July 22, 2022

BEGIN U.S. COMMENTS

The United States and the European Union share a common goal in ensuring that food systems are secure, sustainable, and resilient in the face of significant global challenges, such as climate change and increasing food insecurity. We agree with the European Union's view that new genomic techniques (NGTs), such as genome editing, provide significant potential to help achieve shared goals, and offer the following comments in support of the European Union's initiative to evaluate and update its current approach to these technologies and their products.

The United States encourages science-based and risk-based policy approaches for innovative technologies and their products. The three primary agencies in the United States with responsibilities for regulation of biotechnology products are the U.S. Environmental Protection Agency (EPA), U.S. Food and Drug Administration (FDA), and U.S. Department of Agriculture (USDA). U.S. regulatory agencies have nearly three decades of experience on the evaluation and safe use of products of biotechnology and have extensive experience with products produced by technologies that would meet the European Union's definition of NGTs. We agree with the conclusion in the 2021 European Food Safety Authority Scientific Opinion that "plants obtained by targeted mutagenesis and cisgenesis can have the same risk profile as plants produced with conventional breeding".

The USDA Animal and Plant Health Inspection Service's revised 2020 regulations on plants demonstrate that a science-based, risk-based, and transparent policy approach for innovative biotechnology products fosters the efficient introduction of new, effective products to the market, thus enhancing food security. Prior to the 2020 revision, only a few large companies were able to routinely navigate the USDA regulatory process, typically limiting new product development to the most widely planted crops with traits for insect and herbicide resistance. Under the revised regulations, USDA is implementing a product-based system that is based on the combination of the plant, trait, and mechanism of action and includes exemptions for plants that have certain modifications achievable through conventional breeding or that USDA previously evaluated and determined were safe for agriculture and the environment. These changes reduce regulatory burden without compromising safety and have resulted in a greater number of small companies and research institutions using biotechnology to foster innovation in a wider variety of both plant species and types of traits produced, including products directly aimed at addressing food security and the impact of climate change on agriculture.

The EPA and FDA are currently considering their regulatory approaches to innovative biotechnology products. In 2019, FDA completed a voluntary premarket consultation on food from a genome-edited soybean with modified fatty acid composition, performing a food safety assessment that was science-based and focused on the objective characteristics of the resulting food, consistent with FDA's longstanding policy on foods derived from new plant varieties. FDA intends to take lessons learned from its experience to clarify how its existing policy approach applies to food from genome-edited crops. In October 2020, EPA proposed exemptions for certain plant-incorporated protectants (PIPs) based on sexually compatible plants created through biotechnology. EPA is currently working on finalizing guidance for these exemptions.

The United States welcomes the opportunity to engage with the European Commission, including in regulator-to-regulator discussions, on policies that relate to transparency, traceability, and labeling of the products that would meet the EU's definition of NGTs in the marketplace. The current U.S. regulatory approach to biotechnology does not require the traceability or labeling of some products of targeted mutagenesis and cisgenesis. Negative public perception of biotechnology can pressure regulators to take approaches that are not science-based or risk-based, and do not increase the level of protection for consumers. Likewise, regulatory systems that lack transparency reduce public trust in decision-making, delay product adoption, and disrupt trade. We encourage the European Commission to take an approach that further strengthens public trust in the decisions under its regulatory authorities. We believe that the European Commission could achieve its goals by further aligning its policy approach with major biotechnology producing countries, such as the United States, that have a strong record of the safe use of these products. We also believe increased predictability of the European Union's comitology process and support for science-based safety findings would strengthen public perception of the policy decisions taken by the European Commission.

The United States and the European Union have a shared interest in developing regulatory approaches to products of biotechnology that ensure that their benefits be made widely available to farmers and food producers of all sizes and sectors to enhance the sustainability of agriculture and food systems. Globally, over 25 years of scientific examination and commercial production have demonstrated the safety of products of biotechnology. These products have enhanced sustainable agricultural practices by providing farmers and producers with additional tools to address pest and disease management issues, foster climate-smart production practices such as no-till agriculture, and enable water conservation. Newer technologies, including genome editing, offer new opportunities to enhance sustainability. This includes plant traits that can increase drought tolerance, enhance nutrient profiles, mitigate industrial waste, and help prevent consumer waste are currently under development. Innovative biotechnology approaches are also being used to develop nutritionally fortified tomatoes, stem rust-resistant wheat, and drought- and heat-resistant wine grapes. Significantly, many of these innovations are being jointly developed by United States and European public research institutions. Burdensome regulatory requirements for the approval, cultivation, and marketing of new products are likely to inhibit innovation, and disadvantage producers of minor, specialty, traditional, and other crops not widely produced.

The United States would like to underscore our mutual interest in innovative biotechnology products, the considerable potential they offer to advance agricultural innovation, and the opportunities we jointly have to address key agricultural challenges such as food security, sustainability, and climate adaptation. We look forward to further discussions with the European Union on the important questions raised in this public consultation. We believe that increased cooperation will ensure that farmers globally have the tools needed to produce abundant, safe, and affordable crops for food, feed, fiber, and energy to the benefit of consumers in the European Union, the United States, and around the globe.

END U.S. COMMENTS