



**CITIZEN PETITION TO THE UNITED STATES
DEPARTMENT OF AGRICULTURE**

GENETICALLY ENGINEERED FOOD ALERT,)

1200 18th Street NW, 5th Floor,)
Washington, DC 20036)

Petitioners,)

Filed With:)

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Department of Agriculture)

WILLIAM HAWKS,)

Under Secretary for Marketing)
and Regulatory Programs)
USDA)

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Biotechnology Regulatory Services)

Docket No.

**PETITION ON GENETICALLY ENGINEERED PHARMACEUTICAL-PRODUCING
PLANT VARIETIES**

Pursuant to the Right to Petition Government Clause of the First Amendment of the United States Constitution,¹ the Administrative Procedure Act,² and the United States Department of

¹ The right to petition for redress of grievances is among the fundamental liberties safeguarded by the Bill of Rights. United Mine Workers of America, Dist. 12 v. Illinois State Bar Ass'n, 389 U.S. 217, 222 (1967).

² 5 U.S.C. § 553(e).

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Agriculture's (USDA) implementing regulations,³ the undersigned submit this citizen petition requesting the Secretary of Agriculture, the USDA Under Secretary for Marketing and Regulatory Programs, the Administrator of the Animal and Plant Health Inspection Service (APHIS), and the Acting Director of APHIS's Biotechnology Regulatory Services (BRS) to take steps to prevent public health, environmental, and economic injuries that may result from genetically engineered pharmaceutical-producing plant varieties (hereinafter, "GEPPVs"; the term also here includes GE plants engineered to produce chemical compounds for industrial and other non-food uses). Specifically, Petitioners request the following actions:

1. Promulgate New GEPPV Regulations. Publish draft and then final regulations that promulgate mandatory state-of-the-art protections including broad prohibitions on the use of food crops as GEPPVs and prohibitions on the outdoor growing of GEPPVs in order to prevent unauthorized exposures and to prevent future contamination of the food supply and the environment by unwanted pharmaceutical and chemical compounds.
2. Undertake a Programmatic EIS for GEPPVs. Comply with the National Environmental Policy Act by preparing a Programmatic Environmental Impact Statement (PEIS) assessing the impacts of alternative future approaches for APHIS's regulatory program on GEPPVs. The reasonable alternative approaches assessed should include, but not be limited to, regulatory prohibitions on the use of food crops as GEPPVs and on further outdoor planting of GEPPVs.
3. Change Existing USDA CBI and FOIA Policies and Regulations. Change USDA and APHIS's policies and regulations on confidential business information (CBI) and the Freedom of Information Act (FOIA) to provide more prompt, comprehensive responses and to facilitate prompt disclosure of all relevant CBI when a party who has claimed the CBI protections violates APHIS's containment rules and causes an unauthorized exposure of any person, the grain or food supply, or the environment to a GEPPV.
4. Create a Publicly Available Field Test Violations Database. Maintain an updated list on the APHIS website of all containment violations for GEPPVs, including name of the violator; date of violation; precise location and extent of any contamination; specific identity of the GEPPV involved; response actions by APHIS, the violator, and other entities; and other pertinent information.
5. Institute an Immediate Moratorium. Because of the current regulatory program defects and the uncertainties regarding a broad and frightening array of potential impacts, APHIS should institute an immediate moratorium on all use of food crops as GEPPVs and all further outdoor planting of GEPPVs. This will allow for the development of the requested regulations on state-of-the-art protections, the PEIS, and the improved public disclosure program. While these program improvements are pending APHIS should, with respect to any proposed uses of food crops as GEPPVs and proposed outdoor GEPPV plantings: (1) deny all notifications; (2) deny

³ 21 C.F.R. §§ 10.20,10.30.

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all applications for permits; *and* (3) deny all petitions for deregulated status.

Unless this regulatory program is repaired, the potential human health, environmental, and financial injuries from failure to contain GEPPVs could dwarf the cost of the StarLink GE corn contamination fiasco of 2000-2002. Accordingly, APHIS **must** move proactively now.

PETITIONERS

Petitioners are the Genetically Engineered Food Alert (G.E. Food Alert) (www.gefoodalert.org) is located at 1200 18th Street NW, 5th Floor, Washington, DC 20036. G.E. Food Alert is a coalition of seven organizations united in their commitment to testing and labeling genetically engineered food. The non-profit groups participating are: 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 PIRGs (Public Interest Research Group).

STATEMENT OF GROUNDS

Grounds for this Petition are found in the attached report dated July 2002, which is incorporated fully herein by reference, entitled, *Manufacturing Drugs and Chemicals in Crops: Biopharming Poses New Risks to Consumers, Farmers, Food Companies and the Environment* (hereinafter, the Freese report). This thorough review was prepared for Petitioners by Bill Freese, Policy Analyst, Friends of the Earth. It documents that dozens of crops engineered with pharmaceuticals and chemicals not approved for human consumption are being grown nationwide. The Freese report details a broad array of threats that GEPPV crops pose, describes the regulatory failures and challenges, and concludes with recommendations to protect farmers, consumers, food companies and the environment.

