THE CENTER FOR FOOD SAFETY

660 PENNSYLVANIA AVE., SE , SUITE 302, WASHINGTON, DC 20003
(202) 547-9359 ❧ FAX (202) 547-9429
BLDG. 1062, FORT CRONKHITE, SAUSALITO, CA 94965
(415) 229-9336 ❧ FAX (415) 229-9340
WWW.CENTERFORFOODSAFETY.ORG

March 5, 2003

Hon. Ann Veneman, Secretary,
U.S. Department of Agriculture
Jamie L. Whitten Federal Bldg., Rm. 200-A
1400 Independence Ave. SW
Washington, DC 20250

William Hawks
Under Secretary for Marketing and Regulatory Programs
Jamie L. Whitten Federal Bldg., Rm. 228-W
1400 Independence Ave. SW
Washington, DC 20250

Bobby Acord, Administrator
USDA Animal and Plant Health Inspection Service
Jamie L. Whitten Federal Bldg., Rm. 312-E
1400 Independence Ave. SW
Washington, DC 20250

Cindy Smith, Acting Director
Biotechnology Regulatory Services
USDA APHIS
4700 River Road, Unit 147
Riverdale, MD 20737

Re: Sixty Day Notice of Intent to Sue for Violations of the National Environmental Policy Act and the Endangered Species Act

Dear Secretary Veneman, et al.:

In accordance with the applicable laws and the citizen suit provision of the Endangered Species Act ("ESA"), 16 U.S.C. § 1540(g)(1)(A), the undersigned individuals and organizations advise you of their intent to sue the United States Department of Agriculture ("USDA") for its ongoing failure to adequately analyze the potential impacts resulting from agency actions allowing the open planting of genetically engineered pharmaceutical-producing plant varieties ("GEPPVs").

In particular, the undersigned individuals and organizations are notifying the USDA of the agency's Animal Plant Health Inspection Service ("APHIS"), Biotechnology Regulatory Services ("BRS") violations of law result from its failure: (1) to adequately analyze the potential impacts of its programmatic actions related to the regulation of GEPPVs under the National Environmental Policy Act ("NEPA"), 42 U.S.C. § 4321, et seq.; (2) to prepare any NEPA compliance whatsoever for the various GEPPV field tests around the country that BRS is permitting; and (3) to perform the required endangered and threatened species consultation under Section 7 of the ESA for both the programmatic actions related to the regulation of GEPPVs and the individual GEPPV field tests being conducted

around the country.

The undersigned appreciate BRS Acting Deputy Director Smith's constructive approach in recent meetings concerning this issue and encourage the agency to resolve the legal violations outlined herein to avoid the necessity for litigation.

Background

On December 16, 2002, the Genetically Engineered Food Alert[1] coalition ("GE Food Alert") filed a legal petition requesting that APHIS address the potential human health and environmental impacts associated with the planting of GEPPVs. Specifically, the legal petition requested that the agency, *inter alia*, prepare a Programmatic Environmental Impact Statement ("PEIS") to assess the impacts of GEPPVs.[2] To date, the agency has failed to provide GE Food Alert with a substantive response to the legal petition. The undersigned herein request a response to the legal petition within the next sixty days.

The GE Food Alert legal petition did not address the agency's ongoing NEPA defects at the GEPPV project level, however, current information indicates that project level violations are rampant. Attached hereto is non-exhaustive printout of seven of the agency's 2002 GEPPV field test permits from the www.nbiap.vt.edu/cfdcs/fieldtests3.cfm website. The information shows that the agency has no NEPA compliance documentation available for any of these field test permits. Given the ongoing nature of these field tests, the undersigned consider them to be illegal and want the NEPA non-compliance remedied for all current and all future GEPPV field tests.

As outlined in the GE Food Alert legal petition, APHIS's program of permitting open-air field tests of GEPPVs in human food crops on hundreds (and potentially thousands) of acres poses novel environmental risks that are, in NEPA terms, potentially "significant" because they are "highly controversial" and "highly uncertain or involve unique or unknown risks."[3] The recently published National Academy of Science report, *Environmental Effects of Transgenic Plants*, supports such conclusions, stating in reference to GEPPVs that "**with few exceptions, the environmental risks that will**

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[1] The Genetically Engineered Food Alert (GE Food Alert) coalition is comprised of seven organizations: the Center for Food Safety, Friends of the Earth, Institute for Agriculture and Trade Policy, National Environmental Trust, Organic Consumers Association, Pesticide Action Network - North America, and the State Public Interest Research Groups

[2] GE Food Alert Petition on Genetically Engineered Pharmaceutical-Producing Plant Varieties (December 16, 2002).

