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June 27, 2007

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To the Chief Engineer or to whom it may concern:

The Center for Food Safety (CFS) submits the following comments to the Kansas Department of Agriculture, Division of Water Resources, Chief Engineer, on the pending Water Term Permit applications submitted on behalf of Ventria, for use in field trials of three lines of rice genetically engineered to produce the novel experimental pharmaceuticals – recombinant, rice-expressed human lactoferrin, lysozyme and serum albumin – in Geary County, Kansas. These Water Term Permits include File Nos. 20079034 and 20079035 as well as any other related pending permit applications. CFS understands that these applications are currently being reviewed by the Division and Chief Engineer (Phone Conversation with Lane Letourneau and Carolyn Jordan, June 18, 2007).

Summary

As an interested party, CFS respectfully submits the following comments to be considered by the Chief Engineer in his deliberative administrative process.

We believe the requested Term Permits should be denied.

First, the granting of Ventria's Term Permit applications "prejudicially and unreasonably affects the public interest." K.S.A. § 82a-711(a). The Term Permits will facilitate the experimental Ventria pharmaceutical rice field trials in Geary County, and we believe those open air field trials prejudicially and unreasonably affect the public interest. The consideration of the field trials the Term Permits will permit are relevant to the Chief Engineer's consideration as whether the public interest will be "prejudicially and unreasonably affect[ed]" as part of "all other matters pertaining to the question." K.S.A. § 82a-711(b)(5).

Second, the proposed irrigation of experimental pharmaceutical crops grown by Ventria is not a "beneficial use" as that term is understood in traditional water law, as codified by Kansas law. 82a-711(a).

Third, any grant of the Term Permit applications may well impair existing water rights. 82a-711(a).

CFS respectfully requests a timely carbon copy of the Chief Engineer's decision when it is issued.

Introduction

CFS is a non-profit public interest and environmental advocacy membership organization established in 1997 by its sister organization, International Center for Technology Assessment, for the purpose of challenging harmful food production technologies and promoting sustainable alternatives. CFS combines multiple tools and strategies in pursuing its goals, including litigation and legal petitions for rulemaking, legal support for various sustainable agriculture and food safety constituencies, as well as public education, grassroots organizing and media outreach.

CFS strongly opposes the use of genetically engineered food crops to produce experimental pharmaceuticals, due to potential environmental, human health and economic risks from contamination of food crops with pharmaceutical substances. Outdoor cultivation of pharmaceutical-producing food crops is also opposed by other public interest groups, the food industry,[1] and even the editors of the world's leading biotechnology journal, who compared it to a drug company "packaging its pills in candy

[1] See "Plant-Made Pharmaceuticals and Plant-Made Industrial Compounds," Position Paper of the Grocery Manufacturers of America & Food Products Association, 2007, http://www.gmabrands.com/publicpolicy/docs/Plant-MadePharmaceuticalsandPlant-Madel.pdf.

wrappers or flour bags or storing its compounds or production batches untended outside the perimeter fence."[2] Growing drugs in foods also undermines confidence in the integrity of the U.S. food supply, and in the "coordinated framework" for regulation of agricultural biotechnology products.

CFS has numerous serious concerns about these proposed Ventria field trials in Geary County, Kansas. CFS submitted lengthy comments to the United States Department of Agriculture, Animal and Plant Health Inspection Service (USDA, APHIS) on the Ventria field trials on March 30, 2007. Because CFS believes these concerns are relevant to the Chief Engineer's decision as well, these comments are attached in full (See appendix A, enclosed).

Because we are a public interest organization, and because we recognize that by law the Chief Engineer must consider the public interest in his decision on the pending Water Term Permits,[3] we submit the these comments with the intent to best inform the Chief Engineer's deliberations.

Statutory Framework

K.S.A. § 82a-711
KANSAS STATUTES ANNOTATED
CHAPTER 82A.--WATERS AND WATERCOURSES
ARTICLE 7.--APPROPRIATION OF WATER FOR BENEFICIAL USE
82a-711. Permits to appropriate water; standards for approval of use; review of action on application.