The National Academy of Sciences (NAS) has bolstered these concerns. In February 2002, its Committee on Environmental Impacts Associated with Commercialization of Transgenic Plants wrote in stark terms:

The production of non-edible and potentially harmful compounds in crops such as cereals and legumes that have traditionally been used as food creates serious regulatory issues. With few exceptions, the environmental risks that will accompany future novel plants cannot be predicted. (p. 15) . . . Likewise, it is possible that crops transformed to produce pharmaceutical or other industrial compounds might mate with plantations grown for human consumption, with the unanticipated result of novel chemicals in the human food supply. (p. 68)

The NAS report criticized USDA's failure to adequately evaluate and supervise GEPPV field trials, suggesting the possibility that past or ongoing test plantings might have already resulted in undetected contamination of other crops and the environment with pharmaceutical and/or chemical compounds.

Unfortunately, the Freese and the NAS reports have proven prophetic because, a few months after they

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came out, APHIS revealed that two ProdiGene GEPPV containment violations occurred in Nebraska and Iowa. In November, APHIS quarantined 500,000 bushels of potentially contaminated soybeans in Nebraska due to the presence of pharmaceutical-producing corn and violations of APHIS's containment requirements. In September 2002, APHIS ordered 155 acres of corn in Iowa to be pulled and incinerated, again due to a containment violation that resulted in potential food supply contamination. These incidents manifested the fears of Petitioners, along with many other groups including several large food industry trade associations, that the current *laissez faire* GEPPV regulatory approach in reality poses an unwelcome threat to the integrity of the food supply.

In the ProdiGene cases, the current APHIS regulatory approach proved far too dependent on the company. Despite its reputation as the "leading" company in this field, APHIS could not rely on it either to follow containment requirements or even to provide accurate information as to whether genetic contamination had occurred. Acting BRS Director Smith stated that ProdiGene's testing of the volunteer plants for genetic contamination "provided no level of confidence" in the company's initial assertion that no contamination had occurred (pers. comm.). ProdiGene's failing was vividly demonstrated in the national nightly news. According to the transcript of CBS News of Nov. 13, 2002:

DAN RATHER: CBS has an update tonight on a recent "Eye on America" investigation of biotech corn, corn that's engineered not to grow food, but medicine. In truth, the biotech corn maker said the corn could never contaminate the food supply, no way, no how. Well, the company may now have reason to regret that promise.

The corn not approved for human consumption is being grown in test plots throughout the Midwest by the biotech company ProdiGene. The company says biotech corn from last year's planting sprouted among soybeans grown on the same field this year. Just last month, the president of the company growing the pharmaceutical corn told CBS News correspondent Wyatt Andrews his biotech corn could never get into the food supply.

(Excerpt from October 8, 2002 broadcast)

MR. TONY LAOS (ProdiGene): It's not going to happen, not going to get in the corn flakes.

WYATT ANDREWS: How can you be so sure?

MR. LAOS: How can I be so sure? Because I'm following the procedures that makes it impossible for that to happen.

(End of Excerpt)

RATHER: Some people, not all of them environmental activists, now are demanding an immediate halt to all open-air field trials of these so-called cutting edge crops.

Since the Iowa contamination incident occurred in September 2002, ProdiGene's President plainly was untruthful in his October CBS interview. Further, APHIS had not, in truth, instituted "procedures that makes (sic) it impossible" as ProdiGene's President stated. APHIS also had failed to develop, or require that ProdiGene develop, reliable tests to establish the scope and extent of the contamination that it

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caused. Public health and the environment could have been seriously threatened, yet no one in charge was able to promptly say how far the contamination extended.

Further, APHIS refused to tell affected members of the public anything about the specific pharmaceuticals to which they potentially were being exposed, due to the agency's overly restrictive protections for confidential business information (CBI). APHIS again relied on the goodwill of ProdiGene - the unreliable violator - to voluntarily disclose to the public the nature of the GEPPVs it had planted (C. Smith, pers. comm.). Serious questions have arisen as to how reliable ProdiGene was in making this disclosure. Press reports identifying the biopharmaceutical protein at issue in the ProdiGene contamination cases have been as varied as a "vaccine against travelers' diarrhea,"⁴ a protein used to treat "persistent digestive health conditions,"⁵ and finally (the answer now used by ProdiGene) a pig vaccine.⁶ Yet according to the Food and Drug Administration (FDA), "The pharmaceutical material being produced in the corn plants was being studied under an Investigational New Drug (IND) application."⁷ This would mean that the protein at issue was a human drug. The public, including Petitioners, are still awaiting a truthful disclosure as to the simple question of what biopharmaceutical crops were involved in the Nebraska and Iowa contamination incidents.⁸

These two ProdiGene violations apparently did not lead to broad environmental or human exposure. However, the features of the incidents suggest strongly that such contamination readily could occur in the future if widespread outdoor planting continues, especially utilizing food crops on vastly expanded acreage, as the GEPPV industry and some corn-growing States' politicians seek.⁹ Already it has been reported that unnamed "USDA officials" have "assured" Iowa Senator Charles Grassley that they would place no geographic restrictions on where GEPPVs can be grown.¹⁰ Such reports of political pressure

⁴ Burns and Deardorff. 2002. Modified crops raise fears of contamination, *Chicago Tribune*, Nov. 17.

