AGRICULTURAL BIOTECHNOLOGY: 21ST CENTURY ADVANCEMENTS AND APPLICATIONS

JOINT HEARING

BEFORE THE

SUBCOMMITTEE ON
LIVESTOCK AND FOREIGN AGRICULTURE,

AND THE

SUBCOMMITTEE ON
BIOTECHNOLOGY, HORTICULTURE, AND RESEARCH

OF THE

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AGRICULTURAL BIOTECHNOLOGY: 21ST CENTURY ADVANCEMENTS AND APPLICATIONS

TUESDAY, OCTOBER 26, 2021

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON LIVESTOCK AND FOREIGN AGRICULTURE,
JOINT WITH THE
SUBCOMMITTEE ON BIOTECHNOLOGY, HORTICULTURE, AND RESEARCH,
COMMITTEE ON AGRICULTURE,
Washington, D.C.

The Subcommittees met, pursuant to call, at 10:02 a.m., via Zoom, Hon. Jim Costa [Chairman of the Subcommittee on Livestock and Foreign Agriculture] presiding.

Representatives present: Representatives Costa, Plaskett, Delgado, Hayes, Schrier, Panetta, Harder, Axne, Carbajal, Rush, Lawson, Craig, Johnson, Baird, DesJarlais, Hartzler, Crawford, Davis, Kelly, Bacon, Hagedorn, Jacobs, Mann, Feenstra, Fischbach, Moore, Letlow, and Thompson.

Staff present: Lyron Blum-Evitts, Malikha Daniels, Prescott Martin III, Caleb Crosswhite, Ricki Schroeder, Patricia Straughn, Erin Wilson, and Dana Sandman.

OPENING STATEMENT OF HON. JIM COSTA, A REPRESENTATIVE IN CONGRESS FROM CALIFORNIA

Mr. COSTA. I call to order the joint hearing of the Subcommittee on Livestock and Foreign Agriculture and the Subcommittee on Biotechnology, Horticulture, and Research. And we will come to order, and I want to thank all the Members, and those who are participating via Zoom, on this joint Subcommittee hearing. After opening brief remarks, Members will receive testimony from today's witnesses, and then, as we do *pro forma,* we will allow Members to ask questions. You will have your allocated 5 minutes, alternating between Majority and Minority Members, as we always do, and you will be recognized, and in this day of Zoom, we all have to remember not only to unmute our microphones so that we can make our comments heard, or ask our questions, but just as importantly, as we have all had to painfully learn, to mute your microphones when you are not presenting, and maybe having a sidebar conversation of sorts, because we don't need that necessarily to become a part of the formal hearing. So I just want to remind all of us, maintain muted to minimize background noise, and I hope to get to as many questions as possible.

Let me make my opening statement by saying good morning to everyone again. I want to thank both Chair Plaskett and Ranking Members Johnson and Baird, and other Subcommittee Members from both Subcommittees. We know that biotechnology is a critical subject, with lots of potential in solving some of our most pressing issues as we try to ensure that we maintain our competitiveness in terms of trade, but investing in research and streamlining our regulatory system to help facilitate what America has traditionally done, which has led the world in terms of the transformation of our ability to produce food and fiber in the most nutritious fashion, in the most cost-effective way, that has allowed us not only to feed our nation for all American consumers every day, but also to allow us to export to feed parts of the world.

And we know that with climate change, these challenges become greater, and I would like to hearken back to, we are talking a lot about infrastructure here the last several months, and how we invest in America's infrastructure. And, when you talk about agriculture, and we remember our history, two meaningful pieces of legislation were signed a long time ago, when President Lincoln was trying to keep the country together during the Civil War, perhaps our most divided moment in America's history. And on July 1, he signed the Act that created the transcontinental railroad to bind the nation from coast to coast, but the very next day, July 2, he signed the Morrill Act that created land-grant universities, and I think that is not traditionally seen as infrastructure, but land-grant universities have been part of America's ability to maintain its cutting edge in technology, and how much that has transformed our ability to be so successful.

Throughout our history farmers have researched ways to optimize their ability to produce livestock and crop production, and over the past few decades, but even further back, going back to the development of our land-grant university system, working with the private-sector, we have been able to figure out ways to grow more sustainable food at a faster rate, and therefore it is incumbent upon us, as policymakers, to ensure that we take advantage of the latest cutting-edge technology, because with climate change we know—just last week the Department of Defense highlighted 13 countries in the world in which water allocation is going to be so critical that their ability to maintain stability in those countries is going to be a question mark.

