

June 29, 2009

SUBMITTED ELECTRONICALLY

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

Re: APHIS-2008-0023 Comments

Dear Secretary Vilsack,

On March 19, 2009, eighty-three farm, food, health, public interest and environmental organizations called on the Secretary to revise the ongoing process of amending the regulations for genetically engineered (GE) crops.¹ We requested that the Animal and Plant Health Inspection Service (APHIS) revise its rule-making process in order to provide adequate safeguards and protections of vital farmer, public health and environmental interests, and to maximize transparency and public participation in the process. Specifically, we requested that APHIS:

1. Publish the final Environmental Impact Statement (EIS) on the rules;
2. Withdraw the Bush Administration rules and draft/publish new proposed rules, or initiate an interim rule-making process, in either case addressing the numerous deficiencies in the proposed rules as they stand now;
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 approval until this process is finalized.

In this letter, the undersigned 63 organizations address the second issue by providing recommendations for how APHIS should revise the proposed rules in order to provide adequate oversight of GE crops.

APHIS Must Rely on “Sound Science”

APHIS must rely first and foremost on “sound science,” as required under the PPA and President Obama’s Memorandum concerning “Scientific Integrity.”² The Memorandum stipulates that “[s]cience and the scientific process must inform and guide decisions of my Administration,” with the “highest level of integrity in all aspects of the executive branch’s involvement with scientific and technological issues.” APHIS has frequently violated the tenets of sound science in its decision-making documents on GE crops in numerous ways: excessive reliance on applicants’ analysis and data; frequent citation of dubious, industry-sponsored white papers with little or no

¹ *Diverse Farmer and Public Interest Groups Urge USDA To Freeze Approvals of Genetically Engineered Crops*, http://www.centerforfoodsafety.org/pubs/Final_APHIS-2008-2003%20Supplemental%20Comments.pdf

² Barack Obama, *Memo for the Heads of Departments and Agencies*, March 9, 2009, at http://www.whitehouse.gov/the_press_office/Memorandum-for-the-Heads-of-Executive-Departments-and-Agencies-3-9-09/

scientific merit; egregious factual errors biasing decisions in favor of the applicant; among other unscientific practices. In contrast, sound science requires the agency to undertake its own independent and holistic analysis of the impacts of GE crops; base its decision-making on peer-reviewed scientific literature whenever possible; critically examine applicant claims and analysis rather than uncritically accept them; and call in independent experts from outside the agency for external peer review. In addition, unduly narrow assessments – for example, not assessing impacts from pesticides used in conjunction with herbicide-tolerant GE crops – cannot be considered sound science. Finally, sound assessments must also apply the social sciences, for instance, to analyze the economic impacts of transgenic contamination of non-GE crops.

Retain Oversight for all GE Crops

The proposed rules give biotech firms undue discretion in determining whether APHIS regulations even apply to a new GE crop. It is critical that the scope of regulation cover all genetically engineered crops, “as there is no scientific basis on which to forecast which ones might pose a risk.”³ Straightforward use of the process of genetic engineering as the trigger for regulatory oversight, as recommended by a National Academy of Sciences committee,⁴ is both necessary to protect against potential harms from the introduction of genetically engineered organisms, and provides clarity and consistency to the regulatory process.

Eliminate “Non-Regulated Status” and Adopt Commercial Permits

APHIS should end its practice of unconditionally removing GE crops and their progeny from its oversight through a “determination of non-regulated status.” This deregulation decision is normally sought by companies prior to commercial use of the GE crop. Instead, APHIS should clarify that it retains robust authority to monitor and regulate GE crops for issues not detected in field trials and for threats that emerge or become manifest only after commercial cultivation begins, in line with recommendations made by the Government Accountability Office (GAO) in a recent report.⁵ To this end, APHIS should implement a two-tiered permitting process, one tier for experimental permits for field trials and a second tier for commercial permits allowing GE crops to be sold in commerce. With commercial permits, APHIS should use its existing jurisdiction and authority to continue to monitor GE crops, collect data to confirm risk assessments and detect unanticipated harms, and impose protective measures when necessary to manage GE crop systems and emerging risks.

