July 29, 2020

The Honorable Stephen Hahn
Commissioner
Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hahn,

New innovations capable of advancing plant breeding, such as gene editing, have immense potential to improve agriculture and food production. Researchers are exploring genetic innovations aimed at increasing agricultural productivity; improving environmental sustainability outcomes; providing consumers safer and more nutritious products; and reducing food waste, among many other benefits. However, the future of many of these innovations relies on the existence of a science-based, risk-appropriate regulatory system – one that is consistent across domestic regulatory agencies and internationally – and does not impose unnecessary burdens to market access. FDA has a critical role to play in shaping this regulatory framework by clarifying the agency's approach to plants derived from these new techniques under its 1992 guidance on Foods Derived from New Plant Varieties. To obtain an outcome that best supports regulatory consistency, we urge FDA to issue this clarifying guidance as expeditiously as possible.

We support FDA's voluntary approach to premarket consultations, but we believe there are several important reasons the agency should clarify its approach to these innovations as soon as possible. Many U.S. researchers and developers are making multi-year resource and innovation pipeline decisions. The sooner FDA releases this draft guidance, it will allow researchers and developers greater clarity to make informed decisions regarding these much-needed innovations. Additionally, our trading partners are in the process of developing their own regulatory approaches to plant varieties developed through gene editing methods. FDA is a highly respected leader in the international community, and a thoughtful, science-based approach by the agency could steer trading partners in a similar regulatory policy direction, which would minimize risks of future trade disruptions and, at the same time, encourage innovation.

On October 30, 2018, FDA announced its Plant and Animal Biotechnology Innovation Action Plan, which the agency stated "provides an overview of the key priorities the FDA will pursue to support innovation in plant and animal biotechnology…." In the Action Plan, FDA also expressed that it intended to "publish the [plant] draft guidance for public comment in early 2019," which was over a year ago.

We appreciate the critical work the agency has conducted to maintain a safe food supply during the COVID-19 pandemic; however, every day that elapses without this guidance is another day our trading partners and other key countries grow closer to developing potentially inconsistent, trade-disrupting regulatory approaches. In addition, further delay in publishing the draft guidance leaves researchers and developers without critical information needed to inform innovation pipeline decisions. We urge FDA to publish this draft guidance as quickly as possible to

minimize the risks of these innovation-stifling outcomes and to continue to advance the position of the United States as the global leader in biotechnology development.

We thank you for your attention to this important matter and the other work FDA continues to conduct to support innovation and keep our food supply safe.

Sincerely,

Agricultural Retailers Association
American Farm Bureau Federation
American Seed Trade Association
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 Sorghum Producers
U.S. Canola Association
Western Growers Association

CC: The Honorable Frank Yiannas
The Honorable Susan Mayne, Ph.D.