And so, whether it is biotechnology, more drought-resistant plants, or whether it is technologies to use water more efficiently, are all part of what we have to do. The staggering drought that we have having in the West is a reflection of these changes in climate. And in California we are seeing drought conditions that we have not seen since 1976 and 1977, and so I am very familiar, as a third-generation farmer in California, the consequences, so I am very interested in innovative solutions that the panel will provide today. The testimony of our witnesses provides us opportunities to learn of new technological advancements in light of climate change, and how we optimize the use of our water. As we like to say in California, where water flows, food grows.

So while I believe we must address the underlying problems that are involved in climate change, and we are hoping to do that as a

part of this infrastructure package, we also need to begin to adapt to other changing conditions, and we need to look at the experts on how we can do a better job down the road. And, whether we are talking about at home or abroad, changing populations and straining our food systems, we see how supply chain shocks impact our ability to put food on America's dinner table. When you close restaurants and schools, as we did last spring, you take a complex, complicated food supply chain and you turn it upside down. And we are dealing with the consequences of that.

And then we see—well, obviously we must strengthen supply chains when we see the circumstances in our ports and harbors, and the bottlenecks that have taken place in recent months, how more difficult it is, in fact, to make that supply chain operate in a way that reflects our needs of our country, and who we trade with around the world. So there are a lot of impacts here, there is a lot of complexity, and I think this hearing will help us focus on a number of these issues. I look forward, again, to hearing with the four experts that bring a wealth of knowledge in biotechnology and agriculture. Their testimony will provide important information.

[The prepared statement of Mr. Costa follows:]

PREPARED STATEMENT OF HON. JIM COSTA, A REPRESENTATIVE IN CONGRESS FROM CALIFORNIA

Good morning. To start I'd like to thank our witnesses, Chair Plaskett, Ranking Members Johnson and Baird and the other Members of the Subcommittees. Agricultural biotechnology is a critical subject with lots of potential for solving some of our most pressing issues. Through opening trade, investing in research, and streamlining our regulatory system we can help facilitate the use of biotechnology to address threats like food scarcity and climate change. Throughout history farmers have searched for ways to optimize their livestock and crop production through selecting for the most favorable traits. Over the past few decades scientific advancement has given us an opportunity to safely grow more sustainable food at a faster rate. It is incumbent upon us as policy makers to understand how technological advancement can benefit our food system and create new avenues for promoting the use of biotechnology in novel settings.

Just this year we have seen staggering drought as a result of climate change. Being from California, I am very familiar with the consequences of extreme drought and I am always interested in innovative solutions. In their testimony some of our witnesses will discuss the potential for biotechnological advancements to help address the effects of climate change, specifically through optimizing water use. While I believe we must address the underlying problems that are causing climate change, it is also necessary for us to begin to adapt to changing climate conditions. I look forward to hearing more from our experts on how biotechnology can be used to address climate change and what sorts of innovations are on the horizon that may help us create a more sustainable, less water intensive agricultural system.

Another challenge where I believe biotechnology has a significant role to play is food security. Both at home and abroad changing climate conditions, the economic impacts of the pandemic, and growing populations are straining our food system. While not a silver bullet, biotechnology is an important tool that can help our food system increase its resilience to a changing world. For many years I have worked closely with our international food assistance programs and I believe that if farmers have access to innovation and sound information, they'll be able to reduce hunger around the world.

An important aspect of progress in agricultural biotechnology is acceptance by consumers both domestically and abroad. We have a stringent regulatory process that does an exceptional job of guaranteeing the safety of any product created using biotechnology. Trust in those systems is vital to ensuring that we can realize the benefits that biotechnology has to offer. I look forward to hearing from our witnesses on how they believe we can increase the acceptance of these products in foreign markets.

We have before us four experts in their fields that bring a wealth of knowledge on biotechnology in agriculture. Their testimony will provide us with important in-

formation about the various applications for biotechnology and what needs to be done to catalyze innovation. Before the introduction of our witnesses, I'd like to recognize the Ranking Member, Mr. Johnson of South Dakota, for any remarks he'd like to make.

Mr. COSTA. So now I would like to defer to the Ranking Member from South Dakota, Mr. Johnson, for any opening remarks that he would like to give, and then our Subcommittee Chair from the wonderful U.S. Virgin Islands, Stacey Plaskett, will have her opening statement, with her Ranking Member as well. So, Representative Johnson from South Dakota, please—you have the floor.

