April 22, 2024

Submitted electronically via regulations.gov

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

Re: Foods Derived from Plants Produced Using Genome Editing: Guidance for Industry (FDA-2019-D-4658)

Dear Sir or Madam,

The Food Industry Association (FMI) appreciates the opportunity to comment on the "Foods Derived from Plants Produced Using Genome Editing: Guidance for Industry". As the food industry association, FMI works with, and on behalf of, the entire industry to advance a safer, healthier, and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as a wide variety of companies providing critical services — to amplify the collective work of the industry. Read more about us at www.FMI.org.

Genome edited food products remain an important topic for our member companies and we appreciate the Agency providing clarity on how the Statement of Policy: Foods Derived from New Plant Varieties (NPV policy) applies to foods derived from new plant varieties using genome editing. The use of genome editing techniques to produce new plant varieties for food offers the potential to address and help overcome some global food productions challenges. Yet the intricacies surrounding the regulatory system and consumer awareness gaps create barriers to widespread acceptance and success of these products.

Interagency Alignment

The food industry relies on federal regulatory agencies including the Food and Drug Administration (FDA), United States Department of Agriculture (USDA) and the Environmental Protection Agency (EPA), to establish strong food safety standards, conduct inspections, and maintain strong enforcement programs for new plant varieties produced using genome editing techniques. Currently all three agencies have their own regulatory or policy document outlining their regulatory approach for these genome edited food products. We recognize the agencies' regulatory oversight is dependent on existing laws. However, the fragmentation and inconsistencies between agencies create confusion for developers and consumers alike which may impede the commercialization of genome edited foods. Collaboration between the

agencies to create a unified approach is needed to address inconsistencies and ensure regulatory clarity within the current Coordinated Framework[1]. Through this interagency alignment the agencies can facilitate the responsible development of genome edited foods and successful commercialization.

Consumer Trust and Education

FMI members strongly believe in providing consumers with accurate and credible information to allow them to make informed decisions. Regulatory and scientific language can be confusing to consumers especially when it is coming from different interested stakeholders. Nevertheless, regulatory agencies are well-positioned to serve as a trusted voice. FMI stands ready to work with our partners to echo the agencies' messaging.

According to FMI research on *Consumer Attitudes, Trust, and Acceptance of Bioengineered and Gene-edited Food Under the National Bioengineered Food Disclosure Standard*, surveyed participants indicated having a high level of trust in the USDA, FDA and Food and Agriculture Organization of the United Nations as sources of information[2]. Given that the agencies are considered as a trustworthy information vehicle, we urge the FDA to work with both EPA and USDA to develop a coordinated approach to educate consumers. This trust provides an opportunity to engage directly with consumers.

In the same research, 42% of respondents reported to have never heard the term "gene-edited" while 25% of respondents had heard the term but did not know what it means. Additionally 68% of respondents reported they did not know the difference between bioengineered/genetically modified food and gene-edited food[3]. Addressing consumer knowledge gaps and confusion requires public outreach and the sharing of information from the agencies. These efforts should focus on increasing awareness of the safety and benefits of these genome edited food products, backed by science-based evidence. Increasing awareness and bridging the knowledge gap not only allows consumers to make informed decisions and purchases but also creates trust in these foods.

This initiative and collaborative effort between agencies and stakeholders, not only serve consumers but also supports the developer's responsible development and successful commercialization and marketing of these genome edited food products. Thank you for your attention to this matter and opportunity to submit comments on this topic. Please don't hesitate to contact FMI with any questions.

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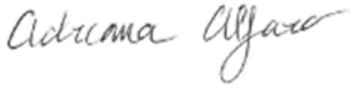
[1] Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology, https://usbiotechnologyregulation.mrp.usda.gov/2017_coordinated_framework_update.pdf

[2] FMI- The Food Industry Association, *Consumer Attitudes, Trust, and Acceptance of Bioengineered and Gene-edited Food Under the National Bioengineered Food Disclosure Standard*, Arlington, VA, 2022, p. 56.

[3] FMI- The Food Industry Association, *Consumer Attitudes, Trust, and Acceptance of Bioengineered and Gene-edited Food Under the National Bioengineered Food Disclosure Standard*, Arlington, VA, 2022, p. 47.

Sincerely,



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