CENTER FOR FOOD SAFETY

660 PENNSYLVANIA AVE., SE , SUITE 302, WASHINGTON, DC 20003
(202) 547-9359 ❧ FAX (202) 547-9429
2601 MISSION ST., SUITE 803, SAN FRANCISCO, CA 94129
(415) 826-2770 ❧ FAX (415) 826-0570
WWW.CENTERFORFOODSAFETY.ORG

March 30, 2007

Regulatory Analysis and Development
USDA APHIS PPD
Station 3A-03.8
4700 River Road, Unit 118
Riverdale, MD 20737-1238

Submitted via Federal eRulemaking Portal: Docket No. APHIS-2007-0006

To whom it may concern:

The Center for Food Safety (CFS) submits the following comments on the single draft environmental assessment (EA) conducted by USDA's Animal and Plant Health Inspection Service (APHIS) for proposed field trials of three distinct lines of rice genetically engineered to produce the novel experimental pharmaceuticals – recombinant, rice-expressed human lactoferrin, lysozyme and serum albumin – under APHIS permit numbers 06-278-01r, 06-278-02r and 06-285-02r.

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 unexplored risks to the environment and potential risks to human health that could result from contamination of food crops with experimental pharmaceutical substances. Like many others, we regard the outdoor cultivation of genetically engineered food crops that produce novel, bioactive substances

that have not undergone review or received approval by U.S. food safety authorities as highly irresponsible. Besides posing unexplored risks to human health and the environment, this practice also undermines confidence in the integrity of the U.S. food supply, and in the "coordinated framework" for regulation of agricultural biotechnology products.

We have numerous serious concerns about these proposed field trials, as discussed in detail below.

BACKGROUND

In the February 28, 2007 *Federal Register*, USDA announced a public comment period on a draft environmental assessment (EA) and on a preliminary decision to permit the field plantings of rice plants genetically engineered to express the human proteins lactoferrin, lysozyme, or serum albumin (biopharm or pharma rice).[1] The EA is in response to three permit applications (APHIS numbers 06-278-01r, 06-278-02r, and 06-285-02r) received from Ventria Bioscience, Scaramento, CA.[2] The plantings in Kansas are planned for harvest in fall 2007, will occur in "at least two locations," and similar plantings are planned for future years.[3] The acreage to plant is said to be "comparable" in size and scope to biopharm rice grown in North Carolina in 2006.[4]

Ventria Bioscience's Applications

Permit applications were submitted by Ventria Bioscience on October 5 and 12, 2006. The proposed stated purpose of the biopharm planting is to obtain and "extract recombinant human lysozyme and lactoferrin from rice flour to be used as supplements in yogurts, meal replacement and performance beverages, bars (for example granola bars) and in nutritional supplement drinks."[5] Ventria also intends to use "lysozyme and lactoferrin in preparation of medical foods such as oral rehydration solutions," and "extract recombinant human serum albumin (HAS) protein to be used primarily in cell culture use."[6]

USDA APHIS' Draft EA

APHIS notes at the outset it would have normally merely approved the field testing as a Categorical Exclusion (CE) from NEPA pursuant to APHIS regulations, 7 C.F.R. § 372.5(c)(3)(i) as a "[p]ermitting, or acknowledgment of notifications for, confined field releases of genetically engineered organisms and products." However, an EA was prepared because Ventria

[1] 72 Fed. Reg. 8959 (February 28, 2007).
[2] Draft EA at 3.
[3] Id. at 3, 5.
[4] EA at 8.
[5] Id. at 4.
[6] Id.

> "intends to have plantings of these engineered plants in Geary County, Kansas for the next several years. The potential for cumulative impacts of these plantings in the same area raises new issues that this EA addresses. Future plantings are anticipated to increase in size . . . ."[7]

In addition, the draft EA is intended to evaluate *three separate* permit applications: 06-278-01r, 06-278-02r and 06-285-02r.[8] Further, APHIS notes that the draft EA incorporates by reference previous EAs on "identical or nearly identical" biopharm rice lines.[9] APHIS concluded that, based on its "review of the data packages" presented by Ventria Bioscience, the proposed field tests do not present a significant impact on any threatened or endangered species and that the proposed field plantings "should not have a significant impact . . . on the quality of the human environment."[10]

CFS COMMENTS

Summary

The draft EA is wholly inadequate. The draft EA is 11 pages long, not counting appendixes, and 22 pages long in total. The so-called "analysis" of potential environmental impacts is a single paragraph.[11] APHIS improperly relies entirely on previous EAs, for different field tests. An EIS must be prepared for the field testing of this pharma rice to properly address the significant environmental impacts that may result from APHIS' approval. The draft EA lacks crucial information that has been withheld by APHIS, in violation of the public right to make informed comment. The draft EA fails to adequately discuss numerous significant environmental impacts on the environment, such as contamination of surrounding crops and alternatives to the proposed action. The draft EA fails to even mention other significant environmental impacts, such as the introduction of rice farming in an area that has never before been impacted by commercial rice cultivation, or the climate change impacts of rice farming. The draft EA fails to adequately discuss cumulative impacts on the environment, the express purported purpose of the EA. APHIS' abysmal history of failing to contain biologically engineered crops illustrates that APHIS' standards and operating procedures are inadequate to protect the environment absent significant amendment. For example, the APHIS regulations for "confined" field testing of GE crops is facially arbitrary and capricious as applied to open air field testing such as that applied for here. The draft EA is arbitrary and capricious and an EIS should be prepared in order to comply with NEPA.

---

[7] Id. at 5.
[8] Id.
[9] Id.
[10] EA at 4.
[11] EA at 10.

The National Environmental Policy Act ("NEPA")

The National Environmental Policy Act ("NEPA") requires a federal agency such as USDA APHIS to prepare a detailed EIS for all "major Federal actions significantly affecting the quality of the human environment."[12] NEPA "ensures that the agency ... will have available, and will carefully consider, detailed information concerning significant environmental impacts; it also guarantees that the relevant information will be made available to the larger [public] audience."[13]

A threshold question is whether a proposed project will "significantly affect" the environment, thereby triggering the requirement for an EIS.[14] As a preliminary step, an agency may prepare an EA to decide whether the environmental impact of a proposed action is significant enough to warrant preparation of an EIS.[15] An EA must "provide sufficient evidence and analysis for determining whether to prepare an EIS or a finding of no significant impact."[16]

If an agency decides not to prepare an EIS, it must supply a "convincing statement of reasons" to explain why a project's impacts are insignificant.[17] "The statement of reasons is crucial to determining whether the agency took a "hard look" at the potential environmental impact of a project."[18]

NEPA regulations require the analysis of both direct and indirect, as well as cumulative, effects in NEPA documents, including EAs.[19] The assessment must be a "hard look" at the potential environmental impacts of its action.[20]

The Council on Environmental Quality (CEQ)

NEPA also established the Council on Environmental Quality and charged CEQ with the duty of overseeing the implementation of NEPA.[21] The regulations subsequently promulgated by CEQ, 40 C.F.R. §§ 1500-08, implement the directives and purpose of NEPA, and "[t]he provisions of [NEPA] and [CEQ] regulations must be read together as a whole in order to comply with the spirit and letter of the law."[22] CEQ's regulations are applicable to and binding on all federal agencies.[23] Among other requirements, CEQ's regulations mandate that federal agencies address all "reasonably foreseeable" environmental impacts of their proposed programs, projects, and regulations.[24]

---

[12] 42 U.S.C. § 4332(2)(C).
[13] *Robertson v. Methow Valley Citizens Council,* 490 U.S. 332, 349(1989).
[14] 42 U.S.C. § 4332(2)(C).
[15] 40 C.F.R. § 1508.9.
[16] *Id.*
[17] *Save the Yaak v. Block*, 840 F.2d 714, 717 (9th Cir. 1988).
[18] Id.
[19] See 40 C.F.R. §§ 1508.8, .9, .13, .18.
[20] *Blue Mountains Biodiversity v. Blackwood*, 161 F.3d 1208, 1211 (9th Cir. 1998).
[21] See 42 U.S.C. §§ 4321, 4344.
[22] 40 C.F.R. § 1500.3.
[23] 40 C.F.R. §§ 1500.3, 1507.1; see, e.g., Hodges v. Abraham, 300 F.3d 432, 438 (4th Cir. 2002).
[24] See 40 C.F.R. §§ 1502.4, 1508.8, 1508.18, & 1508.25.

I. APHIS Has Withheld Information Crucial To Adequate Public Comment, In Violation of NEPA.

APHIS has failed to provide adequate information to enable informed and meaningful public comment on these proposed field trials. Any decision should be delayed until the public is provided with such information and given adequate opportunity to consider and offer comment on it. The public's opportunity for comment "must be a meaningful opportunity."[25] APHIS' withholding here has denied the public that right.

A. The gene for each permit was not reported.

While APHIS lists the acreage requested for each of the three permits, it inexplicably fails to specify which pharmaceutical protein will be grown under which permit. One permit (06-278-01r) would authorize cultivation of up to 3,000 acres, 30 times more than the 100 acres requested for each of the other two permits. 3,000 acres is more than an order of magnitude (ten times) larger than any previous pharma crop field trial permit. Each of the three recombinant proteins has differing properties, presenting different risk profiles. 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 comprehensive review of APHIS performance in regulating GE crops (hereinafter referred to as NAS 2002).[26] Therefore, this information is relevant to informed and adequate public comment on the draft EA.

Further, there is no reason for APHIS to keep this information secret. The acreage of these permits is not considered confidential business information (CBI) of the applicant, as it is not labeled as such on USDA's website. Nor is there any basis for claiming it as confidential, should APHIS attempt to do so in its final EA. In fact, gene designations have been provided for Ventria's past applications for field trial permits (e.g., in North Carolina in 2006).[27] To our knowledge, this represents the first time APHIS has failed to reveal the experimental modification at issue for a particular permit that is the subject of an environmental assessment.

B. The EA lacks crucial information relevant to gene containment.

---

[25] Gerber v. Norton, 294 F.3d 173, 179 (D.C. Cir. 2002) (finding the public could not meaningfully comment on an ESA incidental take permit application which lacked a necessary map); see Fund for Animals v. Norton, 281 F.Supp.2d 209, 228-29 (D.D.C. 2003) (draft EA held to be insufficient after agency failed to provide certain pertinent information because that lack of information had a significant impact on the public's ability to provide meaningful comment).

[26] *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

[27] Permit numbers: 05-332-01r for recombinant human lactoferrin-producing rice (225 acres); 05-332-02r for recombinant human lysozyme-producing rice (100 acres); 05-293-01r for recombinant human serum albumin-producing rice (10 acres), for a total of 335 authorized acres in North Carolina in 2006.

APHIS has failed to make any of Ventria's application materials publicly available, in contrast to its practice for most environmental assessments of past applications by Ventria and other pharma crop companies (e.g. Prodigene) to conduct field trials. 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 offer informed public comment, particularly as regards to the adequacy or inadequacy of Ventria's gene containment measures. APHIS's judgment that the SOPs are adequate to prevent or mitigate gene escape requires critical, independent review, especially in light of several, yet unexplained, contamination episodes involving such regulated articles grown under its jurisdiction over just the past year (see Section VI *infra*). In addition, independent reviewers at the National Academy of Sciences recommended greater, not lesser, transparency by APHIS in this context (NAS 2002).

The SOPs were not declared "confidential business information" (CBI) in APHIS's EA nor in the permit listings on USDA's website, nor do they merit such designation, should APHIS subsequently try to claim them as CBI in its final EA.

An EA such as this one that withholds key scientific information is legally inadequate and circumvent the main purposes of NEPA: informed public participation, government accountability and transparency. NEPA "ensures that the agency . . . will have available, and will carefully consider, detailed information concerning significant environmental impacts; it also guarantees that the relevant information will be made available to the larger [public] audience."[28] Moreover, NEPA "insure[s] that environmental information is available to public officials and citizens before decisions are made and before action is taken."[29] This withholding greatly compromises the public review process, because it makes the public reliant on the interpretation of the data by the submitter, which is not a disinterested or unbiased party. APHIS has purportedly evaluated the data in its EA, but this is not a substitute for the public review process, which is mandated by NEPA.