⁵ Gersema, E. 2002. Biotech case worries food industry, *Associated Press*, Nov. 15; Walsh and Runnigen. 2002. ProdiGene to buy soybeans after biotech scare, *Bloomberg News*, Nov. 19.

⁶ See e.g., Hesman, T. 2002. Crop experiments get more watchful look; USDA ordered destruction of soybeans after contamination, *St. Louis Post Dispatch*, Nov. 22; Weise, E. 2002. Company is fined for "escaped" corn, *USA Today*, Dec. 9.

⁷ "FDA action on corn bioengineered to produce pharmaceutical material," FDA Talk Paper T02-46, Nov. 19, 2002, available at <http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01174.html>

⁸ The Center for Food Safety submitted a Freedom of Information Act (FOIA) request to APHIS, dated Nov. 14, 2002, seeking all information related to the ProdiGene violations on an expedited basis, FOIA file No. 03-118. Petitioners herein support that APHIS's response to that request should be expedited.

⁹ Kilman, S. 2002. Food, biotech industries feud over plans for biopharming. *Wall Street Journal*, Nov. 5, quoting Iowa Governor Tom Vilsack: "We'll make sure Iowa is still the place to be' for biotech firms."

¹⁰ AgWeb.com Editors. 2002. BIO ban: Let the Feds decide. Dec. 4. Online at www.agweb.com/news_show_news_article.asp?file=AgNewsArticle_2002124638_833&articleID=93356&newsCat=GN.

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flat-out undermine public confidence in APHIS's regulatory independence. The agency serves the American people, not individual politicians from States that grow particular crops.

It is vital that APHIS not buckle to special interest pressure and as a result forego strong, science-based, health and environmental protections. To do so would violate the agency's obligations under the Plant Protection Act. Allowing *ad hoc* political pressures to drive the regulation of further GEPPV plantings could lead to harmful human health and environmental impacts such as exposing consumers and farm workers to undisclosed drugs against their wills and poisoning wildlife with toxic chemicals in the grains they eat.

Carefully tailored policy and program improvements can remedy the current unsatisfactory state of affairs. This Petition requests four specific actions that APHIS should promptly undertake.

REQUESTED ACTIONS

1. IMPLEMENT STATE-OF-THE-ART PROTECTIVE REGULATIONS

The need for new GEPPV regulations from APHIS is not a novel idea. Indeed, all serious reviews have acknowledged it. Two key White House environmental and science policy offices identified the need, in a lengthy review of biotechnology regulation. The Council on Environmental Quality (CEQ) and Office of Science and Technology Policy (OSTP) "Case Studies of Environmental Regulation for Biotechnology" were published in January 2001.¹¹ The "sidebar" case study entitled, "III.A. - Pharmaceutical-Producing Plant," states:

The sidebar also notes some issues posed by food crops engineered to produce pharmaceuticals or other non-food material, such as the need to ensure that such products do not inadvertently enter the food supply (p. 47) . . . The agencies are reviewing what procedures will be necessary, and whether appropriate regulations and adequate authority exist, to ensure adequate segregation of such bio-engineered non-food-use varieties of food crop species, both on the farm and when harvested and distributed for processing. Recent experience with StarLink corn has shown the difficulties in mitigating and managing the effects of lack of appropriate segregation. (p. 49) . . . This is a new area, and may require new legislation or regulations. (p. 53)

In line with the CEQ/OSTP report, and in response to the ProdiGene violations, the Acting Director of APHIS BRS has announced that the agency is considering further regulations specific to the GEPPV program.¹² In support of this move, the industry association, the Grocery Manufacturers of America

¹¹ Online at www.ostp.gov/html/ceq_ostp_study4.pdf.

¹² As quoted in Gillis, J. 2002. Biotech firm mishandled corn in Iowa. *Washington Post*, Nov. 14.

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(GMA), has said:

ProdiGene's reported violations of two field trial permits represent the potential for an unacceptable risk to the U.S. food supply. . . . The food industry requires complete assurance from regulators and the biotech industry that the safety and integrity of the U.S. food supply remains intact. However, until the science and federal regulations can guarantee the separation of PMPs [plant-made pharmaceuticals] from the food and feed supply, we strongly urge the biotech industry to direct its substantial research capabilities into investigating the use of non-food crops for the development of pharmaceuticals.¹³

The calls for tighter regulations by the Petitioners here, in accord with the GMA as well as with the National Food Processors Association (two industrial sectors that strongly support biotechnology generally), cannot be ignored.¹⁴

