

April 21, 2016

By Electronic Submission

Docket No. APHIS-20140054

Regulatory Analysis and Development, PPD

APHIS

Riverdale, MD 20737-1238

Re: Comments to Docket No. APHIS-2014-0054 Regarding USDA's  
Programmatic Environmental Impact Statement.

The Center for Science in the Public Interest (CSPI)<sup>1</sup> is submitting this letter in response to the request from USDA's Animal and Plant Health Inspection Service (APHIS) for written comments on its upcoming programmatic environmental impact statement (EIS) (81 FR 6225, Feb. 5, 2016). CSPI supports USDA's announcement that it will be revising its regulations involving genetically engineered (GE) organisms that might be "plant pests" (7 CFR part 340). For more than twenty years APHIS has overseen GE organisms, and now it is appropriate to review and revise its regulations to provide a science-based risk assessment and risk-management approach for both current and future GE products.

The following issues that should be considered during the EIS process as well as considered in the proposed regulations that APHIS develops.

I. All of the Proposed Regulatory Options Should Incorporate the "Noxious Weed" Provisions of the Plant Protection Act.

CSPI supports broadening the scope of the APHIS regulation of GE crops to include "noxious weed" concerns. APHIS should use all the potential regulatory authorities it has been given by Congress to ensure that GE crops do not harm the environment and/or agricultural interests. By incorporating the noxious weed provisions of the Plant Protection Act into the new regulations for GE plants and other organisms, APHIS will broaden the range of potential issues, risks, and concerns it can assess and address when regulating those products. CSPI can find no reason not to use this additional authority to regulate GE crops.

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<sup>1</sup> CSPI is a nonprofit education and advocacy organization that focuses on improving the safety and nutritional quality of our food supply. CSPI seeks to promote health through educating the public about nutrition; it represents citizens' interests before legislative, regulatory, and judicial bodies; and it works to ensure advances in science are used for the public good. CSPI is supported by the 650,000 member-subscribers to its Nutrition Action Healthletter and by foundation grants. CSPI receives no funding from industry or the federal government.

In addition to including the “noxious weed” authority in Alternative #2, APHIS should either state that the “no action” alternative includes adding the “noxious weed” authority or add a new alternative that would be keep the current system in place but add the “noxious weed” authority. Also, the EIS should analyze the impact on environmental and agricultural interests of not including “noxious weed” authority for the alternatives that do not include that legal authority.

II. APHIS Should Propose a Regulatory Program that Regulates GE Organisms Based on Science- and Risk-Based Criteria and Not Whether a GE Organism is a Potential Plant Pest or Noxious Weed.

To date, APHIS has attempted to regulate GE organisms using existing statutes that were not intended for GE organisms. It is not likely (and probably impossible) to turn a corn or soybean plant into a plant pest or noxious weed by adding one or two new genes from another species. In fact, not once in the last twenty years has AHPIS denied a petition for nonregulated status because a GE crop was a plant pest. The process of the GE seed developer collecting data on whether the crop is a plant pest, submitting a petition for nonregulated status, and APHIS granting the petition is a waste of time and resources by the developer, APHIS, and the interested public.

As APHIS considers how best to regulate the potential risks that might arise from certain GE organisms, it would be best to establish a system that is science- and risk-based. Under such a system, the potential risk of the particular GE product would determine if it is regulated, not whether it meets a narrow or broad reading of a “plant pest” or a “noxious weed.” For example, under the current system, the method of how the GE plant was transformed (agrobacterium versus gene gun) determines if the GE crop is regulated. Instead, a better regulatory system for GE crops would be to assess whether the product could have impacts to the environment or agricultural interests (such as development of resistant weeds) and determine, based on those impacts, whether oversight is needed. If APHIS can’t develop a regulatory alternative that is science- and risk-based and covers GE crops with potential risks to the environment or agriculture, then it should request Congress to provide such authority. Only a science-based system will safeguard the environment and agriculture and also garner the support of the public.

III. Issues to Consider When Analyzing Impacts of the Different Proposed Alternatives for the APHIS Regulation of GE Organisms.

