February 3, 2023

By Electronic Submission

(Docket #: APHIS- 2022-0076)

Re: Request for information: Identifying Ambiguities, Gaps, Inefficiencies, and Uncertainties in the Coordinated Framework for the Regulation of Biotechnology.

The Breakthrough Institute (BTI)[1], Center for Science in the Public Interest (CSPI)[2], Consumer Federation of America (CFA),[3] and Environmental Defense Fund (EDF)[4] appreciate the opportunity to comment on the Request for Information from the White House Office of Science and Technology Policy (OSTP) (87 FR 77900-91, December 20, 2022) regarding its Coordinated Framework for the Regulation of Biotechnology. OSTP and the federal regulatory agencies (USDA, FDA, and EPA) are asking for areas to focus on while implementing the regulatory provisions of the recently issued Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy (E.O. 14081 issued September 12, 2022). The Executive Order acknowledges the importance of the bioeconomy and biotechnology to address critical health, energy, and agriculture and food issues facing the United States and prioritizes actions by the federal government in this area, including the establishing of appropriate oversight.

As representatives of non-governmental organizations (NGOs), we request that the federal government establish a national registry for gene-edited (and possibly genetically

[1] BTI is a nonprofit organization located in Berkeley, CA and Washington, DC that envisions a future where major cuts to greenhouse gas emissions and other environmental impact of agriculture such as fertilizer runoff come through the innovation and adoption of advanced technologies in the agriculture sector. It advocates for increasing agricultural productivity, increasing the efficiency of agricultural inputs such as fertilizer, and otherwise making agriculture more environmentally friendly, including through the use of gene-edited and genetically engineered plants and animals.

[2] CSPI is a nonprofit education and advocacy organization that focuses on improving the safety and nutritional quality of our food supply. CSPI seeks to promote health through educating the public about nutrition; it represents citizens' interests before legislative, regulatory, and judicial bodies; and it works to ensure advances in science are used for the public good. CSPI is supported by the over 400,000 member-subscribers to its *Nutrition Action Healthletter* and by foundation grants. CSPI receives no funding from industry or the federal government.

[3] CFA is an association of non-profit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy, and education. Today, more than 250 of these groups participate in the federation and govern it through their representatives on the organization's Board of Directors.

[4] Environmental Defense Fund (EDF), with over 2.5 million members, is an international non-partisan, non-profit organization dedicated to protecting human health and the environment by effectively applying science, economics, and the law.

engineered)[5] plants. We recognize the potential societal benefits of gene-editing technologies, while acknowledging their potential risks. At the same time, we understand that, under the current regulatory regimen, at least some of these products will be released into the market without any mandatory federal oversight. Without regulatory approvals to identify the gene-edited plants that will enter the market, it is important the federal government at least collect information on all products entering the market and make that information available to consumers and other stakeholders.[6]

A National Registry of Commercialized Gene-Edited Plants

Under the USDA SECURE rule, many gene-edited (as well as some genetically engineered) plants will fall within one of the exemptions from oversight; in some cases developers are likely to simply self-determine that their product is exempt. For plants that are also food or feed, FDA's oversight for biotechnology has involved a voluntary consultation process to determine that the product is "generally recognized as safe" (GRAS). A product developer also can self-affirm GRAS without any involvement or notice to FDA. So, it is possible that gene-edited plants have or will enter the market without any notice to the federal government whatsoever.

Regardless of whether USDA or FDA is aware of gene-edited products entering the market, they also could be invisible to consumers, companies in the food chain, and our trading partners. That is because developers (seed companies) usually communicate with their immediate customers (typically farmers), and not necessarily everyone (or anyone else) along the food chain. This has already happened with many genetically modified (GM) plants. Monsanto, for example, touted the benefits of its glyphosate-tolerant soybeans and corn crops to farmers, but neither Monsanto nor food companies made consumers directly aware that they were eating foods made from those products. It is this lack of transparency that in part explains why GM crops have encountered consumer skepticism.

