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National Science and Technology Council
Emerging Technologies Interagency Policy Coordination Committee
Office of Science and Technology Policy
1650 Pennsylvania Avenue NW.
Washington, DC 20504

Re: Docket No. FDA–2015–N–3403 for Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology; Request for Public Comment.

These comments to the National Science and Technology Council are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

We appreciate the opportunity to provide input on the *Update to the Coordinated Framework for the Regulation of Biotechnology*. This update is well past due, as the last revision to the document was in 1992, and biotechnology has changed a great deal in the past 24 years. The *National Strategy for Modernizing the Regulatory System for Biotechnology Products*, released by the Interagency Biotechnology Working Group in September 2016, stated that the current biotechnology regulatory system “effectively protects health and the environment.” This statement is followed by the clarification that the improvements are needed to “promote public confidence in the oversight of the products of biotechnology through clear and transparent public engagement,”¹ which indicates that the Interagency Biotechnology Working Group realizes that the Coordinated Framework fails to create a sense of public trust in the regulatory system. Thus, future updates must deliver substantial changes that will bolster this trust and transparency.

¹ Emerging Technologies Interagency Policy Coordination Committee’s Biotechnology Working Group. 2016. “National Strategy for Modernizing the Regulatory System for Biotechnology Products.” Available at https://www.whitehouse.gov/sites/default/files/microsites/ostp/biotech_national_strategy_final.pdf

The Coordinated Framework is fatally flawed by failing to address the processes that create genetically engineered organisms.

The failure to base regulation of products of biotechnology on the processes that create them means that the Framework cannot address hazards that are novel and unique to genetic engineering. This underlying flaw in the Biotechnology Coordinated Framework is not addressed anywhere in these Working Group documents. The use of existing laws designed for other purposes not only results in a failure to address the unique hazards of biotechnology, but also leaves gaping holes in regulatory coverage.

All genetically engineered (GE) organisms –plants, animals, or microorganisms—should be subjected to systematic assessments of human and environmental effects and indirect economic effects (such as contamination of organic or non-GE crops leading to rejection in foreign markets, spread of resistant pests, etc.) before being allowed on the market. These assessments should be made available to the public for comment. All products from GE organisms in the marketplace should be labeled as such to allow consumer choice and to permit tracking of unintended health effects. Companies that develop GE organisms should be required to disclose any GE trait, marker genes, or other genetic constructs that might be present in a commercial, GE seed product, including traits and genes from obsolete, no longer marketed traits. In addition, the definition of genetic engineering should be broad enough to include all the newer genetic engineering techniques such as RNAi or the new gene-editing technologies (such as CRISPR-cas9, TALEN, ZNF, and meganucleases).

Current laws are inadequate for regulating biotechnology and its products.

The current regulatory criteria use a product-based approach and assume that the process of biotechnology poses no distinctive risks. The product-based approach to regulating biotechnology fails to consider the higher rates of unintended effects that genetic engineering poses when compared to conventional chemical use and conventional plant breeding.² An adequate system of laws for regulating biotechnology would be process-based, as the technologies used to create GE products are rapidly changing, and must incorporate adequate hazard analysis and independent review.

The risk assessments conducted by the agencies fail to consider the efficacy of the technology, the chemical dependency that is built into many of these technologies, and the long-term health and environmental effects that the technology poses. The current laws that address regulation of biotechnology and GE products are also severely outdated and fail to keep pace with technological developments. The three agencies tasked with regulating biotechnology and its products --FDA, USDA, and EPA-- do not have proper statutory authority and are quite limited in the actions they can take to regulate.

² National Academy of Sciences, National Research Council. 2004. "Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects."

FDA

FDA provides guidance on the food safety assessments of GE plant varieties using the concepts of substantial equivalence of the new foods. The “substances expected to become components of food as a result of genetic modification of a plant will be the same as or substantially similar to substances such as proteins, fats and oils, and carbohydrates.”³ A safety assessment should be a necessary component of the safety assessment for GE products prior to their commercialization. This substantial equivalence assumption essentially enables fewer regulatory barriers for the GE product, barriers that are not created with the unique characteristics of genetically engineered organisms in mind.

The claim of substantial equivalence is inconsistent with the fact that these organisms are patented. The patent holder for the GE product maintains that it has unique traits and upholds the patent right from infringement. Thus, in its lawsuit against Percy Schmeiser for patent infringement, Monsanto asserted, “Once the modified gene is inserted in the DNA of the plant cells, the plant, its stem, leaves, seeds, etc., contain the modified gene.”⁴ The equivalence of the product of the transformed GE plant must therefore be assumed to be different from the parent plant unless demonstrated otherwise.