II. The EA's "Analysis" of the Potential Environmental Impacts Is Wholly Inadequate. These Impacts Require An EIS.

The single EA, for three different permit applications, is extremely brief (22 pages), glosses over important issues, and improperly relies on prior EAs. The EA devotes a grand total of one paragraph to "Potential Environmental Impacts."[30] This is clearly inadequate.[31] In addition, the "analysis" of alternatives to the agency action is

[28] Idaho Sporting Cong. v. Thomas, 137 F.3d 1146, 1149 (9th Cir. 1998) (internal quotation marks omitted).
[29] 40 C.F.R. § 1500.1(b), (c).
[30] EA at 10.
[31] APHIS has inexplicably failed to disclose Ventria's SOPs for this proposed planting, making it difficult to offer informed comment. The comments below are based on the abbreviated information available in the EA.

inadequate. Finally, APHIS' comparison to and reliance on previous field trials is inapposite, as the acreage requested by Ventria in this case is substantially increased.

A. One Environmental Assessment for Three Distinct Permits

APHIS has conducted a single environmental assessment for three permits for three distinct lines of rice, each containing a different pharmaceutical protein. These pharmaceutical proteins have widely divergent properties, and present different risk profiles. One permit would grant authorization to plant a rice variety with one of the three proteins (unspecified) on up to 30 times more area than either of the other two. A single environmental assessment is inadequate to address the widely different situations attending the plants proposed for cultivation under the different permits.

B. APHIS Misrepresents the Scale of the Field Trials.

In addition to squeezing three permits into one EA, on page 8 of the EA, APHIS misleadingly states that: "Ventria ***has proposed*** to plant acreages comparable in size and scope to those grown in North Carolina in 2006." (The EA contains no further specification of the acreage to be planted.) The collective authorized acreage for the Kansas permits at issue here – 3,200 acres, as reported in the acreage listing for the permits on USDA's GE crop field trial website – would be nearly 10-fold greater than the collective authorized acreage for the North Carolina field trials in 2006 (335 acres).[32] This is by no stretch of the imagination "comparable in size and scope;" rather this is very clearly a significant increase in size and scope. NAS (2002) agrees that the risks of "gene escape" and potential environmental impacts and economic harms related to these environmental impacts, increase dramatically with the size of the field trial, and that gene containment and inspection procedures that are adequate for smaller-scale trials may be inadequate for larger scale plantings.

B. APHIS' Abdication of its NEPA Responsibilities for these Novel Field Tests, In Complete Reliance On Previous EAs, Is Arbitrary and Capricious.

APHIS' wholesale reliance on previous EAs for different field testing permits is arbitrary and capricious. Instead of providing the necessary analysis required by NEPA, APHIS merely references parts of three previous EAs completed for previous permits it has granted, and rattles off a list of issues that those EAs purport to address.[33] Those numerous issues include:

> 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,

[32] If Ventria plans to plant lesser acreage than stated in the permit applications, then this information should have been included in APHIS's draft EA for public review. Absent such information, we base our comments on the acreage that would be authorized for planting if APHIS grants these three permits.
[33] EA at 10.

> potential impacts on adjacent row crops, fate of transgenic DNA, potential impacts on human health, potential cumulative environmental effects and special considerations regarding other statutes.[34]

This list bears out the truth: there are a plethora of potential environmental impact issues that need to be addressed. Unfortunately APHIS' complete reliance on previous analyses of these issues (even assuming that those previous analyses are adequate, which we do not admit or conclude) is not adequate to comply with NEPA. NEPA demands an action-specific, site-specific analysis. APHIS' reliance on previous analysis is not sufficient to meet its NEPA obligations for the current proposed action. Even when an agency appropriately "tiers" its NEPA analysis, it must still take into account any project-specific characteristics of the site of the proposed action.[35] Judging by the single paragraph in this EA devoted to "analyzing" potential environmental impacts, APHIS has utterly failed to do so here.

"Tiering"[36] is appropriate where the current document is referring back to a broader, more general environmental statement (like an EIS created for a national program, or a policy statement). Tiering is the coverage of general matters in a broader statement with subsequent narrower statements or environmental analyses which incorporate the general discussions of the broader document, while concentrating on the specific issues that impact the narrower decision.[37] Here, APHIS is attempting to tier back to documents which are not broader in scope, but are merely prior EAs for similar rice occurrences in different states, such as Missouri and North Carolina. There is nothing broad or general about the EAs APHIS relies on. In fact, as discussed below, the EAs referred to and relied upon are actually for <u>smaller</u>, not larger, field tests, that are <u>shorter</u>, not longer, in duration.

Moreover, it is arbitrary and capricious to conclude that analyses done for other geographic areas can be wholesale applied to the field testing proposed for Kansas. Two of the EAs that APHIS improperly relies upon were conducted for Ventria field trials conducted under very different conditions and in different states (i.e. 05-332-01r for recombinant human lactoferrin, and 05-332-02r for recombinant human lysozyme, in North Carolina in 2006[38]). In the "Response to Comments" section of its EA's for these two prior permits, a public commenter raised concerns that: "… only one EA would be prepared for this planting and all future plantings and that no future EAs would be prepared as the acreage increases." APHIS responded as follows: "**<u>APHIS intends for this EA to apply to the current field planting.</u>**" Thus, APHIS' "incorporation by reference" of these prior EAs in the abbreviated and inadequate EA at issue here is improper, by APHIS' very own declaration.

---

[34] EA at 10.
[35] <u>Blue Mountains Biodiversity Project v. Blackwood</u>, 161 F.3d 1208, 1214 (9th Cir. 1998).
[36] "Tiering refers to the coverage of general matters in broader environmental impact statements . . . with subsequent narrower statements or environmental analyses." 40 C.F.R. § 1508.28
[37] <u>Klamath-Siskiyou Wildlands Center v. Brueau of Land Management</u>, 387 F.3d 989, 997 (9th Cir. 2004).
[38] See footnote 1.

The third prior EA that APHIS improperly relies upon is for a field trial of pharmaceutical rice engineered to express recombinant human serum albumin in California in 1997 that covered "approximately ½ acre,"[39] or a 200-fold smaller area than the 100 acres proposed for Kansas in two of the permits (06-278-02r, 06-285-02r), and 6,000-fold less acreage than proposed for Kansas in the third permit (06-278-01r). The 200- to 6,000-fold increase in scale, coupled with the different environmental conditions presented by Kansas versus California, makes this prior EA virtually irrelevant to the EA at issue here.

Those trials were not completed in the same area; they were not done for all three of the types of biopharm crops at issue here. So how can they adequately, *inter alia*, address the "potential impact on native floral and faunal communities" in Kansas? How can the previous EAs address the "potential alteration in susceptibility to disease or insects, potential impacts on existing agricultural practices, potential impacts on adjacent row crops, fate of transgenic DNA, potential impacts on human health, potential cumulative environmental effects and special considerations regarding other statutes" in Geary County, Kansas? The answer is that they cannot. The proposed Kansas field testing location raises many novel potentially significant environmental impacts, as discussed herein, the most obvious being that no rice cultivation has ever been done in the region previously. As such, APHIS' EA is wholly inadequate and an EIS must be prepared.

Finally, in relying on these previous EAs, APHIS has still failed to consider cumulative impacts. While APHIS refers back to these EAs as prior consideration of the potential non-location-specific impacts of the field test permit, it does not conduct a new analysis of what the cumulative impacts will be. In fact, they refer back to the EAs as a consideration of "potential cumulative environmental effects," without any analysis of how the approval of *new* field tests may alter those effects. This is arbitrary and capricious action.[40]

D. The EA's "Analysis" of Alternatives is Inadequate.

APHIS' analysis of alternatives in the EA was equally insufficient because USDA failed to adequately analyze the alternatives it identified in the EA.[41] EAs must include analysis of the alternatives to the proposed action.[42] There is only one sentence discussing

---

[39] APHIS EA for permit number 96-355-01r, p. 4, available at: http://www.isb.vt.edu/biomon/releapdf/9635501r.ea.pdf. APHIS cites this EA on page 10 of the EA at issue here.

[40] See Klamath-Siskiyou Wildlands Center v. Bureau of Land Management, 387 F.3d 989, 997 (9th Cir. 2004) (finding EAs to be insufficient for failure to consider the specific incremental impact that would be expected from the specific timber sales at issue); Muckleshoot Indian Tribe v. US Forest Service, 177 F.3d 800, 811 (9th Cir. 1998) (invalidating and EIS because the "cumulative effects" analysis "merely provide[d] very broad and general statements devoid of specific, reasoned conclusions").

[41] *See* Bob Marshall Alliance v. Hodel, 852 F.2d 1223, 1228 (9th Cir. 1988).

[42] Id. at 1229 ("consideration of alternatives requirement is both independent of, and broader than, the EIS requirement. In short, any proposed federal action involving unresolved conflicts as to the proper use of resources triggers NEPA's consideration of alternatives requirement, whether or not an EIS is also required.")

alternative 1 (the no action alternative).[43] There are only three sentences discussing alternative 2.[44] NEPA requires that federal agencies consider alternatives to recommended actions whenever those actions "involve[ ] unresolved conflicts concerning alternative uses of available resources."[45] The goal of the statute is to ensure "that federal agencies infuse in project planning a thorough consideration of environmental values."[46] The consideration of alternatives requirement furthers that goal by guaranteeing that agency decisionmakers "[have] before [them] and take [ ] into proper account all possible approaches to a particular project (including total abandonment of the project) which would alter the environmental impact and the cost-benefit balance."[47] NEPA's requirement that alternatives be studied, developed, and described both guides the substance of environmental decisionmaking and provides evidence that the mandated decisionmaking process has actually taken place.[48] Informed and meaningful consideration of alternatives-including the no action alternative-is thus an integral part of the statutory scheme.[49]

E. Inadequate Gene Containment

1. Seed dispersal via animal

The chief deficiency in gene containment measures is APHIS's virtual neglect of seed dispersal as a route for contamination of other crops. The EA prescribes a mere 50-foot fallow zone around Ventria's rice, and thus would allow plantings of soy, corn, wheat or other crops at any distance greater than 50 feet from Ventria's rice. Rice is a favored food source of birds and mammals, and the EA 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 can easily defecate viable grains beyond the boundaries of the test sites plus surrounding fallow zones. An animal feeding on pharma rice near the boundary between rice and fallow zone would only need to move 100 feet or so to deposit viable grains of pharma rice in surrounding cropland via defecation. The typical foraging distance of the Norway rat is 2-3 miles,[50] which is likely typical of many mammalian species that would consume pharma rice. Thus, even animals feeding in the center of pharma rice fields could easily deposit viable grains in surrounding cropland. Such viable seeds could sprout in the same or subsequent seasons in surrounding fields of soy, corn, wheat or other crops, and be harvested with these crops, contaminating these harvests with pharmaceutical compounds not approved by the FDA.

---

[43] EA at 6.
[44] EA at 6.
[45] 42 U.S.C. § 4332(2)(E).
[46] Conner v. Buford, 836 F.2d 1521, 1532 (9th Cir. 1988).
[47] Calvert Cliffs' Coordinating Committee, Inc. v. United States Atomic Energy Commission, 449 F.2d 1109, 1114 (D.C.Cir.1971) (emphasis added).
[48] Id.
[49] *See* Bob Marshall Alliance v. Hodel, 852 F.2d 1223, 1228 (9th Cir. 1988).
[50] Ballenger, L. 2001. "Rattus norvegicus" (On-line), Animal Diversity Web. Accessed at http://animaldiversity.ummz.umich.edu/site/accounts/information/Rattus_norvegicus.html

Birds present the greatest potential for transporting pharma rice grains beyond the bounds of the field test plots. Informal surveys in the Junction City, Kansas area by birdwatchers report 25 different bird species spotted in 2007,[51] while a total of 123 species were spotted in Kansas as a whole,[52] likely just a fraction of the bird species present. Because the Junction City area lies along the Central Flyway (included in supporting materials), it is visited by many species of migratory birds. The Kansas Department of Wildlife and Parks reports substantial populations of numerous species of waterfowl at wildlife areas in Region 2, which includes Geary County: pintail, gadwall, mallard and ringneck ducks; mergansers; as well as Canadian geese and snow geese.[53]

Studies on rice consumption by birds in Kansas are not available, as commercial rice production is unknown in the state. However, studies conducted elsewhere make it clear that rice is a favored food of many bird species. For instance, a study by APHIS showed that red-winged blackbirds, common grackles and brown-headed cowbirds cause an estimated $11.5 million of damage to newly planted and ripening rice in Arkansas, California, Louisiana, Missouri and Texas, with some rice growers reporting 100% losses due to bird depradations.[54] A study in California's Sacramento Valley showed that plant foods accounted for nearly 100% of the diet of pintail ducks feeding in flooded-unharvested rice fields during the fall; rice seed constituted nearly 94% of this total.[55] There is no question that any bird species can transport consumed rice well outside the boundaries of the field test site. It is entirely likely that all waterfowl can carry some rice grain externally on their feathers and in mud on their feet. It has also been demonstrated that 1% to 16% of various seeds (rice was not one studied) that mallard ducks ingest are still viable in their feces. One study notes that:

> "Although any given duck is carrying only a few viable seeds, the millions of ducks moving among wetlands….collectively are effective dispersal agents for many wetland plant species"[56]

Dr. Doug Levey from the University of Florida Department of Zoology provides the following summary:[57]

---

[51] "The Great Backyard Bird Count," a joint project of the Cornell Lab of Ornithology and the Audubon Society. http://gbbc.birdsource.org/gbbcApps/report?cmd=showReport&reportName=CitySummary&city=Junction%20City&state=US-KS&year=2007.