[3] The GE Food Alert legal petition incorporates by reference the July 2002 report *Manufacturing Drugs and Chemicals in Crops: Biopharming Poses New Risks to Consumers, Farmers, Food Companies and the Environment*, by William Freese of the Friends of the Earth (the Freese report); See also, *Biohazards: The Next Generation: Crop Plants that Manufacture Industrial and Pharmaceutical Proteins*, by Brian Tokar for the Edmonds Institute (2000).

accompany future novel plants cannot be predicted."[4]

Statutory Obligations Under NEPA

USDA/APHIS has a long history of NEPA avoidance in the area of GEPPVs. APHIS has never prepared an EIS on any facet of its GEPPV regulatory program and since 1998 no environmental assessments ("EA") have been prepared to accompany any GEPPV field test permit. These actions conflict with NEPA and APHIS's existing regulations and policies in many ways.

APHIS's regulations implementing NEPA, 7 C.F.R. Parts 1b and 372, require that the agency undertake a formal EIS or an EA for actions involving the introduction of genetically engineered species. Nothing in those regulations supports the notion that a categorical exclusion can apply to a GEPPV field test where the environmental impacts are novel, controversial, uncertain, and potentially significant. While 7 C.F.R. §372.5 "Classification of Actions" adopted in 1995 may have sought to define some genetically engineered crop field trial permits as categorically excluded, the regulation now allows all field tests of GEPPVs to proceed under such exclusions. At best, the regulation is internally contradictory. Specifically, §372.5 indicates that open field trials require EAs:

> (b) **Actions normally requiring environmental assessments but not necessarily environmental impact statements.** This class of APHIS actions may involve the agency as a whole or an entire program, but generally is related to a more discrete program component and is characterized by its limited scope (particular sites, species, or activities) and potential effect (impacting relatively few environmental values or systems). Individuals and systems that may be affected can be identified. Methodologies, strategies, and techniques employed to deal with the issues at hand are seldom new or untested. Alternative means of dealing with those issues are well established. Mitigation measures are generally available and have been successfully employed. Actions in this class include: . . . (5) **Research or testing that: (i) Will be conducted outside of a laboratory or other containment area (field trials, for example)** (emphasis added).

This specific provision stating that outside field trials require EAs is contradictorily refined by other provisions of §372.5 on categorical exclusions which state:

> (c) **Categorically excluded actions**. This class of APHIS actions shares many of the same characteristics – particularly in terms of the extent of program involvement, as well as the scope, effect of, and the availability of alternatives to proposed actions – as the class of actions that normally requires environmental assessments but not necessarily environmental impact statements. The major difference is that the means through which adverse environmental impacts may be avoided or minimized have actually been built right into the actions themselves. The efficacy of this approach generally has been established through testing and/or monitoring . . .
>
> 3) Licensing and permitting. (i) Issuance of a license, permit, or authorization

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[4] National Research Council/National Academy of Sciences. 2002. *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation.* Washington, DC. p. 15

to ship for field testing previously unlicensed veterinary biological products; (ii) **Permitting, or acknowledgment of notifications for, confined field releases of genetically engineered organisms and products**. (emphasis added)

As a result, §372.5 requires that field trials of genetically engineered crops must be accompanied by an EA unless such field trial is "confined". As the recent contamination violations by ProdiGene exemplify, the field trials of GEPPVs are not "confined." Further, an open-air field test or trial as a matter of plain English is not "confined." No bird, wind storm, human error, or other stochastic event that could easily cause an environmental release can be defined away simply by using the adjective "confined." The potential impacts of such readily foreseeable breaks in the (non-existent) "containment" of GEPPV field trials must be assessed under NEPA. **The undersigned request that the agency make it very clear to APHIS BRS personnel that open air GEPPV field tests do not qualify for NEPA categorical exclusions, including, if necessary, amending APHIS's poorly written and internally contradictory NEPA regulations.**

Many of the agency's own actions and policy statements do indicate that GEPPV field tests should not meet the criteria for being categorically excluded from NEPA's purview. Information for GEPPV producers on BRS's website, entitled "Pharmaceuticals - Information on field testing of pharmaceutical plants in 2002", states: "For electronic copies of environmental assessments see http://www.nbiap.vt.edu/cfdocs/fieldtests1.cfm and search for the phenotype - pharmaceutical protein produced." BRS's instructions to GEPPV developers indicate an expectation that EAs will be prepared. Furthermore, the website interprets that field trials of genetically engineered crops, including GEPPVs, are not "confined" but "releases into the environment."[5] Yet, when accessed the website shows that no EAs have been required for the GEPPV category since 1998.

