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By Electronic Submission

Docket No. USDA 2020-0003

Re: Comments to Docket No. USDA-2020-0003 on USDA Agricultural Innovation Agenda

The Center for Science in the Public Interest (CSPI)¹, Consumer Federation of America², Environmental Defense Fund³, and National Wildlife Federation⁴ (referred to as “we”) appreciate the opportunity to submit comments to the United States Department of Agriculture’s (USDA) on its Agricultural Innovation Agenda. We support USDA’s goal of increasing agricultural production in a sustainable manner to meet the needs of the global population in 2050 “while cutting the environmental footprint of U.S. agriculture in half.” These comments focus on the “genome design” innovation cluster described in the Federal Register notice (85 FR 18185) and discuss the use of gene editing as a technology to carry out precision breeding of agriculturally important organisms. We believe gene editing can play a positive role in U.S. agriculture in the future, although it is not a silver bullet approach. To achieve USDA’s goal of increased production to meet the needs of the global population with a decreased environmental footprint, there also needs to be broader investment and innovation in conservation, research, food access, and other key areas in addition to gene editing.

To drive more innovation in the gene editing space, USDA should establish policies and approaches to make gene editing technology broadly accessible and to ensure that it is used for societal benefit. Further, USDA should establish science-based policies and procedures governing the use of gene editing and for the products developed from those techniques. Without the proper policies and procedures that ensure access, transparency, and safety, consumers will not have confidence that gene edited products are safe for humans, animals, and

¹ 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 500,000 member-subscribers to its *Nutrition Action Healthletter* and by foundation grants. CSPI receives no funding from industry or the federal government.

² Consumer Federation of America (CFA) is an association of over 250 non-profit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy, and education. Member organizations include local, state, and national consumer advocacy groups, senior citizen associations, consumer cooperatives, trade unions and food safety organizations.

³ 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.

⁴ The National Wildlife Federation (NWF) is America’s oldest and largest conservation organization, made up of 52 state and territorial affiliates and representing more than 6 million members and supporters across the nation. NWF’s mission is to unite all Americans to ensure wildlife thrive in a rapidly changing world.

the environment, and these products will have difficulty gaining marketplace acceptance, resulting in lost benefits to U.S. agriculture and society more generally.

I. USDA Should Establish Policies that Make Gene Editing Technology Accessible to a Broad Range of Developers and Ensure it is Utilized for Societal Benefits.

Past generations of agricultural biotechnology created significant concerns regarding control of and access to the tools, products, and benefits of innovation. Consumer acceptance and social license for the new generation of gene edited products will be better achieved if developers ensure that gene editing technologies are accessible for use by a wide variety of public, private, and NGO institutions. USDA should invest in research projects with academics and small companies that will develop and commercialize gene edited varieties of plants that will be easily accessible to US and/or developing country farmers. For projects that USDA invests in, USDA should specify that any intellectual property that is a result of that publicly funded research be freely available to others. Also, USDA should create incentives so private developers will make their intellectual property around gene editing broadly available for public goods research.

USDA should establish government policies that promote the use of gene editing to develop products that provide broad societal benefits in a wide range of crops and traits. Products offering societal benefits include those that attempt to address key scientific and social challenges to human health, the environment, agriculture, and rural life, including but not limited to: ecological and social resilience, biological diversity, natural resources, human health and nutrition, animal health and welfare, economic and rural development, equitable societal outcomes, food security and food sovereignty, climate resilience, and energy security. Specifically, USDA should prioritize funding for beneficial gene editing applications in fruits, vegetables, orphan crops, and other underfunded crop and animal applications that have not historically received public and private investment to develop varieties with improved genetics (and urge other funders to do the same).

To achieve societal benefit from gene editing and help prevent gene edited products from being rejected in the marketplace, USDA needs to engage diverse stakeholders in its funding decisions as early as possible, and the researchers it funds need to involve diverse stakeholders in their product development process. USDA and the researchers it invests in need to carry out transparent, meaningful, and respectful two-way dialogue with stakeholders that incorporate diverse viewpoints and the preferences of different regions and cultures, including those that do not support the technology for proposed applications. USDA and researchers should take proactive, inclusive steps to identify, engage, and incorporate diverse input at an early stage in the research and development cycle to ascertain stakeholder priorities, concerns, objections and perspectives on risks and benefits of gene editing applications. Engaging the public in a responsible innovation approach is more likely to result in products that meet societal needs as well as positive reactions to products, ensuring a return on investment.

II. USDA Needs to Ensure Transparency About Which Gene Editing Applications are in Use in Food, Agriculture and the Environment, and Ensure Access to Independent Information about the Benefits and Impacts of Those Products.

Transparency will be essential if agricultural innovation using gene editing techniques is to be adopted by farmers, used by companies in the food chain, and purchased by consumers. USDA needs to take the lead in establishing national policies that provide the necessary information to stakeholders and the public about gene edited products in development and in commercial production. We recommend that USDA establish a national registry of all gene edited products intended for agriculture and environmental use and require that companies submit information at both the open-field trial research stage and before putting products into commerce. Such a registry would ensure basic public transparency and monitoring by USDA, interested stakeholders and the public. In addition, USDA should make sure there is information about gene edited products already in commerce so consumers and stakeholders understand which products involve gene editing and food producers and manufacturers can adequately serve all markets and consumer preferences by providing products to consumers who wish to avoid gene editing. Establishing policies around transparency can build public trust and understanding of gene editing technology and allow U.S. agriculture to utilize gene edited agricultural varieties.