OPENING STATEMENT OF HON. DUSTY JOHNSON, A REPRESENTATIVE IN CONGRESS FROM SOUTH DAKOTA

Mr. JOHNSON. Thank you very much, Mr. Chairman, and I agree with Ms. Plaskett, it is good to see G.T., and good to see you looking well, Mr. Ranking Member. I think it is good we are doing this hearing together, because clearly technological advances, innovation, they have had a tremendous impact on livestock and on horticulture, and we are going to get a lot more done together than we would separately, so thank you to both Chairmen for making this happen.

There is a moral and a technological issue that is facing this Committee and society, how are we going to feed a growing world at the same time that we work to be good stewards of our environment? I suspect you all know the numbers. The United Nations Population Division expects there will be nearly ten billion people on this planet by the year 2050, and we are called to feed the world. But, we are not going to succeed without innovation, without technology, embracing innovation and technology. We will increase yields, we will reduce our carbon footprint, we will improve animal welfare, and, again, we are only going to do these things by embracing ingenuity, progress, and innovation.

And agriculture has a positive story to tell. It is innovation that has allowed our producers to produce more food with fewer resources. And certainly livestock producers in South Dakota and elsewhere have been doing that by adopting things like genetically advanced EPDs, IVF and embryo transfer, as well as extensive artificial insemination to increase profitability and the efficiency of the genetics, which are so critically important. But the technology is advancing even further, though. We have a tendency so often, when we are talking about technological improvements in ag, to focus on crops, and there has been a lot there, but I would tell you that the pace of change is accelerating on the livestock side as well, from disease-resistant pigs to polled Holstein cattle, these innovations have the potential to vastly improve the production landscape.

So I look forward to hearing from our panel on what is and what is not working with our current laws and regulations. For example, where we stand on efforts like the implementation of the National Bioengineered Food Disclosure Standard, and views on how the coordinated framework can, and should be, applied to GE livestock, and any other evolving regulatory hurdles. Making progress on these issues will also require an international approach, and, Madam Chair and Mr. Chairman, as I close, let us just be frank.

There are too many in this world who cast doubts on science as a tool, and they actively lobby international institutions to adopt their anti-innovation agenda. And I look forward to working with this Committee in a bipartisan way to ensure that the United States maintains a science-driven regulatory system, and that we actively advocate that position abroad. That is going to mean a lot of consumer education. It is also going to mean working through trade agreements and relationships so that we can maintain internationally a predictability on standards that our producers need to feed the world, and be good stewards of the environment.

So with that, Mr. Chairman, I look forward to working with you and all others on the Committee on these issues. Thank you, and I yield back.

Mr. COSTA. Well, I thank the gentleman, and I couldn't agree with you more. I think that a strong science-based regulatory framework is what we need to do to have an international standard that we can all comply with. I think phytosanitary standards, not only in this country, but around the world, need to be shared and respected, but I feel that way on all bases. I think public health needs to be science-based as well, and I just get very frustrated when I see some people ignoring the importance and the success that science has allowed us to make such important progress on.

Having said that, I am so excited to have our Subcommittee Chair, Ms. Plaskett from the U.S. Virgin Islands, who I have had the pleasure to work with over the years, and she chairs the Biotechnology, Horticulture, and Research Subcommittee, for opening remarks that I know that she has. And, Ms. Plaskett, the floor is yours.

OPENING STATEMENT OF HON. STACEY E. PLASKETT, A DELEGATE IN CONGRESS FROM VIRGIN ISLANDS

Ms. PLASKETT. Thank you, Mr. Chairman. Well, this looks to be a very informative hearing today, as we discuss the advancements and application, excuse me, of agricultural biotechnology. Thank you, Mr. Costa, Chairman of the Subcommittee on Livestock and Foreign Agriculture Subcommittee, in convening this hearing, and sharing your expertise. This sort of collaboration will help us all—excuse me, all view our work on the Agriculture Committee through a broader lens, and facilitate more holistic conversations as we look ahead to the next farm bill. Today's hearing will be an opportunity for Members to learn and evaluate the regulatory framework of agriculture biotechnology, and engage with experts in plant and animal agricultural innovation.

I look forward to hearing updates on innovation coming down the pipeline, as well as what we on the Agriculture Committee can be doing to ensure these innovations are getting into the right hands to produce a more resilient food supply, and generate opportunities in our agricultural communities. I would like to highlight the exciting research that is going on in my district, in the University of the Virgin Islands Agricultural Experiment Station, in working on vital biotechnology research in traditional Caribbean crops such as papaya, passion fruit, pineapple, casaba, sweet potato varieties, and more.

