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"Agricultural Innovation and the Federal Biotechnology Regulatory Framework"

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I want to thank Chairman Pat Roberts, Ranking Minority member Debbie Stabenow, and other committee members for inviting me as a witness on behalf of the Center for Science in the Public Interest (CSPI). While the current genetically engineered (GE) crops grown in the United States have not been shown to be unsafe and have the potential for delivering benefit, a broader range of biotechnologies, including genome editing, will be utilized to develop the next generation of innovative agricultural products. A federal regulatory oversight system that is science-based, transparent, participatory, and efficient needs to be established to ensure the safety of future products and to provide consumers with confidence about their safety.

I am here today as the director of CSPI's Biotechnology Project. CSPI is a non-profit consumer organization that was established almost 50 years ago. CSPI works primarily on food safety and nutrition issues and publishes the *Nutrition Action Healthletter* to educate consumers on issues surrounding diet and health. Based on the best-available science, CSPI advocates on behalf of consumers before federal agencies, Congress, state and local

jurisdictions, and international organizations as well as in the courts. CSPI does not receive any funding from industry nor do we accept any federal government grants. Our funding primarily comes from our members and individual donors, as well as from independent philanthropic foundations.

CSPI's Biotechnology Project addresses scientific concerns, government policies, and corporate practices pertaining to GE plants and animals that are released into the environment or that end up in our food. The project's goals are to:

- Educate policymakers, media, interested stakeholders, and the public about the benefits and risks associated with GE crops and animals;
- Advocate for strong, but not stifling, federal regulation to ensure safety to humans and the environment; and
- Provide expertise to help developing countries establish their own biosafety regulations and make science-based decisions about adopting GE crops.

CSPI has long advised consumers, journalists, and policymakers that there is no evidence that foods and ingredients made from GE crops currently grown in the United States are harmful or less nutritious than their conventional counterparts. That conclusion is consistent with the conclusions of numerous international and scientific bodies, including the Food and Drug Administration (FDA), the National Academy of Sciences (NAS), the U.N. Food and Agriculture Organization, and others. As stated by the NAS in their 2016 report on GE crops, "no differences have been found that implicate a higher risk to human health safety from these GE foods than from their non-GE counterparts."

The current GE crops also have provided benefits to farmers and the environment in both the U.S. and around the world. While the benefits of GE crops need to be assessed on a case-by-case basis, the NAS 2016 GE crops report and others have reported strong evidence that corn and cotton crops engineered with built-in pesticides (known as Bt crops) have significantly reduced chemical insecticide sprays. That NAS report also found evidence that the extensive use of those Bt crops has lowered pest populations so much that farmers growing vegetables like peppers and green beans, for which there are no GE varieties, also use less chemical insecticide. GE virus-resistant papaya has saved the Hawaiian papaya industry from a deadly plant virus that otherwise could have eliminated the state's papaya industry.

While there have been benefits, there also have been adverse impacts. Overuse of the herbicide glyphosate together with the corresponding herbicide-resistant seeds has resulted in the development of more than a dozen herbicide-resistant weeds, which now require farmers to spray additional (and increasingly more toxic) herbicides. Use of dicamba with seeds engineered to tolerate dicamba has led to significant damage to neighboring farmers' fields from dicamba drift. While GE crops could be used sustainably, some of them have been overused and misused, leading to adverse environmental and/or agricultural impacts.

For years, CSPI has advocated for improvements in the federal biotechnology regulatory oversight system to ensure safety to humans, animals, and the environment. CSPI wants a federal regulatory system that is science- and risk-based, transparent, participatory, and efficient. It should ensure product safety but also allow safe products

from a variety of producers to get to market as quickly as possible so their benefits can be realized. Today, I will limit my testimony to several current issues around the executive branch oversight of GE and genome-edited crops and animals.

The Presidential Executive Order

On June 11, 2019, President Trump issued an "Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products." That order, among other things, instructed the federal government to review its current oversight of agricultural biotechnology products and find opportunities to streamline and minimize regulatory burden, while still ensuring safety. The Executive Order is devoid of details and we fear it is a blank check for the three regulatory agencies discussed below to deregulate whole categories of products. Therefore, the discussion below on the current and future federal regulation of agricultural innovation must be reviewed with the understanding that those agencies have been instructed to implement this Executive Order, which itself presupposes less oversight independent of the potential risks posed by products.

