

**AGRICULTURE INNOVATION AND THE FEDERAL
BIOTECHNOLOGY REGULATORY FRAMEWORK**

HEARING

BEFORE THE

**COMMITTEE ON AGRICULTURE,
NUTRITION, AND FORESTRY**

UNITED STATES SENATE

ONE HUNDRED SIXTEENTH CONGRESS

SECOND SESSION

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MARCH 12, 2020
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C O N T E N T S

Thursday, March 12, 2020

	Page
HEARING:	
Agriculture Innovation and the Federal Biotechnology Regulatory Framework	1
STATEMENTS PRESENTED BY SENATORS	
Roberts, Hon. Pat, U.S. Senator from the State of Kansas, Chairman, Committee on Agriculture, Nutrition, and Forestry	1
Stabenow, Hon. Debbie, U.S. Senator from the State of Michigan	3
WITNESSES	
Johnson, Patrick L. Jr., Producer and Chairman, Environmental Task Force, National Cotton Council, Tunica, MS	6
Parrott, Wayne, Ph.D., Professor, Department of Crop and Soil Sciences, Institute of Plant Breeding, Genetics and Genomics, University of Georgia, Athens, GA	8
Paustian, Michael, Ph.D., Producer and President, Iowa Pork Producers Association, Walcott, IA	9
Jaffe, Gregory, Director of the Project on Biotechnology, Center for Science in the Public Interest, Washington, DC	11
APPENDIX	
PREPARED STATEMENTS:	
Johnson, Patrick L. Jr.	26
Parrott, Wayne, Ph.D.	30
Paustian, Michael, Ph.D.	34
Jaffe, Gregory	37
DOCUMENT(S) SUBMITTED FOR THE RECORD:	
Roberts, Hon. Pat:	
Farmers Access to New Biotechnologies, Letter of Support	52
Development of New Breeding Methods and Agriculture Innovation, Letter of Support	54
QUESTION AND ANSWER:	
Johnson, Patrick L. Jr.:	
Written response to questions from Hon. Pat Roberts	58
Written response to questions from Hon. Mike Braun	58
Written response to questions from Hon. John Thune	59
Parrott, Wayne, Ph.D.:	
Written response to questions from Hon. Pat Roberts	60
Written response to questions from Hon. Mike Braun	61
Written response to questions from Hon. John Thune	62
Paustian, Michael, Ph.D.:	
Written response to questions from Hon. Pat Roberts	64
Written response to questions from Hon. Mike Braun	65
Written response to questions from Hon. John Thune	66
Written response to questions from Hon. Tina Smith	67

IV

	Page
Jaffe, Gregory:	
Written response to questions from Hon. Pat Roberts	69
Written response to questions from Hon. John Thune	70

AGRICULTURE INNOVATION AND THE FEDERAL BIOTECHNOLOGY REGULATORY FRAMEWORK

THURSDAY, MARCH 12, 2020

U.S. SENATE,
COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY,
Washington, DC.

The Committee met, pursuant to notice, at 10:03 a.m., in room 328A, Russell Senate Office Building, Hon. Pat Roberts, Chairman of the Committee, presiding.

Present or submitting a statement: Senators Roberts, Boozman, Ernst, Braun, Grassley, Thune, Fischer, Loeffler, Stabenow, Brown, Bennet, Gillibrand, Casey, and Durbin.

STATEMENT OF HON. PAT ROBERTS, U.S. SENATOR FROM THE STATE OF KANSAS, CHAIRMAN, U.S. COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

Chairman ROBERTS. Good morning. I call this meeting of the Senate Committee on Agriculture, Nutrition, and Forestry to order. I welcome my colleagues, especially our newest member of the Senate Agriculture Committee, Senator Loeffler from Georgia. Senator Loeffler has first-hand experience in production agriculture. She can go into that if she would like, but welcome to the Committee, Kelly. We are very happy to have you. I will applaud.

[Applause.]

Chairman ROBERTS. When I became the Chairman of this Committee five years ago, the first commitment I made to the Committee, and to everybody in farm country, was that this Committee would put farmers and producers first. I promised to be their champion and their voice and to use this committee to ensure that the government would listen to their concerns. Much work has already been done on behalf of producers in the agriculture industry and this morning we continue that effort.

Agriculture biotechnology is certainly not a new topic for this Committee. Over the last few decades, biotechnology has become a valuable tool in ensuring the success of the American farmer in meeting the challenges of increasing yield in a more efficient, safe, and environmentally friendly manner.

That progress continues today through research that has led to new, innovative technologies. These include breeding techniques and tools that our producers will increasingly rely on to produce safe and affordable food to meet demands at home and around the world.

As science and technology evolve, so must the regulation of these products. The coordinated framework for the regulation of biotechnology is the multi-agency Federal system that serves to assess any risks of new biotechnology products and to ensure their safety to the environment and to human and animal health.

Established back in 1986, the United States Department of Agriculture, the Environmental Protection Agency, and the Food and Drug Administration each serve roles in the regulation of the products of modern agriculture biotechnology through the coordinated framework.

The key word here is “coordinated.” There have been efforts over the years by these agencies to update or add to the framework. There were proposed rules issued in 2008 and 2017, at the USDA’s Animal Plant Health Inspection Service, APHIS, and in 2011, at the EPA, none of which were finalized.

Also in 2017, the FDA issued draft guidance addressing animals with altered DNA through new technologies. In June of last year, APHIS published a proposed rule to update and reduce regulatory burdens for technology developers of advanced genetic engineering such as genome editing. This rule is currently under review at the Office of Management and Budget.

Five days later, the White House issued an Executive Order directing these respective agencies to modernize the regulatory framework, I quote, “to facilitate innovation, ensure coordination across regulatory agencies, and safely enable billions of people across America and the world to reap the benefits of such products.”

Additionally, it is our understanding that the EPA has confirmed that the OMB is reviewing their proposed rule on plant-incorporated protectants in light of advanced breeding technologies, though scant detail has been shared regarding that proposal.

As all three of these agencies work to update guidance and regulations, let me point out it is absolutely critical that they listen to those who would produce with and use this new technology every day.

There are many complexities experienced at the ground level by farmers, producers, and ranchers interested in utilizing new technologies. These practical concerns must be considered.

Today, our committee will hear from some of those stakeholders. These witnesses will testify about what they view as important in an updated regulatory framework, and I fully expect that each agency will take these statements into very thoughtful consideration. I fully expect that each agency will take these statements into very thoughtful consideration. I am being repetitive, on purpose.

The technologies being discussed today can provide solutions to deal with some of the world’s most pressing problems—food insecurity, disease risks, and a changing climate. Bottom line: farmers want to utilize technology to meet growing needs in spite of increased pressures.

The regulatory structure must be workable and risk-based. It must not stifle adoption of technologies and ultimately make the U.S. less competitive.

In addition to today's statements, I ask unanimous consent to submit two letters, one from 24 farmer organizations and one from ag State Governors into the hearing record. Without objection, it is so ordered.

[The letters can be found on pages 52 and 54 in the appendix.]

Chairman ROBERTS. My second commitment as Chairman of this Committee was to conduct rigorous and thorough oversight of the departments and agencies within this Committee's jurisdiction. This hearing is an important part of that oversight process.

The Department of Agriculture, along with the EPA and FDA, do have a responsibility to establish policies that are science-based, timely, transparent, and coordinated and functional for the industries that rely upon them.

I thank each witness for providing testimony before the Committee on this important issue, and now I recognize the distinguished Senator from Michigan, Senator Stabenow, with any remarks that she may have.

**STATEMENT OF HON. DEBBIE STABENOW, U.S. SENATOR
FROM THE STATE OF MICHIGAN**

Senator STABENOW. Thank you, Mr. Chairman, and I join you in welcoming the witnesses today for a very important hearing.

Innovation is the foundation of American agriculture. From breakthroughs in plant breeding to advances in crop rotation land-grant universities, researchers, and creative farmers have all revolutionized what we grow and how we grow it.

Today, agriculture faces many challenges that will require us to push the bounds of what is possible. We know we need to increase food production in a sustainable way in order to feed a growing global population that is projected to reach nearly 10 billion people by 2050. At the same time, farmers are seeing the impacts of the climate crisis, which has made growing the food that we eat even more difficult.

Biotechnology has the potential to help us increase our productivity, while also helping farmers address the climate crisis. Drought-tolerant plant varieties can help farmers weather historic dry spells. Cover crops are being improved to have deeper roots to hold more carbon in the soil, creating new opportunities for farmers to sell carbon credits in a voluntary market.

In order to make the most out of the innovative potential of biotechnology, consumers and our trading partners both need certainty. That is why it is critical to ensure that our regulatory system is effective, science-based, and transparent.

It is also important to balance flexibility that encourages new product development with reliable standards that ensure products are safe. I am concerned that the USDA's proposed biotech rule, published last June, does not provide adequate oversight of our biotechnology sector. The hands-off approach proposed by USDA lacks the strong scientific justification that consumers and our trading partners expect. I urge the USDA to include scientific support for the agency's approach when publishing a final rule.

I am also deeply concerned that the proposed rule would allow developers of certain products to determine for themselves whether the regulations apply. Under the proposed rules, a company could

make its own determination that its product is exempt from the rule. That product could then enter the marketplace without any public notification or consumer awareness.

I think that many Americans will find that unacceptable, and I am concerned that many of our trading partners will as well.

As recently as 2013, farmers experienced enormous disruptions when China began rejecting shipments of corn and distillers grains after finding trace amounts of a biotech trait that had been approved by the U.S., but was still under review in China. Right now, our farmers cannot afford to face any more barriers to trade.

I certainly believe in science and I will say again I believe in support science, and science tells us that biotechnology is safe. I will say that again—biotechnology is safe—and it can improve people's lives. However, we need to be fully transparent in order to ensure customers at home and abroad are not doubting the safety of these products.

A broad coalition of biotech industry leaders, agribusinesses, and consumer advocates agree on this. Just last week, they sent a letter to urge the Office of Management and Budget to modify the self-determination provision because they understand the importance of transparent and consistent regulation.

It is really important that we get this right. I join in encouraging the USDA to listen to this broad coalition of stakeholders and modify the rule before publishing it in its final version. This is such an important part of our economy and of the success of agriculture. Again, I want to make sure we get this right.

Thank you, Mr. Chairman.

Chairman ROBERTS. Thank you, Senator.

We want to welcome to our panel the witnesses before the Committee this morning. Our first witness is Mr. Patrick L. Johnson of the National Cotton Council. Senator Hyde-Smith was planning to introduce you, sir, but she apparently has a conflict and so you are stuck with me.

Our first witness, Mr. Patrick Johnson, hails from Tunica, Mississippi. After receiving his bachelor's degree from the University of Mississippi, he returned to his family farm where he and his wife Emily currently reside. He is the owner and operator of Cypress Brake Planting Company, a farming operation that includes cotton, rice, corn, and soybeans.

Mr. Johnson currently serves as the Chairman of the National Cotton Council's Environmental Task Force, and brings unique knowledge and experience on issues related to agriculture production practices and environmental stewardship.

Welcome, Mr. Johnson, and we look forward to your testimony. Senator Loeffler, I turn to you to introduce Dr. Wayne Parrott.

Senator LOEFFLER. Thank you, Mr. Chairman, Ranking Member Stabenow, and my colleagues for your warm welcome to this Committee. Having grown up on a family farm, working in the fields and the feed lots, I am truly honored to serve on this Committee and serve our Nation's farmers. I also thank you for the privilege of introducing one of our witnesses for today, Dr. Wayne Parrott.

Dr. Parrott has pursued an esteemed career in a field I personally hold dear, as well as leading the industry in my home State, which is agriculture. Dr. Wayne Parrott is a distinguished research

professor in the Department of Crop and Soil Sciences at the University of Georgia, alumnus of the University of Kentucky the University of Wisconsin-Madison. He joined University of Georgia in Athens in 1998.

Dr. Parrott has been a Georgia Bulldog for more than 25 years, where he led biotechnology research for the improvement of crop plants, particularly genetic engineering and gene editing. Dr. Parrott's work aims to solve agronomic problems facing farmers in Georgia and across our country, such as resistance to insects and increased efficiency of bioenergy grasses.

Thanks to the work done by Dr. Parrott and his colleagues, UGA has become a world-renowned center for agricultural research. The work done at UGA has changed the game and offered a model for safe, effective, and thorough research and the application of new seed biotechnology.

In addition to his work in academia, Dr. Parrott has made a difference in the professional agriculture industry. Most recently he served on the board of directors for the Society of In Vitro Biology and was elected to the Soybean Genetics Executive Committee and American Society of Plant Biology.

Through his accomplishments and associations, though I have just mentioned a few, they hardly do his career justice. His impact on agriculture science and research, as well as our future farmers' education are lasting. I have heard the term "rock star" used to describe Dr. Parrott and his work in biotechnology, and it is easy to understand when you take a look at his accomplishments.

I thank this Committee for allowing me to introduce Dr. Parrott, and thank him and all of our witnesses for being here with us today.

Chairman ROBERTS. We thank you, Senator.

Our third witness is Dr. Michael Paustian. He is a sixth-generation farmer from Walcott, Iowa—six generations.

Dr. PAUSTIAN. Yes, sir.

Chairman ROBERTS. When did

[Laughter.]

Chairman ROBERTS [continuing]. when did you start? When did your family start?

Dr. PAUSTIAN. My great-great-great-great grandfather came over from the Schleswig-Holstein area of Germany and built the house that I grew up in and my parents still live in, back in the mid 1800's. We have been there ever since.

Chairman ROBERTS. That is outstanding. I can't think of a better word.

His family has a farrow-to-finish hog farm as well as a corn and soybean operation. Dr. Paustian has earned a Ph.D. in microbiology from the University of Minnesota, after which he worked as a research scientist before returning to the family farm. He currently serves as the President of the Iowa Pork Producers Association.