(a) If a proposed use neither impairs a use under an existing water right nor prejudicially and unreasonably affects the public interest, the chief engineer shall approve all applications for such use made in good faith in proper form which contemplate the utilization of water for beneficial purpose, within reasonable limitations except that the chief engineer shall not approve any application submitted for the proposed use of fresh water in any case where other waters are available for such proposed use and the use thereof is technologically and economically feasible. Otherwise, the chief engineer shall make an order rejecting such application or requiring its modification to conform to the public interest to the end that the highest public benefit and maximum economical development may result from the use of such water.

(b) In ascertaining whether a proposed use will prejudicially and unreasonably affect the public interest, the chief engineer shall take into consideration:

(1) Established minimum desirable streamflow requirements;

[2] "Drugs in crops – the unpalatable truth," editorial, *Nature Biotechnology* 22(2), Feb. 2004, p. 133
[3] Term Permits are defined as permits "to appropriate water issued for a specified period of time. At the end of the specified time, or any authorized extension of it, the permit shall be automatically dismissed, and any priority it may have shall be forfeited." K.A.R. 5-1-1(aaaa).

(2) the area, safe yield and recharge rate of the appropriate water supply;

(3) the priority of existing claims of all persons to use the water of the appropriate water supply;

(4) the amount of each claim to use water from the appropriate water supply; and

(5) all other matters pertaining to such question.

(c) With regard to whether a proposed use will impair a use under an existing water right, impairment shall include the unreasonable raising or lowering of the static water level or the unreasonable increase or decrease of the streamflow or the unreasonable deterioration of the water quality at the water user's point of diversion beyond a reasonable economic limit. Any person aggrieved by any order or decision by the chief engineer relating to that person's application for a permit to appropriate water may petition for review thereof in accordance with the provisions of K.S.A. 2006 Supp. 82a-1901 and amendments thereto.

Comments

I. The granting of the Term Permits for Ventria will prejudicially and unreasonably affect the public interest because the permits will facilitate the Ventria experimental pharmaceutical rice field tests and those field tests are not in the public interest.

A. The Public Interest is a Crucial Component of the Chief Engineer's Decision.

For the Water Permits to be granted, the proposed use must not "prejudicially or unreasonably affect[] the public interest." K.S.A. § 82a-711(a). In "ascertaining whether a proposed use will prejudicially or unreasonably affect the public interest," the Chief Engineer must take into consideration a number of factors, including "all other matters pertaining to such question." K.S.A. § 82a-711(b)(5). CFS's concerns about the Ventria project fall under this public interest consideration.

B. Ventria's Experimental Pharmaceutical Field Trials Are Not In the Public Interest Because They Create Environmental, Human Health and Economic Risks.

The field trials involve three distinct lines of rice genetically engineered to produce the novel experimental pharmaceuticals – recombinant, rice-expressed human lactoferrin, lysozyme and serum albumin – in Geary County, Kansas. The USDA has authorized Ventria to plant up to 3,200 acres of pharmaceutical rice, more than an order of

magnitude (ten times) larger than any previous "pharma crop" planting. Although Ventria's actual plantings this year in Kansas may be smaller, the company has stated that future plantings may be ten times larger (30,000 acres).[4] The Ventria plantings in Geary County, Kansas are planned for harvest in fall 2007, and will occur in at least two locations. The possibility of contamination of neighboring food crops, which may be planted at any distance greater than 50 feet from Ventria's rice, creates unnecessary and unacceptable risks to the public and to the environment. The size of a field trial is of great relevance to risk assessment, with larger trials presenting greater risks of "gene escape," as emphasized by the National Academy of Sciences in a critical review of APHIS performance in regulating genetically engineered crops.[5]

CFS has a number of public interest concerns about the experimental Ventria field test, which are summarized below.

First, the experimental rice creates a number of human health risks. The U.S. Food and Drug Administration has not approved the pharmaceuticals Ventria is growing in the rice for human consumption. Fourteen independent scientists have warned of potential adverse health impacts from exposure to even very low levels of one of Ventria's compounds, recombinant human lactoferrin.

Second, Ventria's rice may present environmental hazards, including exacerbation of infections in wildlife, that have not been adequately studied.

Third, while USDA APHIS assures us that there is no danger of Ventria's rice contaminating neighboring cropland, that claim is belied by the agency's abysmal record at regulating genetically engineered (GE) crops, and a string of GE crop contamination episodes that have occurred under its watch. In addition, because Ventria has (inexplicably) chosen to withhold its "standard operating procedures" (SOPs) for cultivating its pharma rice as "confidential business information," it is impossible to judge whether its SOPs will in fact succeed in preventing contamination, as claimed.

