

February 3, 2023

Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Attn: Alan Pearson
4700 River Road
Riverdale, MD 20737

RE: Docket No. APHIS-2022-0076; Request for Information; Identifying Ambiguities, Gaps, Inefficiencies, and Uncertainties in the Coordinated Framework for the Regulation of Biotechnology

The undersigned national organizations representing the United States (U.S.) grain and oilseed handling and storage, export, processing, feed manufacturing and packaged goods companies and retailers respectfully submit these comments in response to the White House Office of Science and Technology Policy's (OSTP) *Request for Information; Identifying, Ambiguities, Gaps, Inefficiencies, and Uncertainties in the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework)* that was published in the December 20, 2022 issue of the ***Federal Register***. (87 Fed. Reg. 77900 (Dec. 20, 2022)).

Biotechnology regulation and clarity is identified as a priority in the National Biotech and Biomanufacturing Initiative. OSTP's stated goal in publishing the notice, on behalf of the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) is to "...request(s) relevant data and information, including case studies, that may assist in identifying any regulatory ambiguities, gaps, uncertainties in the *Coordinated Framework*, particularly with regard to new and emerging biotechnology products."

Presently, the U.S. food and agricultural sector is the world's largest, most efficient, and sustainable. America's safe, reliable, affordable, and abundant supply of food and agro-industrial products result from an innovative, competitive, responsible, and resilient supply chains. This starts with farms and ranches, through to food, feed, energy, beverage manufacturers that deliver choice and affordability to consumers extending throughout North America and around the world.

Our organizations' member companies are engaged daily in storing, handling, processing, exporting, marketing, and selling the vast majority of America's grain and oilseed production to domestic and world consumers. As such, we strongly support the utilization of biotechnology and other safe cropping technologies and practices that enhance the production of safe, affordable, and sustainable food and energy for U.S. and world consumers.

A vast majority of the crop innovation gets delivered to the U.S. and global food system through an inter-connected supply chain from technology companies to the farmer, moved through a commoditized grain system, sold to food/feed ingredient manufacturers, and converted to food and feed products that are ultimately sold to consumers.

We appreciate the efforts by the EPA, FDA, and USDA to provide for more timely and predictable regulatory actions regarding applications for approval of new biotechnology-enhanced traits through the *Coordinated Framework*. The competence and objectivity of the science-based *Coordinated Framework* ensures the safety of biotech-enhanced products for humans, animals and the environment is well proven.

In addition to the *Coordinated Framework*, both the EPA and FDA are addressing biotech-enhanced products through separate rulemaking and guidance documents. For example, the EPA proposed a rule to update the regulations for Plant Incorporated Protectants (PiPs) in 2020 but has never finalized the rule. We believe this rule should be completed and published to give certainty to the regulatory process and an understanding to the food and agriculture value chain that EPA is appropriately regulating all types of covered PiPs.

Further, the FDA sought to update their guidance for biotechnology products, specifically to include guidance for products of gene editing in 2020, but the Agency has still not released any additional guidance to date. We believe they should do so in order to communicate to the food and agriculture value chain that FDA is appropriately regulating food resulting from these products.

We also commend the OSTP for public outreach through stakeholder meetings and public comment on what can be done to clarify the current roles and responsibilities of the agencies primarily involved in the regulation of biotechnology products. Such outreach is essential to improving a complex approval process that further enhances what already is a safe and wholesome food and animal feed supply.

However, while the current regulatory system for the products of biotechnology protects the health of plants and the environment there is still an uncertainty on agency jurisdictions, lack of predictability on timeframe for approval and lack of transparency. Specifically, OSTP must carefully consider on how to best protect those that use gene-edited products without adding unnecessary regulatory burdens and costs that would undermine the U.S. food chain resiliency and security and the industry's ability to provide an abundant and affordable food supply to U.S. and world consumers.

For example, the Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) Rule provides for certain exemptions as it relates to products genetically engineered via gene editing. While science- and risk-based, these exemptions remove regulatory review for these products and hinders transparency over what is being introduced into the marketplace. As such, FDA has an important role to play in filling this gap, but their role within the *Coordinated Framework* is ambiguous. Consultation is encouraged but not mandated. Most concerning is the lack of clarity over FDA's role in reviewing products that may introduce allergens into commodity crops. **With the reduced visibility and transparency for new products produced through genetic engineering (e.g., gene editing) due to the SECURE Rule, it is imperative that a focus on transparency should be concurrent with changes to reinforce and add confidence in the safety and integrity of the entire supply chain. Transparency is key for consumers, grain handlers, food manufacturers and retailers to enable choice and ensure regulatory compliance for U.S. grains, oilseeds, and food/feed products. Therefore, we encourage the OSTP to focus their efforts on both the assurance of safety and transparency. Additionally, the OSTP can inform the supply chain and consumers by clarifying the responsibilities, jurisdiction and structure of the FDA in the *Coordinated Framework* and integrating**

consideration for the market impact of each introduction and innovation of biotechnology in food and agriculture.

