

ORGANIC FARMING RESEARCH FOUNDATION
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April 13, 2004

Docket No. 03-031-2

Regulatory Analysis and Development,
PPD, APHIS, Station 3C71
4700 River Road, Unit 118
Riverdale, MD 20737-1238.

RE: "Environmental Impact Statement; Introduction of Genetically Engineered Organisms" (Federal Register Vol. 69, No. 15, pp 3271-3272).

On behalf of the Board of Directors of the Organic Farming Research Foundation (OFRF), the following comments are submitted to USDA-APHIS-BRS regarding Docket No. 03-031-02. OFRF is a non-profit, charitable 501c(3) organization dedicated to, "the widespread adoption of organic farming practices." The majority of OFRF's Board of Directors are certified organic farmers.

These comments extend and elaborate the comments made in a separate submission (appended below as "Appendix 1") by the National Campaign for Sustainable Agriculture, which OFRF has co-signed.

I. Broad Alternatives for Study in the Intended Environmental Impact Statement.

In considering the "take no action" alternative, APHIS-BRS must examine all of the agricultural and environmental effects resulting from "adventitious presence" or other unintended release of genetically engineered organisms, which have taken place under the existing regulatory regime. This must include a full assessment of economic and agronomic changes related to avoiding or coping with GE contamination of certified organic farms, crops, livestock and products. Full cost analysis should include direct costs and opportunity costs for producers, processors and consumers.

In 2002 OFRF surveyed U.S. certified organic farmers concerning the impacts of genetically engineered organisms, as part of the fourth National Organic Farmers' Survey conducted by the Foundation. A summary of the responses is appended below as "Appendix 2." The results of the Survey are also available at www.ofrf.org. These results demonstrate that organic producers experience tangible impacts and widespread risks from the escape of GE organisms into the environment. For organic producers and their customers (and others), GE organisms inherently behave as plant pests, and should be regulated, remediated, and quarantined as such by APHIS-BRS.

In considering revised regulations for the introduction of GE organisms, APHIS-BRS must study alternative approaches that assume GEOs categorically can behave as plant pests and noxious weeds.

We thank APHIS-BRS for presenting the public with the opportunity to comment on the proposed EIS, and look forward to further participation. Please keep us apprised of any future opportunities to comment or provide data.

Sincerely,

Mark Lipson
OFRF Policy Program Director
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APPENDIX 1

NATIONAL CAMPAIGN FOR SUSTAINABLE AGRICULTURE

Organic Committee

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Docket No. 03-031-2
Regulatory Analysis and Development,
PPD, APHIS, Station 3C71
4700 River Road, Unit 118
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Dear USDAAPHIS-BRS,

Summary

These comments constitute the response of the Organic Committee of the National Campaign for Sustainable Agriculture to Docket No. 03-031-2 requesting public comment on APHIS-BRS' preparation of an Environmental Impact Statement for releases of novel organisms, pursuant to a future update by APHIS of regulations in 7 CFR 340. The National Campaign for Sustainable Agriculture Organic Committee is composed of groups and individuals representing farmers, certifiers, consumers, environmentalists, farm advocates, food system advocates, and organic advocates working in the federal policy arena to maintain the integrity of organic agriculture.

Based on both experience and independent evidence, the undersigned believe that:

- “Genetically-engineered” (i.e., transgenic) organisms in agriculture are, categorically, plant pests capable of causing economic and environmental damage in U.S. agriculture.
- USDA-Certified Organic producers are particularly vulnerable to the consequences of unintended contamination resulting from release of GE organisms, and these concerns have not been considered or examined in the federal permitting process.
- USDA-APHIS-BRS should completely overhaul its regulatory program, with the goal of preventing any and all unintended presence of agricultural GE organisms.
- APHIS-BRS should conduct a comprehensive Environmental Impact Statement process, measuring the consequences of current vs. more stringent regulatory requirements.
- No food or livestock fodder crop species should ever be engineered to make pharmaceuticals or industrial chemicals, because of the irreversible and potentially devastating impact of accidental release. Pharmaceutical/industrial GE plants should be fully confined , and should be non-food, non-fodder plant species.

Background

Abundant evidence shows that contamination of non-genetically engineered (GE) crops with transgenic DNA from genetically engineered crops is a serious and widespread problem in the U.S, The National Research Council recently presented the USDA with a report which found the need for much stricter biological confinement of genetically engineered organisms. Additionally, the Union of Concerned Scientists recently issued a report demonstrating pervasive transgenic contamination in US supplies of non-GE corn, soybean and canola seeds. [See Biological Confinement of Genetically Engineered Organisms, Committee on the Biological Confinement of Genetically Engineered Organisms, National Research Council, 2004; Gone To Seed, Union of Concerned Scientists, 2004].