Notwithstanding attempts to semantically parse the definition of "confined," EAs for all GEPPV field trials still should have been required under the regulations. It is apparent that APHIS personnel have made legal mistakes ever since 1998 (three years after the 1995 NEPA regulation amendments), when without explanation they abruptly began treating all novel GEPPV field tests as categorically excluded.[6] APHIS personnel plainly failed to follow § 372.5(d) "Exceptions for

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[5] See the instructions (in pertinent part) on the APHIS-supported website, http://www.nbiap.vt.edu/biomn/explain.cfm, which clearly states that a field test is a release into the environment, thus is not "confined."

> Field Tests (Release into the Environment) --The ISB Environmental Releases Database contains information on applications for field tests of genetically modified organisms maintained by . . . APHIS . . . USDA regulations state that a "release into the environment" (field test) of a "regulated article" (organism that may pose a plant pest risk) requires a permit from APHIS. A large majority of genetically modified organisms developed for agricultural purposes in the U.S. fall under these regulations. The agency reviews permit applications and prepares an Environmental Assessment (EA) in which the potential environmental impact of the release is evaluated.

[6] APHIS's genetically engineered plant regulations concerning the review of field test permits, 7 C.F.R. § 340.4, clearly indicate that at least an EA, and possibly an EIS, will be required. Section 340.4, footnote 7 therein states: "The 120 day review period would be extended if preparation of an environmental impact statement in addition to an environmental assessment was necessary." Furthermore, the information APHIS BRS provides to GEPPV field test

categorically excluded actions" which indicates that categorical exclusions were not appropriate and that EAs should have been prepared. Section 372.5 does not allow even a "confined" field test to escape NEPA analysis:

> 4) When a confined field release of genetically engineered organisms or products **involves new species or organisms or novel modifications that raise new issues.** (emphasis added).

As previously noted, the NAS has said in reference to GEPPVs that: "**with few exceptions, the environmental risks that will accompany future novel plants cannot be predicted.**" Clearly, GEPPVs containing such compounds as pig vaccines are new organisms, or at the very least organisms with novel modifications, that raise new issues and they cannot be brazenly excluded from NEPA analysis. GEPPVs are new organisms and/or contain novel modifications by any reasonable definition.

Finally, the USDA has participated in interagency reviews of the regulation of genetically engineered crops that concluded that GEPPV field trials are not categorically excluded from NEPA review. The Council on Environmental Quality ("CEQ") and Office of Science and Technology Policy ("OSTP") "Case Studies of Environmental Regulation for Biotechnology," published in January 2001, included the "sidebar" case study designated as "III.A. - Pharmaceutical-Producing Plant," the drafting of which APHIS assisted.[7] That study includes several observations that APHIS will at least prepare EAs for GEPPV field test permits, and that other agencies such as the Food and Drug Administration (FDA) will need to rely on APHIS's EAs. For instance, sound and thorough analysis of issues like gene flow and environmental persistence of biopharmaceutical plants are essential to enable the FDA to assess the potential for contamination of food crops with biopharm traits, and any human health impacts such contamination may have. Thus, APHIS's failure to prepare EAs will also confound regulatory efforts for GEPPVs by other agencies. As a practical matter, preparing adequate EAs for each GEPPV field trial will help all federal agencies avoid contamination incidents such as the costly and frightening ProdiGene containment violations of Fall 2002.

Accordingly, the undersigned seek the USDA's immediate compliance with NEPA and its implementing regulations by performing a programmatic EIS for the agency's entire GEPPV program and performing at least an EA for all ongoing and future GEPPV field trials. We also request an amendment to APHIS's NEPA regulations to the extent necessary to facilitate future EA preparation, although we think that the real problem has not been the words of the regulation, rather its incorrect interpretation by APHIS regulators since at least 1998.

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permit applicants also clearly indicates that at least an EA will be required. Question and Answer #34, www.aphis.usda.gov/bbep/bp/qarel.html , regarding releases into the environment states:

> 34. What is an environmental assessment, and under what law is it prepared?
> A. An environmental assessment (EA) is a document that analyzes the environmental impacts associated with an environmental release permit. EA's are prepared in accordance with the National Environmental Policy Act, Council on Environmental Quality regulations, and the USDA's NEPA procedures.

[7] Case study available at http://www.ostp.gov/html/ceq_ostp_study4.pdf (last visited February 3, 2003).