Welcome, and thanks for being here today, Doctor.

Our last witness is Mr. Greg Jaffe. Mr. Jaffe is the Director of the Project—oh, I am supposed to yield to you to do that.

Senator STABENOW. That is perfectly all right.

Chairman ROBERTS. No, I insist.

Senator STABENOW. I am still trying to figure out, is it six—eight generations? I am still trying to figure that out. That is very impressive. I assume you now have electricity and running water in the house. You have improved it, yes.

[Laughter.]

Senator STABENOW. Okay, good. Indoor plumbing, yes.

Chairman ROBERTS. It is the great-great-great-grandfather, right?

Dr. PAUSTIAN. Three greats, yes.

Chairman ROBERTS. Three, not four. I just did four. Well, there you go.

Senator STABENOW. That is very impressive. Very impressive.

Chairman ROBERTS. You have plumbing in that house?

Dr. PAUSTIAN. Not originally, but there is now.

Chairman ROBERTS. I got it. Okay. Thank you.

Senator STABENOW. Well, it is wonderful to have all of you here, and I do want to welcome Greg Jaffe, who is testifying this morning as the Director of the Biotechnology Project at the Center for Science in the Public Interest. Greg came to CSPI in 2001 after a long and distinguished career in public service. He is a recognized expert on agricultural biotechnology and biosafety, and has published numerous articles and reports on those topics.

He has served as a member of the Secretary of Agriculture's Advisory Committee on Biotechnology under both Democratic and Republican administrations. We welcome you and appreciate your input today.

Chairman ROBERTS. We will start with you, Mr. Johnson. Thank you very much.

STATEMENT OF PATRICK L. JOHNSON, JR., PRODUCER AND CHAIRMAN, ENVIRONMENTAL TASK FORCE, NATIONAL COTTON COUNCIL, TUNICA, MISSISSIPPI

Mr. JOHNSON. Thank you, Mr. Chairman, Ranking Member, and members of the Committee for allowing me to be here this morning. As Senator Roberts said, my name is Patrick Johnson and I am a cotton, rice, corn, and soybean grower in Tunica, Mississippi, and I do serve as the Chairman of the National Cotton Council's Environmental Task Force, and recently was notified of my acceptance to EPA's Pesticide Policy Dialogue Committee for the upcoming term.

Biotech cotton was first introduced in 1996, and U.S. cotton farmers rapidly adopted this new technology. In 2018, USDA reported over 90 percent each of cotton, corn, and soybean acres were planted in biotech varieties.

For cotton production in the U.S., the latest estimates of the benefits of these insect-resistant varieties are 185 million pounds per year increase in production, 1.9 million pounds per year decrease in insecticide use, and \$103 million per year increased in net revenue to farmers.

The benefits of herbicide-tolerant biotech cotton in the U.S. include a 6.2 million pound per year decrease in herbicide-active ingredients applied, and \$133 million per year savings in weed control costs.

As you can see, U.S. cotton farmers have a vested interest in the continued availability of new biotechnology products under a regulatory system that is efficient and streamlined while protecting the health and safety of the public and the environment, and regulations have a large impact on the number of products being brought to market.

Under the coordinated framework, agency review is shared among USDA, FDA, and EPA, depending on the product use, ensuring thorough regulatory oversight. With the President's June 2019 Executive order modernizing the regulatory framework for agricultural biotechnology products, calling for increased transparency and coordination within the agencies, we had hoped for a swift update to the coordinated framework to face the challenges of the newer technologies coming to the forefront.

Recently, though, we have again become concerned at the apparent lack of policy coordination between the three Federal agencies involved in the coordinated framework. This is an issue that occurred in past administrations as well, and we urge the agencies to move swiftly to produce an efficient framework for the future. In fact, APHIS's new regulatory approach is intended to prepare the agency for future advances in the genetic modification of plants. It is important to our industry, and to agriculture as a whole, that the three agencies work together as seamlessly as possible to regulate both older and newer technologies.

Recent reports suggest an apparent lack of coordination between USDA and EPA on the plant side of new technologies. This is concerning to the cotton industry, as it may suggest an absence of communication between those two agencies. It is our understanding that USDA's revised rule has reached OMB and therefore may soon be final. We do not know the status of a proposed companion revision from EPA. As a result, the industry is worried about the future of new technologies if the coordinated framework is not working at its most efficient level.

Our industry needs the framework to operate at peak efficiency across all agencies. Currently it takes 20 to 40 years to bring new traits from diploid cottons into cotton varieties through traditional breeding. Newer biotechnology techniques can perform the same function in two years if allowed to work free of delays created by misunderstandings in the public arena and a slow regulatory regime. In the U.S., wild cotton relatives have valuable alleles that the industry hopes to exchange with commercial alleles using technology such as gene editing. They can be edited into cotton in a timely fashion if the U.S. regulatory agencies can work together within a streamlined coordinated framework.

Cotton Council would also like to point out that consistent policies globally for products of plant breeding innovation are essential to avoid trade disruptions. The U.S. cotton industry exports more than 85 percent of our annual fiber production, and exports of cotton seed to key markets are an important component of the economic health for the cotton seed segment of our industry.

We would like to commend the agencies for their intent to improve the regulatory system for agriculture biotechnology as well as for recognizing the long history of scientific evidence that supports the safety of products developed using these methods. We believe

that making strategic improvements to the current regulatory system in terms of speed, efficiency, transparency, and coordination will engender broader public support, prove easier to implement, and have much more immediate impact with fewer unintended consequences.

Thank you again for the opportunity to testify this morning.

[The prepared statement of Mr. Johnson can be found on page 26 in the appendix.]

Chairman ROBERTS. We thank you very much, Mr. Johnson. Dr. Parrott.

STATEMENT OF WAYNE PARROTT, Ph.D., PROFESSOR, DEPARTMENT OF CROP AND SOIL SCIENCES, INSTITUTE OF PLANT BREEDING, GENETICS AND GENOMICS, UNIVERSITY OF GEORGIA, ATHENS, GEORGIA

Dr. PARROTT. Good morning, Chairman Roberts, Ranking Member Stabenow, and members of the Committee. I am Wayne Parrott, a professor of plant breeding, genetics, and genomics at the University of Georgia. Thank you for the opportunity to be here today to talk about innovations in precision plant breeding. This is really the most exciting time in my 30-year career to be a plant breeder, because of the new tools that are now available and that build-upon the crop modifications that nature and farmers have been doing for thousands of years to improve the food we eat.

Solving problems by creating new crop varieties is what plant breeders have always done. Agriculture has always faced, and will always face, new and emerging threats from pests, diseases, and adverse growing conditions. Agriculture constantly depends on new varieties to help overcome its challenges. At the same time, new varieties help meet consumer expectations for quality, value, and sustainability.

Notably, plant breeding also has an amazing safety record, with hundreds of thousands of new varieties introduced over the past century. With the ability we now have to sequence plant genomes, we see that these varieties have highly variable genomes between them, and that the genomes are always changing, which makes it very clear that modifications at the genomic level are not an indicator of risk.

Now plant breeders have access to gene editing, which is a precision breeding method that allows us to make very specific changes to a genome, resulting in an end product that is often indistinguishable from a plant bred using traditional breeding methods. The only difference is that it is done with far fewer off-target effects than in the past and with far greater efficiency, taking months instead of years, in some cases.

Today, many gene edited crops are coming through the product pipeline. Examples include tomatoes adapted for use in vertical farms for urban areas and edited rice that is showing improved yields in field trials. With my colleagues at the University of Georgia, we are working on a switchgrass that yields twice as much and is easier to convert into biofuels.

We envision future crop varieties that will underpin the bioeconomy by becoming a major source of raw materials for the manufacturing, bioenergy, and pharmaceutical industries.

The benefits from tools like gene editing cannot be disputed, but for these tools to be used the applicable policies must be enabling. The original coordinated framework for regulation of biotechnology, written in 1986, as well as subsequent reviews and Executive orders reaffirm the need for regulatory policy that promotes innovation while protecting health and environment.

The 2019 Executive order also instructed the USDA, the EPA, and the FDA to take steps to have consistency in coordination among them and to streamline regulations. This work has yet to be completed, and it is unclear how much coordination has taken place since the Executive order was published.

At the same time, countries, including Brazil, Argentina, Israel, Australia, and Japan, recognizing the lack of unique risks from editing, already have policies in place that are favorable for the use of gene editing in plants, while the United States remains without a coherent policy.

To conclude, I am excited about these new breeding tools. However, the three Federal agencies must have a coordinated approach and policies that are risk proportionate and scientifically based if the benefits of these innovations are to be realized. Given a sound regulatory policy, there is no doubt in my mind that American agriculture will meet all the challenges that the current century will bring forward.

Thank you for your time.

[The prepared statement of Dr. Parrott can be found on page 30 in the appendix.]

Chairman ROBERTS. Right on the money, Dr. Parrott. Dr. Paustian.

STATEMENT OF MICHAEL PAUSTIAN, Ph.D., PRODUCER AND PRESIDENT, IOWA PORK PRODUCERS ASSOCIATION, WALCOTT, IOWA

Dr. PAUSTIAN. Chairman Roberts, Ranking Member Stabenow, and members of the Committee, I appreciate the opportunity to discuss issues of critical importance to U.S. pork producers. I am the President of the Iowa Pork Producers Association and a hog farmer from Walcott, Iowa. I am also here today on behalf of the National Pork Producers Council, a national association representing the interests of 60,000 U.S. pork producers.

The U.S. pork industry has been built on innovation. Our commitment to continuous improvement has made the United States the world's leading supplier of high-quality, safe, and sustainably produced pork. However, we are currently in danger of ceding this advantage to international competitors due to the FDA's flawed approach to regulating new animal breeding tools.

These tools, which allow for precise changes within an animal's own genome, offer tremendous promise to combat animal health and welfare challenges and produce safer food in a more sustainable fashion. Livestock producers need access to these technologies. While countries like China, Canada, Brazil, and Argentina are moving quickly to gain a competitive advantage in the market, the U.S. is falling behind.

I want to be very clear that we are not advocating for deregulation of these new technologies. Hog farmers support scientifically

sound, transparent, risk-based regulations that ensure that these new tools are effective and safe for both animals and consumers. Regulation should be based on the type of genetic changes being introduced, not the method by which the changes were made. Our concern is not if this technology should be regulated but rather by who and under what authority.

Under the current regulatory framework, FDA has authority over genetic technologies in animals. The agency is proposing regulating these new technologies under the Food, Drug, and Cosmetics Act by approving the altered genome as a drug. In effect, this would regulate the animal, which is indistinguishable from the genetic material on every cell of its body as a drug under U.S. law.

There are myriad problems with this approach. I will highlight two. First, any edit would have to be individually evaluated for every breed, strain, or herd of animals that wanted to incorporate a given trait. This would bog down approval and make this technology inaccessible to most livestock producers like myself.

The second big problem is the real potential for the United States to lose its standing as the top producer of high-quality, healthy, and affordable pork. Competitor nations are already advancing regulatory pathways that are not hampered by red tape. We are losing our competitive advantage. We are subjecting U.S. exports to damaging trade barriers as our own government will have said they are, or at the very least, contain drugs. We have had extensive conversations with regulators in other countries. They are scratching their heads at what we are doing.

The FDA has insisted that farmers are simply misunderstanding its regulatory proposal. Not true. We, along with scientific and trade communities, have clearly stated our strong objections to FDA's proposal. Alternative strategies the FDA could pursue have been put forth by multiple stakeholders and quickly rejected. The agency has not addressed this concern in any meaningful way.

The agency remains entrenched in its flawed approach. The FDA has been given numerous opportunities to address this fundamental issue, only to dismiss it as inconsequential and insist that additional clarification is forthcoming. We are still waiting.

It is clear we need a new approach. It is imperative that the U.S. place primary authority for regulating all agricultural applications of new genetic technologies under USDA. The agency has fostered new breeding techniques in plants for decades under the Plant Protection Act. They can do the same for livestock under the Animal Health Protection Act.

The USDA can regulate agricultural animals, leaving the FDA to focus on other exciting biomedical applications that are under development. This shift will remove many of FDA's obstacles. It will allow for research and development of these technologies to take place at American universities rather than overseas; let farmers adopt these new breeding techniques without fearing loss of international markets; and demonstrate to the world that the U.S. is committed to a pro-innovation, risk-based approach to new technology, not a precautionary one.

In short, this approach will allow U.S. agriculture to maintain its global edge. We ask you to support this move from the FDA to the USDA.

Thank you for the opportunity to testify, and I look forward to any questions.

[The prepared statement of Dr. Paustian can be found on page 34 in the appendix.]

Chairman ROBERTS. We thank you for that testimony, Doctor. Mr. Jaffe.

STATEMENT OF GREGORY JAFFE, DIRECTOR OF THE PROJECT ON BIOTECHNOLOGY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, WASHINGTON, DC

Mr. JAFFE. I want to thank Chairman Roberts, Ranking Minority Member Stabenow, and other Committee members for inviting me as a witness on behalf of the Center for Science in the Public Interest. I am here today as the Director of CSPI's Biotechnology Project.

CSPI is a nonprofit consumer organization that was established almost 50 years ago. CSPI does not receive any funding from the 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.

For years, CSPI has advocated for improvements in the Federal biotechnology regulatory oversight system to ensure safety to humans, animals, and the environment. Today, I will limit my testimony to several current issues around the Executive branch oversight of genetically engineered and genome-edited crops and animals.

USDA regulates genetic-engineered crops under its plant pest authority provided by the Plant Protection Act. In the last few years, however, a loophole that allows developers of genetically engineered 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 genetically engineered crop, even the experimental field trials.