Additionally, FDA is still not required through the Coordinated Framework to conduct any pre-commercialization assessment of food products developed using biotechnology; rather, it is a voluntary practice:

In 1992, FDA issued a *Statement of Policy: Foods Derived from New Plant Varieties*, explaining how existing legal requirements apply to plant-derived food products developed using biotechnology. FDA subsequently established a voluntary premarket consultation process to help ensure that any safety or other regulatory issues associated with food from a new plant variety are resolved prior to commercial distribution... Although the consultation process is not legally required, to the best of FDA’s knowledge, all GE food crops intended for marketing have been the subject of a consultation or other relevant premarket processes prior to marketing.⁵

USDA

The U.S. Department of Agriculture (USDA) regulates GE plants under the Plant Protection Act (PPA) and thus only really considers whether GE plants might act as weeds. In addition, USDA’s definition of a GE plant requires that it have a plant pest component (i.e., genetic material from

³ U.S. Food and Drug Administration. “Statement of Policy – Foods Derived from New Plant Varieties.” Available at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm>.

⁴ Monsanto Canada Inc. v. Schmeiser, 2001 FCT 256. March 29, 2001. <http://decisions.fct-cf.gc.ca/fc-cf/decisions/en/item/38991/index.do#>.

⁵ Emerging Technologies Interagency Policy Coordination Committee’s Biotechnology Working Group. 2016. “Modernizing the Regulatory System for Biotechnology Products: An Update to the Coordinated Framework for the Regulation of Biotechnology.” Available at https://www.whitehouse.gov/sites/default/files/microsites/ostp/biotech_coordinated_framework.pdf

a plant pest) to be considered a “regulated article.” Thus, if a plant is genetically engineered, but does not contain genetic material from a plant pest, the plant is not considered a regulated article (e.g., 7 CFR 340.2). Although early GE crops allowed on the market—the herbicide tolerant crops and *Bacillus thuringiensis* (Bt) crops— contained plant pest DNA by virtue of the GE techniques, use of newer genetic engineering technologies, such as gene-editing techniques, has meant that GE plants can be produced that do not contain plant pest DNA. The result is that developers of these new GE plants can obtain by request a letter from USDA saying these new GE plants are not “regulated articles.”

Coexistence

In the *Update to the Coordinated Framework for the Regulation of Biotechnology*, prior public comments that raised issues related to “compensation for GE crop contamination prevention measures taken by organic farmers” were considered outside the scope of this Update or in the development of the Strategy.⁶ It is unclear to us how this is outside the scope of the White House Memorandum that was released in July 2015 which stated that our regulatory system must “protect public health, welfare, safety, and our environment while promot[ing] economic growth, innovation, competitiveness, and job creation.”⁷ If this was the goal of the update to the Coordinate Framework, it seems necessary to consider the economic growth and competitiveness of all agricultural sectors, including farmers raising organic and identity-preserved crops.

The efforts thus far by USDA to promote coexistence ultimately do not hold any party responsible for causing financial harm to non-GE farmers. In part, this must be due to the fact that lacking a legal framework that regulates GE products based on process –that is, the fact that they are genetically engineered. Lacking a discussion or plan to ensure the prevention and remediation of GE contamination of farm resources, the federal government should assist farmers with information in exercising their right to litigate in order to protect their farms, soil, and food production from any genetic drift, resulting residues and loss of crop value.

USDA must also recognize that farmers of deregulated GE crops are also continually injured by GE cropping systems that by manufacturer direction require the use of or incorporate toxic chemicals contributing to weed resistance and damaged soil ecosystems services, resulting in harm to the long-term productivity and profitability of the crop. Ultimately, though, USDA should not be addressing “coexistence” as though organic farmers must also accept the final economic responsibility regarding genetic drift.

⁶ Emerging Technologies Interagency Policy Coordination Committee’s Biotechnology Working Group. 2016. “Modernizing the Regulatory System for Biotechnology Products: An Update to the Coordinated Framework for the Regulation of Biotechnology.” Available at https://www.whitehouse.gov/sites/default/files/microsites/ostp/biotech_coordinated_framework.pdf

⁷ White House Office of Science and Technology Policy. “Memorandum for Heads of Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture.” Available at https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf

If public confidence in the oversight of biotechnology products is a concern to the USDA, it should also address the fact that non-GE and organic farmers are not confident in the current oversight as it applies to their farms. Contamination and drift are important considerations on organic farms, whether it be from pesticides or genetic material. A 2014 study released by Food and Water Watch and the Organic Farmers' Agency for Relationship and Marketing (OFARM) found that one-third of organic farmers have experienced GE contamination on their farm due to the nearby planting of GE crops.⁸

EPA

The Environmental Protection Agency (EPA) regulates GE microorganisms under the Toxic Substances Control Act, although the risk of GE microorganisms that can reproduce and spread is fundamentally different from the risk of toxic chemicals, which cannot reproduce.