We encourage the OSTP to consider the following changes and improvements to the *Coordinated Framework* that are both critical and necessary.

Mandatory Notification and Transparency - (This subject addresses questions 1, 2, 3, 4, 5 and 6 within the RFI)

Transparency into agency processes is critical to the food and agriculture value chain. Our organizations would like to see more information available to the value chain and consumers to understand what products may be under review, and subsequently when we could expect them to be available in the channels of trade. FDA should require companies who are commercializing new products developed via genetic engineering to notify the FDA and should make that information public, in accordance with public disclosure laws. This is particularly important for commodity crops where there is known commingling in the supply chain.

For example, one of FDA's areas of focus includes allergen oversight. FDA's principal concern regarding allergenicity is that proteins transferred from one food source to another, as is possible with gene-editing or transgenic techniques, might confer on food from the host plant the allergenic properties of food from the donor plant/organism. For example, the introduction of a gene that encodes a specific allergen from another organism into soybeans might make that variety of soybeans newly allergenic to people ordinarily allergic to the other source, and commingling of these soybeans can create safety concerns within the broader agricultural supply chains.

The safety of a food is in part regulated via FDA's authority under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (*21 U.S.C. 342(a)(1)*), i.e., the adulteration provision. Under this provision a food is deemed to be adulterated if a food bears or contains poisonous or deleterious substances (among other reasons). Substances that are expected to become components of food as result of genetic modification of a plant, and whose composition is such or has been altered such that the substance is not generally recognized as safe (GRAS) or otherwise exempt, are subject to regulation as "food additives" under section 409 of the FD&C Act (*21 U.S.C. 348*).

The USDA, through the SECURE Rule that is administered by the Animal and Plant Health Inspection Service (APHIS), regulates the introduction of certain genetically engineered organisms that may pose a risk to *plant health* not *human health*. The EPA regulates pesticides, including those genetically engineered into food crops, to make sure that pesticides are safe for human and animal consumption and will not harm the *environment*. Since an allergen will not impact the health of a plant and is not considered a pesticide then the use of it in a genetically engineered product would not fall into the scope of the USDA's or EPA's responsibilities through the *Coordinated Framework*.

Further, according to the requirements of the SECURE Rule, the public is not mandatorily required to be notified if any gene-editing company has formally submitted an application for a new product to be reviewed and approved, even if it contains a food safety risk such as

an allergen.

Under the current regulatory framework, FDA *encourages* developers of new plant varieties to *voluntarily* consult with the agency before *marketing* their products. In other words, the developer is not mandatorily required to notify FDA that a genetically-engineered trait contains a hazard such as an allergen, which could cause significant harm to the consumer and severely disrupt the U.S. food system.

With some forms of genetic engineering (e.g., gene editing) there is no regulatory authority in the *Coordinated Framework* for the gene-editing company to notify, manage or communicate this type of commercial activity. For example, if a gene-editing company was engineering a known allergen (e.g., casein) for cultivation into a soybean trait that could then be used in other products such as plant-based dairy products, there is no transparency to either the commercialization or an assurance of safety from the regulator.

This highlights a significant gap in the system that neither FDA, EPA nor USDA has the authority to address. Specifically, food manufacturers are **required by law** to identify and mitigate food safety risks. Currently, during the *voluntary* consultation process, the FDA will review the safety and nutritional assessment along with the claim of the function of the new trait, (e.g., high oleic or drought resistance) provided by the gene-editing company. Under the current oversight, that food safety and/or functionality information is not available, either to the government or market. Voluntary notifications only cover genetically engineered crops that are disclosed by the market, and only produce partial information for governments and the market. Therefore, without mandatory notification prior to marketing a new plant/trait produced through genetic engineering, it is likely the food manufacturer and consumers will not be aware of a potential food safety and nutritional risks in commingled raw material(s) used in their food product.

Therefore, the use of any item that can be used in food for humans, domestic livestock or pets must be safe for their intended purpose. This includes a gene-editing company **mandatorily notifying** the FDA when they intend to introduce a biotech-enhanced, (e.g., gene-edited or transgenic) product into the commercial market.

We also encourage the OSTP to clarify FDA's communication to stakeholders on the mandatory notification, this transparency enables choice and regulatory compliance for consumers and the supply chain and should be a top priority for the FDA, USDA, and EPA.

Reorganization of the FDA – (This subject address Questions 1, 3 and 7 in the RFI)

Our organizations believe the Expert Panel report, convened by the Reagan-Udall Foundation, and issued on December 6, accurately captures FDA's challenges involving the structure, leadership, culture, transparency, and accountability within the FDA's human foods program, all of which are limiting the agency from being able to best protect consumers and enable industry to innovate, as previously mentioned.