USDA's decision to exempt certain genetically engineered and genome-edited crops is not based on the 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 and the United States with our trading partners abroad.

In 2019, USDA proposed changes to its regulations for genetically engineered organisms. Those proposed changes, if adopted, would greatly narrow the number of genetically engineered and genome-edited crops that USDA would regulate.

First, the proposed regulations would eliminate oversight of most genetically engineered crops that have previously been regulated because they utilized agrobacterium in the transformation process.

Second, USDA's proposed rule includes several specific exemptions for genome-edited crops without any scientific evidence to support those exemptions. CSPI does not object to exempting genetically engineered or genome-edited crops if there is a scientific evidence that they do not pose risks to the environment or agricultural interests.

Finally, the USDA proposal allows developers to self-determine if they are regulated or qualify for an exemption. While some developers will diligently determine the regulatory status of their GE plants, other may not. USDA should be required to review and confirm those exemptions. That position is supported by both NGO's and also industry stakeholders, as Senator Stabenow stated earlier.

FDA regulates genetically engineered and genome-edited animals under the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act. CSPI supports FDA oversight of animals with intentionally altered DNA. FDA recently made a compelling scientific case for such oversight of genome-edited animals. Using its statutory authority, the FDA should establish a proportionate, risk-based regulatory system with different levels of oversight based on the product's potential risks. FDA's current guidance, Draft Guidance 187, does not establish such a system. Instead, it treats all alterations of an animal's DNA the same, when depending on the alteration of the potential risk could be extremely different.

Several stakeholders have suggested that instead of FDA, USDA should regulate genome-edited animals under the Animal Health Protection Act. Some stakeholders suggest USDA oversight because they hope that it will mimic the USDA's review process for genome-edited plants. That process requires no oversight for most genome-edited plants and will allow 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.

Finally, the Federal Insecticide, Fungicide, and Rodenticide Act requires EPA to register all pesticides sold in the U.S. EPA promulgated a regulation under FIFRA that establishes how it will regulate genetically engineered crops that have been engineered to produce a pesticide. EPA's regulatory system is science-and risk-based, transparent and participatory, and CSPI supports it.

Independent of regulation that CSPI believes is necessary, CSPI supports a national registry identifying genome-edited products. CSPI has advocated that either USDA or FDA should establish a national registry of genome-edited crop products as an easy, economical, and accessible way to provide transparency about genome-edited products in the food supply.

In conclusion, agricultural innovation through biotechnology has and will continue to provide benefits to farmers and the environment, but only if the Federal Government, through appropriate regulatory structures, ensures safety and gives consumers confidence in those products. Thank you.

[The prepared statement of Mr. Jaffe can be found on page 37 in the appendix.]

Chairman ROBERTS. Thank you, Mr. Jaffe.

Dr. Parrott, based on your experience interacting with EPA and the USDA over the years, what would the consequences be if the Department of Agriculture and the Environmental Protection Agency take different approaches to regulating products of advanced breeding technologies?

Dr. PARROTT. Thank you for the question. We already have—we can just look back in past history with previous technologies to answer that question, and the answer is that a lot of crops that would

be very useful to farmers and consumers simply get left on the shelf. Particularly affected are disease-resistant and pest-resistant traits, which as far as biotechnology goes are the low-hanging fruit that are easier to achieve, and, thus the thing that has been deployed the least, because of the barriers that have come from having different criteria for evaluation.

Chairman ROBERTS. I appreciate that very much. Dr. Paustian, as noted in your testimony the FDA is examining options on a regulatory structure for the development and approval of new livestock technologies. My question is, is the FDA working to carry out the commitment made by the administration to foster a regulatory environment in which businesses and industries can thrive and not be stifled by overly burdensome government regulation? How can the FDA best uphold this commitment to keep the interests of producers paramount?

Dr. PAUSTIAN. Thank you for the question. My short answer would be no, they are not, and it is somewhat surprising to me, in the past, with other issues that the livestock industry has dealt with the FDA, most recently putting all antibiotic usage under the supervision of a veterinarian. We have had very good back-and-forth conversation and a productive working relationship with FDA.

On the issue of these new genetic technologies, they appear to be less responsive to the industry's needs and the industry's feedback. That is why, based on the conversations that we have had thus far, we feel that the USDA would be a more natural place for the regulation of these technologies to occur. A lot of that is based on past history with their work on regulating on the plant side. We feel that the USDA understands the needs of the producers and what is going on on the farm and how some of these regulatory decisions will impact producers. We feel like that they are a more natural fit for some of these issues.

Chairman ROBERTS. Thank you, Doctor.

Dr. Parrott, are there loopholes that allow genetically engineered crops to avoid the Department of Agriculture's regulatory process?

Dr. PARROTT. When the Coordinated Framework for Biotechnology was established, the baseline for regulations was supposed to be in comparison to conventional plant breeding. Along those lines, the USDA's role was to ensure there were no plant pests brought forth into agriculture, and we just to have to look back at the history of the past 25 years to see that it has done its job very effectively.

On top of that, because of broad authority under the Plant Pest Act, USDA can intervene with any plant pest problems that a variety might cause if one were ever to cause one.

On top of that, there is an obligation that any food that is sold is safe and that comes through FDA, so, you know, we are never going to escape FDA. Then we still have EPA that will come in and look at several traits. The answer is basically everything is covered by at least one agency or more.

Chairman ROBERTS. I appreciate that. Senator Stabenow.

Senator STABENOW. Thank you very much, Mr. Chairman.

First, Mr. Jaffe, I want you to talk a little bit more about the APHIS proposed rule that allows biotech developers to self-deter-

mine whether or not they are regulated or qualified for an exemption. I share your concern, and there is a broad coalition of agriculture organizations that also share your concern, and so I am wondering: If the USDA declines to modify this provision in the final rule, what will be the impact, from your perspective? What kind of harm could that cause?

Mr. JAFFE. Thank you for the question. There are two things. One, as I stated in my testimony, while many companies may properly self-determine whether they qualify for an exemption, some may not. We may have some products that should be regulated that will not be regulated, and USDA will not even know that they are out there to know to regulate them. That has an impact both on potential safety here in the United States, but it also has impact on international trade and international markets because those products, if they are required to be regulated in the United States and we do not know about them, are probably also required to be regulated in many of our foreign markets, and those will cause trade barriers. In fact, if they are now regulated there in those markets, they may actually be the ones that stop our farmers from growing those crops, not our own regulators but regulators in other markets since we have to export them.

The second thing is also that by allowing USDA to determine whether they are exempt or not, we have a record of what is going out there and there is transparency. Then we have the public knows and the food chain knows, and everybody can then act accordingly. If we do not have that, we are going to have all kinds of organizations, the Non-GMO Project, you know, different organizations will come up with their own list of what is supposedly out there. It will not be accurate. Consumers and the marketplace will be dealing with inaccurate information about what is out there, and that only leads to problems.

Senator STABENOW. Well, how would you improve the regulation?

Mr. JAFFE. I think it is a fairly simple fix for this particular thing, that companies will submit their determination of why they believe they are not exempt. The USDA will either say, "That is correct," and they will qualify for the exemption. Or USDA will say, "No, we need more information" or "We do not think you are exempt." There will be a record of that. The public will have the record of it; USDA will have a public record of it.

I do not think it adds any additional burden, but I think it actually will give a lot more transparency and a lot more confidence to the public and to the regulators that at least the decisions are being made. We can differ about whether they should be exempt, but given that the exemptions may be in the final rule, that would be the reason.

Senator STABENOW. Great. Thank you.

Dr. Parrott, you talked in your testimony about concern that other countries are moving ahead much more quickly on new policies that lead to innovation happening abroad, and I think that is an important concern. Biotechnology can be enormously beneficial, and we want these products developed right here in the United States. I am wondering, how are other countries approaching the issue of regulating gene editing? How are they balancing the need for flexibility and the certainty with transparency?

Dr. PARROTT. I have actually been quite fortunate to travel to various countries and interact with their gene regulators, and some of the legislators have worked on the issue. They are primarily—I guess I side with them in saying that, you know, with our experience as plant breeders and geneticists, we do not see any risk from gene editing, for most types of gene editing that is different from what the conventional plant breeders have been doing for the past century. On that basis, they have a notification requirement that you have to let them know so they can verify that you are not covered by their statutes, and that is pretty much it.

Senator STABENOW. Interesting. So from your standpoint, that is the approach that we should be taking? When we are looking at flexibility and transparency, that, from your standpoint, is the balance?

Dr. PARROTT. In general, Dr. Paustian made the remark that it is not how you do something, it is what you do. It is the product that you are making the trait that you are producing. It is really any—if you look at the traits, you can determine if they are going to present the risk that needs to be managed or not. How you got that trait really is immaterial to the risk.

Senator STABENOW. All right. Thank you. Then if I might just very quickly ask Mr. Jaffe one more question. When we are looking from the FDA's standpoint and the draft guidance that they treat all alterations of an animal's DNA the same when, depending on the alteration, the potential risk could be different. To me that sounds like you are saying the FDA is too one size fits all as they are looking at this. I am wondering, what is your view on their authority and ability to develop a system that is truly science-based, risk-based, if that is the way they are looking at it?

Mr. JAFFE. When you read their Draft Guidance 187, it does seem like it is one size fits all, and that is why I wrote in my testimony that I think they need to figure out how to apply that to different products in different ways. We have seen that they have done that, so for the genetically engineered animals that they have regulated, all of the laboratory mice and rats that they regulated, they did enforcement discretion and decided they did not need to have any oversight of those because they are all in contained laboratories.

For the GloFish, which is the genetically engineered pet fish out there, they also decided to use their enforcement discretion because they did not go into the food supply and because it was, again, because of the way it was going to be used. They all fell within Guidance 187, and yet they used their discretion to figure out a way, because of the risk profile of those products, to regulate them differently. I have confidence that if we give FDA time for the genome-edited animals and the genetically engineered animals, they will put them into categories such that different products, depending on their potential risks, get different levels of oversight, different levels of data that are required, different kind of review, different time for that review. I think, you know, FDA wants to use their resources efficiently, and they will if given time to sort this out.

Senator STABENOW. Thank you.

Chairman ROBERTS. Senator Fischer.

Senator FISCHER. Thank you, Mr. Chairman.

Dr. Paustian, livestock and developer groups have expressed great frustration with FDA's regulatory approach for animal biotechnology. Currently, FDA regulates the animal's DNA as an animal drug under the Food, Drug, and Cosmetic Act, which, let us be honest, it seems to be like taking a square peg and try to put it in a round hole.

The regulatory approach for drugs is extremely long and it is cumbersome. To date, there has been only one biotech food animal approved by the FDA, which took 20 years. FDA also wants to impose unworkable post-approval requirements like saying the animal continues to contain a drug which could jeopardize export prospects for these animals to foreign markets.

Can you share your thoughts on FDA's approach? Should Congress be concerned by it?

Dr. PAUSTIAN. Sure, I would be happy to. You know, going back to the point I tried to make in my statement, we are certainly not saying these things should not be regulated; but the problem is if we go too far and the regulation becomes overly burdensome, as we have seen in the past, that can stifle innovation and it can slow the adoption of new technologies.

You know, one of the issues with FDA's current approach is that anyone bringing a gene-edited animal forward is required to show in multiple generations of that line of animals that—they each have to individually be characterized, and meanwhile none of these animals can enter the food supply. That creates an enormous financial challenge such that, you know, currently there is only one company that I am aware of that is actively going through the FDA process. The reason that concerns me is that when you have overly burdensome regulation, generally it is the smaller companies, the startups, the smaller farmers that get kind of stuck on the outside looking in, because they will not have access to it because to be perfectly honest, I mean, my farm does not have the resources to go through an approval process such as FDA currently has laid out.

I think we run the risk of not only slowing down adoption of the technology, but concentrating the benefits of the technology amongst the few who are able to navigate the maze of red tape and leaving others out.

Senator FISCHER. You know, I think also when we look at FDA and their action in regulating animals as drugs, that to me throws a lot of questions in the minds of many of our trading partners. To continue on that, I understand that some of our trading partners—Brazil, Argentina, China, and others—they are aggressively developing their own animal biotech regulations. You know, we heard about that before, and it is to attract researchers and developers and to grant their producers that first access to innovations, which leaves our livestock producers behind. They start out behind.

Argentina made a non-GMO determination in less than a year for an edited animal. It was a tilapia. That contained no foreign DNA. FDA's regulatory approach could take decades to grant those regulatory approvals.

What risks do you see from foreign regulators establishing themselves as a primary international expert when it comes to this? If you could expand on an earlier answer, I would appreciate that.

Dr. PAUSTIAN. Sure. U.S. producers have enjoyed their position as leading innovation in agriculture. That is what has allowed us to produce more food more safely, more sustainably than anywhere else in the world.

Senator FISCHER. Feed the world.

Dr. PAUSTIAN. Yes. U.S. producers—of course, I am most familiar with pork producers, but I am pretty confident this applies to almost all producers—you know, can compete with anyone in the world as far as productivity. A lot of that is because of innovation. We are also blessed with tremendous natural resources as well and great infrastructure. Those are all strengths that we have been able to take advantage of and put us in the position we are right now.

The rest of the world is catching up, and they are doing it quickly. They have seen the success that we have had, and they are anxious to catch up to us, if not pass us. It is not hard to envision it. We really have a case study to look at right now on the crop side. If you look at the innovation with genetically modified crops and where that has put U.S. production in relation to, say, Europe, where they have been very slow to adopt new technologies due to their precautionary approach, you know, we are far beyond them in production.