EPA also regulates plant incorporated protectants (PIPs) and genetically modified microbial pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). With the advent of PIPs, pesticide use has increased, contrary to claims that these practices would lead to pesticide reduction, and so too the proliferation of resistant weeds and insects.⁹ The continual use of a single pesticide –whether or not the pest is present at economic thresholds— results in strong selection pressure for resistance to the pesticide. In addition, the use of these pesticides can have detrimental ecological impacts, which have not figured prominently in EPA's assessments.

EPA's role in the evaluation of herbicide-tolerant crops is restricted to evaluation of the herbicide. As with PIPs, EPA has not adequately evaluated the problems associated with resistance arising from continual use of the same herbicide in short rotations with herbicide tolerant crops. Scientists studying the phenomenon agree that it is of economic concern, have advised against the dependence on herbicides, and advocate for the use of crop rotations and the rotation to non-GE crops.¹⁰ When EPA finally acknowledged the problem, it supported the solution of crops tolerant of another herbicide. According to EPA, thus far there are 80 weed species that have developed resistance in the U.S., with many developing resistance to multiple modes of action.¹¹ Another problem associated with crops tolerant to an herbicide that kills a broad range of plants is the destruction of plants on field margins that once served as food and habitat for many non-pest organisms. This destruction is contributing to population reductions in species now dependent on those habitats.

⁸ Food and Water Watch, Organic Farmers' Agency for Relationship Marketing. 2014. "Organic Farmers Pay the Price for GMO Contamination." Available at https://www.foodandwaterwatch.org/sites/default/files/GMO%20Contamination%20Farmers%20IB%20March%202014_0.pdf

⁹ The New York Times. 2016. "Doubts About the Promised Bounty of Genetically Modified Crops."

¹⁰ Culpepper, A. S. 2006. Glyphosate-Induced Weed Shifts. *Weed Technology*, 20(2), 277–281.

¹¹ US EPA. 2016. "Draft Herbicide Resistance PRN 2016-XX for Public Comment – May 2016." Available at https://www.epa.gov/sites/production/files/2016-05/documents/pr-2016-xx-guidance-herbicide-resistance-management_0.pdf

EPA also does not address a serious problem associated with herbicide-tolerant crops –the formation of metabolites that are toxic to consumers of the crop during the process in which the genetically engineered crop metabolizes the herbicide to make it nontoxic to the crop.

Agencies can make better use of existing laws

Although the rational approach to regulating genetically engineered organisms and their products would be to create laws specifically addressing them –as most nations have done—the current constellation of laws could be used more effectively.

FDA

The failure to require testing of all GE food crops under existing statutory authority could potentially be mitigated by using the food additive provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), which would require a safety approval process by FDA rather than maintaining the voluntary premarket assessment using industry documents and data.¹²

USDA

The noxious weed authority of the Plant Protection Act could allow many types of known environmental harms of GE crops to be regulated by the U.S. Department of Agriculture (USDA). USDA has the statutory authority, through partial deregulation of crops under the Plant Protection Act, to require monitoring and the creation of buffer zones where there is the potential for genetic drift that is injurious to organic or identify-preserved crops. We would like to see the Interagency Biotechnology Working Group include in the Framework language that, when genetic drift occurs, the responsibility for corrective action is squarely placed on the user of the polluting technology, not the affected party.

EPA

EPA’s risk assessments must include hazards associated with eating the transformed crop in addition to those associated directly with the herbicide itself. These must include the effects of the metabolites of the herbicide arising from the genetic modifications to the plant. They should also include any changes in the nutritional value of the plant.

EPA and USDA should develop a resistance-monitoring program to be carried out by independent scientists and laboratories and paid for by fees imposed on the technology developer. Initial approvals should be contingent on scientific assessment of proposed resistance risk management plans and agency judgments regarding the expected impact of such plans on the risk of resistance emerging.

Decision documents should establish resistance thresholds in target pests and/or secondary organisms that will trigger mandatory resistance management practices. If such additional resistance risk management provisions prove ineffective in reversing the frequency of resistant organisms, the USDA and/or EPA must begin cancellation proceedings.

¹² 21 U.S. C. § 348

Conclusion

We expect that the Update to the Biotechnology Coordinated Framework will deliver substantial changes that will bolster the much needed trust and transparency around biotechnology and its products. In making these updates, we ask that the Interagency Biotechnology Working Group consider the underlying failure to base regulation of products of biotechnology on the processes that create them and use the existing laws more effectively as outlined above.

We appreciate your attention to this important and urgent issue. Thank you in advance for your consideration of our recommendations.

Sincerely,



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