[52] See http://gbbc.birdsource.org/gbbcApps/report?cmd=showReport&reportName=StateSummary&state=US-KS&year=2007

[53] See http://www.kdwp.state.ks.us/news/hunting/migratory_birds/waterfowl_reports/region_2/region_2_waterfowl_report_summary

[54] "Management of Blackbird Damage to Rice," a project of the National Wildlife Research Center, Wildlife Services, APHIS, USDA. http://www.aphis.usda.gov/ws/nwrc/research/rice/index.html

[55] http://www.npwrc.usgs.gov/resource/birds/fwfoods/index.htm.

[56] Mueller, M.H. and A.G. van der Valk. 2002. The potential role of ducks in wetland seed dispersal. Wetlands 22(1):170-178.

> "Seed dispersal by birds is common in North America. Even bird species that typically digest most of the seeds they consume, frequently defecate some seeds in viable condition (Mueller and van der Valk 2002). Furthermore, it's widely agreed that rare dispersal events can be ecologically and evolutionarily important **--** all it takes is one successful transport of a seed to a new location to establish a new set of alleles in that location. Thus, how often such transport occurs[58] is probably less important than whether it occurs. In some ecosystems, seed dispersal by waterbirds such as those found in rice fields may be common.[59]**.** Geese are most likely to consume and defecate relatively large quantities of viable rice grains because they have relatively inefficient digestive systems; they eat large quantities of vegetation and pass it through their digestive tracts quickly. They defecate frequently and those defecations contain poorly digested food stuff. Their ability to disperse viable grains of rice, however, remains untested."

In addition to the movement of rice grains on or in the bodies of live birds, birds and mammals killed by raptors and other predators, and birds shot during hunting season are a possible source of rice dispersal. The Smoky Hill River area is considered prime hunting grounds for both migratory waterfowl and other bird species, such as pheasant, quail, prairie chicken and turkey.[60] Waterfowl reports for the Geary County area (Region 2) reveal numerous wildlife refuges and populations of many species of waterfowl.[61] Pharma rice grain in the gullets and guts of unretrieved birds would be a source of contamination, perhaps miles from the field where they ingested the rice.

In view of this clear contamination risk, one should examine the potential scope of the problem. The average yield of rice in the U.S. in 2006 was 6,868 lbs/acre,[62] which translates to 3.1 million grams/acre. A grain of rice weighs about 10 mg, or 0.01 gram, so 3.1 million grams per acre represents 100-fold more grains of rice, or roughly 310 million grains of rice per acre. If Ventria were to plant the full acreage authorized by these three permits, or 3,200 acres, it would produce on the order of 992 billion grains of rice, or roughly 1 trillion grains of rice. One-tenth the authorized acreage, or 320 acres, would still generate roughly 100 billion grains of rice.

Even if one assumes that only an infinitesimal fraction of these 1 trillion grains of rice (10^{12}) are transported in viable form beyond the bounds of the field test site + fallow zones, and a small fraction of those end up germinating in cropland, the contamination

---

[57] E-mail communication, Feb. 26, 2004, as cited in Californians for GE Free Agriculture (2004). "Briefing on the Proposed Protocol for Pharmaceutical Rice," submitted to the AB2622 Advisory Board of the California Rice Commission, March 5, 2004.

[58] Clausen P., B.A. Nolet, A.D. Fox, M. Klaassen. 2002. Long-distance endozoochorous dispersal of submerged macrophyte seeds by migratory waterbirds in northern Europe - a critical review of possibilities and limitations. Acta Oecologica — International Journal of Ecology 23(3):191-203.

59 Willson, M.F., A. Traveset, C. Sabag. 1997. Geese as frugivores and probable seed-dispersal mutualists. Journal of Field Ornithology 68(1):144-146.

[60] See ttp://www.kdwp.state.ks.us/news/hunting/about_kansas_hunting

[61] See http://www.kdwp.state.ks.us/news/hunting/migratory_birds/waterfowl_reports/region_2.

[62] USDA National Agricultural Statistics Service, at http://www.nass.usda.gov/QuickStats/index2.jsp

potential is significant. For instance, if one conservatively assumes that only 1 in 1 million grains of pharma rice ($1/10^6$) escapes to germinate in cropland, this represents 1 million (10^6) pharmaceutical rice plants sprouting to contaminate the commercial food supply. We offer this calculation not as a definite contamination risk assessment, but rather as an indication of the sort of analysis that APHIS should have conducted.

USDA's past attempts to deal with animal dispersal of rice are totally inadequate, as they wrongly assume 100% digestion of all rice grains by all species. USDA has simply denied the fact that some rice grains will remain viable in the feces of animal species that consume pharma rice, and failed to analyze the consequences this could have for contamination of the commercial food supply, albeit at low levels.

2. 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,[63] 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.[64] 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.[65]

In addition, flooding can prevent harvest of rice. In the aftermath of Hurricanes Katrina and Rita, 36 percent of rice was unharvested in Arkansas, 40 percent in Mississippi, and 80 percent in Missouri.[66] Any unharvested rice would be available for an extended period of time for consumption by animals, increasing the risk of contamination of surrounding cropland.

F. The EA's "Analysis" of Shipped/Transported Seed Contamination and Impacts Is Inadequate.

The EA states that the "majority" of seed would be milled but not shipped.[67] In addition, "most material" will be shipped "only after milling."[68] The obvious implication is that

[63] "Historic Floods of Kansas," U.S. Geological Survey Kansas Water Science Center, http://ks.water.usgs.gov/Kansas/waterwatch/flood/historic.html
[64] EA at 10.
[65] EA at 7.
[66] Capooth, W. "Conditions right for good waterfowling season," Delta Farm Press, November 11, 2005. http://deltafarmpress.com/mag/farming_conditions_right_good/
[67] EA at 3.

some seed will be shipped before milling. What about the seed that is shipped? How much will be shipped? Where will it be shipped? How? What are the possible contamination events and environmental impacts of that seed that is shipped? APHIS fails to adequately assess and analyze the potential impacts from shipping the biopharm crops.

Further, 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,"[69] 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 away from Ventria's storage and processing facility in Junction City, KS.[70] 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.[71] Thus, a significant fraction of the seeds may be shipped long distances, some across state boundaries.[72] 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:

- There will be loss from the combine header and across the screens. This rice remains in the field as a potential source of contamination of other cropland.
- As the combine empties its grain tank, there may be spills.
- Combine dump augers often dribble rice for many minutes after dumping, as rice vibrates out of the auger tube. Bankout wagons have the same problem.
- Truck beds are often poorly sealed, as they are not designed to be biocontainment units. Tarps on trucks traveling at highway speed can act as "pumps" as they flap in the wind, dislodging seeds and releasing them along roadways.
- Seeds get caught in the tires, frames, and landing gear, and many other places on trucks.
- Truck drivers often do not sweep out their trailers after dumping, leaving seeds in the bed and in the tarps.
- Spills occur at the dryers, dump pits are not cleaned adequately, rice remains in the augers, and seed is commingled in the bins.

Rice may be moved between bins in farm storage or warehouses, and is transported by truck to the mills. 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.

---

[68] EA at 9.
[69] EA at 9.
[70] EA at 10.
[71] EA at 3.
[72] EA at 9.

G. The EA Fails to Adequately Analyze Potential Harm to Wildlife, Including Endangered Wildlife, that Consume Ventria's Pharma Rice.

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 depradations. 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.[73] 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. APHIS has failed to analyze this issue in its EA. In the EA for permit number 05-117-01r, APHIS responded to a public commenter who raised this issue. APHIS' dismissed the issue on the grounds that it would be extremely difficult to design experiments to determine whether animals harboring infectious agents that could be promoted by rhLf would experience increased mortality or other harms from consumption of rhLf-containing rice. This response is obviously inadequate. One cannot dismiss a potentially serious harm on the grounds that it would be difficult to assess. This is still another issue that requires serious assessment in the context of an environmental impact statement.

III. There Are Many Significant Environmental Impacts Not Analyzed At All In the Deficient Draft EA. These Impacts Also Require an EIS.

The deficient draft EA entirely failed to address many significant issues and impacts, for instance socio-economic impacts that would flow directly from dispersal of pharma rice seeds into the environment, including surrounding cropland. After expressly raising cumulative impacts as a reason for the EA, they are not thereafter addressed or analyzed. In addition, the environmental impacts of undertaking commercial rice cultivation in an area that never before had such farming are totally ignored. Further, the reasonably foreseeable effects on climate change from rice farming are likewise not analyzed. An EIS is necessary.

A. APHIS Fails to Analyze Economic Impacts from Presence of Pharma Rice in Agricultural Commodities

[73] 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.

The direct socio-economic impact associated with any agency action in granting a permit for field testing of a regulated article must be analyzed prior to taking such action. Indeed, the Council on Environmental Quality (CEQ) regulations implementing NEPA state that such impacts must be analyzed.[74] Specifically, the CEQ regulations state: When an environmental impact statement is prepared and economic or social and natural or physical environmental impacts are related, then the environmental impact statement will discuss all of these effects on the human environment.[75] The economic impacts are related, indeed intertwined with the environmental impacts because the economic impacts stem directly from the fundamental change to the conventional, organic, or wild plant, i.e., the genetic contamination from GE or pharma crops.

Federal courts have also upheld that NEPA requires, where economic analysis forms the basis of choosing among alternatives, that the analysis not be misleading, biased or incomplete.[76] As one court has noted, "In some instances environmental costs may outweigh economic and technical benefits and in other instances they may not. But NEPA mandates a rather finely tuned systematic balancing analysis in each instance."[77] Another Court has recently held that the intertwined economic impacts on organic farmers of the deregulation of a genetically engineered crop must be analyzed in an EIS.[78]

In this instance, the USDA has failed to provide <u>any analysis</u> of the socio-economic impacts on farmers and food processors whose crops or food products are contaminated with Ventria's pharma rice. The agency's EA fails to address these impacts on farmers, users or exporters of either organic and conventional, non-genetically engineered crops. Indeed, given the Plant Protection Act's (PPA) goal of addressing U.S. agricultural product exports and imports, this failure is even more egregious.[79] The impact of pharma rice contamination on exports of agricultural commodities must be assessed.

The EA contains no analysis of socio-economic impacts of the presence of pharma rice in raw and processed agricultural commodities. This oversight is egregious given the demonstrated potential for regulated articles grown under USDA permit to contaminate agricultural commodities.

