

March 20, 2009

**SUBMITTED ELECTRONICALLY**

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

Re: Proposed Rule and Programmatic Environmental Impact Statement for the Introduction of Genetically Engineered Organisms, APHIS Docket 2008-0023

Dear Secretary Vilsack,

On behalf of the undersigned farm, food, public interest, consumer, and environmental organizations, we respectfully request that the Secretary make substantial revisions to the Proposed Bush Administration Rules on genetically engineered organisms to provide adequate safeguards and protections of vital importance to farmer and environmental interests and to revise the rule-making process to maximize transparency and public participation. Specifically, we ask that the Animal and Plant Health Inspection Service (APHIS):

1. Publish the final Environmental Impact Statement (EIS);
2. Withdraw the Proposed Rules and publish new Proposed Rules addressing the deficiencies and problems identified below or initiate an interim rulemaking process that achieves the same result;
3. Extend the comment period to enable thoughtful consideration of the EIS and new Proposed Rules; and
4. Freeze any new or pending genetically engineered (GE) crop approvals until this process is finalized.

**Publication of EIS:** In January of 2004, the USDA initiated an Environmental Impact Statement (EIS) scoping process as part of a new regulatory framework for agricultural biotechnology to cure serious deficiencies in the existing regulatory programs and to meet the new challenges of novel biotechnologies that the current system was not designed to address.

The EIS process is designed to inform the decision-making process before a major federal action is undertaken. In this context the EIS process was designed to provide decision-makers, and the public, with a critical assessment of the failures and shortcomings of the existing regulatory framework together with a comprehensive analysis of the environmental and interrelated socio-economic impacts of various regulatory approaches that would ultimately result in a fair and effective system of regulation that would not unduly burden innovation.

To spend five years developing an EIS as the basis for new Proposed Rules and then deny public access to the final EIS is contrary to intent of NEPA and denies the public the opportunity to make meaningful and informed comments on the Proposed Rules. We request that final EIS be published

immediately and the comment period extended to afford adequate consideration of its contents and its impact on the Proposed Rules.

**Withdraw Proposed Rules or Revise Rulemaking Process:** The Proposed Rules are fatally flawed. Costly contamination events have cost farmers billions of dollars in lost profits, yet the Proposed Rules fail to adopt the corrective measures recommended by an Inspector General Audit (2005) and mandated by Congress in the 2008 Farm Bill to improve the oversight, administration and management of genetically engineered crops that could significantly minimize contamination and the resulting economic harm.

The deregulation process which has been the subject of significant critique in the federal courts for its failure to adequately assess environmental and inter-related economic impacts is not addressed in the Proposed Rules. Despite precedent, existing statutory authority under the Plant Protection Act and the recommendations contained in a recent November 2008 GAO Study conducted at the request of Senators Harkin and Chambliss, the Proposed Rules also fail to account for the economic impact that deregulation of new genetically engineered crops will have on farmers' livelihoods and the economic health of rural communities.

More troublesome is the fact that the Proposed Rules represent a significant weakening of USDA's oversight of agricultural biotechnology. Under the Proposed Rules, regulation can be waived for whole categories of "familiar" crops which the USDA acknowledges will result in increased gene flow between GE and non-GE crops. Through the proposed low level presence policy, contamination is acknowledged and permitted. Conditional exclusions create a loophole that can be used to remove regulatory oversight. Most egregiously, the Proposed Rules delegate to GE crop developers the authority to determine whether the regulations apply, abdicating USDA's responsibilities under the Plant Protection Act.

Correcting these deficiencies and inadequacies is virtually impossible in the context of the existing rulemaking process. The Proposed Rules should be withdrawn, or a new interim rulemaking process initiated, with a new regulatory framework that is developed, proposed, and published for comment in conjunction with the publication of the final EIS. The process adopted must be transparent, and allow for full public participation.

**Freeze pending GE crop approvals:** Given the comprehensive nature of rule revisions contemplated in this Docket and the impact on the deregulation decision-making process, we request an immediate freeze on new GE crop approvals until final regulations are promulgated and published addressing the issues identified above.

