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GMOs in the Hotseat: White House to Overhaul Regulatory Framework on Biotechnology

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Last week, the White House waded into the GMO regulatory fray with the Office of Science and Technology Policy's (OSTP) announcement of a major overhaul of GMO regulation.

In a **statement** released July 2, OSTP noted that the current regulatory system for "biotechnology products" (defined for this purpose as products created through genetic engineering of plants, animals, and microbes), governed by the Coordinated Framework for the Regulation of Biotechnology (CF), creates "unnecessary costs and burdens." It also is difficult for laypeople to understand, thus undermining public confidence in the safety of such products. The White House science advisors are calling for an "update of the CF [...] to facilitate the appropriate Federal oversight by the regulatory system and increase transparency, while continuing to provide a framework for advancing innovation."

Under the current Framework, USDA, EPA, and FDA rely on their traditional statutory authorities and roles to regulate biotechnology products: USDA has authority to approve all releases of GMOs to ensure they don't create an environmental hazard; EPA must approve all crops that contain insect-killing genes; and FDA is responsible for evaluating whether GMOs are safe to eat. In some cases the jurisdictional lines have been unclear, and new technological advancements are making possible developments that were not conceived when the original CF was issued in 1986 (or revised in 1992).

To begin improving predictability, increasing efficiency, and reducing uncertainty in the regulation of biotechnology products, OSTP's memo laid out the following one-year objectives for a new Biotechnology Working Group:

1. Develop an updated CF to clarify the roles and responsibilities of USDA, EPA, and FDA in regulating biotechnology products;
2. Formulate a long-term strategy to ensure that the Federal regulatory system is equipped to efficiently assess the risks, if any, associated with future products of biotechnology while supporting innovation, protecting health and the environment, promoting public confidence in the regulatory process, increasing transparency and predictability, and reducing unnecessary costs and burdens; and
3. Commission an external, independent analysis of the future landscape of biotechnology products (to be undertaken by the National Academies).

The Biotechnology Working Group will consist of representatives from the three affected Federal agencies and the Office of the President. The recent memo also announced three public listening sessions, starting with one in Washington, D.C., in the Fall of 2015, to seek input on the best ways to clarify the current roles and responsibilities of the USDA, EPA, and FDA in the regulatory process. The updated CF will also undergo public notice and comment before it is finalized.

Meanwhile, the tide of GMO legislation at the **Federal** and **State** continues, with Representative Pompeo's "Safe and Accurate Food Labeling Act" (**H.R. 1599**) continuing to gain momentum in the House and a companion bill expected shortly in the Senate.

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