It is really not hard to imagine a situation 10, 15, 20 years down the road where we are significantly behind other nations who have continued to keep pace with advances in genetic technology and have left us behind. In my mind, it is of critical importance that we have an appropriate regulatory structure in place, because as has been mentioned, you know, we need to have appropriate regulation to give consumers confidence in the products that we are providing. I do not want to discount that. Consumer acceptance is kind of a whole other hill that we are going to have to climb, and having appropriate regulation in place does not guarantee that. That is another area where we still have a lot of work to do.

Senator FISCHER. Right. You know, it is good to have good spokespeople out there talking about science. Bill Gates, I love his comment when he says, GMOs, you know, “That has been settled for over 15 years, and that is why we are able to feed the world. There is nothing there.” Thank you.

Chairman ROBERTS. Senator Fischer, thank you, and thank you for those most pertinent questions. Dr. Paustian, thank you for your response. Senator Durbin.

Senator DURBIN. Thank you very much, Mr. Chairman.

Mr. Chairman, many years ago, when you and I were on the Agriculture Committee, I decided to look at the issue of food safety, and I discovered some interesting things. I discovered when it came to the safety of meat and poultry, it was the U.S. Department of Agriculture, their responsibility, and they inspected it on a daily basis. I realized that when it came to the food safety of fish, it was the Food and Drug Administration’s responsibility, and they were not monitoring fishermen and the delivery of the catch on a daily basis by any stretch.

Then I came to realize that when it came to whole eggs and their safety, it was the responsibility of the Department of Agriculture; but broken eggs, Food and Drug Administration. Cheese pizza,

what do you think? Food and Drug Administration. Pepperoni pizza, Department of Agriculture. I thought to myself: Why are we doing it this way? Why do we have so many different agencies looking at these food products from their own perspective? Why don't we put it in a single food agency? I set out to do it. Have not achieved it quite yet. Not sure that I ever will, because it turns out there is resistance from the agencies. They want to keep their responsibility. There is resistance from the interest groups because they are afraid if somebody else gets in on the act, it may change the rules as they know them.

Now, when it comes to this hearing, it appears that we have a similar situation. The Department of Agriculture regulated biotechnology as it affects plant and animal health. The Food and Drug Administration regulates the products from the human health perspective, and the EPA regulates the products from the human health and environment perspective.

Once again we have a general question mark, biotechnology, gene editing, for example, that is being addressed by three different Federal agencies looking at different aspects of it. Now the USDA has changed its basic rule as of June of last year in terms of gene editing, but it does not appear that they have gone outside their lane when it comes to the statutory responsibility.

Mr. Jaffe, can you tell me why this concerns you if they are still in their own lane, they are not dealing with human health or environmental aspects of biotechnology?

Mr. JAFFE. Senator, you get at the major problem here, that we have three agencies dealing with these products on a product basis without any overarching look to make sure that we are ensuring safety to humans, animals, and the environment. Sometimes we have overregulation. We have some products that are regulated by multiple agencies, so we have certain crops that are regulated by both USDA and EPA, and some of that regulation is overlapped. We also have products that escape any regulation, so if you do not have a food product and it is a crop and it is not a pesticide and it is produced using the gene gun, it gets regulation by none of these products. Unfortunately, so you could have the same product produced two different ways, the same gene introduced, the same trait, and they might get regulated by one agency and not get regulated by another.

We have instances of overregulation and underregulation, arguably. It would be better, but the Coordinated Framework back in 1986 made the decision to look at these on product statutes, and so we are putting new technologies into product statutes that really do not fit very well.

Senator DURBIN. What impact does this have on innovation and research that you have three different agencies looking at three different aspects of the same basic research?

Mr. JAFFE. I mean, on one level, as one of the other witnesses said, the U.S. has been the leader on genetically engineered crops. We are the ones who developed them. We are the ones growing them. Even with three levels of oversight of those crops, we have still been the leader worldwide. I do not think regulation alone prevents innovation, and we could still have research and do these things. I do think that long term, we need a better system that is

more science-based, that has science and risk at its core so that we are not overregulating and underregulating, which is what we are doing now.

Senator DURBIN. Does the rest of the panel have any thoughts on that?

Dr. PARROTT. Yes.

Senator DURBIN. Turn your mic on.

Dr. PARROTT. In many ways, we can say that our biotech policy has been a success, and we look at our corn or soybean or cotton. We have to recognize that the majority of crops got left behind. We do not have biotech peanuts. We do not have biotech for most of our vegetables. Specialty crops, barley, got left out of the picture. Even traits of regional importance have been left out of the picture. We have a problem that is so unique to the Southeast, really our current policy cannot cope with it.

Yes, there has been a price to pay. I mean, the three agencies do not even use the same definition of "genetic engineering."

Senator DURBIN. Thanks, Mr. Chairman.

Chairman ROBERTS. I thank the Senator.

Senator Loeffler.

Senator LOEFFLER. Thank you, Mr. Chairman, and good morning to our esteemed panel. I appreciate your willingness to be here today and share your expertise.

As you all know, farmers face an ever-growing number of issues today, both natural and manmade. Whether it is disease, international markets, or natural disasters, it is becoming harder for the American farmer to thrive let alone survive.

I applaud the Trump administration and Secretary Perdue for their work to address the coordination between relevant agencies because we have reached the point where the rollout of improved seeds and biotechnology, there is a clear need. However, issues remain with the Coordinated Framework that affect the speed at which these products are approved.

While I agree we need to ensure that these products are safe, we need to make some changes because ultimately farmers and Americans that they feed and clothe are paying the price.

With that, just a question maybe to build on the last question, Dr. Parrott or Mr. Johnson. We have a very diverse set of commodities grown in Georgia, and I am thrilled by the advances biotech has made for Georgia products like cotton. Commodities like peanuts, blueberries, pecans, and other fruits and vegetables have not seen the same degree of innovation.

Could you just expand on why this is the case and what you think could be done?

Dr. PARROTT. I have referenced several times that particularly with most applications of gene editing, we are just doing what has always been done. We are taking the randomness out of the process, and we are making our changes much more targeted than we have in the past. Yet what all of these agencies do is that the trigger for regulation is not what trait we do. The trigger is what technique we use. The moment we start using a biotech approach, it triggers a series of regulations that do not apply to the same crop or the same trait if we handled them in a conventional way.

Actually, in my work we are about to release an insect-resistant soybean variety for growing in the Southeast, and I have been working on that variety for about 25 years. I could do it in about a year's time using the tools of biotech, but if I did it with biotech, I would have to go through EPA, and it would be considered a plant incorporated protectant, and it would be in many ways treated like a pesticide; whereas, if I did it the slow, less accurate way, then there is pretty much no oversight at all. It is this discrimination then that if you do things one way, you get all these that barriers you have to supersede in order to get something into the market, and the cost of compliance and coming up with the necessary information is simply far greater than the profit margin that the farmer would ever get from using that trait.

Mr. JOHNSON. I would just add briefly that I cannot speak necessarily to those other crops, but even for crops like cotton and some of the larger crops that are grown on larger acreages that have made a lot of advancements, we find ourselves in a position where we are relying on a small number of products heavily, and there is still a real need for a streamlined process to bring new technology to the forefront to allow us to meet the goals we have for stewardship and resistance management and things like that.

Senator LOEFFLER. Thank you so much. Thanks for all you do for this industry.

Chairman ROBERTS. Senator Boozman.

Senator BOOZMAN. Thank you, Mr. Chairman, and thank you Ranking Member so much for having this very important hearing that is so timely. I think we all agree that through safety and science, we want to protect the consumer. We are blessed we have got this cheap, safe food supply that we can be so, so very proud of, and then also have the regulatory atmosphere that keeps us safe and yet does not impede us going forward, not only for our country but for the other countries that are in desperate need of different seed varieties, different whatever, that would make them so much more beneficial.

Dr. Parrott and Dr. Paustian, each of you interact with the FDA, EPA, and USDA often. How would you rate the communication between the stakeholders and the agencies on the topic of the biotechnology regulatory framework? For the primary agency you have been working with, has communication on the specific topics we are hearing about today been consistent with how the administration has engaged the stakeholder community on other subject matter? You know, we are hearing a lot about the problem. Communication is so important. Tell us a little bit about what is going on in that regard.

Dr. PAUSTIAN. Sure. As I have alluded to in some of my earlier comments, we have been having a lot of conversations with the FDA and pointing out some of our concerns in their current draft guidance and the implications we feel that would have for not only research in this area, but also how we at the farm level are able to access the technology and the types of regulation that we might fall under. I have to say so far I have been very disappointed with the communication that we have heard back, which has been, you know, very vague and implying that certain things would be at their discretion, they would not necessarily do it, but no concrete

details, really. That is really why, you know, we have taken the stance of moving the authority over to USDA, who we have had a very productive working relationship with, and we have confidence that the USDA understands production agriculture. That is what it comes down to, is that we have the confidence that they are fully aware of the ramifications of their decisions and what those are going to mean to producers. We feel like they would be able to adequately address both the concerns of consumers, to make sure we have safe products being brought to market, but also balance that against the concerns of producers and the innovators who are working with this technology to make sure that they do not have an overly burdensome hurdle to overcome in order to utilize these technologies to improve things on their farms.

Senator BOOZMAN. Dr. Parrott, can you add anything?

Dr. PARROTT. Yes, sir, I can. Of the various agencies, I am just going to begin with APHIS. APHIS made a very concerted effort to reach out to stakeholders before it drafted its change in its regulatory procedures. They held various stakeholder meetings. In fact, we had one at Georgia. They made a big point of meeting with scientists to make sure they were getting the science right and that they were—that science supported the actions that they have.

As far as the FDA goes, I want to clarify that we deal with different parts of FDA. He deals with the Center for Vet Medicine, and I am with CFSAN, which is Center for, I think it is, Food Safety and Nutrition. CFSAN has actually been also very open to stakeholder input. They have held meetings with scientists at scientific meetings and have held panels where we can go, and, again, they too have been very interested in understanding plant genetics and making sure they get the science side.

I really have not heard much from EPA. I heard there was a meeting in the Midwest, but certainly there has been nothing as far as reaching out to scientific societies or my part of the country.

Senator BOOZMAN. Very good. Thank you, Mr. Chairman, and thank you all for being here and sharing with us your concerns.

Chairman ROBERTS. Senator Grassley.

Senator GRASSLEY. Thank you, Mr. Chairman. Very important Committee. I am sorry. I had two other committees, Judiciary and Budget, before coming here. I did not get your testimony, but we have it written and can study it from that point of view.

First of all, Dr. Paustian, thank you for your leadership of the Iowa Association, and you are a good spokesman for the No. 1 State in pork. You mentioned in your testimony that the United States could fall behind other countries in pork production if we do not fix all the FDA-regulated animal biotechnology. Do you know which countries we could look to as a model for biotechnology regulation?

Dr. PAUSTIAN. Thank you, Senator. Well, I think, you know, Canada, Argentina, Brazil, they have all moved quickly to put frameworks into place to regulate some of these genetic technologies, so I think, you know, we have certainly had conversations with them to kind of try to understand their approach, and we feel that they are for the most part finding a nice balance between regulation and accessibility. You know, we feel like there are some models out there that we can look to, and that gives us confidence that we

might be able to reach some type of international consensus on how some of these technologies are regulated so that we do not encounter some trade barriers in the future. You know, we have a lot of confidence there.

Now, there is a lot of activity going on in China as well. If you just look at the scientific literature, China is producing twice as many research papers as the United States that are related to gene editing in agriculture. Their regulatory path is somewhat murky, though, and I cannot really speak to what they are putting into place. They are moving very quickly on this as well.

Senator GRASSLEY. Could I hear from Dr. Parrott? This will be my last question, even though I have still got a lot of time left. I would like to hear from you by sharing your thoughts on what benefits gene editing will be able to bring to food and agriculture where traditional biotechnology has been limited?

Dr. PARROTT. Yes, sir. When we talk about conventional plant breeding, I normally like to say—when I simplify it, say that, you know, half the time plant breeders are removing traits that they do not need or want, think, say, bitter flavor, think susceptibility to disease. When they are not removing traits you do not want, they are adding traits you do want, say a better quality protein or a resistance to a pest.

Gene editing is an evolving technology, but where it stands at the moment, it is far better than anything we have ever had before on the removal of unwanted traits side. There are genes that limit yields. There are genes that limit nutrition. There are genes that limit seed size. There are genes for susceptibility to diseases that we can be removing. There are also genes that affect how a plant is made—you know, grows so we can actually not only increase yields but we can focus on root development and sequester carbon. We can focus on things like drought tolerance or even flooding tolerance as the case may be.

Overall, it means much more consumer choice in everything from flower color to—we actually have a project in the lab for lawns that do not need to be mowed as much. Flower color, flavor, all the way to resilient higher-yielding crops. As I say, it is a really exciting time.

Senator GRASSLEY. Okay. I am going to yield back my time, Mr. Chairman. Thank you very much.

Senator BOOZMAN. Mr. Chairman, can we ask where we can get the seed about the lawn mowing?

[Laughter.]

Chairman ROBERTS. Senator Grassley, since you had time left, we would always be interested in any further comment that you would like to make given your standing in the Congress.

Senator GRASSLEY. Well, I think I would limit it to ethanol now.

[Laughter.]

Chairman ROBERTS. I think your time has just expired.

[Laughter.]

Senator GRASSLEY. Have the President not appeal the Tenth Circuit opinion.

Chairman ROBERTS. You can never get hurt by what you do not say.

Dr. Parrott, 25 years for a product that you have been working on to bring to the marketplace with regard to soybeans? Is that correct?

Dr. PARROTT. That is correct.

Chairman ROBERTS. That is ridiculous. I do not—

Dr. PARROTT. In part, when we started the project, we did not have the tools that we have today. Nevertheless, with the tools that we have today, if we were starting from scratch, it would still be a decade project if we used conventional methods.

