CENTER FOR FOOD SAFETY

November 13, 2015

National Science and Technology Council
Emerging Technologies Interagency Policy Coordination Committee
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Ave.
Washington, DC 20504

RE: Docket No. FDA-2015-N-3403

The undersigned organizations offer the following comments on the Administration's Federal Register notice *Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology*:

To this point, U.S. regulation of genetically engineered (GE) organisms has been an unmitigated failure. In sharp contrast with much of the rest of the world, the U.S. has prioritized the rapid commercialization of GE organisms over core governmental duties, such as protection of public health, the environment, and the interests of agriculture.

As a result of weak regulation, GE crops in the U.S. are causing significant environmental and economic harms. For example, on the environmental side, the great majority of GE crops are engineered to be resistant to weed-killing pesticides, and have led to dramatic increases in overall pesticide use. Monsanto's Roundup Ready varieties, resistant to glyphosate, have made glyphosate the most used pesticide in history, with over 280 million pounds applied in U.S. agriculture in 2012 alone. On the agricultural front, widespread adoption of these herbicide-resistant crops has generated an epidemic of herbicide-resistant "superweeds" that now cover more than 60 million acres of U.S. farmland. Resistance of corn rootworm to toxins in GE corn is threatening to reverse reductions in use of sprayed insecticides. These agricultural failures of GE crop technologies also have economic consequences, leading to increased production costs to farmers to control resistant pests and weeds. Moreover, transgenic contamination of traditional crops from GE crops has caused U.S. farmers billions of dollars in market losses.

With regard to human health, the Food and Drug Administration (FDA) does not conduct safety tests on GE foods, does not require GE crop developers to do so, and does not approve engineered foods as safe. Instead, FDA has confidential meetings with industry in which it merely

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reviews data generated by and summarized by the industry—and even that is voluntary—and relies on industry assurances of safety. FDA scientists found that these foods could pose serious risks, but have not undertaken any independent assessment of their safety before commercialization. Nor are there any long-term epidemiological studies examining the safety of human consumption of GE foods. Yet FDA decided against mandatory labeling of GE foods, and unsuspecting consumers by the tens of millions are now purchasing and consuming them in the marketplace. Without labeling, there is no ability to investigate potential links between consumption of GE foods and proliferating public health problems, such as food allergies.

All these and other failings have gone unaddressed because of faulty judgments and assumptions underlying the establishment of the original Framework.

The Fundamental Problems with the Coordinated Framework

Failure to Enact New Law(s) Addressing GE Organisms

The failure of the U.S., unlike most of the rest of the world, to enact new legislation to address GE organisms resulted in the application of laws that were written for different purposes, before GE technology was possible, creating oversight based on "square pegs in round holes." It has resulted in gaps, incoherence, agencies lacking relevant expertise, and the failure to keep pace with new technological developments, such as new methods and products of genetic engineering.

Failure to Address the Different and Novel Risks Posed by GE Organisms

Under the Framework, agencies were charged with using existing authorities to regulate GE organisms. The policy rested on the assumption that existing statutory authority was broad enough to address GE risks and impacts. While new authorities specifically geared to the regulation of GE organisms would be desirable, the agencies have failed to utilize the statutory authorities they do have, instead cabining them as applied to GE products, refusing to prospectively apply them, refusing to account for GE organisms' differences and novel risks, and leaving those risks unassessed. For example, the noxious weed authority of the Plant Protection Act would allow many types of known environmental harms of GE crops to be regulated by the U.S. Department of Agriculture (USDA). Also, FDA could regulate GE foods under the food additive provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), which would mandate more extensive tests and generate a safety approval by the agency, rather than the current abbreviated testing by industry and cursory agency review. FDA similarly has authority to require labeling of GE foods under the FFDCA. The self-cabined approach of regulatory review has hobbled the U.S. government's ability to address the novel impacts of GE organisms.