. 1. <u>The Experimental Pharmaceutical Crops Ventria Is Planting Are Unapproved for Human Consumption by the Food and Drug Administration</u>

Pharmaceutical-producing food crops generally produce novel, experimental, bioactive compounds that have not been reviewed for potential adverse impacts to human health by our nation's food safety authority, the Food and Drug Administration (FDA). As such, they should not be present in our food supply at any level. Federal policy supports "zero contamination" of the food supply by "plant-made pharmaceuticals," whose presence in food at any level constitutes "adulteration." For example, in 2002, 500,000 bushels of

[4] Kessinger, S. "Biotech rice company seeking sites in Kansas," Discover Western Kansas, June 29, 2006.
[5] *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation*. Committee on Environmental Impacts associated with Commercialization of Transgenic Plants, National Research Council, National Academy of Sciences, Washington, DC: National Academy Press, 2002. http://books.nap.edu/catalog/10258.html

soybeans contaminated with minute quantities of pharmaceutical-producing corn were seized and destroyed, at a cost of over $3 million.[6]

Ventria has tried for two years to obtain FDA approval of its two lead compounds, recombinant human lactoferrin (rhLf) and recombinant human lysozyme (rhLys), as "generally recognized as safe" (GRAS) food additives. Though FDA normally responds to such GRAS petitions within months, it has failed to act on these petitions, as detailed in Table 1. In particular, Ventria's petition to have FDA grant GRAS status to its rhLf languished at the agency for two years, since December 2004. In November 2006, Ventria withdrew this petition when it became clear that the FDA had safety questions that had not been adequately addressed by Ventria. In its letter announcing the withdrawal of the petition, FDA referred to "complex scientific issues" that required further study.[7] Potential human health impacts presented by Ventria's rhLf and rhLys include aggravation of infections, autoimmune disorders, and allergenicity. These issues are addressed in detail in the supporting material accompanying these comments (See A Grain of Caution: A Critical Assessment of Pharmaceutical Rice).

Table 1

Date of petition	Compound	Intended use	Status at FDA	Comments
Nov. 2003	Lactoferrin (Lf) rice	None. Lf rice as contaminant; Lf rice residues after Lf extraction for human food & animal feed	BNF 082; no action[8]	Ventria sought approval of Lf rice as contaminant while publicly claiming Lf rice would not contaminate food
Dec. 2004	Lactoferrin	Ingredient in foods, beverages, medical foods	GRN. #162; withdrawn on Nov. 20, 2006[9]	Ventria withdrew this petition because FDA indicated it would not approve lactoferrin as safe.
June 2005	Lysozyme	Antimicrobial agent; ingredient in various foods	GRN #174; withdrawn[10]	Ventria withdrew this petition in Sept. 2005 for unknown reasons
Jan. 2006	Lysozyme	Ingredient in infant formulas & pediatric oral rehydration solutions	GRN #191; no action[11]	A 2004 National Academy of Sciences panel recommends more stringent testing of new ingredients in infant formulas

We and the FDA are not the only institutions concerned about the potential adverse impacts of Ventria's pharmaceutical rice. Agennix, Inc., the world's leading producer of recombinant human lactoferrin (rhLF), has been developing rhLF as a potent anti-cancer drug under the regulatory authority of the Food and Drug Administration (FDA) since

[6] For one of many articles, see: Toner, Mike. "Alarms sound over 'biopharming'; Tainted crops cast doubt on gene altering," The Atlanta Journal and Constitution, Nov. 17, 2002.
[7] See http://www.cfsan.fda.gov/~rdb/opa-g162.html
[8] See http://www.cfsan.fda.gov/~lrd/biocon.html. Note that BNF 82, the petition number for Ventria's lactoferrin-producing rice, is not present under FDA's "List of Completed Consultations on Bioengineered Foods."
[9] See http://www.cfsan.fda.gov/~rdb/opa-g162.
[10] See http://www.cfsan.fda.gov/~rdb/opa-g174.html
[11] See GRN No. 191 at http://www.cfsan.fda.gov/~rdb/opa-gn06.html

1996. Agennix submitted detailed comments to USDA APHIS highly critical of Ventria's field trial and opposed its approval. (See Agennix comments, enclosed).