In 2006 and 2007, two unapproved genetically engineered rice varieties developed by Bayer CropScience (LL601, LL604) grown under notification permits issued by USDA massively contaminated conventional rice, causing export market rejection of contaminated rice shipments, lower rice prices, lost income for rice farmers, and/or a severe shortage of uncontaminated conventional rice seed for planting this spring. These

---

[74] The Supreme Court has held that the regulations are entitled to substantial deference by the courts. <u>Marsh v. Oregon Natural Resources Council</u>, 490 U.S. 360, 372 (1989).
[75] 40 C.F.R. § 1508.14
[76] <u>Seattle Audubon Society v. Lyons</u>, 871 F. Supp. 1291, 1324 (W.D. WA 1994).
[77] <u>Sierra Club v. Sigler</u>, 695 F.2d 957, 978 (5th Cir. 1983).
[78] *Geertson Seed Farms v. Johanns*, 2007 WL 518624 (N.D. Cal. February 12, 2007).
[79] <u>See generally</u> 7 U.S.C. 7701.

contamination episodes have occasioned substantial economic harm to U.S. rice farmers and the rice industry as a whole, and a loss of faith in the wholesomeness of the U.S. food supply. LL601 was by some accounts being found in virtually all milled rice samples that had been tested.[80] Japan banned imports of U.S. long-grain rice shortly after USDA's announcement of the contamination episode on August 18, 2006.[81] Though the ban was lifted on September 19th, Japan announced that it would test all short and medium-grain rice imported from the U.S, which comes chiefly from California.[82] Japan's testing of U.S. short- and medium-grain rice was reportedly due to "a lack of information from the U.S. government about how extensive the contamination could be, despite enquiries from Tokyo…,"[83] underlining the USDA's failure to effectively handle or even monitor this debacle. Japan is the nation's largest export market for rice. Russia suspended imports of U.S. rice due to the LL601 contamination episode.[84]

LL601 was found in 33 of 162 rice samples tested by the EU,[85] and rice supplies and/or food products contaminated with LL601 have been detected in up to nine European countries, including the UK, France, Germany, Greece, Norway, Ireland, Austria, Slovenia and Italy.[86] Supermarket products contaminated with LL601 have been withdrawn in the UK, Germany, France,[87] Switzerland, Norway,[88] and perhaps other countries. The UK Rice Industry Association has reportedly stopped importing any U.S. long-grain rice. The world's largest rice processor, Ebro Puleva, has stopped importing U.S. rice since August 2006.[89] The economic fallout from LL601 is huge. Prices on the rice futures market dropped dramatically in the weeks after contamination was first announced. Some in the rice industry predict losses of $150 million.[90]

On March 5, 2007, USDA announced a second contamination episode in which a regulated article (LL604) unapproved for commercial cultivation massively contaminated a popular conventional line of rice, CL 131.[91] As a direct result, both this line of rice and

---

[80] Bennett, D. "Arkansas Secretary of Agriculture addresses GMO rice situation," Delta Farm Press, Aug. 29, 2006. http://deltafarmpress.com/news/060829-arkansas-gmo/

[81] "Japan bans 'contaminated' US rice," BBC NEWS, 8/21/06, http://news.bbc.co.uk/go/pr/fr/-/2/hi/science/nature/5271384.stm

[82] Krauter, Bob. "Japan to test all U.S. rice for GE variety," Capital Press, September 28, 2006

[83] "Japan widens testing of U.S. rice for illegal GMO," Reuters, Sept. 28, 2006, http://asia.news.yahoo.com/060928/3/2qjrf.html

[84] "RUSSIA: US rice imports suspended over GMOs," Just-Food.com, Oct. 2, 2006, full article accessible for subscribers only at http://www.just-food.com/article.aspx?id=96181

[85] "EU confirms presence of tainted GMO rice," Reuters, Sept. 11, 2006. http://today.reuters.co.uk/news/articlenews.aspx?type=scienceNews&storyID=2006-09-11T175711Z_01_BRU004904_RTRIDST_0_SCIENCE-FOOD-EU-GMO-RICE-DC.XML

[86] "EU Due to Tighten Import Rules to Keep Out GMO Rice," Reuters, October 3, 2006, http://www.planetark.com/dailynewsstory.cfm/newsid/38340/story.htm

[87] "Gene-altered profit-killer," Washington Post, Sept. 21, 2006, http://www.washingtonpost.com/wp-dyn/content/article/2006/09/20/AR2006092001903.html

[88] "Illegal rice recalled," Aftenposten, Norway, by Randi Johannessen, Sept. 28, 2006, http://www.aftenposten.no/english/local/article1475411.ece

[89] http://www.greenpeace.org/international/press/releases/world-s-largest-rice-company-h

[90] "Gene-altered profit-killer," op. cit.

[91] USDA APHIS press release, March 22, 2007. http://www.aphis.usda.gov/newsroom/content/2007/03/protein_clearfield131rice.shtml

the one contaminated with LL601 (Cheniere) are unavailable for planting by Southern rice growers this spring, occasioning a severe shortage in the rice seed supply for rice farmers, imposing a great hardship on U.S. rice farmers.[92]

Perhaps most significant is the continued erosion of international confidence in the wholesomeness of the U.S. food supply occasioned by repeated contamination debacles involving unapproved genetically engineered crops. Six years ago, the discovery of massive contamination of U.S. corn products with unapproved, potentially hazardous GE StarLink corn caused massive cutbacks in US corn exports to Asia and other countries as well as numerous product recalls. In 2005, Syngenta announced that it had been mistakenly distributing unapproved GE corn Bt10 for over 3 years before the error was detected, or at least reported.

Such contamination debacles have not been limited to crops grown under notification permits. In 2002, pharmaceutical corn grown under USDA permit by ProdiGene, Inc. contaminated 500,000 bushels of soybeans in Nebraska, resulting in seizure and destruction of the contaminated soybeans at a cost of several million dollars to forestall their entry into the food supply; contamination of conventional corn by pharma corn grown by the same company in Iowa resulted in the destruction of 155 acres of corn to prevent their entry into the food supply. Approval of Ventria's permits to grow pharma rice can only contribute to the growing international consensus that U.S. foodstuffs are to be avoided whenever possible, due to the apparent inability or unwillingness of federal officials to prevent contamination of US crops and foods with unapproved GE varieties, as detailed further in Section V.

Given this history of socio-economic harm to U.S. farmers and agriculture from numerous episodes of regulated articles contaminating the seed and food supplies, and the clear potential for similar harms in the present case, APHIS must analyze the socio-economic impacts of the proposed field tests, in compliance with NEPA.

B. APHIS Wholly Failed To Analyze the Cumulative Impacts of the Proposed Field Tests.

APHIS began the EA by concluding that the EA was only necessary due to the "new issues" created by the potential for "cumulative impacts" of Ventria's proposed multi-year, multi-site field testing of the biopharm rice, including the anticipated increase in size of future plantings.[93] But even after raising the issue itself, APHIS utterly fails to address or analyze any cumulative impacts anywhere in the EA. This is arbitrary and capricious action and a violation of NEPA.[94]

---

[92] Bennett, D. "Arkansas' emergency session on CL 131 rice," Delta Farm Press, March 1, 2007, http://deltafarmpress.com/news/070301-cl131-session/

[93] EA at 5. CFS disagrees that a categorical exclusion (CE) for a "confined" open-air planting is not arbitrary and capricious agency action. See ___ infra.

[94] *See* 40 C.F.R. § 1508.25; Kern v. U.S. Bureau of Land Mgmt., 284 F.3d 1062, 1076 (9th Cir. 2002).

NEPA also requires agencies to consider the cumulative impacts of their proposed actions.[95] By definition, cumulative effects must be evaluated along with direct and indirect effects of a project and its alternatives. "'Cumulative impact' is the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency or person undertakes such other actions."[96] Individually minor, but collectively significant actions, taking place over time, can generate cumulative impacts.[97]

Analyzing cumulative impacts in EAs is crucial: The Council on Environmental Quality has noted that "in a typical year, 45,000 EAs are prepared compared to 450 EISs.... Given that so many more EAs are prepared than EISs, adequate consideration of cumulative effects requires that EAs address them fully."[98] A meaningful cumulative impact analysis, according to the D.C. Circuit, must identify

> (1) the area in which the effects of the proposed project will be felt; (2) the impacts that are expected in that area from the proposed project; (3) other actions–past, present, and proposed, and reasonably foreseeable–that have had or are expected to have impacts in the same area; (4) the impacts or expected impacts from these other actions; and (5) the overall impact that can be expected if the individual impacts are allowed to accumulate.[99]

In this case, when APHIS itself indicates that cumulative impacts are important, APHIS subsequent failure to identify and analyze any of those cumulative impacts is egregiously violative of NEPA.[100] Nowhere in the draft EA does APHIS analyze the cumulative affects of the multiple field tests; in fact, APHIS cannot adequately address those impacts, as it does not know the extent of Ventria's future planting, saying only that the planting is "anticipated to increase in size" in future plantings in the "same area" the "next several years."[101]

Nowhere does APHIS analyze the impacts or expected impacts from these other actions, or from the overall impact that can be expected if the individual impacts are allowed to accumulate. Nowhere does APHIS even mention cumulative impacts in the EA after the initial mention on page 5, except a passing reference as one of the laundry list of issues it has addressed and incorporates by reference in previous EAs, instead of actually

---

[95] 40 C.F.R. § 1508.25(c); Utahns for Better Transp. v. United States Dep't of Transp., 305 F.3d 1152, 1172 (10th Cir.2002); Kern v. United States Bureau of Land Mgmt., 284 F.3d 1062, 1076 (9th Cir.2002); Vill. of Grand View v. Skinner, 947 F.2d 651, 659 (2d Cir.1991).
[96] 40 C.F.R. § 1508.7.
[97] Id.
[98] Council on Environmental Quality, *Considering Cumulative Effects Under the National Environmental Policy Act* at 4, Jan. 1997, available at http:// ceq.eh.doe.gov/nepa/ccenepa/ccenepa.htm (last visited Feb. 26, 2002) (emphasis added).
[99] Grand Canyon Trust v. F.A.A., 290 F.3d 339, 345 (D.C. Cir. 2002).
[100] Kern v. U.S. Bureau of Land Mgmt., 284 F.3d 1062, 1076-77 (9th Cir. 2002).
[101] EA at 5.

providing any analysis.[102] As with the other issues (and arguably more so by its very nature), cumulative impacts analyses are action-specific, site-specific, and must be undertaken for each EA, for each final agency action for which NEPA is to be complied. How can cumulative impacts for some other EA, for some other location, with different geographic and other features, be adequate to address the unique cumulative impacts that APHIS itself notes require the EA in this case? The answer is that they cannot.

C. The EA is Arbitrary and Capricious Because The Significant Environmental Impacts of Commercial Rice Cultivation Where No Rice Production Ever Existed Before Are Not Addressed.

APHIS relies in large part on the fact that no commercial rice grown in Kansas, see, e.g., EA at 3, and therefore erroneously concludes that its biopharm rice could not have any environmental impacts. APHIS then fails entirely to address the obvious potential impacts of instituting the cultivation of a *new* type of crop on an ecosystem in which *rice cultivation has never before been done*.

Instituting a new type of environmentally intensive farming where it has never before been done is novel, and raises numerous potentially significant environmental impacts that require an EIS, such as flooding fields, water usage, fertilizer use, new and unique pesticide and herbicide usage, discharge into waters after field flooding, non-target birds, mammals, and others (in addition to those species threatened and endangered) attracted to the water. The potential significant environmental impacts of rice farming are important and must be addressed as to: 1) rice farming's own impacts on the ecosystem and cumulative impacts and 2) how they will affect the fundamentally novel introduction of Ventria's biopharm rice in the area.

Rice cultivation agricultural practices will be used.[103] For example, the biopharm crops will be grown in flooded/water soaked fields at least two locations.[104] What impacts will this flooding have on species, pesticide use, and discharge and distribution of crop reside? Any devitalized waste from milling will be returned to the soil at the test site or incorporated into the soil.[105] What impact will the flooding have on this practice? In addition, the EA speaks of *repeatedly* "flushing the field with water" and later dry techniques.[106] The EA also notes that "off-season irrigation" may also be used.[107] The Kansas lands in question *have never before been subjected to rice farming*. An EIS is necessary to address the potentially significant impacts of the biopharm rice growing in an area that has never before cultivated any rice.

[102] EA at 10.
[103] EA at 8.
[104] EA at 8.
[105] EA at 9.
[106] EA at 10.
[107] EA at 9.

There are two rivers nearby, the Smokey Hill Run, 1 mile away, and the Kansas River, 3-4 miles away.[108] What impacts might the flood-intensive farming have on those rivers? What about the repeated "flushing"? What impacts might the flooding have on the spread of the biopharm materials?

Herbicides and pesticides such as insecticides and fungicides will be used as necessary.[109] What are the pesticides that will be used? What impacts will they have? What are their human health and environmental impacts that were not discussed or assessed? For example, will Carbofuran be used? Carbofuran enters surface water as a result of runoff from treated fields and enters ground water by leaching of treated crops, including rice. Carbofuran has the potential to cause damage to the nervous and reproductive systems.[110]

Rice fields also serve as the habitat for birds and wildlife for part or all of their life cycle. What about impacts on wildlife and wildlife habitat?