Failure to Use the Process of Genetic Engineering as the Trigger for Regulation

The Framework was based on the misguided "substantial equivalence" assumption—the assumption that GE products are the equivalent of natural organisms. As a consequence, agencies

do not use the process of genetic engineering as the trigger for regulatory oversight, as explicitly recommended by the National Academy of Sciences. This has two serious consequences. First, an increasing number of GE organisms (e.g., GE plants developed without plant pests) go completely unregulated. Second, even when GE organisms are regulated, the serious problems they cause (e.g., transgenic contamination, resistant pests) often go unaddressed. A new Coordinated Framework must ensure that all organisms developed by genetic engineering be regulated, and that each agency promulgate regulations that explicitly address the known and potential risks of GE organisms.

Failure to Embody the Precautionary Principle

After two-plus decades of research and commercialization, there are many established adverse impacts from GE organisms. But there is still much more that we do not know about their risks, since assessment and oversight is limited. But, unlike much of the rest of the world, the U.S. has eschewed the precautionary principle as way of making decisions in the face of scientific uncertainty about genetic engineering. Instead it has favored rapid, reckless commercialization. Reasonable precaution, based on established scientific theory or high quality research showing strong evidence of harm—but short of the near certainty that science often fails to deliver—is a scientifically and socially justifiable principle. The public should not have to accept substantial harm while waiting for final pieces of risk assessment research. Reasonable precaution favors public safety, while risk assessment without precaution favors premature advancement of industry products. The use of precaution is especially justified in agriculture because more sustainable farming systems that are less reliant on pesticides and GE crops have been shown to have multiple benefits, including high productivity and profitability, and less environmental harm compared to the current industrial agriculture that GE crops are designed to support. The U.S. takes a precautionary approach in many other oversight areas.

Voluntary, Not Mandatory, Regulation

The Framework is often thought to be a legal framework, but it is merely a "statement of policy" or guidance document, meaning it is a voluntary—not mandatory—standard. It has no "hard law" requirement for rigorous and adequate regulation.

Failure to Provide Transparency

Under the Framework, GE foods are not labeled, as they are in 64 countries around the world, leaving U.S. consumers in the dark. Without labeling there is no traceability or accountability for adverse effects on health. Neither does FDA publicly disclose the data provided to it by GE crop developers for its "voluntary consultation" process. USDA does not disclose locations of GE crop field trials to enable neighboring farmers to guard against transgenic contamination, nor does it monitor such GE crops to assess whether contamination has occurred, leaving the extent of contamination unknown. Independent academic study of GE crops and risks they may pose is impeded by biotech patents and contract control of GE seeds.

Failure to Regulate the Significant Adverse Impacts of GE Organisms

Over the life of the Framework, regulators have intentionally turned a blind eye to the significant adverse harms that we know GE crops cause, like transgenic contamination, the generation of resistant weeds, and massive increases in pesticide use. Agencies charged with preventing transgenic contamination have repeatedly failed to require adequate gene containment measures, leading to numerous GE contamination episodes that have cost U.S. farmers and the food industry billions in rejected export shipments, reduced prices, food recalls, and testing costs. At the experimental stage, agencies have allowed GE crop developers to essentially regulate themselves, or follow confinement recommendations not designed to reliably prevent contamination. At the commercial stage, the burden to prevent or respond to contamination has been entirely on the harmed community: traditional farmers. This defies basic principles of fairness, as well as venerable tenants of property law, and disadvantages one farming sector in favor of another. The companies that own the patented GE seed should be held legally responsible for addressing this problem through prevention and compensation of those harmed. Traditional farmers should not have to shoulder the burden of lost income due to GE contamination. There is also no monitoring of GE crops by the federal government after commercialization, despite agency post-market monitoring and adaptive response being a major recommendation of the 2002 National Research Council report on the regulation of GE crops.

Further, though herbicide-resistant GE crops make up the vast majority of all commercialized GE crops in the U.S., and their use has led to dramatic increases in pesticide use, the Environmental Protection Agency (EPA) does not evaluate or regulate the environmental risks of these crop systems under the pesticide laws. As a result, introduction of GE crops has fostered an epidemic of herbicide-resistant weeds and increasing herbicide use in response, which harms both farmers and the environment.