Correcting the deficiencies in the proposed regulatory system requires a new, more responsible approach to biotechnology regulation – one that balances the need for innovation with the rights and interests of farmers, their livelihoods and the environment. The public's right to choose the food it eats and farmers' right to plant the crops of their choice is also at risk from continued contamination. That balance cannot be achieved in the existing rulemaking process.

We hope that you share our belief that the steps toward implementation of a responsible system of agricultural biotechnology regulations begins with the process outlined above. If you have any questions, please feel free to contact Bill Wenzel at [bwenzel2@aol.com](mailto:bwenzel2@aol.com) or by calling (877) 968-3276.

Sincerely,

Action Group on Erosion Technology and Concentration (ETC Group)  
Alternative Energy Resources Organization  
Arid Crop Seed Cache  
Arkansas Rice Growers Association  
Beyond Pesticides  
Californians for GE-Free Agriculture  
California Certified Organic Farmers  
Carolina Farm Stewardship Association  
Center for Environmental Health  
Center for Food Safety  
CounterCorp  
Cuatro Puertas  
Dakota Resource Council  
Martin Donohoe, MD, FACP, Chief Science Advisor, Campaign for Safe Foods  
and Adjunct Associate Professor, School of Community Health, Portland State University  
Senior Physician, Internal Medicine, Kaiser Sunnyside Medical Center  
Earth Day Network  
Ecological Farming Association  
Equal Exchange  
Family Farm Defenders  
Farm Aid  
Farm and Ranch Freedom Alliance  
Farmer to Farmer Campaign on Genetic Engineering  
FedCo Seed Company  
Finca Pura Vida Organic Farm  
First Alternative Cooperative Grocery  
Food and Water Watch  
Food First/Institute for Food and Development Policy  
Friends of the Earth  
Global Justice Ecology Project  
GMO Free New Mexico  
Greenpeace USA  
Greenstar Cooperative Market  
Hawai'i SEED  
Health Care Without Harm  
High Mowing Organic Seeds  
International Center for Technology Assessment  
Institute for Agriculture and Trade Policy  
Institute for Responsible Technology  
Institute for Sustainability Education and Ecology  
Institute for a Sustainable Future  
Know Your Farmer Alliance  
Maine Organic Farmers and Gardeners Association  
Missouri Rural Crisis Center  
Montana Farmers Union  
Montana Organic Association

National Cooperative Grocers Association  
National Family Farm Coalition  
National Organic Coalition  
New Mexico Farmers' Marketing Association  
The Non-GMO Sourcebook  
Northeast Organic Dairy Producers Alliance  
Northeast Organic Farming Association (NOFA-VT, NY, NH, MA, RI, CT & NJ)  
Northern Plains Resource Council  
Northwest Resistance Against Genetic Engineering  
The Oakland Institute  
Oregon Physicians for Social Responsibility  
Oregon Tilth  
Organic Consumers Association  
Organic Farming Research Foundation  
The Organic & Non-GMO Report  
Organic Seed Alliance  
Organic Seed Growers and Trade Association  
Organic Valley Family of Farms  
Pacific Coast Federation of Fishermen's Associations  
Partnership for Earth Spirituality  
PCC Natural Markets  
Pesticide Action Network North America  
Pesticide Watch  
Janisse Ray, Naturalist and award-winning author of *Ecology of a Cracker Childhood*  
Rice Producers of California  
River Market Community Co-op  
Rodale Institute  
Rural Advancement Foundation International – US (RAFI-USA)  
San Francisco Bay Area Physicians for Social Responsibility  
Sierra Club  
Slow Food Rio Grande  
Sustainable Living Systems  
Sustain Taos  
Union of Concerned Scientists  
Welsh Family Organic Farm  
Western Organization of Resource Councils  
WholeSoy & Co. /TAN Industries, Inc.  
Wild Farm Alliance