USDA should support research to establish methodologies to quantify, characterize, and compare benefits, impacts, and efficacy of new plant and animal varieties made with gene editing, including in the post-market setting. USDA should commit to funding studies both *ex ante* estimations and *ex post* evaluations of the benefits and impacts of gene edited products, and the agency should make those studies public. It should also advocate for private developers to conduct and release similar analyses of the anticipated benefits and impacts of products and then evaluate the actual benefits and impacts realized after adoption. Interested stakeholders and consumers need accurate and verifiable information about benefits and impacts if they are to purchase gene edited products that claim to affect an issue they care about.

III. To Realize the Full Benefits of Gene Editing and to Manage its Potential Risks, USDA Must Put in Place Science-Based, Transparent, and Participatory Regulations that Ensure Product Safety.

USDA (with other federal agencies) has the responsibility to ensure that all agricultural products are safe for humans, animals, and the environment before they enter commerce. Without independent and transparent oversight by USDA, consumers could become weary of gene edited products and not purchase them, preventing American agriculture from benefiting from safe applications of gene editing.

USDA needs to assess the potential risks of gene edited products before they are released to farmers using a regulatory system that is based on the best scientific evidence available.⁵ The system should be tailored so that it reviews individual products proportionally based on their likelihood of risk. This proportionate risk-based regulatory process should incorporate the

⁵ Until such a regulatory system is in place, USDA should limit its investment in gene editing and not fund commercial product development.

necessary scientific tests, analyses, and production procedures needed to assess the risks and safety of gene-edited products and incorporate expert and stakeholder input to identify relevant risks, data requirements, risk assessment methodologies, and risk management opportunities. Regulations should identify which specific individual products would undergo a streamlined review process and which would require comprehensive risk assessments. Finally, regulatory decisions should be made in a timely and efficient manner to allow for the broadest possible access and application of beneficial gene-edited products. The regulatory process should not be so onerous as to preclude the participation of smaller institutions or public entities in the development of beneficial gene-edited products, but thorough enough to ensure all products are adequately assessed for safety. When the regulatory process determines through science-based risk assessment that the risks associated with a particular use or application of gene editing are substantial and cannot be adequately managed, that product should not be approved for use or released into the environment.

IV. USDA's Recently Issued SECURE Rule Does Not Establish a Science-Based Regulatory System and Should be Revised.

USDA's recently issued revised regulations for genetically engineered organisms (found at 7 CFR Part 340) do not establish a science-based regulatory system that adequately ensures safety for all gene edited products. As a result, the regulation should be revised or withdrawn. While the regulations include gene edited products in the definition of "genetic engineering," many gene edited applications are not regulated because they fall within an exemption or could be encompassed by a future exemption. For example, the regulations broadly exempt all plants for which there was only a single deletion, substitution, or addition within the plant's gene pool, irrespective of the trait introduced, the phenotype of the plant, or the existence of sufficient scientific evidence that the plants do not pose unreasonable risks. The regulations also allow USDA to add exemptions for products with multiple edits if a developer provides evidence that the same result could be achieved with conventional breeding techniques, but do not require evidence that the product does not present unreasonable risks. While we are not opposed to exemptions from oversight based on scientific evidence, USDA exempts these categories of gene edited products because they hypothetically could be obtained through conventional breeding (i.e., based on their method of production), rather than that they don't pose unreasonable plant pest risks. Also, USDA neither addresses the potential for off-target mutations that could result in phenotypic traits that might raise safety concerns, nor puts any obligations on developers to investigate and eliminate off-target effects. A system that exempts large categories of gene edited products without scientific evidence of their safety is not a regulatory system that will ensure safety and engender the confidence of U.S. consumers or our international trading partners. To make science-based, proportionate risk-based regulatory decisions, USDA needs to review information on the phenotype of the new organism along with information on how a product has been produced.

USDA also needs to eliminate the regulatory provisions that allow developers to self-determine that their products meet an exemption and are not regulated. Those provisions set up an inherent conflict of interest because developers have financial incentives to determine themselves exempt. While some developers will diligently determine the regulatory status of their GE plant, others may not. Additionally, when a developer self-determines its product to be

exempt, neither USDA nor the public will know that the GE plant has been released into the environment and entered the food supply because there is no requirement that developers notify the agency of a self-determination. If USDA does not know which GE plants have been deemed exempt, there is no way for the agency to confirm whether those determinations are correct. To ensure safety and transparency, USDA needs to be aware of all GE plants being developed and determine which ones need oversight.⁶

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

Sincerely,

Gregory Jaffe
Director, Biotechnology Project
Center for Science in the Public Interest
gjaffe@cspinet.org

Doria Gordon
Lead Senior Scientist
Office of the Chief Scientist
Environmental Defense Fund
dgordon@edf.org

Thomas Gremillion
Director of Food Policy
Consumer Federation of America
tgremillion@consumerfed.org

Aviva Glazer
Director of Agriculture Policy
National Wildlife Federation
GlaserA@nwf.org

⁶ There are additional problems with the new USDA regulations for gene edited organisms that could lead to safety issues that will impact product adoption. Those additional concerns were set forth in comments submitted by CSPI, EDF, CFA, and NWF to USDA's Animal and Plant Health Inspection Service on their proposed rule in August 2019.