Framework for the Responsible Oversight of Genetically Engineered Organisms

The U.S. government must fix the failings of the biotechnology Framework, not double down on them. To do this, it should reject the misguided decisions upon which the 1986 Framework is based, and instead adopt and implement oversight principles that address GE organisms in a responsible manner, in line with that of the regulatory frameworks in other developed countries.

Now is the moment to correct those core errors and instead adopt governance principles that, when implemented through binding law, could begin to remedy previous errors. Accordingly, we call on the Administration to adopt a new *Framework for the Responsible Oversight of Genetically Engineered Organisms*, based on the following principles:

A Precautionary Foundation

A precautionary approach requires GE-specific oversight mechanisms that account for the unique characteristics of the GE organisms. Within those mechanisms, the protection of public health, farmers, and the environment should be the primary focus. The programs should encourage ongoing risk research and immediate action to mitigate impacts of potential risks.

Mandatory, GE-specific Regulation

Ideally, new legislation should be enacted that is GE-specific. Absent that, agencies should use the robust statutory authority they have to protect the food system, agriculture, and the environment. Regulation should be framed and implemented with the understanding that GE organisms present a greater potential for harms known in other contexts (e.g., herbicide-resistant weeds), but may also pose unfamiliar risks requiring different regulatory analysis, data, and mechanisms. Voluntary mechanisms, such as "statements of policy" or guidance, should not be relied upon. Rather, mandatory regulations at all agencies should be promulgated that fully address known risks and require more thorough testing to better detect and assess unfamiliar ones. Agencies should develop mandatory regulation for organisms developed using genetic engineering processes that independently evaluate engineered foods and organisms for risks, including food safety risks and direct and indirect environmental harm. Until proven safe, GE crops and animals should not be released into the environment or commercialized.

Health, Safety, and Environmental Protection Must Come First

Regulation should prioritize health, safety and environmental protection over commercialization and development interests. This includes both regulation as well as risk research and funding.

Transparency

Assessment and oversight requires mechanisms ensuring transparency throughout the food system and regulatory process, including labeling of GE products, making industry submissions to regulators available to the public for comment, and allowing independent research to be undertaken.

Manufacturer Liability and Fundamental Fairness

Biotech companies that make and sell GE organisms should be held liable for the significant losses their products impose on organic and traditional farmers. Traditional farmers' rights and seed, fish, and livestock choice should be protected and contamination of non-GE crops or animals prevented. The burden of contamination prevention should be shouldered by those companies profiting from the sales of GE organisms, not by those harmed by contamination.

Public Participation and Inclusion of Broader Socioeconomic Concerns

Consideration of genetic engineering's significant effects, including social impacts, should occur at each stage of the regulatory process. Public participation in the regulatory process must be meaningful, timely, and full. When evaluating any alleged future benefits of GE crops, standards of comparison must meaningfully include the kinds of successful sustainable agricultural systems that are emerging and necessary for the future viability of our food production and rural communities, such as organic and agroecological-based farming. Unsustainable and harmful industrial agriculture must not be the accepted standard of comparison against which GE crops, or the pesticides used on them, are judged to be needed and useful.

Conclusion

After 30 years of experience, we now know the consequences of relying on the current deeply flawed Framework to oversee a new and complex technology: public mistrust of the food system, the emergence of untested products with unknown health and environmental risks, soaring pesticide use, epidemic emergence of resistant weeds and pests, damaged relationships with trading partners, and unfair economic burdens on hardworking farmers. However, we now have a long-overdue opportunity to jettison the Framework, and replace it with a responsible regulatory system that adequately addresses both current products and anticipated new GE techniques and organisms. We can do that by promulgating a new Framework consistent with the principles outlined above to produce a strong, protective, and well-designed system for regulation of GE organisms.

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Center for Food Safety
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