

March 9, 2017

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852.

Re: *FDA-2016-N-4389: Genome Editing in New Plant Varieties Used for Foods; Request for Comment*

To whom it may concern:

Thank you for the opportunity to provide information to the Food and Drug Administration (FDA) on the use of genome editing techniques to produce new plant varieties that are used for human or animal food. It is our intent to provide answers and supporting information that address the complexities of the questions and topics posed by FDA in the Request for Comment. For this reason, we are requesting the deadline for comment on FDA-2016-N-4389: Genome Editing in New Plant Varieties Used for Foods be extended to at least June 19, 2017.

We are also seeking this extension to foster greater coordination between regulatory agencies that participated in development of the White House Office of Science and Technology Policy (OSTP) September 2016 report titled "National Strategy for Modernizing the Regulatory System for Biotechnology Products" (the Strategy) that provides a roadmap for updating the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework). In the Strategy, FDA, the Environmental Protection Agency (EPA) and the Department of Agriculture (USDA) committed to clarifying their policies for the regulation of products derived from genome editing techniques. A foundational principal of the Coordinated Framework is that similar products should be treated the same by regulatory agencies. As part of the Strategy, the three agencies also committed to increased coordination of their activities related to regulation.

On January 19, 2017 USDA published a proposed rule titled "Importation, Interstate Movement, and Release Into the Environment of Certain Genetically Engineered Organisms" to update its regulation of genetically engineered organisms under 7 CFR Part 340 (APHIS-2015-0057-0016). Comments for this proposed rule are currently due on June 19, 2017. In order to align the work of the two agencies, we request an extension of the comment period for FDA-2016-N-4389: Genome Editing in New Plant Varieties Used for Foods to at least June 19, 2017.

On January 19, 2017 the FDA released draft guidance for industry (GFI) #187 titled "Regulation of Intentionally Altered Genomic DNA in Animals" which also relates to the regulation of gene editing technology. We are supportive of a parallel request to extend the comment period for that draft guidance to at least June 19, 2017.

The undersigned organizations strongly support a robust commitment to science, research and agricultural innovation by the US government so that scientists, farmers and ranchers have access to the best tools and our customers continue to have access to a wide variety of safe and affordable food. These same organizations also strongly support active engagement by the U.S. Government with our trading partners around the world to secure as much alignment and coherence in regulatory policies as

possible so that trade in U.S. commodities and seed are not hindered nor disrupted. The granting of this extension request will help us simultaneously provide thoughtful comments to both FDA and USDA on proposed regulatory frameworks for foods, plants and animals derived from gene editing techniques.

Sincerely,

Agricultural Retailers Association
American Farm Bureau Federation
American Seed Trade Association
American Society of Plant Biologists
American Soybean Association
American Sugarbeet Growers Association
Biotechnology Innovation Organization
Crop Science Society of America
National Association of State Departments of Agriculture
National Association of Wheat Growers
National Corn Growers Association
National Cotton Council
National Council of Farmer Cooperatives
National Grain and Feed Association
National Oilseed Processors Association
National Potato Council
National Sorghum Producers
Produce Marketing Association
Samuel Roberts Noble Foundation
United Fresh Produce Association
US Grains Council
USA Rice
Western Growers

Cc. Leslie Kux, FDA Associate Commissioner for Policy and Acting Deputy Commissioner for Policy,
Legislation, and Analysis
Jason Dietz, Center for Food Safety and Applied Nutrition
Kathleen Jones, Center for Veterinary Medicine