What about "seepage," the lateral movement of irrigation water through a rice field levee or border to an area outside of the normally flooded production area?[111] Seepage water that that contains high concentrations of pesticides can damage ecosystems and must be addressed. Rice pesticides that do not strongly adsorb to soil particles, for example, molinate, can move with seepage water from treated fields into agricultural drains or other nontarget areas. This seepage water will contain approximately the same concentration of certain rice pesticides as in the field.[112] If efforts are not made to keep seepage water on the farm and out of drains, water quality goals may be exceeded, as they have been exceeded in the past in agricultural drains. Seepage problems can also be compounded by aerial drift. If pesticides have drifted to border levees, perimeter levee roads, or fallow areas, any seepage water, even untreated water, may pick up and carry pesticides to drains and canals. In general, the effects of rice field drainage on receiving waters and biota are not well understood.[113]

D. The EA Is Arbitrary and Capricious Because It Fails to Address the Reasonably Foreseeable Issues of Energy Usage and Carbon Creation and Impacts on Climate Change From the Proposed Field Testing.

Climate change is an environmental issue of paramount import. The global scientific community's findings on the anthropogenic causes of climate change and climate change's current and future impacts demand that prompt action be taken to integrate climate change analyses into governmental agency planning. The extent to which

---

[108] EA at 10.
[109] EA at 8.
[110] EPA, Consumer Fact Sheet on Carbofuran, at http://www.epa.gov/safewater/contaminants/dw_contamfs/carbofur.html
[111] S.R. Roberts, N.K. Gorder, J.E. Hill, J.M. Lee, S.C. Scardaci, *Seepage Water Management Voluntary Guidelines for Good Stewardship in Rice Production,* at http://www.plantsciences.ucdavis.edu/uccerice/WATER/seep.htm
[112] Id.
[113] See, e.g., USGS, *Fipronil and Degredation Products in the Rice Producing Areas of the Mermentau River Basin*, LA, 2000.

governments consider climate change impacts in planning governmental actions and take action to mitigate such impacts will strongly affect the extent to which climate change and its consequential dangers are limited or avoided in the coming century. The National Environmental Policy Act ("NEPA"), as our nation's basic environmental charter, is the mechanism incorporating environmental considerations into federal decision-making. The Council on Environmental Quality ("CEQ") is charged with overseeing NEPA and must ensure NEPA's purposes are met by issuing guidance to federal agencies on compliance with the statute. Congress intended federal agencies to consider impacts and mitigation for actions with potential climate change consequences. By enacting NEPA, Congress commanded agencies to consider the environmental impacts of their actions. Recognizing that agency actions contribute to the release and storage of greenhouse gases, there are obvious short and long-term environmental effects related to climate change. Therefore, climate change is within the sphere of environmental effects that Congress intended agencies to consider.

According to CEQ, agencies shall use all practical means to "restore and enhance the quality of the human environment and avoid or minimize any possible adverse effects of their actions upon the quality of the human environment."[114] If a project has potential greenhouse gas effects, in order to allow the public and agency to make an informed decision, disclosure and analysis of climate change impacts is needed.

NEPA and the CEQ implementing regulations require analysis of climate change and its reasonably foreseeable effects because: 1) climate change effects are encompassed by CEQ's definition of "effects;" and 2) because climate change effects are "reasonably foreseeable."

1. Climate Change Effects Are Encompassed By CEQ's Definition of "Effects."

CEQ regulations require that the scope of agency effects analyses encompass direct and indirect, as well as cumulative, effects in agency NEPA documents.[115] Section 1508.8 of the CEQ regulations, defines "effects" to include:

> (a) Direct effects, which are caused by the action and occur at the same time and place.
>
> (b) Indirect effects, which are caused by the action and are later in time or farther removed in distance, but are still reasonably foreseeable. Indirect effects may include growth inducing effects and other effects related to induced changes in the pattern of land use, population density or growth rate, and related effects on air and water and other natural systems, including ecosystems.
>
> Effects and impacts as used in these regulations are synonymous. Effects include: ecological (such as the effects on natural resources and on the

[114] 40 C.F.R. § 1500.2(f).
[115] See 40 C.F.R. §§ 1508.08 & 1508.25.

> components, structures, and functioning of affected ecosystems), aesthetic, historic, cultural, economic, social, or health, whether direct, indirect, or cumulative. Effects may also include those resulting from actions which may have both beneficial and detrimental effects, even if on balance the agency believes that the effect will be beneficial.[116]

Climate change effects clearly fall within the ambit of ecological, aesthetic, historical, cultural, economic, social, or health, among others. This conclusion is further buttressed by CEQ's proactive, anticipatory definition of "affecting," as including those things that "may have an effect on" the environment.[117]

NEPA also requires agencies to consider the cumulative impacts of their proposed actions.[118] By definition, cumulative effects must be evaluated along with direct and indirect effects of a project and its alternatives. "'Cumulative impact' is the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency or person undertakes such other actions."[119] Individually minor, but collectively significant actions, taking place over time, can generate cumulative impacts.[120] Accordingly, the climate change effects of a proposed action should be discussed in any cumulative effects analysis to determine if the project will add to the ongoing problem of climate change. In fact, CEQ has previously cited climate change effects as a component of cumulative atmospheric effects to be addressed by agencies in describing the affected environment of a proposed action:

> While describing the affected environment, the analyst should pay special attention to common natural resource and socioeconomic issues that arise as a result of cumulative effects. The following list describes many issues but is by no means exhaustive:
>
> . . .
>
> Regional and global atmospheric alterations from cumulative additions of pollutants that contribute to global warming, acidic precipitation, and reduced ultraviolet radiation absorption following stratospheric ozone depletion.[121]

2. Climate Change Impacts Are "Reasonably Foreseeable."

---

[116] 40 C.F.R. § 1508.25.
[117] 40 C.F.R. § 1508.3.
[118] 40 C.F.R. § 1508.25(c); Utahns for Better Transp. v. United States Dep't of Transp., 305 F.3d 1152, 1172 (10th Cir.2002); Kern v. United States Bureau of Land Mgmt., 284 F.3d 1062, 1076 (9th Cir.2002); Vill. of Grand View v. Skinner, 947 F.2d 651, 659 (2d Cir.1991).
[119] 40 C.F.R. § 1508.7.
[120] Id.
[121] Council on Environmental Quality, *Considering Cumulative Effects Under the National Environmental Policy Act*, 24 (January 1997) (emphasis added).

NEPA and the CEQ implementing regulations include requiring analysis of "reasonably foreseeable" effects.[122] An environmental effect is "reasonably foreseeable" if it is "sufficiently likely to occur that a person of ordinary prudence would take it into account in reaching a decision."[123] It is well-established that some "reasonable forecasting" by the agency is implicit in the NEPA process, and that it is the responsibility of federal agencies to predict the environmental effects of proposed actions before they are fully known.[124]

The "reasonably foreseeable" standard is easily met by climate change effects. The overwhelming consensus of national and international scientific evidence supports the conclusion that climate change is resulting from global warming, i.e., the build-up of greenhouse gases in the atmosphere, and that the subsequent changes are adversely affect our global environment. Stated differently, climate change is "reasonably foreseeable," as that phrase is understood in the context of NEPA and the CEQ regulations.[125] The International Panel on Climate Change (IPCC) and the National Academy of Sciences both have concluded that climate change is being caused by the build-up of greenhouse gases in the atmosphere, a result of human activities.[126] The 2002 Climate Action Report provided a long list of widespread and regional impacts on the United States that were likely or very likely to occur as a result of climate change.[127] The National Academies of Science of eleven major nations—including the U.S.—recently issued a joint statement unequivocally declaring that the scientific understanding of climate change is sufficiently certain to justify prompt governmental action.[128] Accordingly, climate change impacts clearly qualify as reasonably foreseeable effects that must be addressed in environmental compliance documents to properly comply with NEPA and CEQ regulations.

---

[122] See 40 C.F.R. §§ 1502.4, 1508.8, 1508.18, & 1508.25.

[123] See, e.g., City of Shoreacres v. Waterworth, 420 F.3d 440, 453 (5th Cir. 2005); Dubois v. U.S. Dept. of Agriculture, 102 F.3d 1273, 1286 (1st Cir. 1996); Mid States Coalition for Progress v. Surface Transp. Bd., 345 F.3d 520, 549 (8th Cir. 2003) (quoting Sierra Club v. Marsh, 976 F.2d 763, 767 (1st Cir. 1992)) (internal quotation marks omitted).

[124] Scientists' Inst. for Pub. Info. v. Atomic Energy Comm'n, 481 F.2d 1079, 1092 (D.C. Cir. 1973).

[125] CEQ expounded on what is a "reasonably foreseeable" effect in its "Forty Most Asked Questions Concerning CEQ's NEPA Regulations:"

> [I]n the ordinary course of business, people do make judgments based upon reasonably foreseeable occurrences. . . . The agency has the responsibility to make an informed judgment, and to estimate future impacts on that basis, especially if trends are ascertainable . . . . The agency cannot ignore these uncertain but probable, effects of its decisions.

46 Fed. Reg. at 18031.

[126] *See generally* The Intergovernmental Panel on Climate Change (IPCC), Third Assessment Report (2001), *available at* http://www.grida.no/climate/ipcc_tar/ ; National Research Council, Climate Change Science: An Analysis of Some Key Questions vii, 3 (2001) (hereafter "NAS report"), available at http://www.nap.edu/catalog/10139.html?onpi_webextra6 .

[127] U.S. Department of State, U.S. Climate Action Report 2002, Third National Communication of the United States of America Under the United Nations Framework Convention on Climate Change (May 2002) (hereafter "Climate Action Report"), available at http://www.gcrio.org/CAR2002/.

[128] National Academies of Science, Joint Science Academies' Statement: Global Response to Climate Change, available at http://nationalacademies.org/onpi/06072005.pdf

Courts have held several instances that climate change impacts must be adequately considered in order to comply with NEPA. In Border Power Plant Working Group v. DOE, a coalition of citizen organizations challenged the Department of Energy's issuance of a FONSI for permits to build electric lines between new power plants in Mexico and southern California. The district court held that the NEPA analysis was inadequate and that the EA failed to disclose and analyze effects of carbon dioxide as a greenhouse gas.[129] In Mid States Coalition for Progress v. Surface Transp. Bd., the Eighth Circuit reviewed a challenge to an EIS for approval of a railroad that would reach coal mines in Wyoming's Powder River Basin.[130] The Court of Appeals held that it would be irresponsible for the Board to approve a project of this scope without first examining the effects, such as global warming, that may occur as a result of the reasonably foreseeable increase in coal consumption.[131] Both cases illustrate that federal courts have interpreted the provisions of NEPA to require that agencies adequately consider the climate change environmental impacts if it is foreseeable that a project will have greenhouse gas effects. Other Courts have similarly grappled with the issues surrounding agency climate change analyses in various forms.[132]

---

[129] Border Power Plant Working Group v. DOE, 260 F. Supp. 2d 997, 1029 (S.D. Cal. 2003).

[130] Mid States Coalition for Progress v. Surface Transp. Bd., 345 F.3d 520, 550 (8th Cir. 2003).

[131] Id.