There are four issues that APHIS should consider in its analysis of the impacts of each of the proposed alternatives.

A. Impact on the Development of Resistant Weeds and Pests.

The Federal Register notice identifies that “weed and insect resistance to herbicides and insecticides” will be one of the many impacts analyzed in the programmatic EIS. CSPI supports inclusion of this issue because it has become one of

the major impacts documented to have occurred from the growing of the current GE crops in the United States. APHIS needs to analyze which alternative can best address this problem so that resistance can be delayed. To date, farmers and the seed developers have not successfully used voluntary actions to prevent the development and spread of resistant weeds and insects. Therefore, USDA has an obligation under its broad mandate to safeguard US agriculture by doing everything in its power to limit resistant weeds and pests.

**B. The Programmatic EIS Should Analyze the Agricultural and Environmental Consequences from Developers and Academics Conducting GE Crop Field Trials without Confinement Conditions Imposed by AHPIS.**

Under Alternative #2, many of the current GE crops that are regulated under either the notification or permitting procedures for field trials would no longer be regulated at all by APHIS. Those academic researchers and/or private seed developers would be under no obligation to keep their field trials confined or to prevent persistence of their GE plant variety with the new engineered trait. Under the current APHIS regulatory system, there have been several instances of “escapes” of GE varieties during the research stage; some of those instances had significant agricultural and/or economic impacts. In addition, APHIS has documented violations of notifications and permits for confined field trials of GE crops.

In the programmatic EIS, APHIS needs to analyze what will be the environmental, agricultural, and economic impacts of not regulating field trials for many of the GE crops that will be developed after the proposed regulatory change. Researchers and developers will no longer be under any obligation to prevent escapes from their trials nor put in place confinement conditions. No government authority will inspect those field trials nor ensure that confinements are sufficient to prevent escapes. Analyzing the impact of such a policy change will be an important part of a thorough EIS.

**C. Impact of State Oversight of GE Crop Field Trials if APHIS Stops Its Oversight.**

From the early 1990s to the present, APHIS has regulated virtually all field trials with GE plants. However, under Alternative #2, many GE plants will no longer be regulated by APHIS as potential “plant pests.” While this may be the correct decision scientifically, it may result in state regulation of GE plants instead. Several states such as Idaho, Minnesota, Oklahoma, Wisconsin, and Washington currently have reserved the right to require state-issued permits prior to release of GE plants into the environment. It would not be surprising if those states began requiring permits if APHIS no longer regulated a GE plant. Similarly, other states could decide to use existing laws or pass new laws to regulate field trials and commercial products. This could result in a patchwork of different regulations that could have environmental and/or agricultural impacts. In addition, seed developers might “forum shop” to conduct field trials in states with lax regulation or no regulation at all. Therefore, the programmatic EIS needs to

analyze whether states would regulate GE plants and if so, the potential impact of as many as fifty different state regulatory systems.

D. Impact of Not Having Developers Complete a Conflict Analysis (CA) and Coexistence Plan (CP).

In response to the USDA Advisory Committee on Biotechnology and 21<sup>st</sup> Century Agriculture's report on coexistence, APHIS proposed that GE seed developers voluntarily develop a conflict analysis (CA) and coexistence plan (CP) when seeking non-regulated status of a GE crop. While CSPI has no knowledge of how many GE seed developers have actually developed a CA and/or CP, APHIS Alternative #2 would significantly decrease the number of GE crops that are required to file a petition for non-regulated status. Therefore, one consequence of Alternative #2 could be a decrease in the development of a CA and CP. That could impact the ability of a new GE crop to coexist with other forms of agriculture. APHIS stated that its EIS will evaluate impacts on "coexistence," and that evaluation should specifically consider on the effect of having or eliminating the CA and CP. CSPI believes APHIS should make the development of a CA and CP a mandatory part of the regulatory process when it grants a petition for nonregulated status.

If there are any questions about the content of this letter, please let me know and I would be happy to answer them. I also would welcome the opportunity to meet with USDA staff to discuss the issues addressed in this letter.

Sincerely,



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