The United States Department of Agriculture

USDA regulates GE crops under its "plant pest" authority provided by the Plant Protection Act. Those provisions were not passed by Congress specifically to regulate GE crops but are used because of the possibility that a GE crop could become a "plant pest" (that is, an organism that is harmful to plants or agriculture). The USDA regulations require that GE crop developers either file a notification or obtain a permit to conduct field trials. Then, when the developer is ready to commercialize its engineered variety, the developer petitions USDA for nonregulated status, providing scientific evidence that the

engineered variety is not a "plant pest". To date, USDA has granted petitions for nonregulated status to more than 125 GE crop varieties and has not found a commercial GE crop that has become a "plant pest" and required continued oversight.[1]

In the last few years, however, a loophole that allows developers of GE crops to avoid USDA's regulatory process entirely has emerged. If a GE plant variety is developed without using any components of a listed "plant pest," then USDA has no authority to regulate the GE crop, even its experimental field trials. For example, if developers use a "gene gun" as their method of transformation instead of agrobacterium (which is a "plant pest"), and design the DNA construct being introduced into the crop without using any sequences derived from "plant pests," the product would not require USDA oversight. USDA has confirmed that numerous GE crops have qualified for this exemption, and any day now those experimental plants could become commercial products without any public announcement (unless the GE developers submits the product for review at either FDA or EPA). USDA has also confirmed that most of the new generation of genome-edited crops are exempt using the same reasoning. USDA's decision to exempt certain GE and genome-edited crops is not based on a scientific analysis that those crops are not risky and need no regulation. Rather, the decision is solely the result of those crops not being captured by the narrow legal hook USDA uses to regulate. Such non-scientific decisions undermine the regulatory system and its reputation with the public in the United States and our trading

[1] United States Department of Agriculture Animal and Plant Health Inspection Service. Petitions for Determination of Nonregulated Status. *Available at:* https://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml. Accessed 10/19/2015.

partners abroad. It also could result in the release of a crop that might cause major harm to the environment or agricultural interests.

In 2019, USDA proposed changes to its regulations of GE organisms. Those proposed changes, if adopted, would greatly narrow the number of GE and genome-edited crops that USDA would regulate. First, the proposed regulations would eliminate oversight of most GE crops that have previously been regulated because they utilized agrobacterium in the transformation process. USDA would no longer considers them to have any possibility of becoming potential "plant pests." Those developers would not be required to get permits for releases into the environment nor conduct field trials under containment conditions. GE crops have escaped from field trials even with USDA oversight in the past and the likelihood of that happening will only increase without USDA oversight. USDA estimates that there are approximately 400,000 to 500,000 acres of confined field trials every year and that their confinement requirements "prevent undesired cross-pollination or comingling with non-GE crops." If an experimental GE crop produces a protein that has not yet been found safe for consumption by humans, its inadvertent escape could lead to food product recalls and rejection of US commodities in export markets. Such an event could decrease consumer confidence in all GE crops, even ones that have been proven safe to consumers. Therefore, USDA needs to continue oversight of GE crops and especially field experiments to protect the environment, human health, and U.S. agricultural interests.

Secondly, USDA's proposed rule includes several specific exemptions for genome-edited crops without any scientific evidence to support those exemptions. Instead, USDA justifies the exemptions based on "logic" and "principles," such as the principle "that the

use of recombinant DNA does not itself introduce unique risks." CSPI does not object to exempting GE or genome edited crops if there is scientific evidence that they do not pose risks to the environment or agricultural interests. However, those exemptions need to include an evidence-based plan for how potential off-target impacts would be addressed. For example, off-target impacts could be addressed through the establishment of specific scientific criteria to minimize potential off-target impacts that must be met in order for a GE or genome-edited plant to qualify for the exemption.

Finally, the USDA proposal allows developers to "self-determine" if they are regulated or qualify for an exemption. This procedure is problematic for several reasons. First, there is 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. Second, if self-determination and the attendant lack of public notice is allowed, neither USDA nor the public will know which GE and genome-edited plants are released into the environment and entering the food supply. This lack of transparency could have market and trade impacts, as U.S. consumers will not know which GE plants are entering the food supply and other countries will not know which products produced in the U.S. need regulatory approval by their governments. The position that "self-determination" without the ability for USDA to review and confirm the exemption should be eliminated from the final rule is supported not just by CSPI but by Consumer Federation of America, The Nature Conservancy, Environmental Defense, and National Wildlife Federation. It is also support by food chain industry representatives, including the Biotechnology Innovation Organization, Consumer Brands Association, Corn

Refiners Association, National Grain and Feed Association, North American Export Grain Association, International Dairy Foods Association, and SNAC International.

The Food and Drug Administration

FDA regulates GE and genome-edited animals under the "new animal drug" provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA). The definition of a drug, in the FFDCA, includes "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals"; and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." FDA determined in its Draft Guidance #187 that any intentionally altered genomic DNA is a "new animal drug" because "such altered DNA is an article intended to affect the structure or function of the body of the animal, and, in some cases, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in the animal."

All "new animal drugs" require mandatory pre-market review and approval by FDA. To approve the drug, FDA must analyze the safety of the drug to the animal, the effectiveness of the drug, and the safety of any human food that will be derived from the animal that is administered the drug.

CSPI supports FDA oversight of animals with intentionally altered DNA. FDA made a compelling scientific case for such oversight of genome-edited animals, even those with modifications that replicate what has or could occur in nature. In a recent article in Nature Biotechnology (February 2020), FDA stated that:

> "genome editing in animals can have unintended consequences and … regulators must be alert to the possibility of such consequences…. Unintended alterations may

> affect protein expression, including the disruption of protein function, changes to expression level of a protein (such as overexpression of a hormone receptor) or creation of a new expression product. Such an event could be of no consequence, or it could affect the safety of food derived from the animal. We can't know this if we don't look."[2]

This article was published after a recent incident in which FDA scientists identified an unintended modification in the DNA of a genome-edited cattle product undergoing review. This incident highlighted the need for independent checks on industry's own safety reviews. FDA, with its independence and expertise, can play a role in ensuring safety, which will alleviate many consumers' concerns as well as those of our international trading partners.