[132] See, e.g., Mid-States Coalition for Progress v. Surface Transp. Bd., 345 F.3d 520, 548-50 (8th Cir. 2003) (addressing a challenge to the approval by the Surface Transportation Board of a railroad to coal mines in Wyoming's Powder River Basin and holding that the EIS was inadequate because, inter alia, it failed to examine the reasonably foreseeable effect on global warming of the subsequent increase in coal consumption); Assoc. Of Pub. Agency Customers v. Bonneville Power Admin., 126 F.3d 1158, 1187-88 (9th Cir. 1997) (addressing a challenge to BPA's EIS for a new business plan on power sales and transmission contracts and holding that the EIS adequately considered climate change effects); Friends of the Earth v. Watson, 2005 WL 2035596, *2-6 (N.D. Cal. 2005) (denying the defendant's motion for summary judgment for lack of standing in a challenge to the Overseas Private Investment Corporation ("OPIC") for its failure to conduct an environmental assessment under NEPA when providing assistance to specific projects that contribute to climate change and finding that the plaintiffs evidence of global warming and its potential impacts were sufficient to demonstrate a reasonable probability that the projects funded by the defendants would harm the plaintiffs' interests); Senville v. Peters, 327 F. Supp. 2d 335, 57-58 (D. Vt. 2004) (addressing a challenge to the Federal Highway Administration's ("FHWA") approval of highway segments because the EIS failed to properly analyze the cumulative and secondary effects of the highway project–including air quality impacts like CO_2 emissions impacting global warming–and holding that the plaintiffs had not established a substantial likelihood of significant new air quality impacts stemming from the challenged approval of a highway segment); Border Power Plant Working Group v. Dep't of Energy, 260 F. Supp. 2d 997, 1028-29 (S.D. Cal. 2003) (addressing a challenge to a FONSI issued for California-Mexico border power plants permits and concluding that the agency had failed to provide adequate environmental analysis, in part because the EA failed to disclose and analyze the effects of carbon dioxide emissions as a greenhouse gas contributing to global warming); Seattle Audubon Soc'y v. Lyons, 871 F. Supp. 1291, 1324 (W.D. Wash. 1994) (addressing a challenge to a forest management plan that included a charge of failing to disclose the impacts of timber harvest on air quality and climate and concluding that the EIS adequately discussed these impacts); see also City of Los Angeles v. Nat'l Highway Traffic Safety, 912 F.2d 478 (D.C. Cir. 1990) per curiam (addressing a challenge to the decision by the National Highway Traffic Safety Administration not to prepare an EIS on fuel economy standards for 1987-89 and holding that the plaintiffs had standing to challenge the standard on global warming grounds, but the lack of an EIS was not arbitrary and capricious); id. at 499-503 (Wald, C. J., dissenting in part) (concluding that the agency should have prepared a programmatic EIS addressing the global warming consequences of the standards approved); Foundation on Economic Trends v. Watkins, 794 F. Supp. 395,

3. The Climate Change Impacts of Commercial Rice Cultivation.

In this agency action, the proposed project will approve the cultivation of rice in a region in which it has never been grown commercially previously. It is well-known that rice fields emit significant amounts of methane, a major Greenhouse Gas that causes Climate Change.[133] Methane is a greenhouse gas that is 20 times more radioactively active than carbon dioxide and strongly influences the photochemistry of the atmosphere. It has been estimated that the increase in methane concentration may have contributed about 15% to anthropogenic greenhouse effects.[134]

Methane forms as a by-product of anaerobic bacterial decomposition of organic matter in the soil and reaches the atmosphere through the roots and stems of the rice plants.[135] Some studies show that up to 20 percent of global methane emissions come from flooded rice fields.[136] Rice cultivation also releases methyl halides, including methyl iodide, methyl bromide and methyl chloride, which, even in small amounts, "pose a significant threat to the ozone layer."[137] Again, it is important that rice cultivation has never before been undertaken in Kansas. Rice farming is a major contributor to global warming and climate change through the production of the greenhouse gases, primarily methane.[138] The following additional sources are herein incorporated by reference.[139]

397-401 (D. D.C. 1992) (holding that plaintiffs challenging the failure of agencies to consider global warming on specific actions lacked standing).

[133] *See, e.g.,* Harald Frazen, *Rice May Hurt Climate*, Scientific American, November 6, 2000; see generally See generally The Intergovernmental Panel on Climate Change (IPCC), Third Assessment Report (2001), available at http://www.grida.no/climate/ipcc_tar/ ; see generally National Research Council, Climate Change Science: An Analysis of Some Key Questions vii, 3 (2001) (hereafter "NAS report"), available at http://www.nap.edu/catalog/10139.html?onpi_webextra6. ; See also National Research Council, Abrupt Climate Change: Inevitable Surprises 107-08 (2003), available at http://www.nap.edu/catalog/10136.html?onpi_newsdoc121101 (subsequent NAS study concluding that greenhouse gas emissions resulting from human activities could trigger abrupt changes in the Earth's climate); National Research Council, Air Quality Management in the United States 234 (2004) available at http://www.nap.edu/catalog/10728.html ; U.S. Department of State, U.S. Climate Action Report 2002, Third National Communication of the United States of America Under the United Nations Framework Convention on Climate Change (May 2002) (hereafter "Climate Action Report"), available at http://www.gcrio.org/CAR2002/. National Academies of Science, *Joint Science Academies' Statement: Global Response to Climate Change*, available at http://nationalacademies.org/onpi/06072005.pdf;

[134] USDA, Reducing Methane Emissions from Rice, see attached.

[135] Id.

[136] USDA, Reducing Methane Emissions from Rice.

[137] Id.

[138] See, e.g., Heinz-Ulrich Neue, *Methane Emissions from Rice Fields*, *Wetland rice fields may make a major contribution to global warming*, *BioScience* 43 (7): 466-73 (1993).

[139] Bachelet, D., and H.-U. Neue. In press. Methane emissions from wetland rice areas of Asia. Chemosphere.

Bauchop, T. 1967. Inhibition of rumen methanogensis by methane analogues. J. Bacteriol. 94: 171.

Borell, A. K., S. Fukai, and A. L. Garside. 1991. Irrigation methods for rice in tropical Australia. Int. Rice Res. News. l6(3): 28.

Bouwman,A.F.,ed. 1989. Soils and the Greenhouse Effect. John Wiley & Sons. New York .

Bronson. K. F., and A. R. Mosier.1991. Effect of encapsulated calcium carbide on dinitrogen, nitrous oxide, methane and carbon monoxide emissions in flooded rice. Biol. Fertil. Soils 7: 116-120.

Cicerone, R. J., and R. S. Oremland. 1988. Biogeochemical aspects of atmospheric methane. Global

Biochem. Cycles 2: 299-327.
Page 10 of 14 composite methane edt
3/23/2007 http://www.ciesin.columbia.edu/docs/004-032/004-032.html
Cicerone, R. J., and J. D. Shetter.1981. Sources of atmospheric methane: measurements in rice paddies and a discussion. J. Geophys. Res. 86: 7203-7209.
Cicerone R. J., J. D. Shetter, and C. C. Delwiche. 1983. Seasonal variation of methane flux from a Californian rice paddy. J. Geophys. Res. 88: 11022-11024.
Conrad, R. 1989. Control of methane production in terrestrial ecosystems. Pages 39-58 in M. O. Andrae and D. S. Schimmel, eds. Exchange of Trace Gases between Terrestrial Ecosystems and the Atmosphere. John Wiley & Sons, New York.
de Bont, J. A. M., K. K. Lee, and D. F. Bouldin. 1978. Bacterial oxidation of methane in rice paddy. Ecol. Bull. 26: 91-96.
De Datta, S.K. 1981. Principles and Practices of Rice Production. John Wiley & Sons, New York.
Denier van der Gon, H. A. C., H. U. Neue, R. S. Lantin, R. Wassmann, M. C. R. Alberto, J. B. Aduna, and M. J. P. Tan. 1992. Controlling factors of methane emission from ricefields. Pages 81-92 in N. H. Batjes and E. M. Bridges, eds. World Inventory of Soil Emission Potentials. World Inventory of Soil Emission Potentials Report 2, International Soil Reference and Information Center, Wageningen, The Netherlands.
Dickinson, R. E., and R. J. Cicerone. 1986 Future global warming from atmospheric trace gases . Nature 319: 109-115.
Garcia, J. L. 1990. Taxonomy and ecologv of methanogens. FEMS Microbiol. Rev. 87: 297-308.
Gomez, A. A., and H. G. Zandstra. 1982. Research strategy for rice-based cropping systems. Pages 381-394 in Rice Research Strategies for the Future. International Rice Research Institute, Los Baños, Philippines.
Harrison, W. H., and P. A. S. Aiyer. 1913. The gases of swamp rice soil.1. Their composition and relationship to the crop. Memoires Department of Agriculture India Chemistry Series 5(3): 65-104.
Hobson, P. N., and B. G. Shaw. 1976. Inhibition of methane production by Methanobacterium formicium. Water Res. 10: 849.
Holzapfel-Pschorn, A., R. Conrad, and W. Seiler. 1985. Production, oxidation and emission of methane in rice paddies. FEMS Microbiol. Ecol. 31: 343-351.
_____. 1986. Effects of vegetation on the emission of methane from submerged paddy soils. Plant & Soil 92: 223--233.
Hyman, M., and P. M. Wood. 1983. Methane oxidation by Nitrosomonas europaea. Biochem.J. 212: 31-37.
Intergovernmental Panel on Climate Change (IPCC).1992. Climate Change: TheSupplementarv Report to the IPCC Scientific Assessment. Cambridge Universitv Press, New York.
International Bank for Reconstruction and Development/The World Bank (IBRD). 1986. Povert- and Hunger: A World Bank Policy Study. Washington, DC.
Page 11 of 14 composite methane edt
3/23/2007 http://www.ciesin.columbia.edu/docs/004-032/004-032.html
Inrernational Rice Research Institute (IRRI). 1989. IRRI Towards 2000 and Beyond. IRRI, Manila, Philippines.
_____. 1991. World Rice Statistics l990. IRRI, Manila, Philippines.
_____. 1992. Program Report for 1991. IRRI, Manila, Philippines.
Khalil, M. A. K., R. A. Rasmussen, M. X. Wang, and L. Ren.1991. Methane emission from rice fields in China. Environ. Sci. Technol. 25: 979-981.
Khalil, M. A. K., and M. Shearer, eds. In press. Global Atmospheric Methane. Springer-Verlag, New York.
Kimura, M. 1992. Methane emission from paddy soils in Japan and Thailand. Pages 43-79 in N. H. Batjes and E. M. Bridges, eds. World Inventory of Soil Emission Potentials. WISE Report 2, ISRIC, Wageningen.
Koyama, T., M. Hishida, and T. Tomino. 1970. Influence of sea salts on the soil methabolism. 11. On the gaseous metabolism. Soil Sci. PlantNutr. 16: 81-86.
Lindau, C. W., P. K. Bollich, R. D. Delaune, W. H. Patrick Jr., and V. J. Law.1991. Effect of urea fertilizer and environmental factors on methane emissions from a Louisiana, USA rice field. Plant &