This important research is working to develop varieties of crops that are disease resistant, better adapted to local soil types, and provide a multiple of other benefits. I would also like to, at this time, submit for unanimous consent the following letter by the agricultural stakeholders' community for the record.

Mr. COSTA. Hearing no opposition, the information will deem accepted.

[The letter referred to is located on p. 64.]

Ms. PLASKETT. Thank you. Again, I look forward to having an informative and productive dialogue today, and to working with the Chairman and both Ranking Members here as we continue this discussion. And with that, Mr. Chairman, I yield back.

[The prepared statement of Ms. Plaskett follows:]

PREPARED STATEMENT OF HON. STACEY E. PLASKETT, A DELEGATE IN CONGRESS FROM VIRGIN ISLANDS

Hello, and welcome to what is sure to be an informative hearing today as we discuss the advancements and applications of agricultural biotechnology.

Thank you, Mr. Costa, Chairman of the Subcommittee on Livestock and Foreign Agriculture Subcommittee, for your partnership in convening this hearing and sharing your expertise. This sort of collaboration will help us all view our work on the Agriculture Committee through a broader lens and facilitate more holistic conversations as we look ahead to the next farm bill.

Today's hearing will be an opportunity for Members to learn and evaluate the regulatory framework of agricultural biotechnology and engage with experts in plant and animal agricultural innovation.

I look forward to hearing updates on innovations coming down the pipeline, as well as what we on the Agriculture Committee can be doing to ensure these innovations are getting into the right hands to produce a more resilient food supply and generate opportunities in our agricultural communities.

I would also like to highlight the exciting research that is going on in my District—the University of the Virgin Islands Agriculture Experiment Station is working on vital biotechnology research into traditional Caribbean crops such as papaya, passion fruit, pineapple, cassava, sweet potato varieties, and more. This important research is working to develop varieties of crops that are disease resistant, better adapted to local soil types, and provide a multitude of other benefits.

Again, I look forward to having an informative and productive dialogue today, and to working with the Chairman and both Ranking Members here today as we continue this discussion. And with that Mr. Chairman, I yield back.

Mr. COSTA. Thank you very much, Subcommittee Chair, for those insightful comments, and I share your enthusiasm for this morning's two Subcommittee joint hearings, I should say. Mr. Baird, you are recognized for any opening remarks you would like to give.

STATEMENT OF HON. JAMES BAIRD, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF INDIANA

Mr. BAIRD. Good morning, and I want to thank you, Mr. Chairman, and Chair Plaskett, for calling this hearing today. I appreciate our friends from the Livestock and Foreign Agriculture Subcommittee for also joining us for this discussion, and I am very excited to see our Subcommittees have the opportunity to discuss this incredibly important topic. I am also happy to see our Ranking Member G.T. Thompson with us as well. And, I really want to thank our witnesses for joining us today for this dialogue. I look forward to hearing from each one of them about the extensive work and research that they have done in this field, and I want to hear from them their vision of the future for biotechnology, and how we can better serve and improve this technology, moving forward.

From my perspective, biotechnology is the future of agriculture, and the future of food security for our changing planet. It has the ability to reshape the direction of our industry, and our world, as we strive to advance the sustainability of agriculture, improve animal health and well-being, and it plays a role in all the efforts to feed, clothe, and fuel our ever-changing planet.

However, this can only be the case if we are able to take advantage of this technology, and allow innovation to happen. At the present time, I don't think our regulatory system is keeping up with the technology of the products that are being developed from this industry, and so our system needs to improve, and become more rapid about approving biotechnology products. So I look forward to our conversation this morning between our guests and colleagues, and truly hope that this hearing will be a fruitful exercise, guiding future debate, legislation, and regulatory changes.

I value this as an opportunity to hear directly from the industry and academia about our current regulatory framework, how the system does or doesn't work, and how we can balance what industry needs to make this technology successful against an important need for consumer trust and confidence. I hope to hear about upcoming changes to these regulatory frameworks, and what benefits and challenges they may bring to the industry rulemaking like the SECURE (Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient) Rule, the National Bioengineered Food Disposure Standard, and rulemakings on the horizon like FDA's guidance on gene editing plants, EPA's PIP (Phenol, Isopropylated Phosphate) Rule, and USDA's ANPR on animal biotechnology.

Ms. Plaskett and I recently sent a letter to USDA, encouraging all involved to take advantage of this tremendous opportunity to shape the industry, and I look forward to hearing directly from our stakeholders to what extent we can take advantage of this technology. So far, in the commercial life of these products, interagency cooperation has had a tremendous impact on the success, or lack thereof, for biotech products. I hope that our witnesses today will share with us their experiences and thoughts regarding this cooperation, and how this process can be improved.

