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By Electronic Submission
Docket No. FDA-2015-N-3403
Office of Science and Technology Policy
1650 Pennsylvania Avenue, N.W.
Washington, DC 20504

Re: Comments to Docket No. FDA-2015-N-3403 Regarding the Draft Coordinated Framework for the Regulation of Biotechnology and the National Strategy for Modernizing the Regulatory System for Biotechnology Products.

The Center for Science in the Public Interest (CSPI)[1] supports the Executive Office of the President's memorandum issued July 2, 2015, directing the primary agencies that regulate products of biotechnology to: (1) update the Coordinated Framework for the Regulation of Biotechnology (CF); (2) develop a long-term strategy; and (3) commission an expert analysis on the future landscape of biotechnology products. In response to the documents released on September 16, 2016, CSPI submits the following comments identifying areas that should be addressed if the federal government wants to achieve its goal of "increasing public confidence in the regulatory system" for biotechnology products.

I. The "National Strategy" Needs to Call for a Mandatory Pre-Market Review and Approval System at the Food and Drug Administration (FDA) for All Genetically Engineered (GE) Crops.

Under the Coordinated Framework for Biotechnology, FDA does not affirmatively approve GE crops before they enter the food supply. Instead, FDA has established a voluntary consultation process for GE crops. In that process, FDA reviews safety data submitted by the GE crop developer and responds with a letter stating that FDA has "no further questions" about the safety of each GE crop. Unfortunately, that policy has not instilled consumer confidence in eating foods and ingredients that come from GE crops. In a 2015 poll conducted by the Pew Research Center, 88 percent of scientists believed that foods from GE crops were safe while only 37 percent of consumers believed the same.

If the federal government wants to increase the public's confidence in its oversight of biotechnology products, the FDA must review the safety data on every GE crop before it enters the food supply and give its expert opinion on the safety of foods and ingredients produced from that crop. The safety of GE crops will continue to be questioned by a significant portion of the U.S. population if the only entity ensuring those foods are safe is the GE crop developer (which is what happens under the

[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 850,000 member-subscribers to its *Nutrition Action Healthletter* and by foundation grants. CSPI receives no funding from industry or the federal government.

current FDA voluntary review). The July 2, 2015, OSTP Memo specifically stated that the long-term strategy could identify "changes to authorities, regulations, and policies," if needed, to achieve its goals. Providing FDA with the legal authority to review and approve GE crops would do more for improving the public's confidence in GE crops than any of the proposed actions announced in the draft "National Strategy."

II. The National Strategy Should Propose that USDA Regulate GE Crops Based on Their Potential Risk, Not the Process by Which They are Produced.

The proposed Coordinated Framework and the National Strategy both state that federal oversight of biotechnology products should be based on potential risk and on the final product, not on the process by which the product was made. However, neither document addresses the fact that USDA's current oversight of GE crops as "plant pests" under the Plant Protection Act is inconsistent with those principles. To resolve this inconsistency, the National Strategy should propose for USDA to regulate GE crops based on their potential risks, not by the method which they are developed with.

When USDA regulates GE crops under the "plant pest" provisions of the Plant Protection Act, oversight depends on whether some component of a "plant pest" is involved in the development of the GE crop. For example, if a developer creates a GE crop using *agrobacterium* to introduce the new DNA, it is regulated. However, if a developer uses the gene gun to introduce the same DNA, the crop is not regulated. Similarly, if the introduced gene construct contains a promoter from an organism that is a plant pest, the GE crop is regulated. If the introduced gene construct contains a promoter from an organism that is not a plant pest, the GE crop is not regulated. In each of the above situations, the GE crops have the same phenotype with the same "potential risk" to agriculture or environment (if any), yet only the GE crop made using *agrobacterium* and the GE crop having the promoter from a plant pest are regulated by USDA.

If a GE crop has a phenotype that has potential risks to agriculture or the environment (such as the potential to develop resistant weeds or pests in the field), USDA should regulate that crop independent of its transformation process or the origin of the promoter sequence. USDA's current regulation of only the GE crops made from *agrobacterium* incorrectly suggests to the public that gene gun transformed plants are somehow less risky than if the same trait is introduced using *agrobacterium*. To solve this problem, USDA should base its oversight of GE crops on their potential risks and not on their relationship to a "plant pest." If USDA cannot do this using existing laws, then the National Strategy should call on Congress to provide USDA with new legal authority to accomplish a regulatory system that is more consistent with the principles set forth in the Coordinated Framework.

III. The National Strategy Should Address Coordination Between EPA and USDA Involving Their Oversight of Herbicides Used in Conjunction with Herbicide-Tolerant Seeds.

Herbicide-tolerant GE crops only provide value to a farmer if they are used in conjunction with the corresponding herbicide. Together the GE seed and the corresponding herbicide constitute one "cropping system" that is used by a farmer, yet the different regulatory agencies regulate the two components of that "cropping system" under different legal mandates. It is unclear if EPA and USDA coordinate the most important parts of this oversight, such as their risk assessments, their compliance

with the National Environmental Policy Act, or their imposition of risk management obligations designed to reduce the impacts of the two components of the cropping system on agriculture or the environment.

In addition, the regulatory approval processes at USDA and EPA are also not synchronized, which can lead to farmers being able to plant herbicide-tolerant seeds while not being able to apply the corresponding herbicide. That exact actual situation happened in the summer of 2016 when farmers began growing dicamba-tolerant plants and then illegally used old formulations of dicamba not approved for use on those plants. Those older formulations of dicamba drifted to neighbors' fields and damaged tens of thousands of acres in ten states.

Finally, overuse by farmers of glyphosate tolerant crops with glyphosate has led to the development of numerous glyphosate-tolerant weeds on millions of acres of farmland. Better coordination between the two agencies and their regulatory oversight could result in both agencies establishing use conditions that reinforce one another and prevent the development of resistant weeds. Therefore, for all reasons stated here, USDA and EPA need to work together to jointly regulate GE herbicide-tolerant seeds and their corresponding herbicides. Those cropping systems are extremely valuable to farmers but only if the regulatory agencies work together to ensure they are safe and used in a sustainable manner.

CSPI appreciates the opportunity to provide this comment to the federal government. CSPI would welcome the opportunity to meet with the members of the Emerging Technologies Interagency Policy Coordination Committee to discuss the issues addressed in this letter in more detail if that would be helpful.

Sincerely,

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