The Organic Farming Research Foundation has documented tangible, negative economic and agronomic impacts of GE crops on organic farmers, in its National Organic Farmers Survey. See <http://www.ofrf.org/publications/survey/GMO.SurveyResults.PDF>, pp. 11-19.

Since widespread planting of transgenic (“GEO”) crops began, farmers (organic and “conventional”) have experienced problems associated with unintended cross-pollination, commingling in supply chains, “adventitious presence” of transgenic DNA in non-transgenic seeds, and other forms of contamination (e.g, in corn-based agricultural inputs).

We wish to emphasize that all of the problems discussed here pertain not only to the transgenic material producing a commercial trait, but also to the markers, promoters and other accessory parts of transgenic “cassettes” as well. The environmental fate and impacts of antibiotic-resistant “marker” genes and viral “promoter” sequences are serious concerns in their own right, and are part of the reason that transgenic crops are inherently plant pests.

The types of problems listed below are perverse and highly damaging. They essentially derive from endemic failure by owners of transgenic crop patents to control the fate of their intellectual property in the environment. This failure in turn is reinforced and magnified by the refusal of APHIS-BRS to consider these consequences in its current permitting process.

The categories of problems, which must be considered in any EIS or future regulatory actions by APHIS-BRS, include:

- **Market Risks.** Not only organic farmers, but also virtually all producers involved in international trade of corn and soybeans have had to bear the burden of proof in the marketplace that their products are not contaminated with transgenic DNA. Both groups need to be able to raise crops and market crop products free from genetically engineered organisms in order to maintain their markets and consumer expectations. Both groups are increasingly unable to do so because of GEO contamination.
- **Potential Disruption of Management Tools.** These problems include potential loss of efficacy (e.g. acquisition of target pest resistance to *Bacillus thuringiensis* toxin), disincentives for development of non-GE management tools by the private sector, and environmental disruption of non-pesticidal production systems (e.g. by unintended and dysfunctional presence of plant-incorporated-pesticides).
- **Agronomic Impacts.** Numerous agronomic management consequences have been imposed on organic and other types of farmers by the threat of GE contamination, through no choice of their own. These include at a minimum: changes in planting times (to avoid pollen drift), loss of production to increased buffer areas, increased demand for testing of inputs and products, shifts in crops grown and inputs used, and loss of the ability to save seed.
- **Legal Liabilities.** Farmers are threatened with tortious action for patent infringement and other liabilities due to “adventitious presence” of patented, transgenic DNA in their fields, crops and products.
- **Economic Damages.** All of the consequences listed above have direct and indirect economic costs for organic growers, processors and others. These costs must be analyzed and taken into consideration by APHIS-BRS in all of its actions related to transgenic organisms.

· Consumer Choices and Health Issues. In the absence of mandatory labeling requirements for agricultural products derived from GE, the unintended presence of transgenic DNA in the consumption stream imposes a loss of choices for consumers. Health issues faced or perceived by consumers regarding GE organisms (e.g., allergenicity, toxicity, or religious requirements) are thus highly problematic. These problems represent another aspect of the categorical behavior of GE organisms as plant pests.

RECOMMENDATIONS:

1. Expanding the Definition of Noxious Weed

For these reasons, the definition of regulated noxious weeds should be broadened to include all crops and crop products produced through recombinant DNA technology that threaten the integrity and subsequent market loss of non-GE crops, and also include crops that result in liability for patent infringement to farmers of non-GE crops. Adventitious presence in commercial crops, food, feed, and seed of GE plant material has caused tremendous harm to producers of non-GE crops, including loss of markets and agronomic loss, as well as legal liability.

Specifically regarding "noxious weeds," APHIS should expand the definition of "noxious weed" under 7 USC 7712 part 360 and 7 CFR 340.3 (b)(iv) to include "any genetically engineered plant or organism that produces pollen carrying recombinant traits that may change the genetic character and/or marketability of an unintentional recipient plant."

2. Full NEPA Review

Each proposal for release of a genetically engineered organism, including ones that produce pharmaceutical and industrial compounds, should undergo individual full NEPA review including an Environmental Impact Statement.