Soil 136: 195-203.
McBride, B. C., and R. S. Wolfe. 1971. Inhibition of methanogenesis by DDT. Nature 234: 551.
Morris, R. A., A. Patanothai, A. Syarifuddin, and V. R. Carangal. 1986. Associated crops in rice-based cropping systems. Pages 59-76 in Progress in Rainfed Lowland Rice. International Rice Research Institute, Manila, Philippines.
Neue, H.-U. 1991. Holistic view of chemistry of flooded soil. Pages 3-32 in Soil Management for Sustainable Rice Production in the Tropics. International Board for Soil Research and Management Monograph No.2, Bangkok, Thailand.
Neue, H.-U., P. Becker-Heidmann. and H. W. Scharpenseel. 1990. Organic matter dynamics, soil properties and cultural practices in
rice lands and their relationship to methane production. Pages 457-466 in A. F. Bouwman, ed. Soils and the Greenhouse Effect. John Wiley & Sons, New York.
Neue, H.-U., and P. A. Roger. In press. Rice agriculture: factors controlling emissions. In M. A. K. Khalil and M. Shearer, eds. Global Atmospheric Methane. Springer-Veriag, New York.
Neue, H.-U., C. Quijano, and H. W. Scharpenseel. 1991. Conservation and enhancement of wetland soils. Pages 279-303 in Evaluation for Sustainable Land Management in the Developing World. International Board for Soil Research and Management Proceedings No. 12(2), Bangkok, Thailand.
Neue, H.-U., and H. W. Scharpenseel. 1984. Gaseous products of the decomposition of organic matter in submerged soils. Pages 311-328 in Organic Matter and Rice. International Rice Research Institute, Manila, Philippines.
Page 12 of 14 composite methane edt
3/23/2007 http://www.ciesin.columbia.edu/docs/004-032/004-032.html
_____.1987. Decomposition pattern of 14C-labelled rice straw in aerobic and submerged rice soils of the Philippines. Sci. Total Environ. 62: 431-434.
Nouchi, I., S. Mariko, and K. Aoki. 1991. Mechanisms of methane transport from the rhizospere to the atmosphere through rice plants. Plant Physiol. 94: 59-66.
Oremland, R. S., L. M. Marsh, and S. Polcin. 1982. Methane production and simultaneous sulfate reduction in anoxic saltmarsh sediments. Nature 296: 143-145.
Patel, G. G., and L. A. Roth. 1977. Effect of sodium chloride on growth and methane production of methanogens. Can. J. Microbiol. 6:893.
Raimbult, M. 1975. Etude de l'influence inhibitrice de l'acetylene sur la formation biologique du methane dans un sol de riziere. Ann. Microbiol. (Inst. Pasteur) 126a: 217-258.
Ramanathan, V., R. J. Cicerone, H. B. Singh and J. T. Kiehl. 1985. Trace gas trends and their potential role in climate change. J. Geophys. Res. 90: 5547-5566.
Salvas, P. L., and B. F. Taylor. 1980. Blockage of methanogenesis in marine sediments by the nitrification inhibitor 2-chloro-6 (trichloromethyl) pyridine (Nitrapin or N-serve). Curr. Microbiol. 4: 305.
Sass. R. L., F. M. Fischer, P. A. Harcombe, and F. T. Turner. 1991. Methane production and emission in a Texas rice field. Global Biogeochem. Cycles 4: 47-68.
Sass, R. L., F. M. Fischer, Y. B. Wang, F. T. Turner, and M. F. Jund. 1992. Methane emission from rice fields: the effect of floodwater management. Global Biogeochem. Cycles 6: 249-262.
Schütz, H., A. Holzapfel-Pschorn, R. Conrad, H Rennenberg, and W. Seiler. l989a. A 3-year continuous record on the influence of daytime, season and fertilizer treatment on methane emission rates from an Italian rice paddy field. J. Geophys. Res. 94: 16405-16416.
Schütz, H., W. Seiler, and R. Conrad. 1989b. Processes involved in formation and emission of methane in rice paddies. Biogeochemistry 7: 33-53.
Schütz, H., W. Seiler, and H. Rennenberg. 1990. Soil and land use related sources and sinks of methane (CH4) in the context of the global methane budget. Pages 268-285 in A. F. Bouwman, ed. Soils and the Greenhouse Effect. John Wiley & Sons, New York.
Seiler, W., A. Holzapfel-Pschorn, R. Conrad, and D. Scharffe. 1984. Methane emission from rice paddies. J. Atmos. Chem. 1: 241-268.
Smith, M. R., and R. A. Mah. 1981. 2-Bromoethanesulfonate: a selective agent for isolating resistant Methanosarcina mutans. Curr. Microbiol. 6: 321.
Takai, Y. 1970. The mechanism of methane fermentation in flooded soils. Soil Sci. Plant Nutr. 16: 238.
Takai, Y., T. Koyama, and T. Kamura. 1956. Microbial metabolism in reduction process of paddy soil.

E. APHIS Failed to Evaluate the Controversial Nature of its Proposed Action.

APHIS failed to evaluate "the degree to which the effects on the quality of the human environment are likely to be highly controversial," as it is required to do.[140] APHIS approval of these field tests are highly controversial. For example, the Public has submitted at least 5,500 comments opposed to the approval of these field tests.[141] The scientific uncertainities of pharm crops, discussed *supra* coupled with APHIS abysmal history of repeatedly failing to contain genetically engineered and pharma crops after assuring the public that such "containment" was possible, discussed *infra* makes these field tests controversial. In addition, the unprecedented scope and duration of these field tests, all crammed into a single EA with very little "analysis" makes the approval controversial.

IV. Failure of FDA or EPA to Review or Approve the Bioactive Compounds in Ventria's Rice Argues Strongly Against Granting the Requested Permits

The U.S. is supposed to have a "coordinated framework" for regulation of the products of agricultural biotechnology. In the area of pharmaceutical-producing crops, however, this framework is profoundly dis-coordinated. It is profoundly disturbing that our nation's agricultural agency should allow the cultivation of thousands of acres of crops producing substances that may harm human health, and may harm the environment, while the federal agenices entrusted with protection of human health and the environment have not even reviewed these serious issues.

A. FDA Has Not Approved Ventria's Pharmaceutical Proteins

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. 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." For instance, the FDA's guidance document on low-level presence of unapproved GE crops in the food supply applies specifically to GE crops that are intended for human food use.[142] It thus excludes Ventria's pharmaceutical rice varieties, because Ventria's rice is being grown

---

Part 1. Soil Plant Food 2(2): 63-66.
Page 13 of 14 composite methane edt
3/23/2007 http://www.ciesin.columbia.edu/docs/004-032/004-032.html
Wahlen, M., N. Tanaka, R. Henry, B. Deck, J. Zeglen, J. S. Vogel,J. Southon, A. Shemesh, R. Fairbanks, and W. Broecker. l989. Carbon-14 in methane sources and in atmospheric methane: the contribution from fossil carbon. Science 245: 286-290.
Wang Zhaoqian. 1986. Rice based systems in subtropical China. Pages 195-206 in A. S.

[140] 40 C.F.R. § 1508.27(b)(4).
[141] See Public Docket No. APHIS-2007-0006
[142] "Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use," Center for Food Safety and Applied Nutrition, FDA, issued June 2006. http://www c san..f'da.gov/dms/$uidance.html

not for human food use, but rather for generation of pharmaceutical substances to be extracted from the rice for a variety of potential uses, subject to regulatory approval. Such regulatory approval has not been granted. In fact, 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). FDA 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. 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 two documents in the supporting material accompany these comments (Pharmaceutical Rice in California, A Critical Assessment of Pharmaceutical Rice to Address Diarrheal Disease in Infants).

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[143]	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[144]	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[145]	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[146]	A 2004 National Academy of Sciences panel recommends more stringent testing of new ingredients in infant formulas

APHIS is not competent to judge whether these recombinant human proteins present human health risks. In fact, APHIS reviewers appear unfamiliar with the basic science behind recombinant production of proteins. In Appendix 2: Description of the Regulated Rice Plants (EA, p. 13), APHIS mischaracterizes the proteins produced by the rice varieties as "human lysozyme, lactoferrin or human serum albumin." APHIS made the same mistake in the prior EAs it references, for example: "Ventria has engineered the rice plant to produce human lactoferrin in the seeds" (EA for permit number 05-117-01r, p. 9).

[143] 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."
[144] See http://www.cfsan.fda.gov/~rdb/opa-g162.
[145] See http://www.cfsan.fda.gov/~rdb/opa-g174.html
[146] See GRN No. 191 at http://www.cfsan.fda.gov/~rdb/opa-gn06.html

In fact, these proteins are ***recombinant*** human lysozyme, lactoferrin and serum albumin. Recombinant human proteins are usually different than their natural human counterparts, and these differences can cause immune system reactions, including allergic reactions, in those exposed to them. Two published scientific articles demonstrate conclusively that recombinant human lactoferrin is different than natural human lactoferrin, a difference with potential health impacts that APHIS repeatedly glosses over in its EA.[147] Both rhLf and rhLys possess properties typical of food allergens, and in fact mothers of two infants involved in a clinical trial of oral rehydration solutions containing Ventria's rhLf and rhLys in Peru reported that their infants became allergic to many foods as a result, reports which deserve further investigation.[148]

APHIS's only attempt to address the difference between rice-expressed, recombinant human lactoferrin and its native counterpart reveals a primitive understanding of the scientific facts, coupled with uncritical reliance on Ventria and its collaborators. APHIS says only that the plant glycosylation patterns do not appear to confer a different stability on rice rLf versus native human lactoferrin. Yet plant glycosylation patterns themselves can induce immune system, including allergic reactions, whether or not they alter the stability of a protein. For the many other potential human health issues that APHIS did not address, and is not competent to address, we refer to the potential human health impacts sections of our two reports on Ventria's rice included in the supporting materials.[149]

B. Ventria's Pharmaceutical Proteins Have Pesticidal Properties that Require Assessment by the Environmental Protection Agency

Ventria's pharmaceutical rice varieties could also have negative environmental impacts based on pesticidal properties of rhLf and rhLys. For instance, carrots genetically engineered to express recombinant human lysozyme exhibit enhanced resistance to certain fungal and bacterial diseases affecting carrots. It is possible that rhLys would confer similar antifungal/antibacterial properties to Ventria's rice, enhancing the ability of dispersed rhLys-containing seeds to survive in the environment or in nearby cropland, and thus increasing its potential to contaminate agricultural commodities. Transgenic proteins may also leak from plant roots in a process known as rhizosecretion. Rhizosecreted rhLf or rhLys could have negative impacts on soil biota. Lysozyme-containing root exudates of potatoes engineered with the T4 lysozyme gene have been shown to kill several times as many bacteria as the root exudates of a control line. We refer to a fuller treatment of this issue in the corresponding section of our 2004 "Pharmaceutical Rice in California" report, included in the supporting materials.

---

[147] Lonnerdal, B. (2002). "Expression of Human Milk Proteins in Plant," Journal of the American College of Nutrition, Vol. 21, No. 3; Fujiyama, K. et al (2004). "N-linked glycan structures of human lactoferrin produced by transgenic rice," Biosci. Biotechol. Biochem. 68(12): 2565-70.

[148] Diaz, D. (2006). "Transgénicos: Niños ya sufren sus efectos," La Republica (Peru), July 14, 2006. http://archivo.larepublica.com.pe/index.php?option=com_content&task=view&id=116503&Itemid=38&fecha_edicion=2006-07-14

[149] Freese, B., M. Hansen and D. Gurian-Sherman, "Pharmaceutical Rice in California," op. cit.; Freese, B. "A Critical Assessment of Pharmaceutical Rice to Address Diarrheal Disease in Infants," Center for Food Safety, 2007, both included in the supporting materials.

Given the potential harms to human health and the environment posed by Ventria's rice, and the failure of both FDA and EPA to review, much less approve, either the plants or the compounds they produce, USDA should deny Ventria's permit requests.

V. APHIS' Dismal Record of Failure at Gene Containment with Regulated Articles Argues Strongly Against Granting the Requested Permits.

In both the present EA and prior EAs that APHIS references, it argues repeatedly that gene escape will not occur or is highly unlikely. For instance, APHIS argues that: "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."[150]

Gene containment protocols are proposed by applicants, and APHIS is supposed to evaluate their adequacy or inadequacy based on its "performance standards." In some cases, APHIS accepts the applicant's gene containment protocol as fully adequate, in other cases it proposes supplemental permit conditions. In all cases, primary responsibility for gene containment in the field rests with the field trial operator, either the applicant or a contract grower hired by the applicant to actually grow the crop. APHIS's involvement after granting a permit is limited to occasional inspections by APHIS or state personnel and receipt of reports prepared by the applicant. History shows that most required inspections are never conducted and many required reports are never submitted by the applicant. APHIS does not conduct tests to determine whether gene escape has occurred, and apparently does not even require applicants to submit test reagents (i.e. primers) to enable it to conduct such testing. Thus, it is not surprising that when contamination episodes do occur, they are detected by some third party rather than APHIS. This also means that reported contamination episodes may represent just a small fraction of those that have actually occurred.

While APHIS believes this system is adequate, the facts belie such confidence. 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 (discussed below). In general, contamination episodes must be due to inadequate gene containment protocols and/or faulty execution of those protocols. The first possibility – unsound protocols – would mean that gene escape occurs even when the protocols are perfectly executed in the field. The second possibility is that theoretically sound protocols are undermined by errors on the part of the field trial operator, and lack of adequate oversight by APHIS to detect and correct the errors before they result in contamination. The situation is complicated by the fact that APHIS does not even aim for "zero contamination," but rather considers

[150] EA at 8.

measures to "mitigate" or "minimize" contamination to be sufficient,[151] where APHIS proposes to "minimize the risk of seed loss, spillage, or commingling," not prevent it). One other possibility less easy to categorize was recently suggested by Bayer CropScience, which blamed "acts of God" for widespread contamination of rice with an unapproved variety it had developed and field tested over five years ago.[152]

A. Are APHIS-Approved Gene Containment Protocols Adequate?

1. Cross-Pollination

There is some evidence that APHIS-approved gene containment protocols are simply inadequate, even when perfectly executed. 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.

> *"In fact, we made sure the distance between the LibertyLink plots and other conventional rice plots was further apart than what the research protocols required. When there was a minimum requirement, we exceeded it."*[153]

Of course, we cannot confirm whether or not LSU breeders in fact met or exceeded APHIS-approved standards, but this at least casts doubt on the adequacy of APHIS approved gene containment protocols for outdoor field testing of regulated articles. At this writing, USDA has still not issued a report, promised in December 2006, of its investigation into the cause of the episode.