The requested new regulations should impose broad prohibitions on the use of food crops as GEPPVs and all outdoor growing of GEPPVs. The Freese report, other expert reviews, and experience to date with GEPPVs and other GE crops indicate that due to the numerous routes of potential exposure it is not feasible to achieve a safe level of containment if plantings are allowed across this huge nation. Nature Biotechnology, a leading industry journal, recently published an article by Smyth *et al.* warning of the virtual impossibility of stopping ProdiGene-style contamination of food crops with biopharm and other engineered traits via “volunteers.” In pertinent part the article states:

There is no harvest system in place in the world that is capable of containing all the seeds produced on a plot of land. Many factors can combine to result in a large number of seeds (>1000/acre) remaining in the fields.¹⁵

In particular, the Freese report shows that broad dispersal of such crops over tens of thousands of acres or more may:

- broadcast new pharmaceutical and chemical compounds into the air, water and soil, and into the human and animal food supplies, that could elicit a public epidemic of disease and allergic reactions, including life-threatening anaphylactic shock,
- pose massive new occupational safety challenges, as some GEPPVs may be harmful by inhalation, dermal absorption, and unintended ingestion, and
- persist in the environment and bioaccumulate in wildlife, plants, and soil microorganisms,

¹³ Nov. 13, 2002, Press Release and statement by GMA Director of New Technologies and Environment, Karil Kochenderfer. Washington, DC.

¹⁴ Nov. 18, 2002, NFPA Press Release, “Use of major food crops as “factories” to produce pharmaceuticals is not appropriate without protective mandatory requirements”, says NFPA”. Washington, DC.

¹⁵ Smyth, et al. 2002. Liabilities and economics of transgenic crops, *Nature Biotechnology*, V. 20 (June) at 537-41.

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leading to both acute and chronic toxicity and major ecological disruption.

Not using food crops for this experimental work is simple common sense in view of the StarLink fiasco's vivid and expensive demonstration that complete segregation is virtually impossible in the "rough and ready" U.S. grain business. The opportunities for segregation failures caused by careless or unscrupulous seed dealers; farmers; silo managers; and grain shippers, handlers, and processors are so numerous that, given the consequences, it is reckless to use our food crops to grow GEPPVs.

Further, a requirement for indoor planting will provide obvious containment advantages; much more reliable controls on access by, and unwanted GEPPV exposures to, humans and wildlife; vastly reduced threats of containment breaches from extreme weather, accidents, animal dispersal, and vandalism; better growing conditions; and other protections. In the words of respected Iowa State University Agriculture Professor Neil Harl:¹⁶

Birds, deer, runoff from fields into rivers—it's hard to list all the ways that seeds and kernels can be carried substantial distances; ultimately, I think we are going to conclude that we have to produce a zero-contamination rule. That requires us to control the total environment—and that means in a greenhouse.

Given the potential to cause "StarLink times ten" financial damage to both domestic and export markets for non-pharmaceutical GE, conventional, and organic crops - and the justified public outrage if further containment violations do occur - APHIS should not allow outdoor planting to continue.

Requested Action 1. Publish draft and then final regulations that promulgate mandatory state-of-the-art protections including broad prohibitions on the use of food crops as GEPPVs and prohibitions on the outdoor growing of GEPPVs in order to prevent unauthorized exposures and to prevent future contamination of the food supply and the environment by unwanted pharmaceutical and chemical compounds.

2. UNDERTAKE A PROGRAMMATIC ENVIRONMENTAL IMPACT STATEMENT

Background.

The National Environmental Policy Act ("NEPA") provides the "basic national charter for protection

¹⁶ As quoted in Nichols, J. 2002. The Three Mile Island of biotech? *The Nation* Dec. 30; online at www.thenation.com/doc.mhtml?i=20021230&s=nichols

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for the environment.”¹⁷ NEPA seeks to “promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man.”¹⁸ The purpose of NEPA is to “insure that environmental information is available to public officials and citizens before decisions are made and before actions are taken.”¹⁹

Recognizing the impacts of new technologies on the environment, Congress explicitly states in NEPA that “new and expanding technological advances” are activities that could threaten the environment.²⁰ In the legislative history, Congress expressed its concern with “[a] growing technological power ... far outstripping man’s capacity to understand and ability to control its impact on the environment.”²¹ Thus, in order to understand and control the effects of new technologies, Congress requires Federal agencies to consider their environmental effects carefully. In addition to environmental concerns, a proposed Federal action’s possible public health impacts must be assessed if they are linked to its environmental impacts.²²

Beyond just assessing the impacts of particular project-related actions, APHIS also is required to assess the broader impacts of its programmatic actions and to consider alternative program approaches. A programmatic EIS (PEIS) is called for under the Council on Environmental Quality’s (CEQ) NEPA regulations. Specifically, 40 C.F.R. § 1508.18(b)(3), defines a “Federal action” very broadly to include, in pertinent part:

... Adoption of programs, such as a group of concerted actions to implement a specific policy or plan; systematic and connected agency decisions allocating agency resources to implement a specific statutory program or executive directive.

