



November 1, 2016

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; Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology

On behalf of the represented member organizations of the National Sustainable Agriculture Coalition (NSAC), we submit the following comments on the Office of Science and Technology Policy (OSTP) request for stakeholder input on the draft Coordinated Framework for the Regulation of Biotechnology and the Long-Term Strategy for the Regulation of the Products of Biotechnology.

NSAC is a grassroots alliance that advocates for federal policy reform that supports the long-term social, economic, and environmental sustainability of agriculture, natural resources, and rural communities. NSAC member organizations are leaders in the sustainable agriculture and food systems sector, and have worked with farmers and communities to pioneer practices, systems, and supply chains that support the multiple goals of sustainability. These include certified organic, sustainable, non-genetically engineered, and farm identity-preserved products, systems, and supply chains that are impacted by the regulation of genetically engineered (GE) organisms, or lack thereof.

Many of the farmers that NSAC works with and represents choose to grow only non-GE crop varieties because the markets they serve demand GE-free products; because they have concerns about potential adverse health, environmental, or agronomic impacts of GE crop technologies; or because they are USDA certified organic and not allowed to grow GE crops. These producers sustain substantial economic losses when their products contain unintended GE material at levels exceeding market or organic certifier specifications.

In addition, exposure of organic or non-GE fields to GE pollen, pesticides, and herbicides from neighboring farms using GE crop technology packages can lead to adverse ecological and agronomic consequences for the non-GE producer, as well as tensions among farmers. Thus, the outcomes of biotechnology regulation directly impact the economic, environmental, and social sustainability of our nation's agriculture and rural communities, and are therefore of great concern for NSAC.

In our comments submitted to the Coordinated Framework docket nearly one year ago (and included as an Appendix to this docket), we made several recommendations. Unfortunately, many of those recommendations do not appear to have been considered seriously in developing this draft update to the Coordinated Framework, or the accompanying long-term National Strategy. We believe these recommendations remain relevant as the agencies make final changes to these documents and their coordinated approach to biotechnology regulations.

First, we recommended that the agencies provide a timeline that illustrates actual and contemplated GE-related actions across agencies, and explains their relation to one another to

improve transparency, stakeholder engagement, and streamlining of inter-agency actions. The fact that this draft was released while the Office of Management and Budget (OMB) reviews USDA's new proposed rule governing biotechnology regulations, yet makes no mention of this nor the relationship between these agency actions, serves to underscore the critical need for timely, transparent, and coordinated information across agency activities related to genetic engineering. The National Strategy document states the agencies intention to establish a "timetable" to work with stakeholders and increase transparency, but there is no information regarding this timetable beyond that statement. The tables provided in the Coordinated Framework update provide information on the agencies' respective roles, but it does not explain those roles in the context of *current and anticipated actions*. More can and should be done to provide this information in user-friendly ways.

We note with approval the annual reporting for Congress that will occur over the next five years, particularly that the annual report could include "a concrete list of regulatory and other activities and timeframes." We assert that this report *should* include this information, and we strongly encourage the agencies to do so, in the same manner that such information be relayed to the public.

Second, we recommended that the agencies use this process to develop a comprehensive and robust regulatory framework for GE technologies and products. With the USDA proposed rule at OMB, it is clear that changes to the regulatory framework are coming, and it is critical that the Coordinated Framework consider the needed changes to the oversight of GE organisms. We refer the agency to our earlier comments on agricultural "coexistence," included here as an appendix, for the aspects we believe are imperative to a robust regulatory framework.

Third, we recommended that the Coordinated Framework ensure that the combined impacts of crop technology packages are fully assessed by better coordinating the agency review processes, in particular by requiring aligned evaluations of the environmental, social, ecological, and economic impacts of the full crop technology package prior to deregulation. This should occur across agencies. USDA and EPA, for example, should ensure herbicide labels are regulated in close coordination with the deregulation of the trait. We do not see how the revised Coordinated Framework will carry out this critical role.