3. Environmental Considerations in the EIS process and the Regulatory Permit Process

The current regulatory requirements should not be relaxed. As the range of genetically engineered crops expand to include industrial and pharmaceutical crops, the dangers posed by recombinant DNA increase geometrically. Instead, APHIS should broaden the scope of regulated items to include GE plants that may become "noxious weeds" in 7 CFR 340.3(b)(iv) and 7 USC 7712 part 360, eliminate the issuance of "courtesy permits" in 7 CFR 340.4(h), and expand the list of environmental considerations to include the following environmental and pest risk criteria. These considerations need to be examined in detail for every organism, both in this proposed EIS, and in a subsequent EIS for the release of each proposed organism:

i. Changes in ecological roles or functions. What are the impacts a GE organisms' presence in the environment on changes in other species' growth rates, reproductive output (fecundity), longevity, and tolerance of physical and chemical factors (e.g. temperature, salinity, water relations, pesticides, etc)?

- ii. Changes in genetic relationships. What are the impacts of a GE organisms' presence in the environment on changes in other species' genetic and metagenetic relationships, including crops' abilities to interbreed, increased out-crossing of self-pollinating crops, and introgressive hybridization that leads to contamination of economically important crops or stocks, or to the extinction of native species or other species of local importance?
- iii. Indirect effects. What are the indirect effects of a GE organisms' presence in the environment on other species' including changes in population mating structure, alteration of competitive hierarchies, disruption of trophic cascades, and modification of the physical and chemical environments upon which native species depend?
- iv. Changes in allergenicity, toxicity, or nutritional composition of foods: Do such genetic modifications produce foreign or novel proteins in familiar foods, or the production of toxins, or produce food contamination by novel genes introduced for purposes other than human consumption? What are the economic and environmental consequences for U.S. agriculture of such changes?

4. Consideration of Economic Impacts

APHIS-BRS' actions (in both conducting an EIS and in carrying out its regulatory processes) should include an examination of economic consequences of the introduction of genetically engineered organisms on all types farmers. These consequences include the loss of markets for organic farmers who are required to grow crops that have not been produced with genetically modified organisms (excluded methods, Organic Foods Production Act 1990). Genetically engineered crops and foods may not be sold under the organic label. Similarly, farmers who sell products worldwide labeled as non-GMO, or other similar labels, face a loss of these markets caused by contamination.

Further economic consequences occur when farmers must adjust planting practices to protect against contamination. For instance, in order to attempt to prevent pollen drift, the timing of planting of crops may have to be delayed or changed, causing economic hardship. In addition, large (and increasingly larger) unplantable buffer zones are becoming necessary to attempt to control drift from neighboring fields.

Liability for contamination must be placed squarely and entirely with the patent holder. Farmers who are being held liable for patent infringements due to adventitious presence or other contamination are likewise facing severe economic impacts in defending themselves against legal action related to contamination that they did not cause. Both farmers who planted genetically engineered crops, and have experienced previously unknown consequences from contamination (both in drift from their properties, and from the presence in related weed organisms), and farmers who have not planted GE crops and have suffered GE contamination, must be protected from liability from this contamination. The only reasonable source for liability is the originator of the patent who must know the full consequences of their product before introducing it to the environment.

5. No Relaxation of APHIS review of GE Organisms

APHIS should not provide for expedited review or exemption from review of certain low-risk GE commodities intended for importation unless those commodities have undergone the same review process required of GEOs in the U.S. The same environmental considerations listed above should apply to all GEOs.

Familiarity and widespread use should not exempt organisms from interstate movement restrictions. All GEOs should undergo the same extensive review process. Additionally, all markers, vectors, and other material used in engineering the new organisms should undergo strict scrutiny for human and environmental impact APHIS should regulate all products of GE organisms, including non-viable plant material. This includes markers, promoters, and vectors used in the production of GE organisms.

No crops containing pharmaceutical drugs and industrial chemicals should be allowed to be released into the environment. Crops genetically engineered to contain pharmaceutical drugs and industrial chemicals should be restricted to greenhouses or other controlled indoor environments with adequate containment systems, operation plans, sufficient security systems, and emergency procedures. GE crops with pharmaceutical and industrial compounds should undergo rigorous food safety evaluations, including not only the proteins transferred, but also the markers, promoters, and vectors used in their creation.

Thank you for the opportunity to comment.

