

The Office of Management and Budget  
725 17<sup>th</sup> Street NW  
Washington, D.C. 20503

March 6, 2020

Re: Docket No. APHIS-2018-0034 (OMB RIN 0579-AE47)

Each of the below signatories submitted comments to the United States Department of Agriculture (the Agency) on its June 6, 2019, proposed rule regarding the movement of certain genetically engineered (GE) organisms [Docket No. APHIS-2018-0034] (OMB RIN 0579-AE47). Those comments reflect the priorities and recommendations of our individual organizations as the Agency contemplates its role in the regulation of agricultural biotechnology. While our organizations may not be aligned in all aspects of our comments on the proposed rule, including the ability of developers to self-determine that they meet proposed exemptions, one area in which we do broadly agree relates to the need for pre-market notification from developers to the Agency, which would provide regulatory certainty for developers and additional information to the marketplace and consumers. We believe there is an opportunity for this rule to do more in that regard.

As drafted, the proposed rule would allow technology developers to self-determine that they meet certain regulatory exemptions. Independent of whether the final rule retains the self-determination provision, we strongly encourage the Agency to include in the final rule a process by which a developer is required to notify the Agency of a GE plant that the developer has determined meets one of the exemptions in proposed 340.1(b) or (c) prior to placement on the market. This mandatory notification process would provide a developer with an opportunity to affirm that a GE plant meets an exemption, and it also would provide additional information to the marketplace and consumers. USDA should make available to the public and stakeholders information regarding what products are about to come on the market, while ensuring that developers are able to keep valuable intellectual property and trade secret information confidential in order to incentivize continued development and innovation in this field.

By providing this additional information to consumers regarding what products are available in the market, the Agency is providing an opportunity to grow consumer confidence in the U.S. food supply. While, as clear from our earlier comments, many of our organizations hope for modification to the original proposal, we believe that USDA's final rule should provide opportunities for transparency that can be achieved without limiting innovation or these new products' potential benefits for society and the environment.

Sincerely,

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Biotechnology Innovation Organization

Gregory Jaffe  
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Cc:

The Honorable Sonny Perdue, Secretary, United States Department of Agriculture  
The Honorable Greg Ibach, Undersecretary for Marketing & Regulatory Programs, United States Department of Agriculture

The Honorable Stephen Hahn, Commissioner, Food and Drug Administration

The Honorable Andrew Wheeler, Administrator, Environmental Protection Agency

The Honorable Pat Roberts, Chairman, Committee on Agriculture, United States Senate

The Honorable Debbie Stabenow, Ranking Member, Committee on Agriculture, United States Senate

The Honorable Collin Peterson, Chairman, Agriculture Committee, United States House of Representatives

The Honorable Mike Conaway, Ranking Member, Agriculture Committee, United States House of Representatives