Building on 30 Years of Experience to Prepare for the Future of Biotechnology

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Summary: EPA, FDA, and USDA unveil two documents as part of the Administration's continuing effort to modernize the Federal regulatory system for biotechnology products.

Today, the Federal government has taken an important step to ensure public confidence in the regulatory system for biotechnology products and to improve the transparency, predictability, coordination, and, ultimately, efficiency of that system.

In 1986, the White House Office of Science and Technology Policy (OSTP) issued the Coordinated Framework for the Regulation of Biotechnology, which outlined a comprehensive Federal regulatory policy for ensuring the safety of biotechnology products. The Framework was updated in 1992. The oversight system established by the Coordinated Framework led, in part, to decades of development and commercialization of biotechnology products with applications in medicine, agriculture, energy, biomanufacturing, and environmental protection. It also contributed to the growth of a large and competitive biotechnology sector in the United States and worldwide.

Advances in science and technology have dramatically altered the biotechnology landscape since 1992. The complexity of the array of regulations and guidance documents developed by the three primary Federal agencies with jurisdiction over biotechnology products—the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA)—can make it difficult for the public to understand how the safety of biotechnology products is evaluated. Navigating the regulatory process for these products can be challenging, especially for small companies.

For these reasons, last year the Administration initiated an effort to modernize the regulatory system for biotechnology products by asking the EPA, FDA, and USDA, to accomplish three tasks:

- clarify the current roles and responsibilities of the EPA, FDA, and USDA in the regulatory process;

- develop a long-term strategy to ensure that the Federal regulatory system is equipped to efficiently assess the risks, if any, of the future products of biotechnology; and
- commission an expert analysis of the future landscape of biotechnology products.

To accomplish these tasks, EPA, FDA, and USDA spent the last 14 months performing a detailed analysis of the Federal system for regulation of biotechnology products, including by reviewing more than 900 comments that were submitted in response to a Request for Information that was posted last fall, and interacting with members of the public at three public meetings that were held in different regions of the country.

Clarifying current roles and responsibilities

Today's proposed Update to the Coordinated Framework represents the first time in 30 years that the Federal government has produced a comprehensive summary of the roles and responsibilities of the three principal regulatory agencies with respect to the regulation of biotechnology products. The proposed update offers the public a complete picture of a robust and flexible regulatory structure that provides appropriate oversight for all products of modern biotechnology. Within that regulatory structure the Federal agencies maintain high standards that, based on the best available science, protect health and the environment, while also establishing transparent, coordinated, predictable and efficient regulatory practices.

In order to help product developers and the public understand what the regulatory pathway for products might look like, this proposed Update to the Coordinated Framework presents information about agency roles and responsibilities in several forms, including:

- graphics that illustrate agency-specific overviews of regulatory roles;
- case studies that demonstrate how a product developer might navigate the regulatory framework, and;
- a comprehensive table that summarizes the current responsibilities and the relevant coordination across EPA, FDA, and USDA for the regulatory oversight of an array of biotechnology product areas.

This comprehensive set of information should also give the public the confidence that products that are making it to market have been appropriately reviewed for safety.

The Administration is seeking public comment on this proposed Update to the Coordinated Framework, and will finalize it taking into account comments received. Once the notice of request for public comment has posted in the Federal Register, the public will have 40 days from the date of publication to comment. To submit comments, follow the instructions in the notice.

Preparing for the future

The *National Strategy for Modernizing the Regulatory System for Biotechnology Products* sets forth a vision for ensuring that the Federal regulatory system is equipped to assess efficiently the risks, if

any, associated with future products of biotechnology while supporting innovation, protecting health and the environment, maintaining public confidence in the regulatory process, increasing transparency and predictability, and reducing unnecessary costs and burdens. In the *Strategy*, the Federal agencies demonstrate their sustained commitment to ensure the safety of future products of biotechnology, increase public confidence in the regulatory system, and prevent unnecessary barriers to future innovation and competitiveness.

The *Strategy* highlights many existing and new activities at EPA, FDA, and USDA, including the following key commitments:

- EPA, FDA, and USDA will review existing communication tools and, as appropriate, may revise existing or develop new user-friendly sources of regulatory information for product developers and the general public.

- EPA, FDA, and USDA are emphasizing their commitments to interagency communication and collaboration in order to make timely decisions on regulatory jurisdiction for biotechnology products and to optimize the review and use of scientific data for regulatory assessments.

- EPA and FDA intend to clarify their respective approaches for oversight of products developed using genome editing techniques, including, for example, pesticidal products at EPA and genetically engineered animals at FDA.

- EPA, FDA and USDA will continue to examine their regulatory structures with the goal of clarifying how the U.S. Federal Government will regulate genetically engineered insects in an integrated and coordinated fashion to cover the full range of potential products.

- EPA, FDA, and USDA commit to reporting annually, for at least the next five years, on specific steps that they are taking to implement the *Strategy*, as well as any additional actions being taken to improve the transparency, predictability, and efficiency of biotechnology regulation and the coordination among the regulatory agencies.

- EPA, FDA, and USDA will continue to provide leadership in international fora to promote scientific competency, understanding of the U.S. regulatory approach, and regulatory compatibility worldwide for biotechnology products.

- EPA, FDA, and USDA commissioned a study by the National Academy of Sciences, entitled "Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System." A report is forthcoming, which will be used by the EPA, FDA, and USDA to inform ongoing and future agency activities.

We want to hear from you

The documents released today represent major steps forward for the Federal government's effort to modernize the regulatory system for biotechnology products.

But, there is more to be done. In the *Strategy*, the agencies have identified areas where additional work is needed, including the key commitments highlighted above. These ongoing and future activities, along with the commitment from the agencies to report annually on implementation progress, provide direction for the federal regulatory system for biotechnology products to keep pace with advances in science and technology.

We also need continued engagement from key stakeholders, including public and private organizations such as companies, universities and research institutes, trade associations, scientific societies, foundations, consumer organizations, non-profits, and individual citizens.

The Administration looks forward to receiving feedback on the proposed Update to the Coordinated Framework.

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