2. APHIS virtually ignores seed dispersal as mode of contamination.

LSU personnel maintain they adhered to APHIS-approved isolation distances between LL601 and other rice varieties, which are designed to prevent contamination via cross-pollination. APHIS has consistently ignored the other major mode of contamination, seed dispersal, which many view as presenting a greater threat of contamination.[154]

For instance, in a field trial proposed by Ventria in 2004 in California, the Sacramento Bee reported that Ventria's gene containment protocol "…is light on some details,

---

[151] EA at 19.
[152] Weiss, R. "Firm Blames Farmers, 'Act of God' for Rice Contamination," The Washington Post, 11/22/06, http://www.washingtonpost.com/wp-dyn/content/article/2006/11/21/AR2006112101265_pf.html.
[153] As quoted in: Schultz, B. "LibertyLink 601 found in LSU AgCenter foundation seed rice," Delta Farm Press, 8/31/06.
[154] ROYAL SOCIETY OF CANADA (2001). Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada, An Expert Panel Report on the Future of Food Biotechnology, *Royal Society of Canada*, p. 123. http://www.rsc.ca/foodbiotechnology/index/EN.html

including how Ventria will prevent birds from spreading its rice…"[155] Public commenters, citing wildlife experts, have repeatedly raised the issue of birds and other animals spreading Ventria's rice through consumption and defecation of undigested grains.[156] APHIS has consistently downplayed the contamination risk from seed dispersal, and failed to require any measures to prevent it. **The issue of seed dispersal goes almost completely unaddressed in the EA at issue here**.

More scientifically-oriented regulators in other countries have taken this mode of contamination seriously, and required measures to prevent it. For instance, regulators with Brazil's CTNBio (National Technical Commission on Biosafety) ordered field trials of genetically engineered, LibertyLink rice destroyed due to the failure of AgrEvo, developer of the rice, to install protective netting over the field trial to prevent birds from dispersing the GE rice beyond the bounds of the test plot.[157]

3. Faulty Execution of Protocols / Inadequate APHIS Oversight

Even if one follows APHIS in ignoring the potential for contamination via seed dispersal, and assumes that gene containment protocols are theoretically sound, faulty execution can lead to gene escape and contamination. 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 several authoritative reviews of APHIS performance over the past 12 years which support this assertion.

In 1994, the USDA's Office of the Inspector General (OIG) issued an audit report[158] identifying problems with APHIS's oversight of genetically engineered organisms – specifically, a lack of procedures to track inspection reports and follow up on violations or potential violations of permit standards for genetically engineered crop field trials. APHIS's Biotechnology, Biologics and Environmental Protection (BBEP) unit (precursor to today's Biotechnology Regulatory Services) generally agreed with the recommendations to improve management and handling procedures and to create a new management information system for tracking permit and notification information.[159]

In 2001, APHIS issued a study covering its performance at regulating GE crop field trials under the streamlined notification system for the period from mid-1997 to 2000. Then as

[155] Lee, M. and Lau, E. "Biotech company cultivates new field," Sacramento Bee, Jan. 25, 2004.
[156] Freese, B. et al, "Pharmaceutical Rice in California," op. cit.; Freese, B. "Pharmaceutical Rice in Missouri," Friends of the Earth, 2005.
http://www.foe.org/camps/comm/safefood/biopharm/PharmRiceinMO.pdf.
[157] "Commission refuses to allow test planting of genetically modified rice," Folha de Sao Paulo, October 14, 1999.
[158] Audit Report 33099-9-Hy, dated August 1994.
[159] As decribed in "Audit Report: Animal and Plant Health Inspection Service Controls over Issuance of Genetically Engineered Organism Release Permits," USDA Office of Inspector General, Southwest Region, Audit Report 50601-8-Te, December 2005, hereinafter referred to as OIG (2005). Available at

now, applicants for notification field trials are not required to submit written protocols (including gene containment measures) with their applications, and so APHIS personnel do not review protocols for adequacy prior to granting notification permits.[160] The 2001 APHIS study concluded that some notification protocols might not be adequate to meet its field test performance standards and identified several major areas in need of improvement. According the USDA's Inspector General, the study showed that APHIS should in fact review these protocols prior to granting permits (see reference in footnote 9, p. 20, hereinafter referred to as OIG (2005)). OIG (2005) noted that APHIS still does not require companies to submit written protocols for scientific review prior to granting notification permits, and recommended that it do so. APHIS flatly refused to implement this recommendation.[161]

In 2002, a committee of the National Academy of Sciences (NAS) issued a book-length, exhaustive review of APHIS' performance at regulating GE crops, and found numerous serious flaws in its regulatory practices. Inadequacies noted by the NAS committee include failure to conduct environmental assessments for most field trials; deficiencies in those EAs that are conducted; mis-regulation of plants producing potentially toxic compounds under the streamlined notification procedure; lack of transparency and too little public participation in decision-making process; excessive claims of confidential business information by companies; lack of external scientific peer review of APHIS decisions; scientific deficiencies in decision documents; lack of adequate enforcement in the field, including failure to inspect neighboring fields for contamination to determine whether gene containment is working; and poorly trained personnel.[162]

In 2005, the USDA's Inspector General conducted an audit covering GE crop field trials conducted in 2002 and 2003, finding numerous basic deficiencies in APHIS oversight.[163] It should be noted that this audit covered by 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 are noted below:

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.

---

[160] In APHIS parlance, the agency issues an "acknowledgement" to the applicant's "notification." Since "acknowledgement" is required for a notification field trial to proceed, it functionally amounts to a permit. APHIS's choice of terminology is revealing, in that neither term – notification nor acknowledgement – contains any hint that APHIS review or permission is required to proceed.

[161] Id. at 22.

[162] "Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation," op. cit.

[163] 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*.

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 (described above), 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. Some of the measures APHIS refused to implement include:

1) Development of policies to restrict public access to edible GE crops, especially pharmaceutical-producing crops.
2) Require submission of written protocols prior to approving notification permits
3) Require APHIS review of notification protocols.
4) Distribute written protocols to inspection personnel for notification inspections
5) Impose sanctions for missing or late progress reports from the field trial operators
6) Require applicants to report planned date of disposal of harvests of GE crops producing pharmaceuticals or industrial proteins.
7) Develop and implement written policies and procedures for selecting specific field tests sites for inspection based on risk.
8) Require submission of planting notices, 4-week reports, and harvest/termination reports.

In addition, in the past year, three federal district court judgments have criticized the Department for its poor oversight of GE crops.[164] 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.[165]

---

[164] *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

[165] *Id.*

As discussed above in section III.A, 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 expressing the three same substances 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 the Union of Concerned Scientists in a Freedom of Information Act request dated January 2006.[166] 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 unwillingess to carry out its regulatory duties with respect to experimental GE crops, including pharmaceutical-producing crops such as Ventria's. These deficiencies are corroborated by three federal district court rulings against APHIS over the past year. Basic flaws in APHIS regulation identified over this twelve-year period have not been corrected. APHIS has refused to implement or fully implement nine of the 28 recommendations made by its own Inspector General to correct these defects. The GE rice contamination episodes represent the real-world consequences of APHIS's regulatory deficiencies.

Finally, APHIS' failure to adhere to its own policies and permit conditions in regulation of the Ventria field trials in North Carolina in 2005, especially in light of its 12-year

[166] "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

history of mis-regulation and failure to correct its regulatory deficiencies, undermine any confidence in its ability or willingness to enforce its policies and proposed permit conditions for Ventria's proposed field trials in Kansas. These permits would authorize nearly 10 times the area approved in those 2005 North Carolina field tests, significantly increasing the scope for adverse impacts.

In sum, APHIS' dismal failure to carry out its regulatory responsibilities provides more than sufficient grounds to justify rejection of Ventria's proposed planting, especially given the sensitive nature of the substances produced in the rice, the large scale of the planting, and the "zero contamination" standard in force for pharma crops, until and unless APHIS proves itself capable of properly regulating GE field trials in general.

VI. The APHIS regulations for "confined" field testing of GE crops are facially inconsistent, arbitrary and capricious and contrary to law as applied to open air field testing such as that applied for here. All open-air field testing cannot be logically "confined."

APHIS claims at the outset that the field trials at issue here would have been granted NEPA categorical exclusion as "confided" field tests pursuant to 7 C.F.R. § 372.5(c)(3)(i) except that Ventria plans to do several more plantings over the next several years, raising new cumulative impacts that the EA purports to address (and doesn't.) APHIS' starting point of statutory and regulatory analysis is arbitrary and capricious. Open air field tests such as those at issue here cannot be "confined" and APHIS' regulatory interpretation to the contrary is arbitrary and capricious. Read consistently, Defendants' regulations establish that an outdoor field trial of a GE crop is never "confined." Under the agency's regulations the introduction of any regulated article is considered to be a "release into the environment."[167] The agency's further defines "release into the environment" as:

> The use of a regulated article outside the constraints of physical confinement that are found in a laboratory, contained greenhouse, or a fermenter or other contained structure.[168]

Similar terms used in different parts of the same statute or regulation presumptively have the same meaning.[169] Unless a regulated article such as biopharm rice is subject to "confinement" its is consider a release into the environment under § 340.3(b)(1). By definition such releases mean that they are not confined in a laboratory, contained greenhouse, fermenter or other structure. Accordingly, the very structure of APHIS's NEPA regulations, with nothing further, makes the field trials at issue subject to the EA requirements of §372.5(b)(5)(I).

Open-air plantings such as those at issue here are, as a matter of fact and science,

---

[167] 7 C.F.R. § 340.3(b)(1).
[168] 7 C.F.R. § 340.1 (emphasis added).
[169] See *Gustafson v. Alloyd Co.*, 513 U.S. 561, 570 (1995) (acknowledging that "identical words used in different parts of the same act are intended to have the same meaning").

unconfined.[170] "Confine" is defined as "to keep or restrict within certain limits."[171] Yet use in open fields creates unstoppable, foreseeable, confinement-breaking events such as wind storms that would blow the pharma pollen far beyond the field release boundaries; the actions of birds and rodents, human error, and so on that easily could cause the GE or pharma material to move outside the limited boundaries of field trial plot. Moreover, "confinement" measures accepted by APHIS are often wholly inadequate to prevent gene flow.[172] Given the structure of the agency's regulations and the fact that the field trials cannot logically be considered as "confined," they cannot be considered to be categorical exclusions and require, at a mininium, EAs.

In Exxon Co., U.S.A. v. F.E.R.C.,[173] the agency's valuation of certain petroleum products was found not "logical," therefore remanded "to determine a logical" approach. The Court stated, that while some deference to agency discretion was called for: "Nonetheless, the Commission must engage in rational decisionmaking."[174] Such rational decisionmaking was not present here, when APHIS began its analysis by assuming that a NEPA Categorical Exclusion for "confined" field testing might apply to open-air field testing of biopharm crops.

APHIS should revise its NEPA regulation on Categorical Exclusions for the permitting of "confined field releases" under 7 C.F.R §372.5(c)(3)(ii), so as to make it logically consistent with its definition of "release into the environment," at 7 C.F.R. § 340.1, or to otherwise remedy the contradiction.[175]

CONCLUSION

For the foregoing reasons, we request that the field testing permit applications be denied, or in the alternative, that APHIS prepare an EIS adequately addressing all the significant environmental impacts of this action.

---

[170] See generally and hereby incorporated by reference, Doug Gurian-Sherman, Ph.D., Center for Food Safety, *Contaminating the Wild? Gene Flow from Experimental Field Trials of Genetically Engineered Crops to Related Wild Plants*, 2006, available at http://www.centerforfoodsafety.org/pubs/Contaminating_the_Wild_Report.pdf

[171] Oxford American Dictionary, Oxford University Press, New York (1980).

[172] See Gurian-Sherman, *Contaminating the Wild*, supra note 29.

[173] 182 F.3d 30, 42 (D.C. Cir. 1999).

[174] Id. at 38 (citing Motor Vehicle Mfrs. Ass'n of the United States, Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)).

[175] Ctr. for Food Safety v. Johanns, 451 F. Supp. 2d 1165, 1184 (D. Haw. 2006) (concluding that a field test acknowledged or permitted under § 340 may not necessarily be "confined" for purposes of § 372.5(c)(ii)).

Respectfully submitted,

Bill Freese
Science Policy Analyst
The Center for Food Safety

George Kimbrell
Staff Attorney
The Center for Food Safety