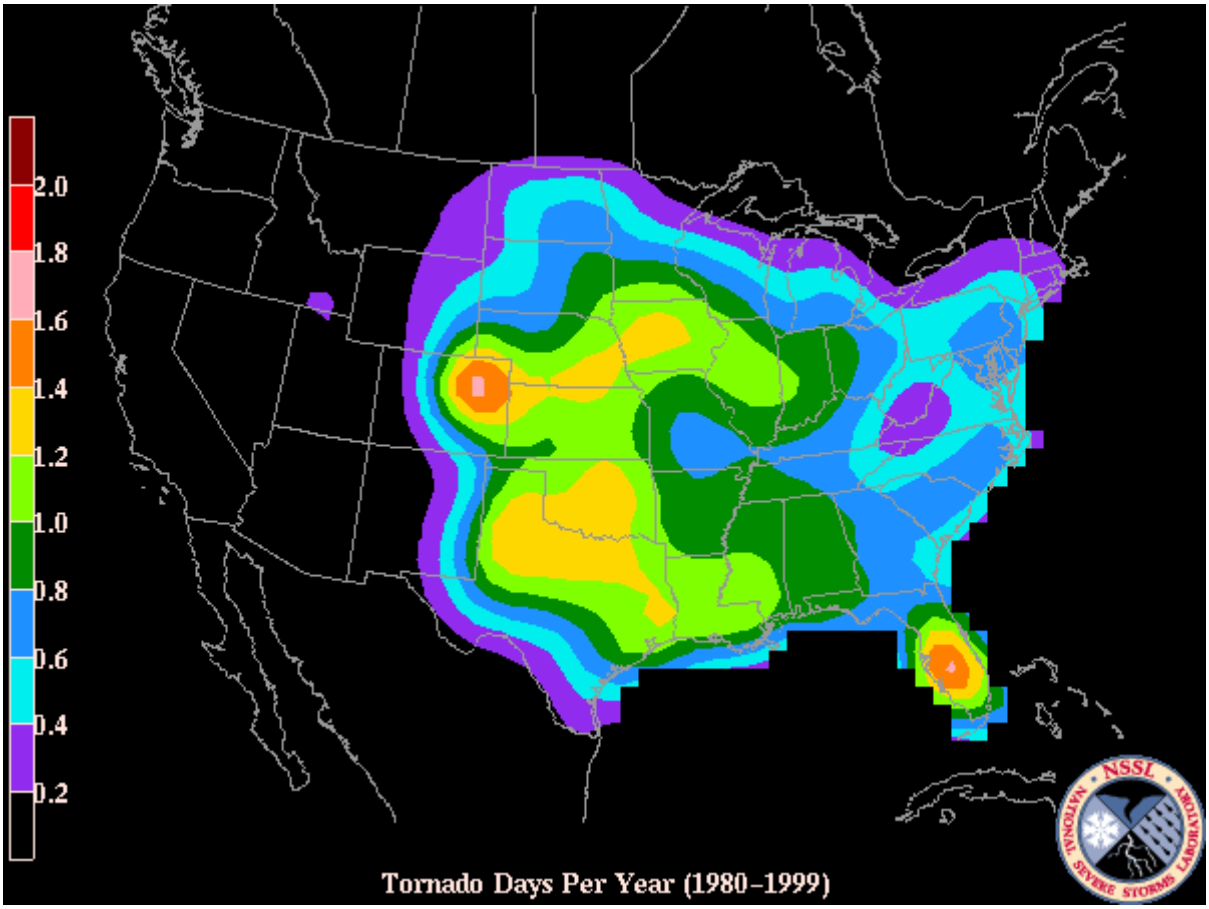
4. All dedicated storage/ dedicated use equipment shall be labeled indicating for NON-FOOD/ NON-FEED USE ONLY using labels/placards supplied by APHIS.

5. Ventria must monitor for recombinant lactoferrin, lysozyme and serum albumin in the soil surrounding the plants mid way through the growing season and after the crop is harvested. These data must be submitted with the field data report.

Appendix 5: Extreme Weather Events

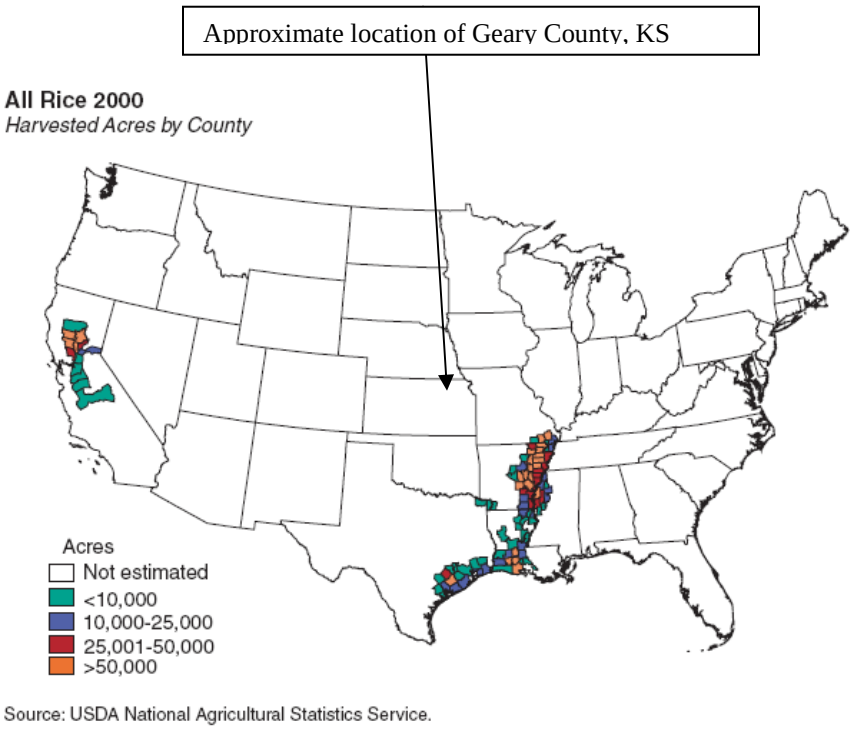


Historical probability of occurrence of a tornado during any 24-hour period in the Geary County, Kansas area from January through December. From http://www.nssl.noaa.gov/hazard/hazardmap.html (accessed 4/10/2007).



Mean number of days per year with one or more events within 25 miles of a point.
From: http://www.nssl.noaa.gov/hazard/totalthreat.html (accessed 3/29/2007).

Appendix 6: Commercial rice growing regions in the U.S. and location of Ventria's proposed plantings in Geary County, Kansas



Location of Rice Acreage and Regions

Rice is grown in the United States in two distinct areas: (1) northern California and (2) an area in the southern United States that follows the Mississippi River from the boot heel of Missouri south to northeastern Louisiana and then continues along the Gulf Coast from southwestern Louisiana down through the lower Gulf Coast of Texas (see maps).

From Livezey, J. and L. Foreman, Characteristics and Production Costs of U.S. Rice Farms. 2004. Electronic Report from the Economic Research Service, Bulletin Number 974-7 (www.ers.usda.gov).