CENTER FOR
Science IN THE
Public Interest
The nonprofit publisher of
Nutrition Action Healthletter

June 19, 2017

By Electronic Submission
Docket No. APHIS-2015-0057
Regulatory Analysis and Development
PPD, APHIS
Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

Re: Comments to Docket No. APHIS-2015-0057 Regarding the Proposed Changes to 7 CFR part 340.

The Center for Science in the Public Interest (CSPI)[1] appreciates the opportunity to submit comments on the United States Department of Agriculture's (USDA) proposed changes to 7 CFR part 340. CSPI supports science- and risk-based oversight by USDA of genetically engineered (GE) crops to ensure they are safe to humans and the environment before farmers can grow them. While CSPI supports some of the proposed changes, CSPI is concerned that the proposal eliminates USDA oversight of some "traditional" GE crops,[2] which could result in harm to the environment or agricultural interests. The gaps in regulation resulting from the proposed rule changes, which are set forth below, need to be addressed by USDA before any changes to 7 CFR part 340 are finalized.

I. CSPI supports incorporating the "noxious weed" provisions of the Plant Protection Act into 7 CFR part 340.

CSPI supports broadening the scope of the Animal and Plant Health Inspection Service (APHIS) regulation of GE crops to include "noxious weed" concerns. APHIS should use all its potential regulatory authorities that Congress included in the Plant Protection Act to ensure GE crops do not harm the environment and/or agricultural interests. By incorporating the noxious weed provisions into 7 CFR part 340, 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.

[1] 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 600,000 member-subscribers to its *Nutrition Action Healthletter* and by foundation grants. CSPI receives no funding from industry or the federal government.

[2] The proposed changes to 7 CFR part 340 define "genetic engineering" to include not just adding a new gene to a plant (which CSPI calls "traditional" genetic engineering) but also gene editing changes made within a plant's own genome. In this comment, when CSPI's discusses gaps in oversight that will be occur if the proposed changes are adopted, CSPI is primarily referring to "traditional" genetic engineering and not gene editing within a plant's own genome.

By including the "noxious weed" authority in 7 CFR part 340, USDA would be able to assess and address potential risks that might arise from a GE crop that it otherwise could not assess using only its "plant pest" legal authority. The Plant Protection Act defines "noxious weed" to mean

> any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.

A plain reading of that definition would support APHIS carrying out assessments to address potential impacts to the environment, public health, and "other interests of agriculture." This could include impacts to non-GE farmers, impacts of resistant weeds on the environment (because farmers need to kill them with additional herbicides), and economic impacts from potential trade disruptions if farmers grow GE crops that are not yet approved in export markets. Therefore, USDA should incorporate its "noxious weed" authority into 7 CFR part 340 and interpret that authority broadly to manage the wide range of potential impacts of GE crops.

II. USDA's proposed changes to 7 CFR part 340 will eliminate oversight over the planting of some traditional GE crops, resulting in impacts on humans, the environment, or U.S. agricultural interests. Until those gaps are eliminated through oversight from USDA or another federal agency, the proposed changes to 7 CFR part 340 should not be finalized.

A. USDA needs to continue to regulate traditional GE crop field trials.

USDA states in its Federal Register notice that if its proposed changes to 7 CFR part 340 are adopted, it will no longer regulate genetically engineered versions of most domesticated crops. This will mean that anyone who engineers a domesticated crop (both private developers and academic scientists) will no longer be required to get a permit (or file a notification) to conduct a field trial. Persons conducting field trials for GE crops will no longer need to follow the USDA permit requirements or implement any confinement conditions that ensure GE crops do not persist in the environment when field trials are completed.

USDA states that it expects many developers to continue to follow "best practices" for confined field trials, but there will be no legal obligation to do so. It is likely that at least some field trials will be carried out without procedures preventing the release of the GE crop from the test site. If that happens, there could be adventitious presence of the GE trait in a crop of a neighboring farmer, leading to economic losses throughout the food-supply chain. In addition, if the GE crop produces a substance that has not yet been found safe for consumption by humans or animals, it could lead to food product recalls and consumer concerns about all GE crops, even ones that are safe to consume. Therefore, USDA needs to analyze the potential problems that could arise to the environment, the food supply, and consumer perceptions if it is no longer overseeing

most field trials with traditional GE crops (and no other federal agency is taking over that responsibility). More importantly, until USDA is assured that confined field trials with traditional GE crops will be conducted in a manner that protects the environment, human health, and U.S. agricultural interests, it needs to continue its oversight over GE crop field trials under the Plant Protection Act.

