

June 19, 2017

The Honorable Sonny Perdue
Secretary
United States Department of Agriculture
Jamie L. Whitten Federal Building
1400 Independence Avenue SW
Washington, DC 20250

Re: Proposed revisions to USDA agricultural biotechnology regulations (7 CFR part 340), Evaluation of Existing Regulations; Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms, Docket No. APHIS-2015-0057

Dear Secretary Perdue:

We, the undersigned organizations, are pleased to submit these comments in response to the United States Department of Agriculture's (USDA) request for public input on the proposed revisions to its biotechnology regulations (7 CFR part 340). Our member organizations represent a broad cross-section of stakeholders having a significant interest in the future of U.S. agriculture. In addition to the comments here, many of the organizations listed below intend to submit additional comments to the record reflecting the individual perspectives of our organizations.

Our organizations each have a major stake in the ability of U.S. growers to have access to products of cutting-edge technologies, as well as fostering continued public confidence in the U.S. regulatory system and in preserving U.S. access to international markets. Innovative plant and animal breeding methods hold enormous promise for improving the productivity and environmental sustainability of food, feed, fiber, horticulture, biofuels, health, and animal production. We are fully committed to engaging constructively with the USDA Animal and Plant Health Inspection Service (APHIS) to help the agency reach its regulatory goals, including development of a successful, broadly-supported system of regulation that provides risk-appropriate oversight consistent with the need for growers to have timely, reliable access to the products of innovative breeding techniques without disrupting access to markets.

We are supportive of USDA's efforts to modernize its regulations, ensuring that they are up-to-date with the best-available science and utilize the more than 30 years of experience USDA has in reviewing the safety of these crops. We believe it is imperative USDA not only continues its important work to "right size" its oversight of agricultural biotechnology and other biology-based plant breeding innovations, but also provides strong leadership and vision to encourage other U.S. regulatory agencies as well as foreign governments to adopt consistent or compatible approaches.

The proposed revisions to USDA biotechnology regulations, published at the end of the previous administration, take some very positive steps in the right direction. USDA should be commended for making bold moves in proposing new regulations. The proposed revisions send clear, positive signals about the need to foster innovation by ensuring such regulatory oversight is proportional to actual risk— a message we strongly support. We also particularly appreciate the strong position USDA provided regarding the exclusion of products of newer breeding methods such as gene editing from the regulation based on the similarity of many products developed using these methods when compared to those developed using more traditional plant breeding methods.

Despite these positive aspects, regrettably, we believe that the regulatory system proposed by USDA has significant shortcomings that could make it harder for USDA to meet its goals. The following shortcomings are significant enough that we are unable to support the regulatory revisions as proposed:

- Researchers and developers cannot learn the regulatory status of new genetically engineered (GE) organisms without undergoing complex and lengthy risk assessments, providing little transparency and clarity about which products will actually be subject to regulation, and risking arbitrariness.
- Risk assessments would be conducted for plant products, merely based upon the technology used in their production, regardless of the actual risk posed by the product. This runs counter to USDA's 30+ years of experience regulating products of biotechnology.
- The proposed system shifts regulatory burden from commercialization stages to research and development phases of product innovation. Each new GE plant variety will have to undergo complex risk assessment and public comment before a single plant can even be planted in a small-scale field trial.
- The proposed assessment process is unlikely to have the throughput capacity to accommodate the scale of U.S. research and development, potentially leading many products to be trapped in regulatory limbo while their regulatory status is being assessed.
- The proposed system would be a significant expansion of the authorities under Part 340, creating a redundant weed risk regulatory process, which currently works under USDA's Part 360 regulations. The merging of the Part 360 authority into Part 340 would add significant complexity and raise barriers to innovation. We urge USDA to maintain the distinction between these two authorities.
- The significant departure from the current regulatory system may have unintended consequences for other regulatory agencies, and domestic and international markets, and lead to significant new litigation risks.

We are concerned that these flaws will have a significant negative impact on innovation, particularly for small companies and universities hoping to develop agricultural products for specific regional or environmental needs or to develop minor use crops that could be important domestically and internationally. Ultimately, we believe that problems with USDA's proposed regulatory system are significant enough that USDA will need to substantially revise the proposed rule in order to address them.

