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ALERT

President Trump Issues Executive Order on Modernizing the Regulatory Framework for U.S. Agricultural Biotechnology Products

June 14, 2019

On June 11, 2019, President Trump signed a Presidential Executive Order (EO) mandating that U.S. Federal regulatory agencies implement specific policies to modernize the regulatory framework applicable to agricultural biotechnology. *Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products*.[1] The EO directs the Secretary of the Department of Agriculture (USDA), the Administrator of the Environmental Protection Agency (EPA), and the Commissioner of the Food and Drug Administration (FDA) to take specific actions to facilitate science-based, timely, efficient, and transparent oversight of products agricultural biotechnology.[2] We strongly recommend that the ag biotech industry continue to work with these agencies to ensure implementation of the EO's directives.

It is important to note that the EO states explicitly that it is the policy of the Federal Government "to protect the public health and the environment by adopting regulatory approaches for the products of agricultural biotechnology that are proportionate responses to the risks such products pose, and that avoid arbitrary or unjustifiable distinctions across like products developed through different technologies." Although this has been the stated policy of the U.S. Government since the issuance of the Coordinated Framework in 1986 and 1992, the goal of a risk-based regulatory approach that does not impose greater burdens on the products of genetic engineering has never been fully achieved across the Federal government.

Practice Areas

Environment & Product Regulation

The EO mandates specific actions by the Coordinated Framework agencies to achieve the goal of a fully risk-based regulatory approach to the products of agricultural biotechnology:

First, by December 8, 2019, USDA, EPA, and FDA must (1) identify relevant regulations and guidance documents that can be streamlined to ensure that products of agricultural biotechnology are regulated consistent with the EO's stated policy and (2) take the steps "appropriate and necessary" to accomplish such streamlining.[3] The agencies must use their existing authorities to exempt "low-risk" ag biotech products from "undue regulation." This directive provides a time-sensitive opportunity for the ag biotech industry to engage with the agencies to meet the goal of establishing concrete, realistic regulatory reforms that will result in streamlining regulatory requirements applicable to ag biotech products. The agencies will need this outside assistance to meet the December 8 deadline.

Second, the EO addresses genome edited ag biotech products specifically. The EO requires USDA, EPA, and FDA to conduct a review of regulations and guidance that may apply to "genome-edited-specialty-crop-plant products"[4] that are "designed to have significant health, agricultural, or environmental benefits." Each agency must "take steps to update its regulations and guidance, as necessary and appropriate, to remove undue barriers that impede small, private United States developers, the United States Government, and academic institutions from bringing innovative and safe genome-edited-specialty-crop-plant products to the marketplace." Notably, USDA already has taken the lead in issuing a policy statement that the agency would not regulate genome edited plants (and plants altered by other new breeding techniques) differently, if such plants could have been developed through traditional breeding techniques.[5]

The Executive Order highlights the importance of these regulatory changes applicable to genome editing by requiring that every 90 days for the two years following the issuance of the Executive Order, each of the agencies provide to the Director of the Office of Management and Budget, the Director of the Office of Science and Technology Policy, the Assistant to the President for Economic Policy, and the Assistant to the President for Domestic Policy, an update of the progress meeting these requirements.

Third, by December 8, 2019, USDA, EPA, and FDA, along with "any other Administration officials that the Secretary deems appropriate," are to coordinate the development of an action plan to "facilitate engagement with consumers in order to build public confidence in, and acceptance of, the use of safe biotechnology in agriculture and the food system." This consumer engagement plan is an exceedingly important aspect of the EO. No matter how many regulatory agencies and scientific bodies worldwide confirm both the safety and environmental benefit of genetically altered food, if large numbers of individuals believe false information spread by anti-science activists on social media, wide acceptance of ag biotech products will continue to be inhibited. We recommend that clients work together with the agencies to develop this engagement plan. Ultimately, we predict that the ag biotech community will be the driving force behind this communication strategy, which will be crucial to the success of the deregulatory directives.

In developing the consumer engagement action plan, the agencies must consider supporting research and

education on effective science communication; developing educational materials that integrate agricultural biotechnology into science education; creating consumer-facing web content; and developing other outreach materials that clearly communicate the demonstrated benefits of agricultural biotechnology, the safety record of the regulatory system, and how biotechnology can address agricultural challenges. In addition, the development of the action plan must take into account FDA's and USDA's existing Agricultural Biotechnology Education and Outreach Initiative. USDA also must coordinate with State leaders in public health and agriculture in developing the strategy.

Fourth, by October 9, 2019, USDA and the State Department, in consultation with the United States Trade Representative (USTR), EPA, FDA, and any other appropriate agencies, are to develop an international communications and outreach strategy to facilitate engagement abroad with policymakers, consumers, industry, and other stakeholders. The goal of this strategy is to increase international acceptance of ag biotech products to open and maintain markets for United States agricultural exports abroad. Thus, it is essentially the international version of the above domestic outreach and education effort. Non-science-based views of ag biotech by foreign governments, their citizens and international institutions are a significant barrier to exports of U.S. ag biotech products. As with the case of the domestic outreach and education effort, clients should work with the involved agencies to effectively develop, support, and disseminate this messaging.

Finally, also by October 9, 2019, USTR, in consultation with USDA, the State Department, and other agencies involved in developing U.S. trade policy, is required to develop an international strategy to remove unjustified trade barriers and expand markets for ag biotech products. Although USTR and other agencies have often been successful in eliminating foreign countries' trade barriers against U.S. ag biotech products, many countries still have baseless or otherwise discriminatory policies. This requirement also ensures that all involved U.S. government agencies fully support efforts to expand U.S. ag biotech product exports. This is a good opportunity for clients to engage and educate USTR and other agencies about the trade barriers they face and ensure that ending those barriers is part of the U.S. government's overall strategy.

[1] The Executive Order is available at https://www.whitehouse.gov/presidential-actions/executive-order-modernizing-regulatory-framework-agricultural-biotechnology-products/.

[2] Defined as "a plant or animal, or a product of such a plant or animal, developed through genetic engineering or through the targeted in vivo or in vitro manipulation of genetic information, with the exception of plants or animals, or the products thereof, developed for non agricultural purposes, such as to produce pharmaceutical or industrial compounds."

[3] We understand that the identified regulations and guidance must be "streamlined" in that timeframe, to the extent the law permits.

[4] The Executive Order does not define "genome-edited-specialty-crop-plant products," but we understand the term to include any genome-edited agricultural crop and not be limited to some subset of genome-edited plants.

[5] Secretary Perdue Issues USDA Statement on Plant Breeding Innovation.