Fourth, we recommended that OSTP oversee a public education period to explain in simple terms the risks and benefits of any particular approach to product- versus process-based regulations in order to assist the public in evaluating the various options for the regulation of biotechnology – including product, process, hybrid, or alternative approaches. As part of that process, OSTP, USDA, EPA, and FDA should provide the public with clear, objective information assessing the relative risks and benefits of each approach, followed by another opportunity to provide comment. The Coordinated Framework does not appear to heed this request that increased information be made available to stakeholders on the merits of the various regulatory approaches being considered. There is some discussion about providing user-friendly tools to explain agency *decisions* to the public, but not about providing the public with better information to inform their participation in rulemaking processes.

Fifth, we recommended that the agencies improve data collection and analysis on the long-term direct and indirect environmental and economic implications of GE crop packages, and – as part of a long-term strategy – prioritize and coordinate research on the environmental impacts of biotechnology, including effective contamination prevention strategies. By collecting, compiling, and analyzing data, the agencies will better understand the scope of GE contamination and best practices for preventing contamination in the future. We believe OSTP has a vital role to play in the compilation and dissemination of this data.

We note with approval the intention presented in the updated draft Coordinated Framework that the agencies are committed to relying on the best available science, and will “develop a coordinated and goal-oriented plan for supporting the science that informs regulatory activities with regard to the assessment of biotechnology products, and to reflect these priorities in agency budget submissions.” And the agencies intend “to adjust activities based on experience with specific products and the environments into which those products have been introduced.” However, the drafts are short on details as to how these intentions will be carried out, and we are concerned that stakeholder input – particularly from stakeholders representing farmers that do not use GE crop technologies – will not be adequately integrated into these research or data collection plans, not to mention the mechanisms by which agency activities will be “adjusted.” **We urge the agency to elaborate on these plans and mechanisms in the final Coordinated framework.**

A comprehensive regulatory framework and approach to scientific analysis and data collection should address not only the regulation of the technology and products, but also the secondary environmental and socioeconomic impacts of the full technology package’s use in the field. Research is specifically needed to inform contamination prevention strategies. **We urge the agencies to include in the research plan a process to fully analyze the long-term direct and indirect environmental effects of GE contamination and the implications of managing GE crops, including the increased risk of pesticide drift, the development of pest resistances, and the scope of contamination.**

Indeed, an effective long-term strategy requires both consideration of the users of biotechnology products, and also those that may be indirectly impacts by others’ use of such technologies. **Accordingly, we recommended that the agencies use the long-term strategy and Coordinate Framework process to guide a way to mandate best practices to prevent GE contamination by farmers who use GE seed and require concrete contamination prevention measures on those farms to supplement measures already used by organic and other non-GMO producers.** Moreover, the long-term strategy should include a process by which the agencies develop a compensation mechanism based on a fund model and should rely on GE patent holders to provide the majority of funds to compensate for losses of GE contamination.

We assert that the current biotechnology regulatory framework fails to fully assess the combined impacts of crop technology packages and protect all farmers from economic losses due to the unintended presence of GE material in farm products. We believe that all producers should feel secure that their choices of production system and markets will not be compromised or foreclosed due to the impacts of contrasting production systems employed by other producers. Robust regulatory improvements are necessary to prevent contamination to begin with and place responsibility with the patent holders, not the farmers affected by contamination. Given that this is just a draft update to the Coordinated Framework, we believe there is still time for the agencies to provide additional detail and put these critical ideas and processes in motion before the Coordinated Framework is finalized.

NSAC and the farm, food, and rural organizations we represent wish to remain engaged in the conversation as OSTP, USDA, FDA, and EPA work together to improve the Coordinated Framework for biotechnology regulations and create a long-term strategy that truly allows all sectors of American agriculture to thrive. We thank you for giving serious consideration to our recommendations.



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