B. GE crops that produce pharmaceuticals or industrial compounds need to remain regulated by 7 CFR part 340.

Under the current regulations at 7 CFR part 340, USDA requires GE crops that produce plant-made industrials or pharmaceuticals to only be grown outdoors in the environment after they receive a permit that prevents any escape from the approved planting location. Those GE crops are not allowed to take advantage of USDA's expedited notification process because there are significant potential impacts if the GE crop escaped from the planting site. In most cases, those GE crops are not intended to enter the food supply because it is unknown whether they could be harmful to humans.

USDA recognizes that the proposed changes to 7 CFR part 340 will result in a regulatory "gap" where most GE crops that produce plant-made industrials or pharmaceuticals will no longer be regulated. USDA identifies several options that could replace its current oversight but admits there are challenges to enacting any of its proposed options and that none of them might ever be adopted. Given the potential impacts that could arise if a GE crop with a plant-made industrial or pharmaceutical were inadvertently released from a field, USDA should not go forward with the portions of its proposal that will eliminate USDA oversight of this subset of GE crops unless another office within USDA or a different federal agency is prepared to regulate the release of those GE crops into the environment.

C. GE crops that produce biological pesticides need to remain regulated by 7 CFR part 340 until the Environmental Protection Agency (EPA) or another federal agency regulates trials of less than 10 acres.

The Federal Register notice accompanying the proposed changes to 7 CFR part 340 states that the proposed changes will likely eliminate any USDA oversight of small-scale field testing of GE crops that produce a biological pesticide (called "plant-incorporated protectants" or "PIPs"). As stated by USDA, "such plants could be grown outdoors without the need for an APHIS permit and without undergoing APHIS oversight."

EPA, which registers PIPs for commercial use, has historically regulated PIP field trials when they exceed 10 acres. USDA states that in the absence of its oversight of small-scale field trials, "EPA may decide to require experimental use permits for **all, some or none** of such PIPs…" (emphasis added). USDA also states that it will work with EPA during any interim period if EPA decides to regulate those small-scale trials. However, if EPA does not require permits for experimental plantings of less than 10 acres, those trials will go unregulated, which will mean there will be another gap in the

federal oversight of GE crops. Therefore, USDA should not implement its proposed changes to 7 CFR part 340 until the federal government has determined how it will regulate PIP-field trials or makes a scientific determination that those trials do not need any oversight because they will not result in any adverse impacts.

D. USDA's proposal does not state whether it will regulate GE crops that contain a "gene drive."

The proposed definitions of "genetic engineering" and a "genetically engineered organism" could include adding a "gene drive" into an organism. A genetically engineered organism with a gene drive could have significant impacts on the environment and/or agricultural interests. However, the proposed changes to 7 CFR part 340 don't state whether organisms with "gene drives" will be captured under USDA's new regulations. This is a significant gap in the proposed regulations and needs to be addressed before any final rule is released.

III. The elimination of USDA oversight for most confined field trials for traditional GE grains, fruits, and vegetables could lead to a patchwork of state oversight, which is less desirable than the current USDA oversight.

USDA states in its proposal that many GE crops that have been regulated by USDA to-date would no longer be regulated if the proposed changes to 7 CFR part 340 are finalized. The preliminary environmental impact statement (PEIS) identifies several state laws that allow those states to regulate the movement and release of GE crops. In addition, the PEIS states that "in response to the expected reduction in the number of permits issued by APHIS, some states may decide to enact legislation to impose state level regulation on GE organisms." If confined field trials for domesticated GE crops are not regulated by USDA, it is reasonable to assume that at least some states will regulate those confined field trials. This could lead to a patchwork of state oversight with each state having different requirements and raising the cost of carrying out confined field trials by public and private seed developers. It could also lead to "forum shopping," where the seed developer conducts their field trials in states with lax regulation or no regulation at all. CSPI believes the current notification and permitting process at USDA is working reasonably well, and a state patchwork of oversight is less desirable because it could increase compliance costs and may not adequately ensure that GE crops grown in experimental trials do not persist in the environment.

IV. The elimination of USDA oversight for most GE grains, fruits, and vegetables could lead to trading partners determining when U.S. farmers can grow and export those GE crops.

