

August 6, 2019

U.S. Department of Agriculture  
Regulatory Analysis and Development  
Plant Protection Division  
Animal and Plant Health Inspection Service  
Station 3A-03.8, Unit 118  
4700 River Road  
Riverdale, Maryland 20737-1238

RE: Movement of Certain Genetically Engineered Organisms (Docket No. APHIS-2018-0034)

Dear Sirs and Madams:

The undersigned associations appreciate the opportunity to provide input to the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) related the proposed rule on movement of certain genetically engineered organisms (Docket No. APHIS-2018-0034). While we appreciate deregulatory actions by USDA, we have substantial concerns with the regulatory framework suggested in the proposed rule, as noted in the comments below.

In the proposed regulatory framework, APHIS would not regulate certain genetically engineered plants if they could be produced via traditional breeding techniques and therefore would not likely pose a plant pest risk. This new framework also permits a developer to make a self-determination as to whether their genetically engineered plant is exempt from APHIS regulation. While a developer making a self-determination may request confirmation from APHIS that the plant does not pose a plant pest risk, this does not appear to be a requirement when making a self-determination in the proposed rule. Therefore, it is quite possible there could be genetically engineered plants in the market that are not recognized by USDA or the remainder of the food value chain. We are concerned that this lack of recognition of what is in the market poses a significant risk for consumer transparency and trust. Further, it introduces potential consequences for export of US products.

If APHIS is not aware of all the genetic engineered plants entering the market, this could significantly limit consumer confidence in the USDA. Consumers continue to express keen interest in what is in the foods they consume. If USDA is unable to inform consumers on what is available in the market, it is likely that consumer confidence in USDA will wane. Additionally, we believe the proposed regulatory framework opens the door for significant criticism of APHIS and genetic engineering technologies. We strongly support these crop technologies with appropriate government oversight determined through prudent scientific risk assessment. However, a lack of regulatory transparency would undermine trust in the regulatory system and the use of genetic engineering.

Further, as noted, consumers have strong interests in what is in their food. If food manufacturers are unable to confirm or verify from their suppliers whether or not a plant or ingredient is produced or derived from certain genetic engineering techniques, which are self-regulated by technology providers, they are unable to address consumer questions or concerns about their products. Our members are committed to transparency to consumers regarding the foods our members sell. An opaque regulatory scheme will invite highly inefficient voluntary labeling programs that could increase consumer food costs.

With regard to trade implications, we are concerned the proposed regulatory framework puts the US at odds with many regulatory approaches for genetic engineering technologies and products around the

world. We are concerned that this asymmetrical regulatory approach has the potential to cause significant market and trade disruptions. We believe this proposed framework does not fit within the obligation of APHIS to protect the health and economic value of US agricultural and food exports. USDA and APHIS should strive to protect access to export markets, and we are concerned that lack of regulation of certain genetically engineered plants risks access of US products to foreign markets.

Finally, we are concerned that this proposed rulemaking does not further the Coordinated Framework established in the 1980's between USDA, the US Food and Drug Administration (FDA), and the US Environmental Protection Agency (EPA) regarding federal biotechnology regulation. We are concerned that the proposed rule amends part of this Coordinated Framework without the full engagement of EPA and FDA in a manner that provides a holistic approach to update the regulatory landscape for certain genetically engineered plants. We are supportive of interagency dialogue on this issue and strongly believe APHIS should follow the intent of the Coordinated Framework.

We respectfully recommend modifications of the proposed rule to address the concerns stated above. Specifically, APHIS notification of use of genetic engineering should be mandatory and the rule should be tailored to avoid trade disruption resulting from asymmetrical approvals.

We appreciate your consideration of our comments as APHIS works on this rulemaking and addresses this issue with other relevant regulatory agencies.

Sincerely,  
American Bakers Association  
American Frozen Food Institute  
Corn Refiners Association  
Grocery Manufacturers Association  
Institute of Shortenings and Edible Oils  
International Dairy Foods Association  
International Food Additives Council  
National Grain and Feed Association  
National Oilseed Processors Association  
National Restaurant Association  
North American Millers Association  
SNAC International