CENTER FOR
Science IN THE
Public Interest
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Nutrition Action Healthletter

November 13, 2015

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 OSTP's Request for Information on the Coordinated Framework for the Regulation of Biotechnology.

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 recently issued Request for Information (October 6, 2015) to provide relevant information and data that could be helpful to the effort set forth in the July 2th memorandum, CSPI submits the following comments to the questions posed in that notice.

Question 1: What additional clarification could be provided regarding which biotechnology products areas are within the statutory authority and responsibility of each agency?

Today, it is unclear which genetically engineered (GE) plants are regulated by Animal and Plant Inspection Service (APHIS) under the Plant Protection Act. Developers of GE crops submit letters of inquiry to APHIS about the origins of the introduced DNA and the techniques they used for the transformation. APHIS then makes a case-by-case determination of whether the particular GE crop is regulated. GE developers and the public deserve to know beforehand which engineering techniques are regulated and when a GE crop is deemed exempt from regulation. APHIS should clearly identify the traditional recombinant DNA techniques and the new DNA-editing techniques that are regulated and therefore require permits and a petition for non-regulated status. Such a policy statement should also be updated on a regular basis as

[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.

new and different DNA-editing techniques are used for engineered products. Finally, when USDA establishes its current policy and any regular updates, USDA should take into consideration whether other countries will also regulate or exempt a particular recombinant technique or category of products and determine whether its decision is consistent with or contrary to the position taken by our major trading partners.

A second area that should be clarified is the regulatory requirements for GE products ***imported*** into the United States. Most of the current GE crops planted around the world, with just a few exceptions, originated in laboratories in the United States and therefore completed the U.S. biosafety regulatory process before or simultaneously with the regulatory process of other countries.

In the future, other countries will commercialize GE crops with different traits (e.g. GE rice in China) and those GE seeds or products from those crops (such as processed rice noodles) will be imported into the U.S. The biosafety regulatory structures set forth in response to the CF, however, primarily anticipate the oversight of GE crops and products whose development started in the U.S. Many questions about the oversight of imported GE seeds and products have never been answered by the regulatory agencies, such as:

- How will new GE imported seed be regulated by APHIS?
- Will they require field trials conducted in the U.S.?
- How will the data and a risk assessment from another country on whether a GE crop is a "plant pest" be utilized by APHIS?
- Will the GE crop developer be required to repeat experiments in the U.S.?
- How will FDA regulate imported food products that were derived from a GE crop that is not grown in the U.S.?
- What data will be reviewed by FDA and how will it deal with the fact that importers of food products may not have access to all the safety data on a GE seed variety?
- What will be the process at EPA to register a plant incorporated protectant that was developed outside the U.S.?
- How will they set a tolerance for food products where the plant-incorporated protectant is not registered in the U.S.?

To have oversight that is transparent and understandable to all stakeholders, the three agencies implementing the CF need to set forth how imported GE seeds and food products will navigate their regulatory oversight.

A third area of clarification involves FDA's 1992 policy. FDA stated that most GE crops will be treated in the category of foods that are "generally recognized as safe." However, it did reserve the right to determine that a unique GE crop could be a "food additive." To date, FDA has reviewed the safety data from over 150 GE crops and it has never determined that any of those crops should be considered a "food additive." With more than twenty years of experience, FDA should update that portion of its policy and either state that GE crops are not "food additives" or state what types of GE crops still

might be considered a "food additive" in the future. Additional clarification of its current thinking on this issue, using examples of current or future GE crops, would make FDA's regulatory system more transparent and understandable.

Question #2: What additional clarifications could be provided regarding the different roles that each agency plays for different biotechnology areas, particularly for those product areas that fall within the responsibility of multiple agencies, and how those roles relate to each other in the course of a regulatory assessment?

Herbicide-tolerant GE crops only have value to the farmer if they are used in conjunction with a particular herbicide, which must be approved for use with those GE seeds. The GE seed and the corresponding herbicide constitute a "cropping system" to be used by a farmer, yet the different regulatory agencies oversee the two components of that "cropping system" under different legal mandates; USDA regulates the herbicide-tolerant seed and EPA regulates the uses of the herbicide. It is unclear to the public, however, whether those two agencies coordinate their risk assessments, their compliance with the National Environmental Policy Act, or any risk management obligations they impose to reduce the impacts of the cropping system on agriculture or the environment.