Apply the Noxious Weed Authority Fully

APHIS should properly interpret and apply its robust noxious weed authority under the Plant Protection Act (PPA). This includes assessing potential harm from GE crops to “the interests of agriculture,” the environment, and public health, in fulfillment of its statutory mandates under the PPA. Both direct and indirect harms can independently trigger APHIS’s authority and both must

³ USDA (2007). *Introduction of Genetically Engineered Organisms: Draft Programmatic Environmental Impact Statement*, USDA Animal and Plant Health Inspection Service, July 2007, p. 20.

⁴ NAS (2002). *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation*, Committee on Environmental Impacts Associated with Commercialization of Transgenic Plants, National Research Council, National Academy of Sciences, 2002, pp. 79, 83.

⁵ GAO (2008). *Genetically Engineered Crops: Agencies are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring*, Report to the Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, Government Accountability Office, GAO-09-60, November 2008, pp. 30-31.

be assessed. Application of the PPA's noxious weed authority is particularly important in the following three areas:

Economic harms from GE crop contamination: Contamination from GE crops, whether via cross-pollination or admixture of seeds, is a physical harm that poses risks to organic and conventional farmers' livelihoods. These risks are properly assessed under this authority and cannot be dismissed as mere marketing or perception issues.

Herbicide-tolerant crops, resistant weeds and pesticide use: The most widely planted class of GE plants – herbicide-tolerant (HT) crops – are specifically designed to withstand application of one or more herbicides (one form of pesticide). HT crop systems – defined as the HT crop and use of the associated herbicide(s) – require regulation as noxious weed risks for their propensity to: 1) Foster the rapid evolution and spread of herbicide-resistant weeds, which can: (a) lead to increased use of and pollution of the environment with toxic herbicides, with attendant harms such as adverse impacts on farmworkers and wildlife; (b) spur increased soil erosion through greater use of tillage to control resistant weeds; and c) increase weed control costs for growers of all crops; 2) Lower agricultural productivity through the adverse impacts of excessive pesticide use on soil life; and 3) Reduce the availability of weed control options by undermining the efficacy of the HT crop-associated herbicide(s), among other harms.

Public Health: APHIS must implement its authority to regulate and assess the safety of GE crops for human and animal consumption for several reasons: 1) Absence of mandatory assessment of GE crops by the FDA; 2) The use of food crops as biofactories for potentially hazardous pharmaceutical and industrial compounds; and 3) Policies permitting the contamination of commercial food, feed and seed with untested GE crop material.

Prohibit Outdoor Cultivation of GE Biopharmaceutical Crops and Any Such Cultivation of Biopharmaceutical Food Crops (Indoors or Outdoors)

Biopharm crops produce experimental pharmaceuticals that in some cases may pose risks to human health or the environment, yet no risk assessment is required before they are grown out of doors. Public interest groups, the food industry, many scientists and even some in the biotech industry advocate an end to outdoor cultivation of biopharm crops to avoid the inevitable contamination of food. In its programmatic EIS, APHIS proposed (and rejected) alternatives that would either bar outdoor cultivation of ALL biopharm crops, or of all biopharm food crops.⁶ APHIS's "current thinking" – that concerns about biopharm crops are nothing more than "marketing" or "public perception" issues – is wrong. Biopharm crops can pose real risks to human health and the environment. Thus, APHIS should prohibit the outdoor cultivation of plants for drug production and the cultivation of ANY such food crops (indoors or outdoors).