Agennix also included a scientific assessment by 14 independent scientific experts showing that there are significant, unresolved safety concerns regarding recombinant human lactoferrin in rice. (See Agennix Scientific Assessment, enclosed). These safety concerns are not dose-related and include important questions about the potential for rice-derived rhLf to cause allergic or other hazardous immune system reactions. The key points of this expert scientific assessment include:

* "allergic and immunological reactions could occur even with trace exposures to rice-produced rhLf" (p. 6), hence even at levels to be expected if neighboring food crops become contaminated with rhLf;
* USDA APHIS's assessment of rhLf relied on comparison to a cow-derived version of lactoferrin that is very different in structure to Ventria's rhLf and may present wholly different risks (pp. 1-2);
* Ventria's rhLf, by the company's own admission, has a high probability of triggering the specific immune system response (IgE antibodies) characteristic of food allergies (p. 4);
* Totally unexpected, life-threatening reactions have occurred to other recombinant, immunomodulatory proteins in the context of strictly controlled clinical trials, hence the utmost caution is called for in preventing inadvertent human exposure to Ventria's rhLf (TeGenero Case, p. 8)
* Due to the possibility of cross-contamination with other human food, the planting of rice that produces rhLF, before these safety issues are satisfactorily resolved, would create an unnecessary and unacceptable risk to the public and to the environment (pp. 9-10).

2. Unknown Risks From The Lack of Transparency

There are many unknowns about the risks of the field trials because of the lack of transparency. USDA APHIS failed to make any of Ventria's application materials publicly available. In particular, APHIS has failed to make available to the public the "Standard Operating Procedures" (SOPs) that Ventria says it will follow in conducting these field trials. These SOPs contain crucial information that public interest groups like CFS need to assess the plantings or offer informed public comment, particularly as regards to the adequacy or inadequacy of Ventria's gene containment measures.

3. Inadequate Gene Containment

There are many indications that Ventria will not be able to prevent its pharmaceutical rice from escaping the bounds of the field test site and contaminating neighboring crops.

Below, we briefly describe three avenues of contamination that are treated at greater length in our comments to USDA (see supporting materials).

Animal dispersal of seed

Rice is a favored food source of birds and mammals, and the USDA APHIS Assessment lists no measures to exclude animals of any sort from Ventria's rice. While animals that consume pharma rice will digest most of the ingested grains, some fraction will remain undigested and be defecated in viable form. Animals that consume pharma rice could easily defecate viable grains beyond the boundaries of the test sites plus surrounding fallow zones, which are only 50 feet. Such viable seeds could be deposited in neighboring cropland, sprout in the same or subsequent seasons in surrounding fields of soy, corn, wheat or other crops, and be harvested with these crops, adulterating these harvests with pharmaceutical compounds not approved by the FDA.

Birds present the greatest potential for transporting pharma rice grains beyond the bounds of the field test plots. The Junction City, Kansas area has resident bird populations and also lies along the Central Flyway, and so is visited by many species of migratory birds. The supporting material contains an analysis of rice consumption by common resident bird species as well as migratory birds, and the accompanying risk of crop contamination.

Dispersal of seed by severe weather events

Tornadoes are relatively frequent in Kansas. Tornadoes, but also lesser severe weather events, have the potential to uproot rice plants and/or strip plants of grains and send them great distances. Another risk presented by severe weather with heavy rains is flooding, which can transport rice in floodwaters. APHIS says the sites are not prone to flooding, but offers no references to support this statement, or analysis of the frequency of severe weather/heavy rain/flood events. In fact, the U.S. Geological Survey reports at least four major floods affecting the area of the proposed field trials, and the Smoky Hill River in particular, in 1935, 1951, 1973 and 1993,[12] a list which excludes lesser flooding events. The Smokey Hill River passes just one mile from two different rice plots, and the rice fields are 3-4 miles from the Kansas River.[13] Pharma rice could be swept far from the field test sites on floodwaters of these rivers. Severe weather accompanied by heavy rain would very likely undermine the one measure required by APHIS to check seed dispersal: screens on irrigation outlets.[14]