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 resistant weed development. USDA and EPA need to work together to jointly address the impacts that are caused when herbicide-tolerant crops are used with their corresponding herbicide.

Question #4: Are there relevant data and information, including case studies, that can inform the update to the CF or the development of the long-term strategy regarding how to improve the transparency, coordination, predictability, and efficiency of the regulatory system for the products of biotechnology?

An excellent case study that would inform the update of the CF and how to improve transparency, coordination, predictability, and efficiency in the regulatory process would be for OSTP and the regulatory agencies to study, analyze, and critique how USDA regulated crops engineered to be tolerant to 2,4,D and how EPA regulated the use of 2,4,D herbicide with those engineered seeds. How those two agencies carried out their legal mandates and how they coordinated their risk assessments and risk management measures would enlighten the public, stakeholders, and the interagency committee on some of the strengths and the weaknesses of the federal biotechnology regulatory system. The interagency committee should conduct that analysis and make it public when it proposes any changes to the current Coordinated Framework.

Question #5: Are there specific issues that should be addressed in the update of the CF or in the long-term strategy in order to increase the transparency, coordination, predictability, and efficiency of the regulatory system for the products of biotechnology?

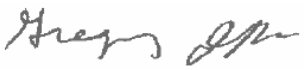
CSPI believes there are three issues that need to be addressed in the update of the CF and in the long-term strategy. The first issue is that FDA does not affirmatively approve GE crops. Under the current policy, FDA has established a voluntary consultation process for GE crops, where it reviews safety data and responds with a letter stating that FDA has "no further questions" about the safety of the particular GE crop. That policy will not ensure the safety of GE crops or foods made from GE crops in the future and does not instill consumer confidence in eating foods and ingredients that come from GE crops. The safety of eating foods and ingredients from GE crops will always be questioned by a significant portion of the U.S. population as long as FDA does not review and approve their safety. Therefore, the process established in the July 2nd OSTP memo needs to take whatever steps are necessary (such as supporting legislation in Congress) to change FDA's oversight from a voluntary consultation process to a mandatory approval process in which FDA gives its opinion of the GE crop's safety to the public. A safety assessment from an independent and respected regulatory agency such as FDA will go a long way to quelling the concern that GE crops are not safe to eat.

Secondly, the CF and any federal government oversight of biotechnology products should be based on science and focused primarily on potential risks. While the CF states that oversight should be based on science and potential risks, its implementation today does not follow those principles. For example, when USDA regulates GE crops under the "plant pest" provisions of the Plant Protection Act, some GE crop are not regulated based on their potential risk. If a developer creates a GE crop using the gene gun to introduce the new DNA, it is not regulated. However, if a developer uses agrobacterium to introduce the same DNA, the crop is regulated. Both crops have the same phenotype and should impact agriculture or environment in the same manner, yet only one is regulated. From the public's perspective, USDA has not determined that a gene gun transformed crop is less risky than the agrobacterium transformed crop. Until both of those engineered crops are regulated by USDA to address their real "potential" risks and impacts (such as the development of resistant weeds), the public, stakeholders, and our trading partners will question the thoroughness of USDA's oversight and question whether only safe products are being released into the market.

The third area that needs to be addressed in any updated CF is the extent to which the many new DNA editing techniques will be regulated, if at all. To be transparent, all stakeholders and the public should know whether products made with TALENS, CRISPR, or other techniques will be regulated and, if so, how and by which agency or agencies. In addition, there should be a mechanism for the three regulatory agencies to regularly review DNA manipulation techniques as they are developed and determine if products made from those new techniques require oversight. Given the fast progression of the scientific discoveries in this area, a mechanism for annual or biennial reviews needs to be established as a routine government practice. Any long term strategy should inform the public how the government agencies will keep updated on the new DNA techniques as well as what criteria will be used to judge whether products made from those techniques require regulation.

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. In the interim please let me know if there are any questions about the content of this letter, and I would be happy to answer them.

Sincerely,



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