Sincerely,

Michael Sligh, Rural Advancement Foundation International, USA
Elizabeth Henderson, Peacework Organic Farm, and
Northeast Organic Farming Association of New York (NOFA-NY)
Mark Lipson, Organic Farming Research Foundation
Brise Tencer, Organic Farming Research Foundation
Joe Mendelson, Center for Food Safety
Robert Hadad, Humane Society of the United States
Marty Mesh, Florida Organic Growers
Roger Blobaum
Steve Etko, National Organic Coalition
Tom Hutcheson, Organic Trade Association
Jeff Schahczenski, Western Sustainable Agriculture Working Group
Jonda Crosby, Alternative Energy Resources Organization (AERO)
Russell Libby, Maine Organic Farmers and Gardeners Association
Jody Aliesan, PCC Farmland Fund
David Engel, Midwest Organic Services Association, Inc.
Steve Sprinkel, Ojai Center for Regenerative Agriculture
Mark Schonbeck, Virginia Association for Biological Farming
Brian Leahy, California Certified Organic Farmers
Karen Anderson, Northeast Organic Farming Association of New Jersey

Tina Ellor, Phillips Mushroom Farms

APPENDIX 2

Summary of OFRF Survey Data of Impact of GMOs on Organic Farmers

The 4th National Organic Farmers Survey.

The NOFS is not a random poll. Results were determined from 1034 surveys voluntarily returned, out of 6,489 sent out (15.9% return rate nationally) to certified organic farmers. Questionnaires were completed in the spring of 2002.

7.1 – Organic growers perceived risk of GMO contamination.

Q - Based on what you know today about the use of GMOs in agriculture, what do you believe is the risk of exposure and possible contamination of your organic farms product(s) by GMOs?

-Nationally: 30% of respondents said risk “high” or “very high”.

-In nine “upper tier” states (ND, MN, WI, IA, IL, IN, MI, OH, NY), which provide the vast majority of organic corn and soybeans, 48% said risk “high” or “very high”.

-West coast respondents (CA, OR, WA): 16% said risk “high” or “very high”.

-In Iowa, 66.7% of all that state’s respondents said risk “high” or “very high”

7.2 – Perceived sources of risk for GMO contamination.

Q – What sources, if any, do you feel present risks of GMO contamination to your organically grown products, and to what degree?

Nationally, 23% of respondents said risk of contaminated seed stock was high, and 25% said seed risk was moderate.

Nationally, 22% said risk of GMO contamination from pollen drift was high, and 20% said risk from drift was moderate.

7.3 – Organic growers’ responses to risks.

Q – What, if any, of the following measures have been carried out on (or on behalf of) your farm in response to your organic farm product(s) risk of exposure to GMO contamination?

-Nationally, 48% of respondents carried out some measure in response to risks.

-Measures with potential financial consequences included: increased size of buffer zones (19%); discontinued certain inputs (18%); adjusted planting times (15%).

7.4 – Parties requesting or requiring testing for GMO contamination.

Q – What entities, if any, have requested or required that any of your farm’s seed, inputs, or products be tested for GMOs?

Nationally, 27% of respondents had a GMO test requested or required by either an organic certifier or a product buyer.

7.5 – Actual testing that growers were aware of.

Q – Has any of your farm’s seed, other inputs or organic farm product been tested for GMOs?

-Nationally, 17% of respondents indicated that testing had occurred.

-Respondents in the nine “upper tier” states accounted for 64% of those who said that testing had occurred.

-West coast respondents represented 6% of those saying that testing had occurred.

-Iowa respondents accounted for 21.5% of all tests reported nationwide, the most for any single state.

7.6 – Results of tests conducted for GMO contamination.

Q – Did any of those seed, input, or organic products test positive for GMOs?

-Nationally, 11% of those who had tests conducted received positive results (indicating contamination).

-“Upper tier” states accounted for 61% of the positive tests.

-Corn and soybeans accounted for ALL of the positive tests on seed and finished products.

-Iowa respondents accounted for 22% of all positive tests nationwide, the most for any single state.

7.7 – Direct costs to organic growers of contamination/avoidance.

Q – Has your organic farm operation borne any direct costs or damages related to the presence of GMOs in agriculture?

-Nationally, 8% of respondents indicated some type of direct cost.

-Respondents in the nine “upper tier” states accounted for 60% of those who indicated any costs.

-The most common direct cost was payment for testing, borne by 55% of those who indicated any costs. (Note, this means that growers bore the cost of 25% of tests reported, rather than buyer/processor bearing the costs.)

-39% of those reporting some costs had lost sales as a result of GMO presence or risk.

-Iowa farms reporting at least one category of impact were 14.6% of all farms impacted nationally, the most for any single state.

7.8 – Perceived adequacy of regulatory system for GMOs.

Q – Do you feel that a regulatory framework is in place to adequately protect your organic farm product(s) from damages due to possible contamination by GMOs?

Nationally, 90% of respondents said No or Don’t Know.