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March 29, 2007

Via eDocket

Docket No. APHIS-2007-0006

Regulatory Analysis and Development, PPD APHIS

Station 3A-03.8, 4700 River Road, Unit 118

Riverdale, MD 20737-1238.

Re: Docket No. APHIS-2007-0006 - *Ventria Bioscience; Availability of an Environmental Assessment for Field Tests of Rice Genetically Engineered To Express Lactoferrin, Lysozyme, or Serum Albumin.*

The USA Rice Federation (USA Rice), located at 4301 N. Fairfax Drive, Suite 425, Arlington, VA 22203 is the national advocate for all segments of the rice industry. The USA Rice Producers' Group, the USA Rice Millers' Association, the USA Rice Merchant's Group and the USA Rice Council form the membership of the Federation. Through our charter members we represent the industry in Arkansas, California, Florida, Louisiana, Mississippi, Missouri, and Texas.

The purpose of this letter is to provide comment on the February 28, 2007, Federal Register notice (72 FR 8959) concerning the environmental assessment for a permit for Ventria Bioscience (Ventria) to grow pharmaceutical rice in Kansas. The USA Rice Federation respectfully requests that the permit be denied based on several outstanding factors. Our policy on the issue of introducing genetically modified (GM) rice in the U.S., as established by our Board of Directors states in part:

“We support the development of genetically modified rice varieties, but do not support their commercial release prior to scientific-based regulatory approval and consumer acceptance (i.e., no negative impact on commercial sales of U.S. rice).”

Prior to August 18, 2006, our foreign markets made it clear that they would not risk adverse public reaction by even the appearance that U.S. non-GM food and feed rice could be commingled with any type of GM rice, be it food and feed, pharmaceutical or plant industrial. Since August 18 the U.S. rice industry has been hit hard by the loss of foreign markets and required destination testing as a result of the accidental introduction of Liberty Link Rice 601 (LL601) and Liberty Link Rice 62 (LL62). The legal and financial repercussions of those accidental releases are still ongoing. To resolve the domestic crisis LL601 was given expedited approval here in the U.S. however it remains a regulated genetic event everywhere else in the world and will do so because Bayer CropScience is not willing to pursue foreign deregulation.

LL62 on the other hand is deregulated here in the U.S. and in a very few foreign countries, but its deregulation is being held up in major markets like the European Union.

As a result of the market repercussions, the U.S. rice industry took the unprecedented action of banning Cheniere, a popular variety of rice that was infiltrated by the LL traits, and initiating seed testing to ensure the world a clean U.S. rice supply.

Now, APHIS is requesting comment on allowing the planting, harvesting and milling of a pharmaceutical rice with human genes/proteins, albeit in a traditionally non-rice state. However, immediately after the publication of this proposed permit, the agency announced that Clearfield 131, the popular replacement variety for Cheniere, has been infiltrated by an unknown GM trait and the agency took the unprecedented action of issuing an Emergency Action Notification detaining all Clearfield 131 seed. The GM trait has only recently been identified as yet another Liberty Link event – Liberty Link Rice 604 (LL604).

Taken together, the announcements and actions of the last seven months are unfortunate but certain evidence that the U.S. regulatory regime for biotech research is unable to achieve its goal of protecting the environment and the public's food and feed supply from unwanted intrusions of genetically engineered material. If Ventria's pharmaceutical rice were to escape into the commercial rice supply, the financial devastation to the U.S. rice industry would likely be absolute. There is no tolerance, either regulatory or in public perception, for a human gene-based pharmaceutical to end up in the world's food supply.

While APHIS may base its decision on the stringency of its permit controls and not on market and financial considerations, it is still negligent for the agency to risk an entire industry for the sake of profit for one company. Already, the USA Rice Federation is receiving complaints from the public that are confusing the Ventria permit with the latest Liberty Link rice issue and assuming the worst. Markets are already questioning the same thing. Also, as previously stated, the agency has shown that existing controls approved for genetic events in rice (and other crops such as corn) have failed repeatedly.

A review of the APHIS Environmental Assessment (EA) in response to the three permit applications from Ventria Bioscience raises several concerns.

1. On page 3, APHIS states that “the **majority** of harvested seeds will be milled to flour and will not be shipped to any outside milling facilities.” On page 9, APHIS states that “**some viable seed** may be stored ...and/or shipped to other locations for analysis or planting...” The next sentence refers to controls on “interstate shipping”.¹ This infers that the seeds will be shipped out of state while at the same time seemingly abrogates any control of *intrastate* shipping. Taken together these statements appear to infer that some seed will be saved and shipped to other unknown, out of state locations that are not covered in this Environmental Assessment. (emphasis added)
2. Ventria will extract lysozyme and lactoferrin, commonly found in milk and saliva, to be used in various commercial food and drinks as well as medical foods. However the company will also extract recombinant human serum albumin (HSA) protein, which

¹ USDA/APHIS Draft Environmental Assessment In response to Permit applications 06-278-01r, 06-278-02r and 06-285-02r received from Ventria Bioscience to conduct field planting of rice (*Oryza sativa*) genetically engineered to express human lysozyme, lactoferrin and serum albumin