For NEPA purposes, agency actions speak louder than words, as provided in the 40 C.F.R. § 1508.23 definition of “Proposal”:

... A proposal may exist in fact as well as by agency declaration that one exists.

The CEQ’s implementing regulations for NEPA list factors to determine whether a Federal action, such

¹⁷ 40 C.F.R. § 1500.1.

¹⁸ 42 U.S.C. § 4321.

¹⁹ 40 C.F.R. § 1500.1(b),(c).

²⁰ 42 U.S.C. § 4331(a).

²¹ Found. on Economic Trends v. Heckler, 756 F.2d 143, 147 (D.C. Cir. 1985) quoting S. Rep. No. 91-296 (1969).

²² 40 C.F.R. § 1508.8(b); Baltimore Gas & Elec. Co. v. NRDC, 462 U.S. 87, 106 (1983)(explaining that “NEPA requires an EIS to disclose the significant health, socioeconomic, and cumulative consequences of the environmental impact of a proposed action”).

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as APHIS's programmatic approach to GEPPV regulation, is "significant." The USDA has specifically adopted these CEQ regulations.²³ The factors include:

- *the degree to which the proposed action affects public health or safety;*
- *the degree to which the effects on the quality of the human environment are likely highly controversial; and*
- *the degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks;*

According to the courts, the presence of one or more of these factors should trigger an agency decision to prepare a full EIS.²⁴ As outlined in the Freese report, APHIS's program of allowing the open field testing of GEPPVs in human food crops on thousands of acres poses novel and frightening potential effects on "public health or safety" and environmental effects that are, in NEPA's terms, "highly controversial" and "highly uncertain or involve unique or unknown risks." Again, the NAS report on transgenic plants, quoted *supra*, specifically states, in reference to GEPPVs, "with few exceptions, the environmental risks that will accompany future novel plants **cannot be predicted.**" That authoritative declaration, in combination with the CEQ definition of what a "significant" impact is, unambiguously mandates preparation of a full EIS.

As it develops new policies and approaches in its unprecedented GEPPV regulatory program, APHIS already is partly along the way of implementing concerted, systematic, and connected Federal decisions on the future of this controversial technology. APHIS has treated GEPPVs differently from other GE crops by requiring permits instead of just notifications. Notifications overwhelmingly predominate for field tests of non-pharmaceutical GE crops, whereas, according to its own website:

*APHIS envisions that plants which produce drugs and biologics will always be grown under APHIS permit.*²⁵

APHIS also issued a regulatory document unique to GEPPVs in May 2002 entitled, "Guidance for Industry - Guidance on Plant-Derived Biologics for Use in Human and Animals." It is a draft of a non-mandatory approach to GEPPV regulation. Its contents and very existence indicate that a unique GEPPV program is under development. APHIS is making regulatory choices now about fundamental issues such as whether GEPPVs can be grown in all crops, or just limited crops, and in all States, or just limited States, that clearly are programmatic in nature and whose outcome will impact the environment in clear and definable ways.

²³ 7 C.F.R. § 372.4

²⁴ Public Service Co. v. Andrus, 825 FSupp 1483, 1495 (D. Idaho 1993).

²⁵ Online at www.aphis.usda.gov/ppq/biotech under Pharmaceuticals.

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The OSTP also has identified the distinctive nature of the GEPPV program at APHIS in comparison to normal food crop biotechnology:²⁶

USDA has strengthened field-testing controls for permits on those bioengineered traits that are not intended for commodity uses, such as pharmaceuticals, veterinary biologics, or certain industrial products. This has been accomplished by requiring specific additional safeguards as a condition of permits for confined release into the environment of such products.

As stated under Requested Action 1 in this Petition, the APHIS BRS Acting Director and several others have indicated the need for unique GEPPV regulations, further confirming the separate character of this program of regulation of unique new plant products.

The solution.

APHIS should use the PEIS process to assess the best of several alternative regulatory approaches. It is well-known that certain GEPPV companies and politicians from States that rely on certain specific agricultural products oppose potential crop-based and geographic restrictions that would leave them out of what they see as the future “biotech pharming bonanza.” Such opposition likely could come in the form of a challenge to APHIS’s NEPA compliance in issuing any such State-based or crop-based regulations. APHIS should proactively consider the possibility of such a challenge and embrace a full PEIS as the best way to handle this, i.e., to formally facilitate a broad spectrum of input from industry, States, outside experts, and the public - including Senators and Governors - into a fair, structured, analytical, non-political process to achieve the best result.

To date, APHIS has never prepared NEPA compliance on any facet of its GEPPV regulatory program. However, programmatic compliance that looks at the cumulative impacts of an agency’s programs and policies is both required and useful. A key NEPA court case is instructive:

*In many ways, a programmatic EIS is superior to a limited, contract specific EIS because it examines an entire policy initiative rather than performing a piecemeal analysis within the structure of a single agency action.*²⁷

With a comprehensive PEIS in hand looking at the broad impacts of alternative regulatory approaches to GEPPVs, taking into account broad categories of potential impacts, APHIS would be much better prepared to issue adequate EAs for future project permitting actions that could “tier” off of the broad PEIS.²⁸

²⁶ White House Office of Science and Technology Policy. Proposed Federal actions to update field test requirements for biotechnology derived plants and to establish early food safety assessments for new proteins produced by such plants. 67 Fed. Reg. 50578; Aug. 2, 2002.