We appreciate the FDA announcement on January 31 which outlines FDA's proposal to unify the human foods program by combining the Center for Food Safety and Applied Nutrition, the Office of Food Policy and Response, and the relevant functions of the Office

of Regulatory Affairs. Our organizations have noted and continue to believe that having a single leader who is empowered and accountable for the success of the foods program is central to its success. While we understand that FDA is contending with how it will execute its proposed vision for transformation of the human foods program, our organizations encourage the OSTP to monitor how this restructure may impact the agency's food safety focus, particularly regarding biotechnology.

Additional Agency Involvement in the Coordinated Framework – (This subject addresses Questions 1, 3 and 7 in the RFI)

A cornerstone of U.S. agriculture's competitiveness is its ability to efficiently and cost-effectively market America's agricultural abundance with our key export market customers as part of a global food system. It is our sector's ability to both leverage new agricultural innovations while at the same time providing safe, competitively priced food and feed supply for global consumers that ultimately allows the benefits of agricultural biotechnology to be realized in the commercial marketplace – both domestically and globally.

While we support innovation and science-based decision making, there remains a gap with respect to international marketability of innovative technologies. We strongly believe *if* government policies contribute to a commercial environment that ultimately leads to disruptions of the efficient, seamless movement of agricultural products, these enhanced production technologies will have little utility– indeed, they instead have the potential to create large-scale economic damage – to the overall U.S. economy, the agricultural value chain, supply chain, food security and/or the American farmer (as occurred periodically with previous trade disruptions involving transgenic biotechnology traits).

Therefore, it is necessary to complement the science-based risk assessment with a process to consider international marketability of innovative technologies and define U.S. government strategies and outreach to overcome potential non-science based barriers to enable the introduction of innovative technologies, while minimizing the potential for adverse commercial impacts.

As such we recommend adding a notification process to include the Agricultural Marketing Service, the Foreign Agricultural Service and/or the Office of the U.S. Trade Representative to enhance the marketability of new technologies. Each agency has an important role in maintaining access to domestic and foreign markets and works with foreign countries to maintain their food security by improving their agricultural systems and trade capacity. Currently, each Agency works with our trading partners and can provide clarity to APHIS, FDA and EPA on how the approval process in the U.S. corresponds with the status of similar traits that are also being reviewed in other countries. The greater the transparency between agencies and other governments (if necessary), the easier it is to identify common areas of interest for eliminating non-scientific trade obstacles to support food security through food/feed production and trade resiliency.

Outreach and Communication – (This subject addresses questions 1, 3 and 7 in the RFI)

To enhance stakeholder certainty and public trust, we also encourage agencies to develop and publish *clear and simple* guidance on the scope of regulations, data requirements,

regulatory processes, and bases for decision-making for regulatory reviews of biotechnology-enhanced products, as well as oversight of field trials and other regulatory activities.

Specifically, the details of the regulatory processes covered by the *Coordinated Framework* at FDA should be shared more broadly with stakeholders in the food and agriculture value chain to provide confidence in the processes as well as allow for clear communication around expectations for completing the processes. Timelines and outcomes are critical for FDA to share broadly to create transparency.

Further, in its publications on the FDA website, explanations of the regulatory systems should provide additional clarity about how FDA regulates food with broad authority. FDA should provide additional clarity about how it addresses adjacent issues in the food and agriculture value chain such as ensuring the food ingredient will not introduce unexpected food safety risks (e.g., allergens) or otherwise behave in a way that may affect other food items being produced using regulated products.

Periodic Review of the *Coordinated Framework* – (This subject addresses questions 1, 3, 6 and 7 in the RFI)

Finally, given the rapidly advancing science and innovation in genetic engineering, we strongly recommend that the U.S. government commit to reviewing the *Coordinated Framework* at least every five years, and more frequently if needed, to keep them current and maintain their relevance.

In conclusion, we support the use of agricultural biotechnology and other forms of plant breeding innovation that contribute to an abundant, affordable and environmentally sustainable human and animal food supply, thereby enhancing global food security. However, for our organizations' member companies, as well as the farmers and downstream customers they serve, the importance of clarifying the structure and responsibilities of the FDA to ensure food safety and security for domestic and global consumers, without disrupting domestic or foreign markets, is of paramount importance. Of equal importance is the need for transparency in the commercialization of products produced through genetic engineering to enable choice and regulatory compliance for consumers, grain handlers, processors, food/feed manufacturers and retailers.

We appreciate the opportunity to provide our views and would be pleased to respond to any questions the OSTP may have.

Sincerely,

American Frozen Food Institute
Corn Refiners Association
Institute of Shortening and Edible Oils
National Grain and Feed Association
National Grocers Association
National Oilseed Processors Association
North American Export Grain Association
North American Millers' Association