Seed dispersal during transport of rice

Grain losses upon harvest and transportation of the rice crop are inevitable. Harvested seed will be transported some undefined distance for drying and cleaning in a "designated/dedicated staging area in the same county,"[15] which could mean transport of viable seeds over miles to dozens of miles. It is not clear whether this "staging area" is an enclosed facility. The proposed planting sites (which may change) are up to 10 miles

[12] "Historic Floods of Kansas," U.S. Geological Survey Kansas Water Science Center, http://ks.water.usgs.gov/Kansas/waterwatch/flood/historic.html
[13] EA at 10.
[14] EA at 7.
[15] EA at 9.

away from Ventria's storage and processing facility in Junction City, KS.[16] It is not clear if the staging area is in Junction City or elsewhere. If not, viable pharma rice will be transported twice before being milled. Only "the majority" of the harvested seeds will not be shipped to any outside milling facilities.[17] Thus, a significant fraction of the seeds may be shipped long distances, some across state boundaries.[18] Some of the many ways in which it is impossible to contain rice during harvest and transportation, based on normal rice cultivation, harvest and trasnportion practices, are described below. In the absence of Ventria's SOPs, we are unable to provide more specific analysis, but the supporting materials contain a description of the the rice harvest, milling and transportation process where unintended dispersal of rice seed can occur.

The conclusion is that there is no way to completely contain rice in its passage from from field to mill, and therefore no way to obtain a guarantee of zero contamination.

4. Dangers to Wildlife

Given the apparent complete absence of measures to exclude animals from the field test sites, animals will ingest pharma rice in undetermined amounts. As demonstrated above, birds in particular often consume large quantities of rice whenever it is available. In some cases, rice farmers suffer 100% losses of their rice crops from bird depredations. Migratory birds, such as the pintail duck, but non-migratory birds as well, may consume large quantities of rice. In addition, the protected Least Tern which is present in Geary County may also consumer pharma rice. One of the compounds produced at high levels in Ventria's rice, recombinant human lactoferrin (rhLf), is known to promote infections by certain infectious microbes and parasites. Human pathogens that can utilize lactoferrin as a source of needed iron and whose populations could be increased by consumption of rhLf-containing rice include *Helicobacter pyloris*, *Haemophilus influenza*, *Bordetella pertussis*, *Legionella pneumophila*, two species of the genus *Neisseria* that cause gonorrhea and meningitis; and Trichomonas vaginalis, a protozoan responsible for genital disease.[19] Animal pathogens might also be promoted by rhLf. Animals harboring such infectious agents that consume rhLf rice may experience an exacerbation of their infections, which could result in increased mortality.

Please note that specific risks to human health, wildlife, and the environment generally are above summarized. More detailed analyses of these issues are included in the enclosed documents referenced in these comments.

C. That USDA APHIS Has Approved the Field Trials Does Not Mean That They Are Safe Or That They Will Not Prejudicially and Unreaonably Affect the Public Interest Because USDA APHIS Has A Long, Dismal Track Record of Failing To

[16] EA at 10.
[17] EA at 3.
[18] EA at 9.
[19] Freese, B., M. Hansen and D. Gurian-Sherman, "Pharmaceutical Rice in California," Friends of the Earth, Center for Food Safety, Consumers Union, July 2004, pp. 8-9. This report is included in the supporting materials submitted with these comments.

Adequately Assess Potential Impacts and Permitting Food Supply Contaminations.

Despite substantial concern expressed by 20,000 public commenters, USDA APHIS approved the Ventria field trials on May 9, 2007. This approval is however by no means a good indicator of whether or not Ventria's experimental project will prejudicially and unreasonably affect the public interest.

USDA's 15-year history regulating pharma crops has demonstrated the immensity of the biological challenge inherent in forcing genes and seeds used in the open air to stay put. A growing string of episodes in which regulated articles unapproved for human consumption have contaminated the general food and seed supply have occasioned much harm to farmers and U.S. agriculture as a whole.

For instance, last summer, an unapproved GE rice variety developed by Bayer CropScience (LibertyLink 601, or LL601) widely contaminated commercial rice supplies. LL601 had been tested along with other rice varieties by the Louisiana State University (LSU). AgCenter Rice Research Station from 1999 through 2001. According to LSU rice breeder Steve Linscombe, AgCenter breeders strictly followed standards set by the USDA in experimental plantings of LL601.[20] This at least casts doubt on the adequacy of APHIS approved gene containment protocols for outdoor field testing of regulated articles.