²⁷ *Assoc. of Public Agency Customers, Inc. v. BPA et al.*, 126 F.3d 1158, 1184 (9th Cir. 1997).

²⁸ CEQ’s implementing regulation, 40 C.F.R. § 1508.28, describes tiering.

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In the past, APHIS has engaged in what can only be characterized as “EIS avoidance” in the biotechnology area. APHIS has approved dozens of past GE crop proposals based only on sparse EAs or on categorical exclusions. Today, more than 80 million acres of GM crops exist and serious genetic contamination sources have been allowed literally to take root across the country all without preparation of a single programmatic or crop-specific EIS.

The well-known StarLink corn fiasco illustrates this EIS avoidance phenomenon. This GE corn product was approved only for industrial and livestock feed uses due to human allergenicity risks, but the grain was then diverted by farmers and distributors into the human food supply. Many non-GE corn fields were contaminated by StarLink corn pollen. It amounted to a national crop segregation failure crisis leading to widespread food product recalls, several credible cases of allergic reactions to a GE protein (Cry9c) expressed by a gene inserted into the corn, international import bans, hundred of millions of dollars in costs to the crop’s manufacturer, and significant other monetary damages at all levels of the grain industry.

This entire fiasco could have been avoided had APHIS not engaged in EIS avoidance. Plainly, the risks of segregation failure existed at the time APHIS deregulated the crop, which on the whole amounted to “potentially significant impacts” under NEPA, but the agency only required an EA that failed to look in-depth at the foreseeable risks of a future segregation failure. An EIS, with associated scoping and input from outside experts, would have opened the proposal up to greater scrutiny. The potential for segregation failure and resulting contamination impacts could have been assessed in advance and likely mitigated through appropriate precautionary measures. In the end, APHIS’s “EIS avoidance” strategy was penny-wise and pound foolish. The same lesson applies here in the case of GEPPVs, which pose far more varied and sweeping potential impacts than StarLink corn.

The APHIS obligation to comply with NEPA and prepare a PEIS is immediate and continuing, so long as further permits are granted and field tests allowed. The obligation is not contingent on future rulemaking, requested in Requested Action 1, above (although logically a PEIS should come before rulemaking). If the agency abstains from future GEPPV rulemaking, a PEIS still must be prepared because APHIS still will have a *de facto* distinct regulatory program. **APHIS’s failure to promptly commit to doing so, through publishing a Notice of Intent to prepare an EIS in the Federal Register, may compel Petitioners to seek judicial review.**

Requested Action 2. Comply with the National Environmental Policy Act by preparing a Programmatic Environmental Impact Statement assessing the impacts of alternative future approaches for APHIS’s regulatory program on GEPPVs. The reasonable alternative approaches assessed should include, but not be limited to, regulatory prohibitions on the use of food crops as GEPPVs and on further outdoor planting of GEPPVs.

3. VASTLY IMPROVED PUBLIC DISCLOSURE

The Freese report, once again directly supported by the NAS transgenic plant report, explains some of the problems with USDA and APHIS’s current approach to public disclosure, CBI, and FOIA responses

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(emphasis in original):

USDA does not reveal the location of any field trial (beyond citing the state), in contrast to the practice in many other countries. Britain and Australia, for instance, keep publicly accessible registers that give the precise locations of field trials (Reuters 2001a; GeneWatch UK 2001). Without this information, a farmer has no means of finding out whether open-air biopharm experiments are being conducted in his/ her vicinity, and so no way to defend against potential contamination. The general public is also kept ignorant.

*Even if people knew where the field trials were, in most cases they would not know what was being grown there. This is because the identity and/ or source of the biopharmaceutical or biochemical gene(s) is almost always claimed as “confidential business information” (CBI) of the applicant. In fact, **CBI is cited 362 times for the 198 permits considered here.** In 206 cases, the identity of a biopharm gene is kept secret as CBI; there are 156 cases in which even the gene donor is claimed as CBI. The pertinent company decides whether the gene’s identity is to be kept secret from the public. The USDA’s stated policy is to disclose this information on its website only if the company does not claim it as CBI, or if the firm had previously chosen to publicize the gene’s identity in the media (personal communication, James White, USDA).*

This excessive secrecy was criticized by an expert committee of the National Academy of Sciences (NAS) that recently reviewed the USDA’s performance at regulating transgenic plants (NAS 2002, p. 177). The committee found that the broad use of CBI not only impairs the public’s right to know, but also hampers scientific peer review of APHIS decisions:

“The committee finds that the extent of confidential business information (CBI) in registrant documents sent to APHIS hampers external review and transparency of the decision-making process. Indeed, the committee often found it difficult to gather the information needed to write this report due to inaccessible CBI.” (NAS 2002, Exec. Summ., p. 11)

One explanation offered by the committee is that “the agency is not working to provide as much information as possible to the public” (NAS 2002, p. 177). Even the size of a field trial is often kept secret on the grounds that it provides a clue as to how close the company is to commercialization (personal communication, James White, USDA).