Chairman ROBERTS. Mr. Johnson, international trade, as we all know, we have seen the administration work hard to improve the trade situation, and more especially with China, especially cotton and soybeans. As long as American farmers have a landscape that allows them to be competitive, they will be successful in the global marketplace. Can you characterize, however, how other countries such as Japan and China might be striving—well, they are striving—to improve their scientific understanding on the future of these new plant breeding technologies and their countries' policies with regard to gene editing?

Mr. JOHNSON. I do not know that I can speak specifically to what those countries are doing, but I know from the cotton industry's perspective, it is a high priority that USDA and USTR are working with those countries that are trade partners, and we certainly would like to come to a place where approval in the U.S. met the regulatory requirements in those countries we trade with. That is a high priority for us.

Chairman ROBERTS. One last question. Dr. Paustian, the jurisdiction on the animal side, this Committee has clear jurisdiction over livestock and meat. USDA administers authority such as the Animal Health Protection Act, guarding against pests and diseases, as well as the Federal Meat Inspection Act, which provides for safe, wholesome, and accurately labeled meat. As the three agencies weigh the risks of new technologies and are urged to consider risk consistently among them, does the Secretary have adequate authority under these acts to regulate these new technologies?

Dr. PAUSTIAN. Well, Mr. Chairman, I am not a lawyer, but I have friends who are lawyers, and in my conversations with them, we have come to the conclusion that, yes, USDA does have the authority if they choose to exercise it. As I have stated before, you know, we feel like it is a natural fit to have animals and food being regulated, animals and animal products as well as plants regulated through USDA. We are confident that they have the tools in place to ensure that, you know, only safe, healthy products reach the marketplace.

Chairman ROBERTS. Maybe we could make it possible for those lawyers to be helpful to the Coordinated Framework.

That will conclude our hearing today. I want to thank each of our witnesses for taking time to share your perspectives on agriculture innovation and the Federal Biotechnology Framework.

To my fellow members, we ask that any additional questions you may have for the record be submitted to the Committee Clerk five business days from today or by 5 p.m. next Thursday, March 19th.

The Committee stands adjourned.

[Whereupon, at 11:25 a.m., the Committee was adjourned.]

A P P E N D I X

MARCH 12, 2020

Testimony of Patrick Johnson
on *Agriculture Innovation and the Federal Biotechnology Regulatory Framework*
Committee on Agriculture, Nutrition, and Forestry
United States Senate
March 12, 2020

Mr. Chairman, ranking member, and members of the committee, thank you for the opportunity to testify today on this important issue. My name is Patrick Johnson and I'm a cotton, rice, corn and soybean grower in Tunica, Mississippi. I have been the Chairman of the National Cotton Council's Environmental Task Force since 2016. I was a member of EPA's Farm Ranch and Rural Communities Committee from 2012 to 2017 and I was recently notified of my acceptance to EPA's Pesticide Policy Dialogue Committee for their new term. I have been and continue to serve in leadership roles of several farming, environmental and conservation groups in the Mississippi Delta region.

The National Cotton Council (NCC) is the central organization of the United States cotton industry. Its members include producers, ginner, cottonseed processors and merchandizers, merchants, cooperatives, warehouse and textile manufacturers. A majority of the industry is concentrated in 17 cotton-producing states stretching from California to Virginia. U.S. cotton producers cultivate between 10 and 14 million acres of cotton with production averaging 12 to 20 million 480-lb bales annually. The downstream manufacturers of cotton apparel and home furnishings are located in virtually every state. Farms and businesses directly involved in the production, distribution and processing of cotton employ more than 125,000 workers and produce direct business revenue of more than \$21 billion. Annual cotton production is valued at more than \$5.5 billion at the farm gate, the point at which the producer markets the crop. Accounting for the ripple effect of cotton through the broader economy, direct and indirect employment surpasses 280,000 workers with economic activity of almost \$75 billion. In addition to the cotton fiber, cottonseed products are used for livestock feed and cottonseed oil is used as an ingredient in food products as well as being a premium cooking oil.

Biotech cotton was first introduced in 1996 and U.S. cotton farmers rapidly adopted the new technology. In 2018, USDA's Economic Research Service reported approximately 94% of U.S. cotton acreage, 94% of soybean acreage and 92% of U.S. corn acreage was planted with varieties that encompassed either insect resistant, herbicide tolerant, drought tolerant, or stacked combinations of these genetic enhancements. All sugar beet acreage in the U.S. is planted with herbicide tolerant varieties and canola is at 90%. For cotton production in the U.S., the latest estimates of the benefits of these insect resistant varieties are 185 million lbs/year increase in production; 1.9 million lbs/year decrease in insecticide use; and \$103 million/year increase in net revenue for U.S. cotton farmers. The benefits of herbicide tolerant biotech cotton in the U.S. include a 6.2 million lbs/year decrease in herbicide active ingredients applied and \$133 million/year savings in weed control costs. Overall, in the 20 years of commercialization of biotech crops (1996-2015), the United States accrued the highest benefits at \$72.9 billion with \$6.9 billion for 2015 alone.

Over the last 35 years, cotton producers, researchers, and industry organizations working together led to dramatic reductions in land use, soil loss, water use, energy use and greenhouse gas emissions. Innovation in technologies, managements systems, and conservation practices created opportunities for advancements in yield while taking stewardship of the land and environment for cotton production to the highest level of the world. The availability and adoption of biotechnology has been a key driver in these industry gains of productivity and sustainability.

In another positive technological development for cotton and the world, in 2019 the Food and Drug Administration (FDA) approved ultra-low gossypol cottonseed to be utilized as human food and in animal feed. In cooperation and support from Cotton Incorporated, it took a team at Texas A&M close to 25 years to develop, test and obtain deregulation for the transgenic cotton plant, TAM66274. This plant has ultra-low gossypol levels in the seed, which makes the protein from the seeds safe to consume. However, the variety still maintains normal levels of plant-protecting gossypol in the remainder of the plant, meaning that it is still a practical choice for farmers to grow. In many cotton-producing countries of the world, protein-rich cottonseed from this plant can now be used for human food, offering oil, flour and kernels as some of the products that could be made available to ease hunger. There will also be animal feed uses such as for poultry and aquaculture.

U.S. cotton farmers have a vested interest in the continued availability of new biotechnology products under a regulatory system that is efficient and streamlined while protecting the health and safety of the public and environment. Regulations have a large impact on the number of products being brought to market and a key issue is open and transparent coordination among the United States Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA) as they each work to regulate new technologies within the guidelines of the Federal Coordinated Framework. NCC and others within the industry have consistently commented on past proposals, including those regarding the Coordinated Framework and Part 340 regulations.

The mission of the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) as derived from the Plant Protection Act (PPA) is to protect U.S. agriculture by preventing the introduction and dissemination of plant pests and noxious weeds into the U.S. APHIS has authority within PPA to protect U.S. agriculture from these potential risks. Additionally, under the Coordinated Framework, agency review is shared among USDA, FDA and EPA, depending on the product use, ensuring thorough regulatory oversight. With the President's June 2019 Executive Order, "**Modernizing the Regulatory Framework for Agricultural Biotechnology Products**", calling for increased transparency and coordination within the agencies, we had hopes for a swift update to the Coordinated Framework to face the challenges of the newer technologies coming to the forefront. Recently though, we have again become concerned at the apparent lack of policy coordination between the three federal agencies involved in the Coordinated Framework. This is not a new issue. For example, in 2016, USDA published a notice in the Federal Register announcing plans to update its biotechnology

regulations at CFR part 340. This action was taken independently of the then-ongoing review of the Coordinated Framework.

In fact, the agencies attempted to clarify EPA's regulation of the plant incorporated protectant (PIP) molecule produced by a GE plant. The distinction lies between regulating the pesticidal substance while not regulating the GE plant. At the same time they attempted to clarify that FDA's regulatory authority was over the recombinant DNA construct inserted into "GE animals" and not the animal itself.

APHIS' new regulatory approach is intended to prepare the Agency for future advances in the genetic modification of plants. It is important to our industry, and to agriculture as a whole, that the three agencies work together as seamlessly as possible to regulate both older and newer technologies.

Recently we have seen reports that suggest an apparent lack of coordination between USDA and EPA on the "plant side" of new technologies. This is concerning to the cotton industry as it may suggest an absence of communication between those two agencies. It is our understanding that the USDA's revised rule has reached the Office of Management and Budget (OMB), and therefore may soon be final. We do not know the status of the companion, proposed revision from EPA. As a result, the industry is worried about the future of new technologies if the Coordinated Framework is not working at its most efficient level. The U.S. cotton industry needs the Framework to operate at peak efficiency across all the agencies. Currently, it takes 20 to 40 years to bring new traits from diploid cottons into Upland or Pima cotton varieties through traditional breeding. Newer biotechnology techniques can perform the same function in 2 years, but that is only if the process is allowed to work free of the delays and road blocks created by misunderstandings in the public arena and a slow regulatory regime. In the U.S., wild cotton relatives have valuable alleles (for resistance to drought, disease, etc.) that the industry hopes to exchange with Upland alleles using technology such as gene editing. These alleles contain traits needed to insure the continuation of fiber, food, feed and fuel for the growing population. They can be edited into Upland and Pima cotton in a timely fashion if the U.S. regulatory agencies can work together within a streamlined Coordinated Framework.

NCC would like to point out that consistent policies globally for products of plant breeding innovation are essential to avoid trade disruptions. The U.S. cotton industry exports more than 85% of our annual fiber production, and exports of cottonseed to key markets are an important component of the economic health for the cottonseed segment of our industry. Therefore, U.S. government agencies should be encouraged to actively engage with our trading partners around these policies as soon as possible to work toward consistent, science-based policies across countries to ensure synchronous approvals of traits in export markets.

NCC would like to commend the agencies for their attempt to improve the regulatory system for agriculture biotechnology as well as for recognizing the long history of scientific evidence that supports the safety of products developed using these methods. U.S. cotton farmers have a vested interest in the continued availability of new biotechnology products under a regulatory system

that is transparent, efficient and streamlined while protecting the health and safety of the public and environment.

The current regulatory system has operated quite successfully for decades and has resulted in no adverse plant health impacts to U.S. agriculture. In the end, we believe that making strategic improvements to the current regulatory system in terms of speed, efficiency, transparency and coordination will engender broader public support, prove easier to implement, and have a much more immediate impact with fewer unintended consequences.

Thank you again for the opportunity to present this testimony.

**Testimony of Dr. Wayne Parrott
Professor of Plant Breeding Genetics & Genomics
University of Georgia**

**Before the
U.S. Senate Committee on Agriculture, Nutrition and Forestry**

**Agriculture Innovation and the Federal Biotechnology Regulatory Framework
March 12, 2020**

Good morning, Chairman Roberts, Ranking Member Stabenow and members of the Committee. I am Wayne Parrott, a professor of Plant Breeding Genetics & Genomics at the University of Georgia. I'm pleased to be here today to talk about innovations in precision plant breeding. This is an exciting time to be a plant breeder, probably the most exciting time in my 30-year career. The reason is because we have an unprecedented number of tools to work with, which are enabled by our understanding of plants and how they work. Such an understanding has improved dramatically from what it was when the original Coordinated Framework for the Regulation of Biotechnology was drafted over thirty years ago. Thanks to technology, we have better tools like gene editing that build on what nature, farmers, and now breeders, have been doing for hundreds and thousands of years to enhance and improve the food we eat. Today, we can fully utilize our deeper understanding of plants to better target these improvements, allowing us to respond more efficiently to new and emerging challenges.

Why is the topic of innovation in breeding so important? Agriculture has always faced and will always face new and emerging threats from pests, diseases, and adverse growing conditions. So, agriculture must constantly adapt to continue to succeed in the future. For example, farmers face unprecedented fluctuations in drought and moisture conditions from a changing climate, as well as rapidly evolving pests and diseases. At the same time, crops must be profitable for farmers, and they must meet public expectations for sustainability while providing a larger variety of wholesome and affordable food options for consumers. This requires a collaborative effort along the agriculture and food value chain – from lab, to field, to market. In order to meet all of these demands, we need to have access to all of the tools available to develop plants that can thrive and meet societal needs.

Solving problems is what plant breeders have always done, and we have achieved significant success. Looking at USDA Economic Research Service data, U.S. output has increased 2.5 times since 1948 while crop inputs have stayed flat.¹ Improved plant varieties are the major factor behind this success. Now, plant breeders have an opportunity to address problems more quickly and precisely, just at a time when rapid advancement is needed. Innovative new precision breeding methods, many developed at land-grant universities, allow breeders to make very specific changes to a plant, resulting in an end-product

¹ USDA-ARS. 2020. Agricultural Productivity in the U.S. Summary of Recent Findings.
<https://www.ers.usda.gov/data-products/agricultural-productivity-in-the-us/summary-of-recent-findings/>

that is often indistinguishable from a plant bred through more traditional breeding methods and done with greater efficiency—taking months instead of years.

Pre-commercial research is well underway. These include tomatoes adapted for growing in vertical farms, opening new farming opportunities in urban areas. Other crops are showing improved yields in field trials. Importantly, crops are being adapted to grow over wider areas and climates. As an example, there is a wild variety of lettuce that is capable of germinating at high temperatures in the Central Valley of California. Using new precision breeding methods, researchers have developed a lettuce variety that has the same heat tolerance as its wild relative, but with the same taste and nutritional value as the salad lettuce we enjoy today. With my colleagues at the University of Georgia, we are working on switchgrass that produces twice as much and is easier to convert to biofuels.

Plant breeding can help ensure that agriculture is a driving force in a flourishing bioeconomy. Not only can plant breeding help plants defend themselves from threats, it offers real solutions to global challenges, like building a more sustainable agriculture in the face of growing population pressure. We also envision that new crop varieties will strengthen the bioeconomy by providing a major source of raw materials for the manufacturing, bioenergy, and pharmaceutical industries.