Eliminate the Low Level Presence Policy

While APHIS touts "co-existence" of biotech, conventional and organic agriculture, its proposed "Low Level Presence" ("LLP") policy would make co-existence impossible. The LLP policy would allow APHIS to take no recall or similar action when experimental GM crops grown in field trials are found contaminating food, feed or seed. Exposure to experimental GM crops contaminating food may pose health risks, yet the LLP policy contains no protocols for assessing such potential harms. Despite its appellation, the LLP policy proposes no quantitative, maximum

⁶ USDA (2007), op. cit., Alternatives 3 and 4, pp. 32-33.

threshold for contamination, so “low level” essentially means unlimited contamination. The LLP policy could easily cause non-GE crop growers to lose markets for their goods, and organic growers could lose their organic certification. Without the threat of recall, biotech companies testing new GE crops will have little incentive to assume the expense of adequately isolating their experimental plots to prevent transgenic contamination in the first place, and may be able to use the LLP’s “non-actionable” (i.e no mandatory recall) status to help avoid liability for their irresponsible practices. APHIS should eliminate this unscientific policy and instead make “zero tolerance” its management goal by mandating recalls whenever experimental GM crop material contaminates the food, feed or seed supply.

Implement the Congressional Mandates of the 2008 Farm Bill

Costly GE crop contamination events have cost farmers billions of dollars in lost profits. With the adoption of the 2008 Farm Bill, Congress mandated that APHIS “improve the management and oversight” of GE crop field trials (§ 10204), implement measures outlined in the agency’s “Lessons Learned” document prepared in the wake of the 2006 ‘Liberty Link’ rice contamination debacle, and adopt a series of other new measures to mitigate transgenic contamination. The proposed rules, however, fail to comply with many of the Farm Bill mandates, such as requiring representative samples of GE crops to be retained by GE crop field trial permit holders, submission of contingency and corrective action plans to address contamination episodes, and use of cutting edge science and technology to ensure effective isolation of GE crops grown in field trials from commercial supplies, among several others. APHIS must revise its proposed rules so as to comply with these Congressional mandates.

We hope that you share our belief that these steps are crucial for your implementation of a responsible system of agricultural biotechnology regulations.

Sincerely,

Arid Crop Seed Cache
Bon Appetit Management Company
Breast Cancer Action
California Certified Organic Farmers
Californians for GE-Free Agriculture
Center for Environmental Health
Center for Food Safety
Clean Production Action
Clif Bar & Co.
Consumers Union
Cuatro Puertas
Dogwood Alliance
Ecological Farming Association
Equal Exchange
Farmer to Farmer Campaign on Genetic Engineering
Farmworker Association of Florida
Food and Water Watch
Food First / Institute for Food and Development Policy
The Food Project
Friends of the Earth
GMO Free New Mexico
Grassroots Environmental Education

Grassroots International
Greenpeace
Health Care Without Harm
Institute for Responsible Technology
Institute for Social Ecology
International Center for Technology Assessment
Janisse Ray, environmental activist and award-winning author of *Ecology of a Cracker
Childhood*
La Montanita Coop
Lori Jeanne Peloquin, PhD, Genesee Valley Organic Community Supported Agriculture
Martin Donohoe, MD, FACP, Adjunct Associate Professor, School of Community Health
Portland State University; Chief Science Advisor, Campaign for Safe Foods and
Member, Board of Advisors Oregon Physicians for Social Responsibility; Senior
Physician, Internal Medicine, Kaiser Sunnyside Medical Center
National Cooperative Grocers Association
National Family Farm Coalition
The Nature Institute
Northeast Organic Farming Association
The Oakland Institute
Oregon Physicians for Social Responsibility
Oregon Tilth
Organically Grown Company
Organic Consumers Association
The Organic & Non-GMO Report
Organic Trade Association
Organic Valley Family of Farms / CROPP Cooperative
Pacific Coast Federation of Fishermen's Associations
Partners for the Land & Agricultural Needs of Traditional Peoples (PLANT)
PCC Natural Markets
Pesticide Action Network North America
Pesticide Watch
Rodale Institute
Real Food Challenge
The Rural Coalition
Say No to GMOs
Sierra Club
Slow Food Rio Grande
Slow Food USA
John Stauber, author of *Trust Us, We're Experts*
Sustainable Living Systems
Ukiah Natural Foods Coop
Washington Biotechnology Action Council
Whole Foods Co-op
WholeSoy & Co. / TAN Industries, Inc.
Your Own Health and Fitness