Given the current system in which applicants or their contract growers essentially regulate themselves, stringent oversight by APHIS personnel is absolutely required to detect at least the more egregious lapses and errors on the part of field trial operators, or seed dispersal via severe weather events. Unfortunately, there is abundant evidence indicating that APHIS is unable or unwilling to execute its oversight responsibilities properly. Below, we describe just one of several authoritative reviews of APHIS performance over the past 12 years which support this assertion (see supporting materials for a fuller treatment)..

In 2005, the USDA's Inspector General published an audit covering GE crop field trials conducted in 2002 and 2003, finding numerous basic deficiencies in APHIS oversight.[21] It should be noted that this audit covered notification field trials as well as many field trials conducted for pharmaceutical crops, which are supposedly subject to stricter regulation closely approximating the conditions proposed by APHIS for the Ventria field trials proposed in Kansas. A few of the more flagrant deficiencies identified by USDA's IG (OIB) include:

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[20] As quoted in: Schultz, B. "LibertyLink 601 found in LSU AgCenter foundation seed rice," Delta Farm Press, 8/31/06.

[21] USDA, Office of Inspector General, Southwest Region. 2005. Audit report: Animal and Plant Health Inspection Service controls over issuance of genetically engineered organism release permits. Audit 50601-8-Te, December. Online at *www.usda.gov/oig/webdocs/50601-08-TE.pdf*.

1) APHIS often doesn't know where or even if many field tests have been planted. In 85% of the permits and 100% of notification field trials that OIG reviewed, only the company's business address, or the state and county of the field trial, was listed as the planting location.

2) APHIS does not require submission of written protocols, and thus does not review them, prior to issuing a notification permit.

3) "APHIS did not maintain a list of planted GE fields." This recalls a similar deficiency in tracking permit information noted by a previous IG report in 1994, suggesting that APHIS has not corrected this defect since that time, over a decade ago.

4) APHIS failed to conduct scheduled inspections of numerous field trials of pharmaceutical-producing crops. Only 1 of 12 sites inspected by OIG in 2003 had all 5 required inspections; only 18 of the 55 required inspections were performed for the other 11 sites.

5) In two cases, the OIG inspectors discovered that 2 tons of harvested pharma crops had been stored onsite for over 1 year, without APHIS' knowledge, and thus without APHIS inspection of the storage facility.

The OIG made 28 recommendations to APHIS to remedy these egregious deficiencies and lapses in its regulatory performance. APHIS rejected 7 of these recommendations, and agreed to only partially comply with two others.

In addition, in the past year, three federal district court judgments have criticized the Department for its poor oversight of GE crops.[22] In this string of recent cases, judges found that the environmental assessments done by the USDA prior to the testing or commercialization of several genetically engineered (GE) crops was either non-existent or severely lacking, and in violation of our nation's environmental protection laws.[23]

As mentioned above , two regulated articles (unapproved GM rice varieties LL601 and LL604) and one unregulated but unwanted GM rice variety (LL062) massively contaminated commercial long-grain rice supplies in the South, causing severe hardship to Amercian rice growers.

Finally, APHIS' performance at regulating field trials of pharma rice by Ventria in North Carolina in 2005 should be sufficient to dispel any notion that the agency's performance has improved. The information provided below is based on USDA records obtained by

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[22] *See* CFS press releases, *available at* http://www.centerforfoodsafety.org/Alfalfa_DecisionPR2_14_07.cfm , http://www.centerforfoodsafety.org/GTBC_DecisionPR_2_7_07.cfm , & http://www.centerforfoodsafety.org/Hawaii%20biopharm%20crop%20judgement%20Aug%2010,%202006.cfm

[23] *Id.*

the Union of Concerned Scientists in a Freedom of Information Act request dated January 2006.[24] USDA records show that:

1) APHIS completed only 3 of 5 "required" inspections of each of three field test plots.

2) APHIS failed to inspect the Ventria sites during the critical planting and harvesting times, as its policies require.