- according to APHIS, is produced in the liver and has no “oral or dermal activities.”² Also, past NEPA Decision Worksheets, while listing FDA GRAS (Generally Recognized As Safe) decisions for lysozyme³ and lactoferrin⁴, note no such GRAS decision for HSA.⁵ These facts would appear to indicate that HSA has no possibility of being declared safe should it accidentally enter the food supply.
3. APHIS repeatedly⁶ states that it requires a ¼ mile (1320 ft) isolation from other rice, basing this figure on going one hundred thirty-two times beyond the Association of Official Seed Certifying Agencies (AOSCA) standard of 10 feet of separation for “foundation certified rice seed”.⁷ Using the AOSCA figure as the basis of their minimum isolation distance, by definition, makes the ¼ mile distance meaningless and arbitrary. The reason is that the AOSCA distance, while unarguably being a benchmark in terms of seed isolation standards, was designated for issues of non-GM, varietal purity. It was not created to be used to ensure genetic purity. This is a blatant case of comparing apples to oranges and APHIS would have done just as well using apple standards to set their isolation standards for pharmaceutical rice. Furthermore, the agency goes on to state, “In practice, there is no known commercial rice grown in the state of Kansas.”⁸ In other words, since APHIS knows of no other rice being grown in the state, it opted for an arbitrary isolation distance without utilizing the scientific process to determine a distance appropriate for the crop and the GM event. This begs the question of what will happen should someone start growing conventional rice in Kansas, possibly near the fields of pharmaceutical rice?
 4. In the 2004 EA for Ventria’s pharmaceutical rice project in Missouri, the equipment was all dedicated, including onsite storage and milling.⁹ For the Kansas project, the EA states that storage and milling is approximately 10 miles away. The EA allows for other uses of the equipment, storage and milling facilities after cleaning.¹⁰ Since the rice is being grown next to other crops (listed as corn, soybeans and winter wheat)¹¹ it is possible that human error coupled with the multiple use of the equipment and facilities may lead to an infiltration of the pharmaceutical rice in other harvested food supplies.
 5. APHIS also states there are post harvest land use restrictions on planting non-pharmaceutical rice food and feed crops in the fallow zone or the field test perimeter during the monitoring period, however the agency allows that permission can be obtained.¹² For purposes of environmental safety, it should be plainly stated that no food or feed crops will be allowed. After all, while it might be easy to see volunteer rice in a soybean crop, it won’t be too easy to see rice in a wheat field.

² EA appendix 2, pg. 14.

³ NEPA Decision Worksheet and Summary for Permit 05-332-02r

⁴ NEPA Decision Worksheet and Summary for Permit 05-332-01r

⁵ NEPA Decision Worksheet and Summary for Permit 06-285-01r

⁶ EA. pp 7 & 8.

⁷ EA. pg 7.

⁸ EA. pg 7.

⁹ USDA/APHIS Environmental Assessment In response to permit application (04-302-01r) received from Ventria Bioscience for field-testing of rice, *Oryza sativa*, genetically engineered to express human lactoferrin, pg 4.

¹⁰ EA. Appendix 4, Section IV, pg 18.

¹¹ EA. pp 8 & 10.

¹² EA. Appendix 4 Section VIII, pg 19.

6. We also note certain static language carried over with little or no modifications from past supporting documents and EAs year after year. One phrase we could not find in this EA is as follows: “Hundreds of field trials have been performed with transgenic rice plants under APHIS authority, and APHIS is familiar with rice biology and methods to manage confined rice field trials. Ventria previously grew rice in these same locations in North Carolina in 2005 and satisfactorily maintained confined plantings.”¹³ First, as we now know not all of the “hundreds” of the rice field trials under APHIS authority resulted in no adverse impact to the commercial rice crop since we now are dealing with three escaped genetically engineered events. Second, noticing the time delay between when the industry reasonably believes the aforementioned events escaped and their subsequent discovery, APHIS cannot be assured that Ventria’s past field trials were “satisfactorily maintained.”

Therefore the USA Rice Federation has no choice but to request in the strongest possible terms that the permit for Ventria’s pharmaceutical rice be denied. A denial by APHIS would be in accordance with Alternative #1 in Section IV, page 6 of the Draft Environmental Assessment for Ventria’s permits.

In addition, because of no assurance or confidence that Ventria pharmaceutical rice can be kept separate from commercial food and feed rice, we believe that USDA must engage FDA in a risk analysis and risk assessment of the potential health affects that could occur when genetic material from the pharmaceutical rice is eventually found in commercial rice. In addition, APHIS should conduct a full Environmental Impact Statement concurrent with FDA’s analysis. Further production of Ventria’s pharmaceutical rice should not occur in the U.S. until, at a minimum, the FDA and APHIS have concluded the studies, assuming the agencies determine that there are no potential health effects. At that time, if Ventria still seeks a permit, the issue can again be reviewed through the public notice and comment process of USDA.

Thank you for your consideration of this request. Please contact me if I can be of further service at 703-236-1445.

Regards,



Steven Hensley
Director Regulatory Affairs
USA Rice Federation

¹³ NEPA Decision Summary for Permit 05-332-01r. January 19, 2006