Disease resistance is another area of promise for new breeding tools. By making the plant itself more resistant to disease, we can cut down on the use of pesticides while at the same time reducing pre- and post-harvest losses. Until now, plant breeders addressing disease resistance have mostly been limited to using traditional cross-breeding-- an inefficient method which takes years to produce the desired result, and thus is often not efficient enough to keep pace with new and rapidly evolving diseases.

Biotechnology methods in use for the past 25 years can also achieve the same goal, but these have gone mostly undeployed because the regulatory burdens and costs to use these methods prevent the majority of disease resistance products from being commercially viable. If newer tools face regulation that is disproportionate to risk, not scientifically based, and without any safety benefit, an opportunity to develop plants with resistance to major types of plant diseases, including viruses, bacteria, and fungi, will be lost.

Plant breeding has a tremendous safety record with hundreds of thousands of new plant varieties introduced over the past century, including major commodity crops developed using biotechnology. Now that we are in the era of genome sequencing, we know that it is completely natural for even two seemingly similar varieties of plants to have very different genetic make-ups. Importantly, the existence of differences at the genomic level is not an indicator of a risk. Plant breeders have well-established screening and quality management processes to evaluate newly developed varieties, regardless of the plant breeding method. All crop breeding programs assess thousands of plants in multiple locations and eliminate the vast majority because they do not meet rigid performance standards.

In order for public sector scientists to use evolving innovations now and in the future, the U.S. government needs rational and clear policies that allow developers to bring safe products to market. The benefits to growers and consumers from new breeding tools like gene editing cannot be disputed. But in order for these tools to be used, the surrounding policies must be risk proportionate. The original

Coordinated Framework written in 1986 as well as subsequent reviews and Executive Orders reaffirmed the need for regulatory policy that promotes innovation while protecting health and the environment. The *2019 Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products* reiterated long-standing government policy that regulations should be flexible enough to accommodate new scientific evidence and meet regulatory objectives in the least burdensome way. In the intervening 30 years since the Coordinated Framework was operationalized, significant experience and familiarity with new plant/trait combinations has accrued. Scientists and regulators can predict more precisely which products require more or less stringent oversight, and which ones could be exempted from review altogether whenever they lack identifiable hazards from the use of biotechnology in their development.

For plants that could have been produced through more traditional plant breeding methods, a pre-market review is actually not necessary because the plant's characteristics do not go beyond the range and variability of what is found in nature already. The principles imbedded in the Coordinated Framework affirmed that similar products should be treated the same by regulatory agencies and that new products should meet the same safety standards and criteria as existing products. Any new regulations under the Coordinated Framework should focus only on those plants that present a new potential risk, when compared to similar plant/trait combinations that have a history of safe use and consumption.

The 2019 Executive Order also instructed USDA, the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) to take steps to have consistency and coordination among the three agencies and to streamline regulations. This work has yet to be completed, and it is unclear how much coordination has taken place amongst these three agencies since the Executive Order was published. USDA is nearing completion of a final rule updating its biotechnology regulations, including those for gene-edited plants. EPA has submitted a proposed rule to the White House Office of Management and Budget to update its regulations for Plant Incorporated Protectants to address new technologies, but we do not know its content. FDA published a *Plant and Animal Biotechnology Action Plan* in January 2019 in which it committed to publish guidance for industry in early 2019 on how their regulations apply to new plant varieties that use innovative breeding methods. This guidance has yet to be published.

While other countries are quickly moving forward to develop policies for plants developed using new breeding methods—and many have even sought input from the U.S.—at the moment, the United States has no coherent policy. Without a clear, consistent policy from USDA, EPA and FDA, the United States is unable to provide global leadership and it puts us at a global disadvantage. While it is fortunate that a number of countries including, Brazil, Argentina, Israel, Australia and Japan have put policies in place that are favorable for the use of gene editing in plants, U.S. developers and farmers will very soon start to lose their ability to compete as these products are brought to market by other countries.

As a public sector scientist, I am excited that these innovative new breeding tools have the potential to be readily employed by university as well as private plant breeding programs for the benefit of our consumers and farmers alike. The tools are very accessible to the science community, they can be used

across a broad range of crops, and result in more predictable outcomes than older breeding methods. However, the three federal agencies must have a coordinated approach that allows the benefits of current, and future, innovations to be fully realized. With a scientifically based regulatory environment, there is no doubt in my mind that American agriculture will meet all the challenges that the current century will bring forward.

Chairman Roberts, Ranking Member Stabenow, and members of the Committee, I appreciate the opportunity to discuss issues of critical importance to U.S. pork producers. I am the president of the Iowa Pork Producers Association and a hog farmer from Walcott, Iowa.

I am also here today on behalf of the National Pork Producers Council, a national association representing the interests of 60,000 U.S. pork producers.

The U.S. pork industry has been built on innovation. Our commitment to continuous improvement has made the United States the world's leading supplier of high-quality, safe and sustainably produced pork. However, we are currently in danger of ceding this advantage to international competitors due to significant flaws in the current U.S. approach to regulating animal biotechnology. While countries like Canada, China, Brazil and Argentina are moving quickly to gain a competitive advantage in the market, the U.S. is falling behind.

New animal breeding tools such as gene editing, which allow for precise changes within an animal's own genome, offer tremendous promise to further improve animal health and care, and produce safer food in a more sustainable fashion. Gene editing may allow us, for example, to finally stamp out Porcine Reproductive and Respiratory Syndrome (PRRS), a highly contagious disease that costs the pork industry more than \$1 billion dollars annually. Livestock producers need access to these technologies.

I want to be very clear that we are not advocating for de-regulation of these new technologies. Farmers support scientifically sound, transparent, risk-based regulations that ensure that these new tools are effective and safe for both animals and consumers. Our concern is not if this technology should be regulated, but rather by who and under what authority.

Under the current regulatory framework, the Food and Drug Administration (FDA) has authority over all applications of genetic technologies in animals. The agency is proposing regulating new tools such as gene editing in exactly the same manner that they have regulated older transgenic technologies under the Food, Drug and Cosmetics Act (FDCA) by approving the altered genome in specific lineages of animals put forward for evaluation as a "drug." In effect, this would regulate the animal—which is indistinguishable from the genetic material in every cell of its body—as a drug under U.S. law. Furthermore, this designation would apply to all offspring of edited animals in perpetuity.

There are myriad, grave problems with this approach. I will highlight several. First, the FDA proposal does not offer a staged, risk-based approach to regulatory oversight that recognizes the important distinctions between the many tools now available to affect genetic changes, and the different types of changes that can be made. Both the Coordinated Framework itself, and the National Academies of Sciences in its review of the document, recommend a more nuanced approach. Simply put, we need a regulatory system that recognizes that simple, familiar changes within an animal's own genome—changes that mirror natural genetic diversity and

harness it in a controlled fashion—do not need to go through a lengthy drug approval process and become saddled with a drug designation that will never go away.

Second, the FDA proposal does not appear to offer any path forward for species-level approval of a given edit. Rather, any edit would have to be individually evaluated for every breed, strain, family, and flock or herd of animals that wanted to incorporate a given trait. This is untenable. Not only does it not make sense from a scientific standpoint—a gene edit should be presumed to work in any member of a species with a shared genotype of interest unless compelling evidence suggest otherwise—but it sets up this regulatory pathway for failure. It will result in three outcomes: tremendous loss of genetic diversity in our herds and flocks, as entire industries move to the few approved animal lines with highly valued edits; a regulatory system bogged down with hundreds, if not thousands, of costly and time-consuming approval applications; and farmers simply not having access to this technology because the cost and ramifications of the regulatory system are simply too great to bear. None of these are acceptable outcomes. Simply put, this approach would severely slow down regulatory approval and makes this technology inaccessible to most U.S. livestock producers who maintain their own seedstock.

Third, the FDA has not demonstrated that it understands the complexity and breadth of the U.S. animal breeding—and indeed commercial production—industries. This is very concerning given the potential scope of authority FDA would be assuming for all aspects of animal agriculture under this proposal. Given even the assumption that an animal has a gene-edited ancestor, the FDA could bring authority under the FDCA to bear against any aspect of breeding, raising or processing that animal and the distribution, marketing and consumption of any product it produces. For example, the FDA could determine that any commercial sale of semen is potentially a drug sale. The agency could determine that any farm producing animals with gene-edited ancestors is a drug manufacturing facility. FDA could make the decision that any meat products produced from these animals would have to bear drug labels. We acknowledge that the FDA has said it does not intend to do any of these things, but that doesn't mean the agency wouldn't have the authority to do so. FDA's current assurances that regulatory discretion would be used do not provide sufficient comfort to ignore the huge potential disruptions this could cause.

The final significant problem is the very real potential for the United States to lose its standing as the top producer of high-quality, healthy and affordable pork in the global marketplace. Competitor nations are advancing reasonable regulatory pathways that aren't hampered by regulatory red tape. We are already seeing investments in research and development moving overseas, and ceding our global edge in animal breeding. If we continue down this path, our country will lose its competitive advantage in all animal agriculture.

In effect, we are subjecting U.S. exports from gene-edited livestock to damaging trade barriers, as FDA has said they will be regulated as drugs. It is naïve to think that this determination will not impact trade in animal products. Trading partners may be required under their bodies of law and regulation to bring their requirements for drug importation, which are very different

from those for agricultural products. There are countries who wish to exclude U.S. agricultural products on spurious grounds; this will certainly give them new ammunition. We have had extensive conversations with regulators in other countries and they are scratching their heads at what we are doing.

The FDA has insisted that farmers simply misunderstand its regulatory proposal. This is incorrect. We, along with the scientific and trade communities, have clearly stated our strong objections to FDA's proposal. Alternative strategies the FDA could pursue under its authority have been put forth by multiple stakeholders and quickly rejected, if considered at all. The agency has not addressed these concerns in any meaningful way. Inexplicably, the agency remains entrenched in its flawed approach. The FDA has been given numerous opportunities to address this fundamental issue, only to dismiss it as inconsequential and insist that additional clarification is forthcoming. We are still waiting.

It is clear we need a new approach. Fortunately, we have a model that we can look to. The U.S. Department of Agriculture (USDA) has fostered the development and application of new breeding techniques in plants for decades under the Plant Protection Act. The USDA has acknowledged the real need to make development of genetically edited crops affordable, timely and accessible to smaller producers. Their approach will ensure that this technology can be broadly researched, developed and implemented at a pace that will maintain U.S. global leadership. The USDA approach means that we are poised for a revolution in crop production that will pay huge dividends to farmers, consumers and the environment. The USDA can do the same thing for agricultural applications of animal biotechnology in animals under the Animal Health Protection Act.

The USDA has the authority and expertise available to effectively regulate gene-edited livestock, leaving the FDA to focus its attention and resources on other exciting biomedical applications under development. As they do with plants, the USDA can draw upon the expertise of other agencies, such as the FDA, to make assessments as needed to ensure a complete and trustworthy evaluation has taken place—and then approve under their authority the resulting product.

This shift will remove many of the obstacles that the current FDA approach is placing on the development of gene editing and similar technologies in livestock agriculture. It will:

- allow for research and development of these technologies to take place at American universities rather than overseas.
- let farmers adopt these new breeding techniques without the fear of losing access to international markets.
- demonstrate to the world that the U.S. is committed to a pro-innovation, risk-based approach to new technology, not a precautionary one.

In short, this approach will allow U.S. agriculture to maintain its global edge. We ask you to support moving oversight of gene-edited livestock on American farms from the FDA to the USDA.

Testimony of Gregory A. Jaffe

Biotechnology Project Director

Center for Science in the Public Interest

Senate Agriculture Committee Hearing

“Agricultural Innovation and the Federal Biotechnology Regulatory Framework”

March 12, 2020

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 consider 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's 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.

**DOCUMENTS SUBMITTED FOR THE
RECORD**

MARCH 12, 2020

February 25, 2020

The President
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear Mr. President:

We the undersigned Governors would like to draw your attention to an important issue facing U.S. agriculture. Farmer access to new biotechnologies, such as gene editing, is critical to maintaining the security and stability of the rural economy and our nation's food supply. These technologies offer significant promise to enhance the health of animals and plants, make better use of agricultural resources, and produce safer food. This potential can only be realized with appropriate, science-based regulation at the federal level.

The United States Department of Agriculture has a long history of providing regulatory oversight of the use of biotechnology in plant breeding under the Plant Protection Act and has moved swiftly and thoughtfully to ensure that their regulatory framework is kept current with recent advances in gene editing. Farmers have had, and will continue to enjoy, access to many important innovations that contribute greatly to the strength of American crop production.

The Food and Drug Administration, which does not have the same track record with fostering new biotechnologies in agricultural animal production, insists on regulating agricultural applications of gene editing and similar technologies in animals under the Food, Drug and Cosmetics Act. This approach is having a chilling effect on the development and adoption of new gene edits that promise significant benefit to livestock and poultry producers and the public they serve. As other nations move forward with more appropriate, science-based regulatory frameworks, the U.S. is in danger of losing its global preeminence in livestock production.

We ask that you move all agricultural applications of biotechnology in animals under the regulatory authority of the USDA. As plant applications are regulated under the Plant Protection Act, so too should agricultural animal applications be regulated under the Animal Health Protection Act. Not only will a common policy under the USDA better foster development of this technology for the public good, it will also far better serve U.S. interests in marketing our agricultural products overseas. The current situation—having significantly different regulatory approaches under different agencies for plants and animals—is simply not tenable.

The U.S. agriculture sector is vital to the American economy, generating over \$1 trillion in annual economic activity. The continued success of American agriculture depends on access to new biotechnology that has been well-vetted under a rational, science-based regulatory system administered by the USDA. We appreciate your attention to this matter.