Statutory Obligations Under the ESA

As recognized by the Supreme Court, the ESA is "the most comprehensive legislation for the preservation of endangered species ever enacted by any nation."[8] Section 7 of the ESA requires that every federal agency act to conserve species listed as endangered or threatened.[9] It also mandates that "in consultation with and with the assistance of the Secretary," each federal agency shall "insure that any action authorized, funded or carried out by such agency . . . is not likely to jeopardize the continued existence of any endangered species or threatened species . . ."[10]

The failure to prepare EAs indicates BRS also has failed to adequately consider the Federally listed or proposed threatened or endangered (T/E) plants or animals in the vicinities of the GEPPV field tests, or their designated or proposed critical habitats. The CEQ/OSTP case study indicates that any T/E impact issues would be identified by APHIS during its preparation of EAs, but as stated herein APHIS has stopped preparing them. Additionally, APHIS appears not to have consulted with the U.S. Fish and Wildlife Service (FWS) at any point and thus failed to do even rudimentary ESA compliance. Each GEPPV permit approval must be based on a detailed description of the listed or proposed T/E species, including designated or proposed critical habitat, and analysis of any potential impacts. This T/E impact description is to be obtained after first consulting and/or conferring with FWS Section 7 scientists, who then must be identified in the list of agencies or persons consulted in the EA.

As the Freese report attached to the original GE Food Alert legal petition indicates, there are obvious risks to birds, insects, and other animals from consuming or contacting GEPPVs in fields. The ESA prohibits an agency from proceeding with an action that may impact a listed species or designated critical habitat before the analysis required by Section 7 is complete, 16 U.S.C. § 1536(a)(2)(stating that an agency must "insure" that its actions will not jeopardize a listed species). Yet, APHIS BRS has not done the required analysis, either for particular field tests or for its programmatic regulatory actions.

Therefore, unless the USDA commits in writing within the next sixty days that the agency will fully and completely comply with the ESA's Section 7 statutory requirements concerning the impacts on threatened and endangered species from GEPPVs, then the undersigned parties will have no alternative but to seek relief in federal court.

Conclusion

Conducting careful and public NEPA and ESA compliance on the record would serve various BRS goals that Acting Deputy Director Smith mentioned in recent meetings on GEPPVs, including: 1) providing redundant safety protections, 2) enhancing transparency, and 3) raising the level of the science applied to GEPPV proposals. Preparing EAs and formal Section 7 consultation for each

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[8] Babbitt v. Sweet Home Chapter of Comm. for a Great Oregon, 515 U.S. 687, 698 (1995).

[9] 16 U.S.C. § 1536(a)(1)

[10] Id. at § 1536(a)(2)

proposal will shed more public and outside scientific light on potential safety problems and the feasibility of redundant protections. These public documents would dramatically increase the transparency of BRS decisions if made promptly available by announcement in the Federal Register and on the BRS website. And the quality of science in BRS decisions would improve as the agency considers and responds to outside scientific comments (including those from other federal agencies) on its preliminary NEPA and ESA analyses.

If necessary, NEPA and ESA documentation may be slightly redacted to prevent the revealing of precise locations of field tests to prevent actual threats of vandalism. Under the current situation field tests represent a "black box" to the public and outside experts, who are denied access to information concerning the identity of the biopharmaceutical, implementation of (or failure to implement) particular safety protections, inspection and enforcement records, as well as, the precise field test locations. The failure to disclose this information prevents members of the public from assessing the impacts posed by GEPPV to their environment and local food supply and agricultural producers from analyzing their susceptibility to crop contamination from GEPPVs. More specific location information, such as the particular county and the surrounding habitat types, can be made public without revealing the exact location. Nonspecific fear of vandalism cannot be used to deny public access to meaningful GEPPV field test information.

Accordingly, the undersigned signatory organizations provide this 60-day notice of intent to sue latter and thank the agency in advance for careful attention to, and action on, these matters:

Center for Food Safety
Beyond Pesticides/National Campaign Against the Misuse of Pesticides
Edmonds Institute
Friends of the Earth
Greenpeace
Institute for Agriculture and Trade Policy
International Center for Technology Assessment
National Family Farm Coalition
Organic Consumers Association
Pesticide Action Network - North America
United States Public Interest Research Group

In sum, we request a prompt response to the GE Food Alert Petition and to the violations of law set forth in this 60-day notice of intent to sue by no later than May 5, 2003. A failure to respond to this letter within the specified time may result the signatory organizations seeking judicial review of this matter. If there are any questions, please contact Peter T. Jenkins, CFS Attorney/Policy Analyst, at 202.547.9359 or email: peterjenkins@icta.org.

On behalf of all the signatory organizations,

Peter T. Jenkins
Attorney/Policy Analyst
Center for Food Safety and
International Center for Technology Assessment

Joseph Mendelson III
Legal Director
Center for Food Safety and
International Center for Technology Assessment

Enclosure

cc: Secretary of Interior Gale Norton
Secretary of Commerce Donald Evans
USFWS Director Steve Williams
NMFS Director William T. Hogarth
Rebecca Bech, Acting Head, BRS Regulatory Division
Carl Bausch, APHIS Director of Environmental Services