Using its statutory authority, FDA should establish a proportionate, risk-based regulatory system with different levels of oversight based on a product's potential risk. FDA Draft Guidance #187 does not establish such a system. Instead, Draft Guidance #187 treats all alterations of an animal's DNA the same when, depending on the alteration, the potential risk could be extremely different. For example, intentionally making a single nucleotide deletion to silence a gene to mimic an existing phenotype found in nature does not have the same potential risk as introducing three new genes from a different animal that confer resistance to a disease. Similarly, silencing one gene in an animal genome does not have the same potential risk as editing 30 different genes in a single animal's genome. FDA should establish different categories of intentionally altered animals based on their

[2] Solomon S. Genome editing in animals: why FDA regulation matters. *Nature Biotechnology.* 2020; 38:142-150.

potential risk and then match its regulatory requirements to the potential risk of the products in each category. This approach would be consistent with a recent NAS report on *Preparing for Future Products of Biotechnology* which suggested proportionate risk-based oversight based on how "familiar and complex" the product is compared to existing products.

Several stakeholders have suggested that, instead of FDA, USDA could regulate genome-edited animals under the Animal Health Protection Act. While USDA might be able to put in place a regulatory system comparable to FDA that ensures safety, engenders consumer trust, and satisfies domestic and international market concerns, the stakeholders pushing for the change in jurisdiction clearly hope for USDA to impose little or no regulation. The National Pork Producers' "Keep America First in Agriculture" campaign website specifically states that "the USDA's review process for genome edited plants could easily be adapted for livestock."[3] That process, as discussed elsewhere in my testimony, requires no oversight for most genome-edited plants and allows developers to self-determine whether they are regulated. Clearly such a process would not address the legitimate and science-based concerns that FDA believes need to be assessed to ensure the safety of genome-edited animals. Therefore, much more needs to be known before one can assess if moving regulatory oversight to USDA will ensure safety and provide confidence to consumers.

[3] National Pork Producers Council. Keep America First in Agriculture. n.d. http://nppc.org/kafa/. Accessed March 6, 2020.

The Environmental Protection Agency

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires EPA to register all pesticides sold in the United States. More than twenty years ago, EPA promulgated a regulation under FIFRA that established how it would regulate GE crops that had been engineered to produce a biological pesticide (such as the Bt-corn and Bt-cotton varieties currently on the market). Those plant-incorporated protectants (PIPs) are assessed in a mandatory review for impacts on the environment and human health because they are pesticides. EPA also determines if any tolerance level is needed for the residues of the pesticide on food products derived from the crops. EPA's registration process helps ensure that any PIP will not result in unreasonable risk to human health or the environment when used appropriately. EPA' regulatory system is science- and risk-based, transparent, and participatory.

To date, EPA has not stated whether it will regulate genome-edited plants that have pesticidal properties in the same manner as it has regulated Bt crops. However, if a genome-edited plant has been altered to act as a pesticide (which is defined as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating a pest"), then EPA should require registration after ensuring that the pesticide will not result in unreasonable risk to human health or the environment when used appropriately. EPA has the flexibility to proportionately regulate pesticides under its current authority – it already has significantly different requirements and procedures for chemical pesticides, biological pesticides, and PIPs – and CSPI expects that EPA will tailor its oversight based on the risk profile of different plants edited with pesticidal properties.

Need for a National Registry for Genome-Edited Products

Independent of the regulation that CSPI believes is necessary by USDA, FDA and EPA, CSPI also supports a national registry identifying genome-edited products. Depending on how the three agencies regulate genome-edited agricultural products, many of those products may escape federal oversight. However, at a bare minimum, some consumers and portions of the domestic and international markets will want to know which products have been produced with genome editing. If we learned anything from the controversy over GE 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. CSPI has advocated that either USDA or FDA should establish a national registry of genome-edited agricultural products as an easy, economical, and accessible way to transparently provide information about gene-edited crops and traits in the U.S. food supply. Gene-edited-product developers could fill out a short form—a "gene editing data sheet"— that could be uploaded into a public database with a search engine, and a summary of all the data sheets could be generated, making it easy for anyone to quickly determine which products and/or traits are in the food supply. Such a registry would foster transparency and ensure the public and interested stakeholders have access to basic information about the food supply.

In conclusion, agricultural innovation is important to our farmers, the food supply and consumers. Congress and the Executive Branch must ensure that there is sufficient science-based oversight to protect our health and safety and allow markets to operate and provide choice. Agricultural innovation through biotechnology has and will continue to

provide benefits to farmers and the environment but only if the federal government, through an appropriate regulatory structure, ensures safety and gives consumers confidence in those products.