Sincerely,

Hon. Doug Burgum, Governor of North Dakota
Hon. Kristi Noem, Governor of South Dakota
Hon. Mike Parson, Governor of Missouri
Hon. Kim Reynolds, Governor of Iowa
Hon. Pete Ricketts, Governor of Nebraska

cc:

The Honorable Lawrence Kudlow
Director, National Economic Council

The Honorable Joe Grogan
Director, Domestic Policy Council

The Honorable Sonny Perdue
Secretary, U.S. Department of Agriculture

The Honorable Robert Lighthizer
Ambassador, Office of the United States Trade Representative

March 10, 2020

The Honorable Pat Roberts
Chairman
U.S. Senate Committee on Agriculture,
Nutrition and Forestry
328A Russell Senate Office Building
Washington, D.C. 20510

The Honorable Debbie Stabenow
Ranking Member
U.S. Senate Committee on Agriculture,
Nutrition and Forestry
328A Russell Senate Office Building
Washington, D.C. 20510

Dear Chairman Roberts and Ranking Member Stabenow:

The farmers, ranchers, cooperatives, technology developers, scientists, co-regulators and seed companies represented by the organizations signed below strongly support the ongoing development of new breeding methods which have the potential to bring incredible advances to agriculture, the environment, and our global food system. In order for U.S. agriculture to succeed in the future, we must have access to every tool available to address future challenges such as catastrophic weather events and rapidly evolving pests and diseases. We must do this while meeting consumer expectations for reductions in the use of crop inputs and new varieties of healthy and affordable food options.

Providing legal certainty through interagency coordination among the U.S. Department of Agriculture (USDA), the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) is necessary to encourage the continued domestic and global adoption of evolving plant breeding methods, provide certainty in domestic and international markets, promote consistency of global policies and facilitate predictability in the development of new gene edited plant varieties.

Our associations strongly support a system which fosters innovation and recognizes the long and safe track record of plant breeding and genetic engineering in plants. We applaud USDA for engaging with stakeholders while developing a rule to update their Part 340 biotechnology regulations. We urge EPA and FDA to similarly engage with stakeholders and other agencies in the development of their respective policies as instructed in the *2019 Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products* which directs agencies to adopt science- and risk-based regulatory approaches that avoid undue burdens for the products of agricultural biotechnology.

Congress should continue to encourage Federal agencies to broadly communicate how their policy decisions related to new plant varieties protect human and environmental health to increase consumer confidence in the products of agricultural biotechnology.

Countries around the world are adopting policies for precision breeding so that farmers and scientists will have access to these important tools. Our organizations urge swift action by USDA, EPA and FDA to advance the position of the United States as a global leader in the area of plant breeding and further encourage the U.S. government to continue to engage with other countries to support open and fair trade for products of innovative breeding tools. It is our hope that through timely completion of an updated U.S. regulatory framework at USDA, EPA and FDA, our trading partners will be encouraged to adopt similar science- and risk-based regulatory approaches.

Thank you for your support for innovation. We look forward to continuing to work with you to ensure U.S. agriculture remains a world leader in innovation.

Sincerely,

Agricultural Retailers Association
American Farm Bureau Federation
AmericanHort
American Seed Trade Association
American Soybean Association
American Sugarbeet Growers Association
Biotechnology Innovation Organization
California Specialty Crops Council
Corn Refiners Association
CropLife America
Crop Science Society of America
Florida Fruit and Vegetable Association
National Association of State Departments of Agriculture
National Association of Wheat Growers
National Cotton Council
National Council of Farmer Cooperatives
National Corn Growers Association
National Sorghum Producers
Produce Marketing Association
Society of American Florists
United Fresh Produce Association
USA Rice
U.S. Beet Sugar Association
U.S. Canola Association

QUESTIONS AND ANSWERS

MARCH 12, 2020

Senate Committee on Agriculture, Nutrition & Forestry
Hearing on Agriculture Innovation and the Federal Biotechnology Regulatory Framework
March 12, 2020
Questions for the Record
Mr. Patrick L. Johnson, Jr.

Chairman Pat Roberts

- 1) Since 1975, conventionally bred plants with pesticidal properties have been subject to review by USDA, but not EPA. Since 1986, plants derived from biotechnology have been regulated by USDA and the food from those plants by FDA. In 2001, EPA finalized its plant-incorporated protectant rule regulating pesticidal substances produced in plants derived from biotechnology while expressly stating it was not regulating the plants themselves. In 2011, a draft EPA proposal regarding plant-incorporated protectants included broad assertions of authority over plant genes, nucleic acids and pesticidal traits under FIFRA and FDCA, as well as broad assertions of intent to actively regulate genes, nucleic acids and pesticidal traits in plants. Is your organization concerned during this new round of rulemaking about potential overreach by the EPA and any jurisdictional claim by the agency over the entire plant?

We are always concerned about regulatory overreach and have seen it happen in the past on various issues. Since we have not yet seen EPA's proposal in this instance we cannot specifically comment on any theoretical overreach, but such an overly broad authorization would probably slow down technological advancement

Senator Mike Braun

- 1) Biotech crops are already helping American agriculture production serve as a climate solution by reducing on farm CO2 emissions.

Innovations such as gene editing will only increase these benefits by helping farmers grow food using less water, soil, and fertilizer, and fewer pesticides.

How can we ensure that our regulatory structures consider the positive benefit agriculture biotechnology can have on providing for cleaner air and water, and healthier soils?

The solution to this question will be very difficult. The various regulatory agencies will need to cooperate with each other and disseminate information to each other, and then insert that

data into their respective models. For example, USDA will need to provide data on environmental savings from the use of biotechnology and gene editing to EPA who will then need to accept that data and place it in models for everything from water pollution to pesticide registrations to climate change. This will be a difficult cultural change for many agencies. For example, in pesticide registrations agencies sometimes take the maximum allowed label rate and calculates risk assuming every grower applies the maximum rate, the maximum allowable number of applications. New genetic technologies have the promise of further reducing the use of certain pesticides and this will need to be accounted for. For anything positive to come of this, the agencies must learn to communicate better.

Senator John Thune

- 1) What can the U.S. government do to ensure innovative breeding techniques remain available for use by public and private sector plant breeders?

The U.S. government would do well to publicly support these breeding techniques and back up the claims with impeccable science. It will inevitably be public opinion that helps or hurts the continued use of new technologies. In addition, each Administration will have to support these technologies within each agency.

- 2) What can the United States do to promote similar policies with our international trading partners?

The U.S. government will need to be proactive in promoting our science as reliable to our trading partners, especially those that are severely risk adverse. This will be an important task as we see some trading partner's exporting "the precautionary principle" as a regulatory/risk assessment means to deny sound science and overly regulate many technologies.

Senate Committee on Agriculture, Nutrition & Forestry
Hearing on Agriculture Innovation and the Federal Biotechnology Regulatory Framework
March 12, 2020
Questions for the Record
Dr. Wayne Parrott

Chairman Pat Roberts

- 1) Since 1975, conventionally bred plants with pesticidal properties have been subject to review by USDA, but not EPA. Since 1986, plants derived from biotechnology have been regulated by USDA and the food from those plants by FDA. In 2001, EPA finalized its plant-incorporated protectant rule regulating pesticidal substances produced in plants derived from biotechnology while expressly stating it was not regulating the plants themselves. In 2011, a draft EPA proposal regarding plant-incorporated protectants included broad assertions of authority over plant genes, nucleic acids and pesticidal traits under FIFRA and FDCA, as well as broad assertions of intent to actively regulate genes, nucleic acids and pesticidal traits in plants. Is your organization concerned during this new round of rulemaking about potential overreach by the EPA and any jurisdictional claim by the agency over the entire plant?

EPA regulates substances intended for use as pesticides under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In the case of pesticidal substances produced and used in the plant itself, EPA refers to these substances and related genetic material as "plant incorporated protectants," or "PIPs" and regulates them for human and environmental safety.

PIPs produced in conventionally bred plants have been exempted by EPA from virtually all FIFRA requirements if they meet certain science-based criteria. If the same PIP is produced in a genetically engineered plant (i.e., GMO) rather than a conventionally bred plant, then the exemption does not apply. I understand that EPA is considering an exemption for PIPs in some gene-edited plants, which is supported by the science as well as the long history of safe use of GMO crops. This would also be consistent with the approach to many gene-edited plants taken by USDA. It remains to be seen what the regulatory burden would be on the applicant to prove their products fall under an EPA exemption.

If EPA were to go a different direction by broadly viewing all gene-edited plant products as PIPs or proposing a narrow exemption with burdensome requirements unsupported by the science, it would have a hugely detrimental effect on agricultural innovation in the area of developing crops that require application of fewer pesticides.

There are also some gene-edited plants that do not produce a pesticidal substance and would not meet the PIP definition at all. If there is no active ingredient – for example,

deleting a gene so the plant is not susceptible to a disease - regulation by EPA would signal for the first time that it intended to regulate the plant itself as a pesticide, and not the pesticidal substance as has been the case with traditional biotechnology (i.e. GMOs) under the Coordinated Framework for decades. The plant itself should not be regulated as a pesticide, particularly if it is defending itself from a pest or disease by exhibiting defensive traits, such as growing a thicker stalk or waxier leaves, or removing its susceptibility to a pest or disease. If EPA were to take this approach, consumer acceptance of gene-edited plant products would be irreparably harmed, and it would automatically create a barrier to entry that will continue to be too great a hurdle for public sector researchers. This would force researchers such as myself to invest their R&D budget elsewhere.

Senator Mike Braun

- 1) Biotech crops are already helping American agriculture production serve as a climate solution by reducing on farm CO2 emissions.

Innovations such as gene editing will only increase these benefits by helping farmers grow food using less water, soil, and fertilizer, and fewer pesticides.

How can we ensure that our regulatory structures consider the positive benefit agriculture biotechnology can have on providing for cleaner air and water, and healthier soils?

Gene editing holds tremendous potential in advancing sustainability in agriculture and combatting changing climates. These issues pose a very real threat to the future of U.S. agriculture, and no one understands this better than plant breeders. There is research being conducted in California to breed heat-tolerant lettuce using a crop wild relative. This is just one example of the way plant breeders are breeding new varieties to solve environmental and climate challenges.

Another example of research is taking place at the Salk Institute in California. Researchers there are breeding plants to encourage growth of suberin, which is a waxy substance in the plant's root. With this additional growth and deeper, larger roots, the plants can fight climate change as they grow. The roots will store CO2, and when farmers harvest their crops in the fall, those deep-buried roots will stay in the soil and keep their carbon sequestered there. These technologies are playing key roles in developing bioenergy crops, which also play a role in reducing CO2 emissions.

However, excessive, non-science-based regulations simply become barriers to market entry, without a concomitant increase in safety. If the three regulatory agencies do not coordinate in formulating regulations that are scientifically based and risk-proportionate, it will continue to be cost-prohibitive and these new varieties will never

make it to the farmer. Furthermore, Congress must ensure that Executive branch actions – policy directives, regulations, trade policies, and otherwise – foster the growth of a strong 21st century bioeconomy through sufficient funding of research programs and science-based decision making. This includes ensuring USDA, FDA and EPA have consistent, science-based policies that promote a climate of innovation, particularly for university researchers and small companies.

Congress also has appropriations authority to ensure the relevant agencies have enough resources to fund public-sector research and development. It is critical that agencies like USDA, the National Science Foundation, the Department of Energy, and other agencies include the development of gene editing and use of technology in their research grant portfolios, and that they are allocated enough funds to continue to invest in long-term R&D. The research effort has fallen behind that from other countries. Nowhere is this more evident than in scientific research journals. Thirty years ago, the majority of published research came from labs based in the United States. Now they mostly come from other countries.

Senator John Thune

- 1) What can the U.S. government do to ensure innovative breeding techniques remain available for use by public and private sector plant breeders?

Congress must ensure that Executive branch actions – policy directives, regulations, trade policies, and otherwise – foster the growth of a strong 21st century farming economy through science-based decision making. This includes ensuring the three regulatory agencies (USDA, EPA, and FDA) have consistent, risk-proportionate, science-based policies that promote a climate of innovation, particularly for university researchers and small companies. Congress must also ensure funding is sufficient for research programs.

- 2) What can the United States do to promote similar policies with our international trading partners?

Promoting international engagement is critical, and USDA, FDA, and EPA should work with the US Office of the Trade Representative to develop an international engagement strategy to prevent trade barriers due to non-harmonized regulations.

The June 2019 Executive Order recognized that this is an international issue. Many governments around the world are currently considering how to create policy environments that ensure safety and cultivate investment in the use of these tools to build their economies and address local and global challenges, and this is one area where the US could be leading by example. The Executive Order also acknowledges this

and calls for the Office of the U.S. Trade Representative to develop a strategy to remove unjustified trade barriers and expand markets for products of agricultural biotechnology.

While agencies such as the USDA have established goals for U.S. agriculture, there must be enough funding¹ through the USDA and other agencies, the Department of Energy and the National Science Foundation to conduct the necessary basic research. Otherwise, we will continue to cede the leadership to China when it comes to agricultural biotechnology such as gene editing.

Furthermore, it is essential that Congress ensures that the three agencies that oversee biotechnology foster the growth of strong 21st century farming and the bioeconomy through consistent, science-based decision making. Whereas the US leads the world in terms of biotech crops, it is also true that this success is limited to globally useful traits in major crops. Crops of regional importance and traits that are only needed in certain regions were completely left out of the biotech revolution due to the significant costs, time commitments and other burdens associated with the biotech regulatory process. To that end, U.S. biotechnology regulation must be both science-based and risk-proportional. Anything less will discourage a climate of innovation, particularly for university researchers and small companies.