If the changes to 7 CFR part 340 are finalized as proposed, the ability of farmers in the U.S. to grow GE crops will be impacted by the laws and regulations of nations that have agricultural trade with the United States. First, if most GE domesticated crops are no longer regulated by USDA, that does not mean our trading partners will not regulate the introduction of those crops into their countries. U.S. farmers may not be able to grow new GE seed varieties until those export countries approve the GE variety. Therefore, the time and cost savings

envisioned by the USDA proposal may not materialize if the GE crop is exported to a country that requires government approval. Secondly, if a GE crop is not regulated by USDA but is regulated by another country, that country will no longer have the USDA approval or its underlying evidence to support that country's regulatory process. Under USDA's proposal, our trading partner countries will now become the regulators of "first impression" on the safety of a GE crop. This could slow down a foreign government's approval of a GE crop developed in the U.S. because that country cannot rely on a decision by the U.S. government stating that the GE crop is safe to grow. Finally, if GE crops can be grown by farmers in the U.S. without oversight by USDA but with oversight by exporting countries, the chances for adventitious presence of unapproved GE crops will increase. This could lead to the loss of export markets or significant economic impacts if a GE crop grown in the U.S. is rejected when it arrives at a foreign port. Therefore, reducing oversight in the U.S. may not benefit seed developers and farmers as much as envisioned by the proposed changes to 7 CFR part 340.

V. USDA should regulate gene-edited plants proportionately based on their potential risk to the environment and/or agricultural interests.

The proposed changes to 7 CFR part 340 treat gene-edited plants the same as traditional genetically engineered crops (where a new gene has been added to the crop's genome). However, USDA's proposal is not based on scientific evidence that the risk profile of gene-edited crops is identical to traditional GE crops. Instead, USDA is proposing that gene-edited crops should receive the same regulatory treatment because they are not any more likely to raise "plant pest" or "noxious weed" issues any more than traditional GE crops. In fact, when a scientist uses gene-editing to modify the genome of a crop, the scientist could silence a single gene, add one or more new genes (from the same species or a different species), add or delete base pairs from one gene in the crop, or modify more than a dozen genes in the crop. Therefore, USDA should proportionately regulate gene-edited crops based on the introduced phenotype's potential risks to the environment and/or agriculture. Simple gene deletions that produce phenotypes (or genotypes) found in nature might only get minimal or no oversight, while the introduction of an herbicide-resistance gene using gene-editing might be regulated with risk-management conditions that delay the development of resistant weeds. If USDA cannot implement a risk-based regulatory system under existing laws, Congress should provide USDA with the legal authority to set up such a regulatory system.

VI. The proposed definition of a "genetically engineering" and "genetically engineered organism" are ambiguous and need clarification.

The proposed definition of "genetic engineering" is unclear and needs to be clarified. In the definition of "genetic engineering," USDA needs to define "traditional breeding techniques." It is helpful that USDA provides some examples of "traditional breeding" within the definition of "genetic engineering." However, CSPI is not aware of any consensus definition of what plant breeding techniques qualify as "traditional breeding." Therefore, USDA should provide a more complete list of which techniques qualify as "traditional breeding" (such as hybridization, cloning, etc…) either in 7 CFR part 340 or in an agency guidance document that can be continually updated as needed.

Similarly, the definition of "genetically engineered organism," is unclear. In subparagraph (1), it is unclear to the reader what is meant by the phrase "which could otherwise be obtained through the use of chemical- or radiation-based mutagenesis." How is someone supposed to determine if the change could happen through radiation mutagenesis? What evidence or analysis is needed to qualify for this exception and how will USDA determine which deletions and substitutions qualify for this exception? In addition, the term "naturally occurring nucleic acid sequences from a sexually compatible relative" in subparagraph (2) is also unclear. Since most agricultural crops have gone through decades of manipulation in the laboratory by scientists and centuries of selective breeding by farmers, how does one determine if the DNA sequence that is being introduced is a "naturally occurring nucleic acid sequence." USDA needs to provide clarification about what is meant by this phrase and how a developer would prove that the change made in the plant's genome qualifies for that exemption.

CSPI appreciates the opportunity to provide this comment to the USDA. CSPI would welcome the opportunity to meet with the staff at USDA's Animal Health and Plant Inspection Service to discuss the issues addressed in this letter in more detail if that would be helpful.

Sincerely,

Gregory Jaffe
Director, Biotechnology Project
Center for Science in the Public Interest
gjaffe@cspinet.org
(202)777-8369