In the meantime, university and private plant breeders urgently need certainty regarding the regulatory status of new varieties of plants developed using tools such as gene editing. USDA should use the rationale described in the proposed rule for the exclusions to the definition of "genetically engineered organism" and their responses to the "am I regulated" inquiries to make a clear policy statement on applications of gene editing. Equally important, USDA should actively champion its proposed approach in ongoing international discussions.

The new administration has an opportunity to refine the proposal laid out by the previous administration to set a path forward for agricultural biotechnology and products derived from other precision breeding tools. We believe USDA can better meet its goals with fewer risks and disruptions by charting a different regulatory course, and we look forward to continuing to engage with USDA in its policy dialogue with a broad array of stakeholders and interests to identify the best path forward.

Signed,

Agricultural Retailers Association
Alabama Farmers Federation
American Farm Bureau Federation
American Feed Industry Association
American Phytopathological Society
American Seed Trade Association
American Society of Plant Biologists
American Soybean Association
American Sugarbeet Growers Association
AmericanHort
Arizona Farm Bureau Federation
Arkansas Farm Bureau Federation
Arkansas Soybean Association
Association of Public and Land-grant Universities
Bio Nebraska Life Sciences Association
Biocom
BioNJ
Biotechnology Innovation Organization
California Association of Winegrape Growers
California Citrus Quality Council
California Farm Bureau Federation
California Life Sciences Association
California Specialty Crops Council
College of Agriculture and Natural Resources at the University of Delaware
Colorado BioScience Association
Colorado Farm Bureau
Crop Science Society of America
CropLife America
Florida Fertilizer & Agrichemical Association
Georgia Farm Bureau
H2 Research Innovation
Hawaii Crop Improvement Association
Hawaii Farm Bureau
Idaho Farm Bureau Federation
Idaho Potato Commission
Illinois Farm Bureau
Illinois Seed Trade Association, Inc.
Illinois Soybean Association
Indiana Farm Bureau
Indiana Seed Trade Association
Iowa Farm Bureau Federation
Iowa Seed Association
Iowa Soybean
Kansas Agribusiness Retailers Association
Kansas Cooperative Council

Kansas Farm Bureau
Kansas Grain and Feed Association
Kansas Wheat
Kentucky Farm Bureau Federation
Kentucky Life Sciences Council
Kentucky Soybean Association
Louisiana Farm Bureau Federation
Maryland Farm Bureau
Michigan Agri-Business Association
Michigan Biosciences Industry Association (MichBio)
Michigan Farm Bureau
Minnesota Crop Production Retailers
Minnesota Farm Bureau Federation
Mississippi Farm Bureau Federation
Missouri Biotechnology Association
Missouri Soybean Association
National Alliance of Independent Crop Consultants (NAICC)
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 Potato Council
National Sorghum Producers
Nebraska Farm Bureau
Nebraska Soybean Association
New York Farm Bureau
New York State Agribusiness Association
Noble Research Institute, LLC
North Carolina Agribusiness Council, Inc.
North Carolina Farm Bureau
North Dakota Soybean Growers Association
North Dakota State University
Northern Seed Trade Association
Ohio AgriBusiness Association
Ohio Farm Bureau Federation
Oklahoma Farm Bureau
Oregon Farm Bureau
Oregonians for Food & Shelter
Pennsylvania Farm Bureau
Produce Marketing Association
Rural & Agriculture Council of America
Society of American Florists
South Dakota Biotech
South Dakota Farm Bureau
South Dakota Soybean Association

Southern Crop Production Association
Texas Citrus Mutual
United Fresh Produce Association
USA Rice
Utah Farm Bureau
Virginia Bio
Virginia Farm Bureau
Washington Farm Bureau
Washington State Potato Commission
Western Growers
Wisconsin Farm Bureau Federation
Wyoming Farm Bureau Federation

cc: Michael Gregoire, Acting Administrator, USDA Animal and Plant Health Inspection Service
Michael Firko, Deputy Administrator, USDA-APHIS Biotechnology Regulatory Services