Finally, if the three agencies are not consistent in their regulations, it will be meaningless for the U.S. to promote similar regulatory policies with our trading partners. We will have created inconsistency and uncertainty at the domestic level, which will render any U.S. influence on the topic meaningless.

¹ Solicitation of Input From Stakeholders on Agricultural Innovations, 85 FR 18185 (2020)

Senate Committee on Agriculture, Nutrition & Forestry
Hearing on Agriculture Innovation and the Federal Biotechnology Regulatory Framework
March 12, 2020
Questions for the Record
Dr. Michael Paustian

Chairman Pat Roberts

- 1) Your testimony mentioned that other countries, including Argentina, Canada and Brazil, are establishing regulatory structures for animal breeding technology. How much do these countries produce and export, compared to the United States, in terms of global pork and animal protein?

Using 2020 estimates from the USDA, we can see that the US produces more pork than Brazil, Canada and Argentina combined (Figure 1). Canada and Brazil are significant competitors in the pork export market, while Argentinian production is currently consumed primarily by their domestic market (Figure 2). Looking ahead, the annual growth rate of pork production is expected to be around 3.5% in both Canada and the US, while Brazil (4.5%) and Argentina (6.9%) are notably higher, highlighting the rapid expansion taking place in the meat sector within these countries. Regarding beef production, Brazil, Argentina, and Canada combined produce more beef than the US (Figure 3). However, Brazil exports nearly as much beef as the US, Argentina, and Canada combined (Figure 4). In summary, while the US currently leads Argentina, Canada and Brazil in both pork and beef production, these countries are already currently significant competitors in export markets and are poised for rapid growth in the coming years due to world demand and the availability of feedstuffs. Access to advanced breeding technology would certainly accelerate this growth.

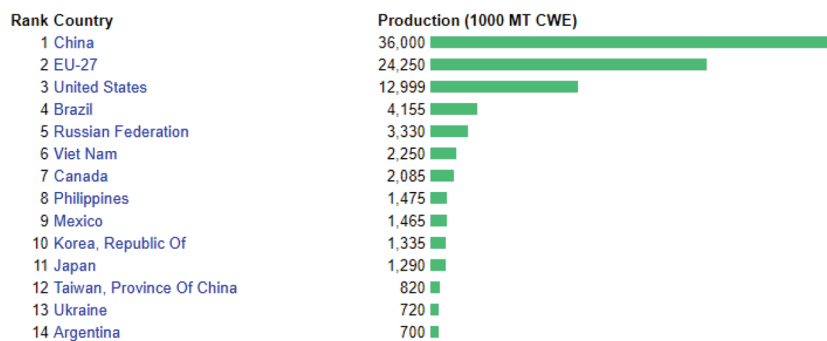


Figure 1 - 2020 estimated pork production (USDA via IndexMundi)

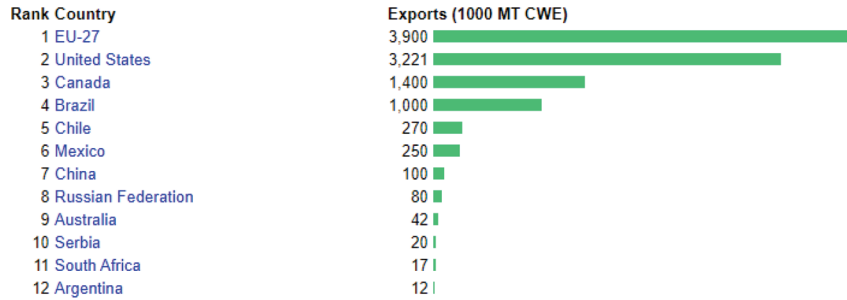


Figure 2 - 2020 estimated pork exports (USDA via IndexMundi)

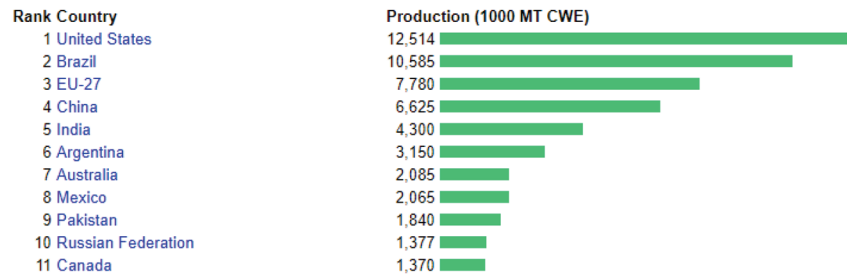


Figure 3 - 2020 estimated beef production (USDA via IndexMundi)

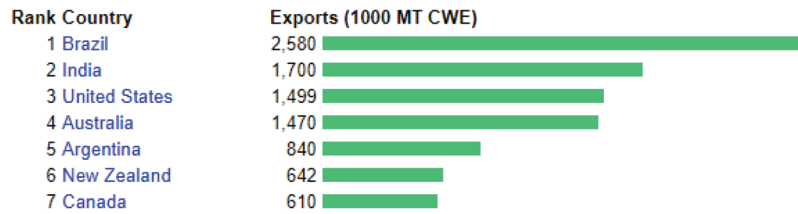


Figure 4 - 2020 estimated beef exports (USDA via IndexMundi)

Senator Mike Braun

- 1) Last year, AquaBounty Technologies’ fish hatchery in Albany, Indiana began raising the country’s first genetically engineered animal approved for human consumption by the U.S. Food and Drug Administration (FDA).

Not only has the FDA determined that AquaBounty salmon as safe to eat as conventional salmon, but its production is also more environmentally friendly. With the human population projected to rise over 9 billion by midcentury and the world's marine fish stocks increasingly overfished, this Hoosier-produced product is a great example of how 21st century agriculture technology can help sustainably feed our growing population.

Despite these benefits, it took nearly 20 years for the FDA to approve this technology. I remain concerned that such a lengthy process steers investors away from the U.S. market, costing the U.S. jobs in this high-tech sector.

- a. Do you share my conclusion that these regulatory barriers and delays are driving innovative technologies from the U.S. putting our producers at a competitive disadvantage?

Yes - excessive regulation certainly stifles innovation in agriculture and especially excludes small farms and companies that are unable to financially afford a burdensome review process. The experience of the AquaBounty salmon and the existing regulatory environment at the FDA has most likely discouraged the development of additional genetic techniques in livestock unless there is a significant financial incentive that warrants a sizeable investment in navigating the regulatory process. It should be noted that some of the barriers AquaBounty salmon faced were due to activist groups who are opposed to the use of genetic technologies in animals. This illustrates that there is still work to be done in regards to the public acceptance of these technologies.

- b. What recommendations would you suggest to streamline this process, so we can ensure the safety of, and bring technologies like AquaBounty to market in a timely manner?

I will reiterate an important point I made in my testimony, which is that regulation should be based on the type of genetic change being made, not on how it was made. This means that transgenic modifications in which genetic material from one organism is moved into another should be subject different regulatory scrutiny than a single nucleotide change that has been demonstrated to frequently occur in nature. This would help ensure that techniques making very small genetic changes or replicating changes observed in nature could be approved relatively quickly, allowing regulators to focus more time and energy on other types of modifications. It is important to ensure that food from genetically modified animals is safe for both humans and the environment, but excessive regulation only serves to inhibit innovation.

Senator John Thune

- 1) Developing a risk- and science-based regulatory pathway for products of animal biotechnology to be approved is critical so that farmers and ranchers can better insulate themselves and our food production from the risks of disease.

SAB Biotherapeutics, a Sioux Falls clinical-stage biopharmaceutical company, is rapidly working to develop what could be the first treatment specifically designed to target COVID-19. SAB has a platform that leverages genetically designed cattle and produces large amounts of fully human polyclonal antibodies in response to a disease such as COVID-19 in a short amount of time.

Given the importance of new biotechnologies, such as gene editing, for maintaining the security and stability of the rural economy, the nation's food supply, and human and animal health it is critical our producers have the tools they need to adapt to these challenges.

- a. Do the technologies to help address disease in animals have a viable regulatory path to market?

Currently, I would describe the path laid out by FDA as murky at best. We absolutely need to move away from the precautionary based regulation that has notably hamstrung the productivity European Union agricultural sector. As both a scientist and a farmer, it is very frustrating for me to see possible solutions to important production challenges (drought, disease resistance, animal welfare) sit on the shelf due to a lack of resources with which to navigate the regulatory bureaucracy.

- b. What steps can the government take to ensure that producers will have access to these technologies?

The US government needs to formalize and modernize a risk- and science-based approach to biotechnology regulation will be able to protect the safety of consumers and the environment while at the same time foster innovation in agriculture. This needs to include clearly defined roles for each regulatory agency. A transparent and clearly defined regulatory pathway would streamline the both the development of new genetic techniques as well as the adoption of these technologies by producers such as myself. In my personal opinion, the USDA is best equipped to shepherd these new technologies from the lab to the farm.

Senator Tina Smith

- 1) Gene editing seems to have already produced a number of amazing innovations in livestock, such as hogs incapable of contracting Porcine Reproductive and Respiratory Syndrome (PRRS) – a disease that costs American farmers nearly two-thirds of a billion dollars annually – and poultry immune to avian-influenza – a disease which wreaked havoc in my state in 2014 and 2015, resulting in the deaths of over 50 million birds. There are other diseases threatening American agriculture and our natural resources –

such as the African Swine Fever outbreak devastating global hog populations, or Chronic Wasting Disease affecting deer and elk across the country.

- a. What are the prospects that genetic solutions exist to help address these threats? Are you aware of any research taking place on these diseases or others?

The previous 20 years have seen an enormous amount of time and money spent (much of it by the US Government) on genome sequencing and analysis. New genetic techniques such as gene editing are now allowing us to reap the benefits of this accumulated knowledge by making precise genetic changes to areas of the genome that we know are linked to specific genotypes, such as disease resistance. Often (as is the case for the PRRS-resistant pigs that you mentioned) making a very small change to a single protein that is used by a virus to enter a cell can result in increased resistance to infection. I do not personally know of specific research to attempt this for other diseases, but now that a proof-of-concept has been established, I suspect that a large amount of public and private resources are being used in this area.

- b. Are there research, regulatory, trade, market, or other needs being unmet in the space of animal gene editing or biotechnology? What can Congress do to help meet these needs?

I believe that there are two critical needs in animal biotechnology that Congress can address. First, there needs to be a transparent, science-based regulatory framework that is driven by the type of genetic change being made, not the method by which it is achieved. Along with this, there should be a clear division of responsibility amongst the regulatory agencies while still allowing for the sharing of expertise. The USDA is a natural fit to regulate technologies that deal with food animals and plants. Second, Congress should demand that our trading partners around the world adhere to a similar science-based approach regarding the acceptance of animal biotechnology, as export restrictions could also serve to block innovation in this field.

Senate Committee on Agriculture, Nutrition & Forestry
Hearing on Agriculture Innovation and the Federal Biotechnology Regulatory Framework
March 12, 2020
Questions for the Record
Mr. Greg Jaffe

Chairman Pat Roberts

- 1) Your written testimony mentions that, “much more needs to be known before one can assess if moving regulatory oversight [of genome-edited animals] to USDA will ensure safety and provide confidence to consumers.” However, it appears CSPI is open to the regulation of genome-edited crops at USDA with various considerations based upon scientific evidence and guardrails mentioned.

Is there a science-based difference between USDA’s ability to regulate these new technologies in plants, but not animals?

Answer: USDA has scientific capacity to regulate genome-edited plants and it may have some of the technical and scientific capacity to regulate genome-edited animals. However, to date USDA has not made its regulatory decisions for genome-edited plants based on scientific evidence. Instead, USDA has proposed categories to exempt most genome-edited plants from USDA oversight without providing an administrative record or scientific evidence supporting those exemptions. CSPI does not object to exempting genome-edited crops if there is solid scientific evidence that they do not pose risks to the environment or agricultural interests.

Does CSPI support FDA’s proposal to regulate genome-edited animals as walking drugs?

Answer: It is imperative that the Federal government ensures the safety of genome-edited animals. If FDA regulates those animals under the “animal drug” provisions of the FDCA, that requires FDA to find that there is a “reasonable certainty of no harm” for any food eaten from animals with the drug. While FDA’s oversight of genome-edited animals using the FDCA’s animal drug provisions is not a perfect fit, FDA currently is the only federal regulatory program that addresses any potential safety issues that might arise from a genome-edited animal. Therefore, CSPI supports FDA carrying out case-by-case oversight of genome-edited animals that is science- and risk-based, transparent, and participatory. If another agency, such as USDA, were to establish regulatory oversight of genome-edited animals that is science- and risk-based, transparent, and participatory, and had the scientific know-how to enforce it, CSPI would review such a proposal to determine whether to support it.

Senator John Thune

- 1) What can the U.S. government do to ensure innovative breeding techniques remain available for use by public and private sector plant breeders?

Answer: CSPI suggests several actions that the federal government could take to ensure that innovative breeding techniques are available to public and private sector plant breeders, while still ensuring safety:

- Adequately fund regulatory agencies so that they can make science-based decisions in a timely manner.
 - Make sure that federal oversight is science-based and transparent so that consumers and our trading partners will have confidence in the safety of products produced by public and private sector breeders using innovative breeding techniques.
 - Fund public research to develop new plant and animal varieties using innovative breeding techniques that become public goods.
 - Support research by government and academic scientists that independently documents and analyzes the economic and social benefits and impacts of products produced by public and private sector plant breeders using innovative breeding techniques.
 - Provide incentives for those who have patents on innovative breeding techniques to make them available to public sector plant breeders for product development at little or no cost.
- 2) What can the United States do to promote similar policies with our international trading partners?

Answer: The United States should be as transparent as possible about its policies around innovative breeding techniques, its oversight of products made with those breeding techniques, and information about the products currently on the market (including accurate information about their benefits and impacts).