Establishing a federally-operated national registry for gene-edited plants will be beneficial for several reasons. First, if we learned anything from the controversy over GM crops, it is that if consumers believe that key information about a food is being hidden from them, they may question the food's safety or quality, and may leave it on the grocery store shelf. It is only a matter of time before consumers start asking retailers or food manufacturers whether they sell foods that contain gene-edited ingredients. If those companies don't even know which gene-edited crops are being grown, how can they approach suppliers to find out if they use ingredients from those gene-edited crops? And will consumers even accept the companies' assertions when there is no comprehensive, publicly available source to

[5] While this comment specifically calls for a national registry for gene-edited plants, the recent changes to the regulatory system may result in some genetically engineered plants also entering the market without any mandatory oversight or notice to the federal government. In this case, the national registry could be broadened to include any plants developed with these technologies that could be marketed with notice to the federal government and interested stakeholders.

[6] This letter responds to questions #1, 4 and 7 of the Request for Information issued on December 20, 2022.

corroborate those claims? For the sake of transparency, food companies and retailers need to make this information available *before* consumers ask for it, to preempt any assumptions that the food industry has something to hide when it comes to gene-edited ingredients and the resultant impact upon sales of potentially beneficial products.

Second, a national registry will allow all food chain actors, including consumers, to learn the potential benefits of individual gene-edited plants. In this way, by creating transparency around what gene-edited foods are on the market, a registry can help consumers feel more comfortable about purchasing gene-edited foods. If consumers understand the benefits that using gene-editing might provide – for example that gene-editing can produce more nutritious foods or crops that are more environmentally friendly – they are more likely to accept these foods. However, that can't happen if no one—not consumers, manufacturers or retailers—knows which gene-edited crops are being grown or their associated claimed benefits.

Third, information about which gene-edited products are on the market is critical for international trade. Without a centralized registry containing that information, a country with concerns about gene-editing may put up trade barriers if it believes gene-edited products being grown in the U.S. have not been through the importing country's regulatory procedures. No one wants a repeat of what happened when cargo ships were not allowed to offload U.S.-grown GM grains in China in 2013 because a GM corn variety approved in the U.S. but unapproved in China was found onboard. Some countries may go one step further, out of an abundance of caution, and refuse to import a crop if any gene-edited variety of that crop exists in the exporting country. The USDA and other agencies currently certify some crops as non-GM so they can be exported to certain countries. How will the government be able to conduct trade conversations with other governments about what products are on the market if certain products can enter commerce without even the government being aware?

In addition, while the United States is not a party to the Cartagena Biosafety Protocol, the United States biosafety regulatory system has been compliant with many of the obligations under that international agreement. The United States has regularly submitted information about covered products to the Cartagena Biosafety Protocol's Biosafety Clearinghouse. To the extent that new gene-edited (and new genetically modified) plants should be added to the Biosafety Clearinghouse database, the United States government will need notice from developers about the products in the marketplace.

Finally, a national registry will help domestic markets to meet consumer preferences and manage the coexistence of gene-edited and non-gene-edited products. Currently, there are consumers who do not want to purchase products with gene-edited ingredients. Some food companies, food manufacturers, grocery stores, and other food chain actors have made commitments to segregate products to meet market demand. But this is only possible if those stakeholders have information about products on the market.

For all these reasons, the U.S. should establish a national registry for gene-edited plants. Developers who are preparing to commercialize a gene-edited plant, or who have already done so, would be required to fill out a short form—a "gene-editing data sheet"—with information about the crop, including the type of edits performed, the changed characteristics due to the

edits, and a summary of data about the benefits of the trait and any testing for safety concerns. These sheets should be uploaded into a public database, and a summary table with key information from all the data sheets could be generated, making it easy for anyone to quickly determine which crops and/or traits are in the food supply. That information would allow all relevant stakeholders to engage in meaningful conversations around utilization, acceptance, benefits, and impacts of this technology and its products.

The establishment of a national registry should be a high priority for the federal government in the short term (i.e., within the next year). Several gene-edited plants are currently being grown commercially and products from those plants are entering the food supply. More products are on the way and we don't want the lack of transparency to prevent our country (or others) from capitalizing on the climate, nutrition, and other benefits these gene-edited plants may convey.

We appreciate the opportunity to provide these comments to the OSTP and would welcome the opportunity to meet with the staff at OSTP to discuss the issues addressed here in more detail.

Sincerely,

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