On April 11, 2001, Friends of the Earth submitted a Freedom of Information Act (FOIA) request to APHIS for full documentation concerning 131 permits involving field trials of biopharmaceutical and related proteins. As of this writing in June 2002, over one year later, APHIS has responded with the files for just two permits for which no confidential business information was claimed (USDA FOIA response 2001). A second reply consisted of just 7 environmental assessments (EAs) – the only ones that were conducted. These seven were already available on the USDA website. In its replies, APHIS blames a backlog of prior FOIAs for the excessive delay in fulfilling our request.

Given the potential for health and environmental impacts, and the associated public controversy,

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USDA's CBI and FOIA approach for GEPPVs needs reform. Slow and insufficient FOIA responses are symptoms of a failed disclosure system. Excessive secrecy shields the agency from outside expert and public review and prevents needed scrutiny of potential impacts.

At a minimum, APHIS should promulgate a new CBI policy for cases of containment violations that pose potential environmental and human health risks, so as to ensure prompt public disclosure of all CBI relevant to the risks. The recent ProdiGene violations potentially posed contamination of the environment, neighboring property, other crops, and the food supply. Nevertheless, the Acting BRS Director stated that, due to the CBI protections, she had no legal ability to release the identity of the contaminating GEPPV, thus she refused to do so despite a direct request (C. Smith, pers. comm.). This is unacceptable.

BRS Acting Director Smith apparently based her refusal on an outdated 1985 APHIS Policy that addressed CBI and biotechnology long before GEPPVs had ever been field-tested or even considered.²⁹ This 1985 Policy flat-out restricts public CBI disclosure, failing to consider possible cases of containment violations that may harm public health and the environment if the CBI is not disclosed.

APHIS has discretion to change its CBI policy and it should promptly exercise this discretion on behalf of the public interest. USDA's current FOIA regulations underscore that discretion.³⁰

Sec. 1.12. Handling information from a private business. Each USDA agency is responsible for making the final determination with regard to the disclosure or nondisclosure of information in agency records that has been submitted by a business . . .

.....

Sec. 1.19. Exemptions and discretionary release. (a) All agency records, except those specifically exempted from mandatory disclosure by one or more provisions of 5 U.S.C. 552(b), shall be made promptly available to any person submitting a request under this subpart. (b) Agencies are authorized, in their sole discretion, to make discretionary releases when such release is not otherwise specifically prohibited by Executive Order, statute, or regulation.

In sum, APHIS may release information that otherwise may be exempt under FOIA if the circumstances, as judged under the agency's discretion, justify it.³¹ However, some CBI releases could nevertheless be

²⁹ APHIS Policy Statement on the Protection of Privileged or Confidential Business Information, 50 Fed. Reg. 38561 (Sept. 23, 1985), online on the APHIS BRS website, at <http://www.aphis.usda.gov/ppq/biotech/pdf/instruction.pdf>.

³⁰ In 7 C.F.R. Part 1.

³¹ See *Bartholdi Cable Co. v. FCC*, 114 F.3d 274, 282 (D.C. Cir. 1997) ("FOIA's exemptions simply permit, but do not require, an agency to withhold exempted information").

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restricted under the Trade Secrets Act unless release is authorized by a specific regulation.³² APHIS should note that the Environmental Protection Agency's (EPA) regulations allow disclosure of CBI to potentially exposed people in emergencies involving releases of potentially toxic chemicals. Specifically, 40 C.F.R. § 2.306(k), on CBI obtained under the Toxic Substances Control Act, allows public disclosure under circumscribed procedures "when necessary to protect health or the environment against an unreasonable risk of injury." APHIS should adopt a parallel regulation allowing disclosure of CBI when GEPPV containment violations occur and similar risks are present.

The main avenue by which such information is released to the public is under FOIA. Plainly, in cases of violations of containment regulations for GEPPVs, the expedited processing of such requests must be allowed to provide urgent information releases to the public, and not just to the media, in a timely way. The current USDA FOIA regulation provides (emphasis added):

*Sec. 1.9. Expedited processing. (a) A requester may apply for expedited processing at the time of the initial request for records. Within ten calendar days of its receipt of a request for expedited processing, an agency shall decide whether to grant it, and shall notify the requester of the decision. Once the determination has been made to grant expedited processing, an agency shall process the request as soon as practicable. If a request for expedited processing is denied, the agency shall act expeditiously on any appeal of that decision. (b) A request or appeal will be taken out of order and given expedited treatment whenever the agency determines that the requester has established either of the following criteria: **(1) Circumstances in which the lack of expedited treatment could reasonably be expected to pose an imminent threat to the life or physical safety of an individual;**
...*

Using the aforementioned EPA model, USDA should modify the justifying circumstances in this regulation so that expedited FOIA processing is required when the information is "necessary to protect health or the environment against an unreasonable risk of injury." The current USDA FOIA provision in §1.9(b)(1), above, is restricted to "imminent threat to the life or physical safety of an individual." Broadening this will expedite information releases that will help to avoid and mitigate environmental threats, damage to wildlife, food supply contamination and public health threats that are not necessarily identifiable to "an individual" person.

