

June 22, 2015

Kevin Shea, Administrator
United States Department of Agriculture Animal and Plant Health Inspection Service
1400 Independence Avenue SW
Washington, DC 20250

**RE: New Stakeholder Engagement on APHIS Biotechnology Regulations
(Docket No. APHIS-2015-0036)**

Dear Mr. Shea,

We, the undersigned organizations and companies, submit the following recommendations regarding the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS)'s potential changes to biotechnology regulations under the Plant Protection Act (PPA). The undersigned organizations and businesses represent millions of farmer and consumer members who reside in every state across the country, and who support sustainable food systems.

Specifically, we believe that APHIS should: regulate based on the process by which biotechnology products are created, add noxious weed provisions to its biotechnology regulations, utilize its authority to regulate biotechnology to the fullest extent, and regulate biotechnology via binding federal regulations.

APHIS Should Regulate Biotechnology Based on Process, Not Product

APHIS should regulate biotechnology based on the process by which products are created, rather than the characteristics of the products. Genetic engineering may have higher rates of unintended and potentially harmful effects than traditional breeding.¹ Newer genome editing processes use *in vitro* recombinant nucleic acid technologies, and should therefore be included under the APHIS regulatory umbrella. It makes sound scientific sense for APHIS to regulate based on the process by which biotechnology products are created, using genetic engineering as the trigger for regulatory review. The National Research Council of the National Academy of Sciences agrees,² as has APHIS in the past.³ This would give regulatory authority to APHIS over all genetically engineered (GE) organisms and would provide clarity, consistency, and transparency to the regulatory process. APHIS should not give permit applicants the authority to decide whether a GE organism is subject to regulation. Giving industry such discretion would create uncertainty, rely on the industry interpretation of risk, and undermine the integrity of, and public confidence in, federal oversight. Virtually all parties agreed to this during the comment periods on the proposed rules.

¹ National Academy of Sciences, National Research Council, SAFETY OF GENETICALLY ENGINEERED FOODS: APPROACHES TO ASSESSING UNINTENDED HEALTH EFFECTS (2004), at 64.

² National Academy of Sciences, National Research Council, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS: THE SCOPE AND ADEQUACY OF REGULATION (2002) ("2002 NAS Report"), at 79, 83.

³ USDA APHIS Draft Programmatic Environmental Impact Statement (DPEIS), "Introduction of Genetically Engineered Organisms, July 2007 at 20, 168.

APHIS Should Add Noxious Weed Provisions to Its Biotechnology Regulations

APHIS should expressly implement its noxious weed authority in developing new GE crop regulations under the PPA, as it proposed to do in 2004 and 2008. Unlike the current biotechnology rules that limit APHIS to a plant pest analysis, using noxious weed authority will allow APHIS to conduct a more comprehensive analysis, using the proper statutory scope of its authority. APHIS should clarify that, based on the plain language of its statutory definition⁴, it can be used to regulate direct and indirect harms from GE crop production systems such as transgenic contamination, herbicide-resistant weeds, loss of biodiversity or ecosystem services, impacts to public health, and harm to the livelihoods of GE, non-GE, and organic farmers. Further, the magnitude of harm needed to trigger regulatory measures should not be excessively high, as was the case for the noxious weed standard of the previous Noxious Weed Act, which the PPA replaced. APHIS also can and should assess the safety of GE crops for human and animal consumption. Addressing and preventing these harms should be explicit protection goals.

APHIS should oversee and regulate all GE crop production systems throughout the crop life cycle, rather than unconditionally removing GE crops and their progeny from oversight through a determination of non-regulated status. For instance, APHIS should monitor herbicide-resistant crop systems for their potential to foster herbicide-resistant weed populations or loss of ecosystem services, and impose appropriate control measures if monitoring reveals a problem. Monitoring should include measurement of changes associated with harm to ecosystems beyond the local farm scale, such as degradation of water quality, air pollution, climate impacts, or loss of biological resources. APHIS should also actively monitor, assess, mitigate, and prevent harmful impacts of GE crop production systems on farmers' livelihoods, the health of rural communities, and the environment, including non-target organisms. Further, in contrast to its current practice of maintaining secrecy APHIS should make the field trial process transparent.

APHIS Should Utilize Its Authority to Regulate Biotechnology to the Fullest Extent

Aside from the PPA, the 2008 Farm Bill further bolstered APHIS's authority to regulate biotechnology. The Bill mandated that APHIS "improve the management and oversight" of GE crop field trials, 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.⁵ These include requiring GE crop field trial permit holders and USDA to collect and retain representative samples of GE crops and relevant means to detect engineered products, submission of contingency and corrective action plans to address contamination episodes, and new means to ensure effective isolation of GE crops grown in field trials from commercial supplies, among several others. Given the history of contamination and gene flow events from field trials, APHIS should also periodically test crops

⁴ The statutory definition of "noxious weed" harm encompasses both direct and indirect injury to crops and other interests of agriculture, public health, or the environment.

⁵ See Food, Conservation, and Energy Act of 2008, Pub. L. No. 110-230, § 10204, 122 Stat. 923 (2008) (codified at 7 U.S.C. § 7701 note); APHIS, *Lessons Learned and Revisions Under Consideration for APHIS' Biotechnology Framework* (2007), *available at* <http://www.aphis.usda.gov/newsroom/content/2007/10/content/printable/LessonsLearned10-2007.pdf>.

and crop wild relatives for genes used in field trials. APHIS should utilize this robust authority to the fullest extent to regulate GE crop production systems.

APHIS Should Regulate Biotechnology via Binding Federal Regulations

As APHIS stated, there is *no substitute* for binding federal regulations with the force of law. To date, APHIS's regulatory oversight of GE crop production systems has been a failure. Numerous, costly transgenic contamination events have occurred demonstrating the significant harms presented by such systems during field testing and after commercialization. It is clear that mandatory regulations requiring proponents of GE crop production systems to demonstrate the crops' safety and continue reporting to APHIS after commercialization are necessary to adequately protect the environment, economy, farmers, consumers, and public health. Anything less would fall short of APHIS's mandate under the PPA and would undermine the purpose of the Act.

Thank you for the opportunity to provide comments on this important issue.

Sincerely,

Amy's Kitchen
Biofuelwatch
Center for Biological Diversity
Center for Environmental Health
Center for Food Safety
Clif Bar & Company
Consumers Union
Earthjustice
Eden Foods
Equal Exchange
Family Farm Defenders
Food and Water Watch
Food Democracy Now
Foundation Earth
Friends of the Earth
Good Earth Natural Foods
Green America
Indigenous Environmental Network
Institute for Agriculture and Trade Policy

National Family Farm Coalition
National Organic Coalition
Nature's Path
New England Farmers Union
Northeast Organic Dairy Producers Alliance
Non-GMO Project
Northern Plains Resource Council
Organic Consumers Association
Organic Seed Alliance
Our Family Farms Coalition
PCC Natural Markets
Pesticide Action Network North America
REAL Cooperative
Rising Tide of the Florida Keys
Rodale Institute
Sierra Club
Small Planet Institute
Veritable Vegetable
Western Organization of Resource Councils