3) APHIS failed to enforce Ventria's supplemental permit conditions, which required submission by Ventria of a total of nine reports in the period covered by UCS's FOIA request, three reports for each of the three field test plots: a pre-planting report due seven days in advance of planting; a planting report due 28 days after planting; and a termination report due 21 days before harvest. The record shows that Ventria submitted only one of these nine reports.

4) The record obtained by UCS shows no evidence of communication between APHIS and Ventria, or any inspections of the planting sites by APHIS personnel, after Hurricane Ophelia passed close by the site in September 2005. Hurricane force winds and the associated flooding quite likely spread Ventria's pharma rice into the environment, and quite possibly to a government rice breeding station located just 0.6 miles from Ventria's field test sites.

In sum, high-level reviews of APHIS performance over the past twelve years demonstrate an ongoing pattern of inability or unwillingness to carry out its regulatory duties with respect to experimental GE crops, including pharmaceutical-producing crops such as Ventria's.

For these reasons, CFS submits that the grant of Ventria's Term Water Permits, which will facilitate its experimental rice field trial, should be denied as "prejudicially and unreasonably" affecting the public interest.

II. The Water Term Permits Should Be Denied Because the Use of the Water Is Not A "Beneficial Use."

To grant the Permits, the Chief Engineer must also find that the water is used for a "beneficial purpose." K.S.A. 82a-711(a). The appropriation of Kansas Water to facilitate a private firm's speculative research and development efforts with an unmarketable crop is not a beneficial use of water, for several reasons. First, Ventria's proposed water use is solely for research and development efforts on an inherently unmarketable and experimental crop. This should not be construed as a "beneficial" use of water under Kansas law. Second, to be a "beneficial use," the water use must not be

[24] "UCS Uncovers Lax USDA Oversight of Pharma Crops: New Evidence Points to Need for Ban on Pharma Food Crops," Union of Concerned Scientists, http://www.ucsusa.org/food_and_environment/genetic_engineering/usda-ventria-oversight.html

wasteful. Because the amount of water requested by Ventria (3.5 acre-feet per acre) exceeds the Kansas per acre feet legal limit for Geary County by more than three-fold, it is wasteful as well as not beneficial.

A. Ventria's Use of the Water Under the Term Permits Is Not A "Beneficial Use" Under Kansas Law or Traditional Water Law.

In Kansas the listed "beneficial" uses of water are:

domestic uses	artificial recharge
stockwatering	hydraulic dredging
municipal uses	contamination remediation
irrigation	dewatering
industrial uses	fire protection
recreational uses	thermal exchange; and
waterpower	sediment control in a reservoir.

- K.A.R. 5-1-1(o) (definitions). None of the uses could possibly apply except irrigation. In addition, the type of use authorized by a term permit "shall be limited to one of the types of use authorized by the base water right or rights." K.A.R. § 5-16-4(b). In this case CFS believes the existing water rights are irrigation use water rights, for use on commercial crops. "Irrigation" is defined as including "the growing of crops." K.A.R. 5-1-1(rr). However the experimental pharmaceutical rice grown by Ventria is not a food or feed crop at all, but rather is intended as a "biofactory" for production of experimental pharmaceutical substances to be extracted from the rice. Further, since even the pharmaceutical substances produced for extraction from the rice have not been approved for any human food or medical use, Ventria's rice-derived pharmaceuticals cannot be considered as commercial products, but are better described as experimental materials for the company's highly speculative research and development efforts. Ventria's rice is thus neither a "crop" nor a commercial product. For these reasons, it is easily distinguishable from the common use of the term "crops" or the irrigation of commercial agriculture crops. Rather, here Ventria has applied for water in order to facilitate speculative research on inherently unmarketable rice that may well never lead to any commercially viable products. History supports this assessment. Despite issuance of over 300 field trial permits for cultivation of genetically engineered pharmaceutical crops since 1991, the FDA has not approved even one "plant-made pharmaceutical" derived from such crops for medical, human food, or animal feed use. (See Plant-Made Pharmaceuticals: Financial Risk Profile in supporting material)

Such use was surely not contemplated by the Kansas legislators and regulatory officials when they enacted the applicable "beneficial use" requirement and included irrigation of crops. Nor is Ventria's water use encompassed in the traditional understanding of "beneficial use" in Prior Appropriation Water Law. See generally Joseph Sax *et al.*, LEGAL CONTROL OF WATER RESOURCES (West 2000) 122-129. The Chief Engineer should find that the proposed use of water in the Term Permits is not a beneficial use.