As Petitioners and others have previously indicated to APHIS BRS directly, FOIA is not adequate alone to keep the public informed about GEPPVs that may affect health and the environment in novel and profound ways. APHIS needs to take extra steps when any GEPPV (and other plant pest field trial) containment violations occur and proactively make the information about the violation public. This will help to address public fears and will aid all levels of government in responding quickly and appropriately. Some precedents/models for this are the Enforcement Reports and Notices of Market Withdrawals that the USDA Food Safety and Inspection Service (FSIS) posts on its website with respect to reported safety

³² RSR Corp. v. Browner, 924 F. Supp. 504, 512 (S.D.N.Y 1996).

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violations for meat and poultry products.³³ Many other examples exist. Such lists serve not only an information function, but also a deterrent function. If implemented, companies such as ProdiGene will be more likely to comply with regulatory and permit requirements and restrictions so as to avoid visible public “shaming” in this controversial, cutting-edge area.

Requested Actions 3(a). Change USDA and APHIS regulations and policies on CBI and FOIA to provide more prompt, comprehensive, public responses and to facilitate prompt disclosure of all relevant CBI when a party who has claimed the CBI protections violates APHIS’s containment rules and causes an unauthorized exposure of any person, the food supply, or the environment to a GEPPV.

3(b). Maintain an updated list on the APHIS website of all containment violations for GEPPVs, including name of the violator; date of violation; precise location and extent of any contamination; specific identity of the GEPPV involved; response actions by APHIS, the violator, and other entities; and other pertinent information.

4. IMPLEMENT AN IMMEDIATE MORATORIUM

Given the sum of the program defects and scientific uncertainties, the *status quo* should be maintained and no new permits or approvals should be issued for any use of food crops as GEPPVs or any outdoor planting of GEPPVs. This will allow for the development of the new regulations on mandatory state-of-the-art protections, the requested PEIS, and the new CBI and FOIA regulations, without imposing further unacceptable risks of harm.

As the United States Supreme Court recently observed in Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Planning Agency, “moratoria ... are used widely among land-use planners to preserve the status quo while formulating a more permanent development strategy.”³⁴ Plainly, APHIS’s task in designing a regulatory strategy for GEPPVs must consider adjacent land uses, land area and physical buffers between GEPPV plantings and non-GEPPV plantings, crop use and specific State restrictions as far as GEPPV plantings, and so on. As in the land use area, a regulatory moratorium is needed for GEPPVs to prevent unwanted damage until the needed regulatory system is in place. Until APHIS resolves the uncertainties regarding potential impacts and formulates an adequate strategy for this technology, it would be foolish to risk further containment failures.

Requested Action 4. APHIS should institute an immediate moratorium on all use of food crops as GEPPVs and all further outdoor planting of GEPPVs. This will allow for the development of the requested regulations on state-of-the-art protections, the PEIS, and the improved public disclosure

³³ See list found at FSIS website www.fsis.usda.gov/OA/newsinfo.htm, under Enforcement Reports and Withdrawal Notifications. Such lists must be maintained up-to-date frequently to be useful.

³⁴ 535 U.S. 302 (2002) 2002 U.S. LEXIS 3028, at p. 63-64.

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program. While these program improvements are pending, APHIS should, with respect to any proposed uses of food crops as GEPPVs and proposed outdoor GEPPV plantings: (1) deny all notifications; (2) deny all applications for permits; and (3) deny all petitions for deregulated status.

.....

As established at 7 CF.R. § 1.28, Petitioners request that the agency provide an answer to this petition within the reasonable time of 90 days. Failure to respond within a reasonable time will be construed as constructive denial of the requests contained here and may subject the agency to litigation for, *inter alia*, unreasonable delay. Petitioners look forward to your earliest response to each of the Requested Actions and ask for the opportunity to discuss them with you personally. Please promptly publish notice of this Petition in the Federal Register and create a formal open docket for it, or otherwise assign an identification number and communicate that to us. For further information, please contact Joseph Mendelson, Legal Director, Center for Food Safety, tel: 202.547.9359; fax: 202.547.9429.

Respectfully submitted on behalf of the Petitioners,

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Dated: December 16, 2002.

ATTACHMENT INCORPORATED BY REFERENCE IN PETITION

Manufacturing Drugs and Chemicals in Crops: Biopharming Poses New Risks to Consumers, Farmers, Food Companies and the Environment by Bill Freese, Policy Analyst, Friends of the Earth, for Genetically Engineered Food Alert, July 2002. 97 pp.