B. Ventria's Use of The Term Permits Water Is Not a "Beneficial Use" Because it is Wasteful.

"Beneficial Use" is commonly understood to encompass two main elements: 1) that the use is permissible and 2) that the use is not wasteful in amount. See generally Joseph Sax *et al.*, LEGAL CONTROL OF WATER RESOURCES (West 2000) 122-129. The general rule is that water rights can only be acquired for non-wasteful use. See, e.g., *In re Water Rights of Escalante Valley Drainage Area*, 10 Utah 2d 77 (1960).

Here, Ventria's proposed use of the water via the Term Permits is arguably wasteful for several reasons. First, it is unclear whether Ventria needs the water, or could use less intensive irrigation methods. See Cindy Baldwin, *Grass and Grain* article, April 24, 2007 (quoting Ventria officials as unsure how much water they would use). Indeed, Ventria has confusingly requested precisely the same amount of water (3.5 acre-feet per acre) for rice to be grown on 90 acres with flooding (Permit #20079034) and on a second plot of 144 acres with center-pivot irrigation (Permit #20079035), despite the fact that the latter method is generally understood to be less water-intensive. To add still more confusion, Ventria has floated the possibility of using a third method, drip-irrigation, which is much less water-intensive than either of the above methods, and would by no conceivable stretch of the imagination require the requested amount of 3.5 acre-feet per acre. Unnecessary use of water by Ventria is wasteful and the Term Permits should be denied if the water is unnecessary.

Second, it is "wasteful" to use water for irrigation in excess. Many States, including Kansas, have an acre feet per acre maximum limit that can be lawfully applied to ensure water is not wasted by excess application. Here, as noted above, Ventria has applied for over 3 times the Kansas irrigation limit for Geary County, which is a maximum 1.1 acre feet per acre. See K.A.R. 5-3-24 (Reasonable quantity for irrigation use) (map showing Geary County with 1.1 AF/acre limit). The pre-existing water rights allow for use of 325 acre feet of water on a total of 280 acres, slightly exceeding the 1.1 AF/acre maximum for Geary County. Ventria has requested 500.4 additional acre-feet, an increase of over 150%, to meet its alleged need for 3.5 AF/acre on the 234 acres to be planted with its rice. Term Permit applications should be denied as wasteful because they request water appropriation well beyond the maximum limit.

There appears to be an exception to the maximum limit, but "only if the applicant demonstrates both."

1) That the limit is insufficient, because of "specialty crops or other unusual conditions,"
AND
2) That the "requested quantity is reasonable for the intended irrigation use, is not wasteful, and will not otherwise prejudicially and unreasonably affect the public interest." K.A.R. 5-3-20(c).

As noted above, we question whether Ventria's "biofactory" rice can be considered a crop at all, specialty or otherwise, given that it is not intended and cannot be marketed for human food or feed use, and furthermore in light of the fact that even the compounds it produces are unmarketable for any human food or medical use. Yet even if Ventria's experimental pharmaceutical rice qualifies as a "specialty crop" or under the rubric "other unusual conditions," Ventria must demonstrate that the use is not wasteful and will not prejudicially and unreasonably affect the public interest. As explained above, CFS believes the Chief Engineer has sufficient grounds for a contrary finding on both the wastefulness and adverse public interest considerations.

III. The Water Term Permits Should Be Denied Because Granting Them Will Impair Existing Water Rights.

Ventria's use of water under the Term Permits cannot impair existing water rights. K.S.A. § 82a-711(a). As detailed above, Ventria is requesting a use of water more than three times greater than the legal limit for Geary County. Term permits are normally granted for purposes that require water but do not consume it, such as sand and gravel operations, fish farms, and not for agricultural uses. In this case, Ventria's use, depending on the irrigation method used, may consume the water and thus possibly affect existing water rights. The Chief Engineer should review the applicable data on existing water rights possibly affected by Ventria's proposed use and determine whether any will be impaired because of it. If so, the Term Permit applications must be denied.

Conclusion

For the foregoing reasons we request the Chief Engineer **DENY** the pending Water Term Permit applications associated with the Ventria Field Trial in Geary County, Kansas.

Respectfully submitted,

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