As we continue to work domestically on how best to bring current and future biotech advancements to market, it is tremendously important that we keep an eye on, and actively participate, in how our trade partners, particularly those with large impacts on the demand for U.S. ag products, advance their own regulations for these products. We must continue to ensure that these partners continue to regulate on the basis of science and risk, not speculation and fear, and ultimately ensure that we don't inadvertently innovate ourselves out of the global marketplace.

As I have mentioned many times before, I have a real passion for agriculture, and for better understanding the opportunity that surrounds innovation and technology in our industry. At a time when technology continues to quickly advance, our policy must be able to keep up an effort to ensure safety, transparency, and fairness in the marketplace. I truly hope that today's conversations will shed additional light on what this policy should look like in the ideal world, and I look forward to today's conversation, and really appreciate the opportunity to engage, and to hear from such tal-

ented stakeholders. Thank you all again, and with that, Mr. Chairman, I yield back.

Mr. COSTA. I thank the gentleman from Indiana for his comments, and, as is customary when Subcommittees hold hearings or meetings, we always afford the opportunity for the Chairman of the full Committee, or the Ranking Member of the full Committee, to make any comments that they might like to make, and it is my understanding Chairman Scott is unable to be here at this point in time, although if he joins us later on, we will certainly love to hear his comments or thoughts. I do see the Ranking Member of the full Committee, Representative G.T. Thompson from Pennsylvania. And if the Ranking Member would like to make some comments at this time, we certainly would afford him that opportunity.

OPENING STATEMENT OF HON. GLENN THOMPSON, A REPRESENTATIVE IN CONGRESS FROM PENNSYLVANIA

Mr. THOMPSON. Well, Mr. Chairman, thank you so much. Thank you for this hearing. First of all, just thank you for all the well wishes, thoughts, prayers, the texts. It is great to work with such a great farm team that works hard for the best interests of rural America, and those folks who work so hard each and every day to provide us our food, our fiber, our building resources, and our energy. Thank you to you, Chairman Costa, Chair Plaskett, Ranking Member Johnson, and Ranking Member Baird, for holding a hearing on this exciting topic. I will say, Chair Plaskett, you made me hungry when you were going down that list of great agricultural products that you all produce. And I want to say thank you to our distinguished panel of witnesses for agreeing to participate, and share your expertise.

If appropriately embraced, agriculture biotechnology holds tremendous promise for addressing many of the challenges facing our nation, and namely the challenge of sustainably feeding a rapidly growing population. We all know this, and this hearing is important because it puts it on record, American agriculture is about science, technology, and innovation. That is what it always has been about, since those very first early days. It was crude, it was rudimentary; but, and the reason settlers worked through it was just so their family could live through another season.

But today it is so much more sophisticated, and, if embraced, there is so much more that we can do with it. I look forward to hearing from each of you about the promising advancements on the horizon. I also look forward to your perspectives on any hurdles that may be getting in our way, whether that be cumbersome regulation, conflicting international standards, a lack of consumer knowledge and acceptance of technologies, or, quite frankly, government bureaucracy that is resistant to adopting this science, technology, and innovation.

The United States has long been a leader in agriculture innovation, and to maintain that competitive edge, it is important that our nation's policies don't inadvertently hamper innovation domestically, and ultimately drive that important work overseas. Now, thankfully, the modernization of the regulatory framework for biotechnology has been a bipartisan effort spanning multiple Administrations, multiple generations, and I am very pleased at the

progress made under the Trump Administration, from the Executive Order regarding agriculture biotechnology products, the USDA SECURE Rule, updating plant technology regulations for the first time in 30 years, to the advance notice of proposed rulemaking on much-needed reforms to the regulation of genetically engineered animals. I remain hopeful the current Administration will continue listening to the needs of the agriculture community as it works to build off that important work.

Now, again, thank you all for being here. I look forward to today's conversation. With that, I yield back.

Mr. COSTA. Well, we thank the gentleman from Pennsylvania, and wish you a quick recovery, and hope to see you next week. With those opening statements concluded, we now move into the real purpose of the hearing, and that is to listen to some of the distinguished guests that we have who are experts in their field. We have four witnesses on the panel this morning, and we want to thank them for their time and their efforts to provide their presentation to the two Subcommittees.

Let us begin with our first witness, Dr. Fan-Li Chou, who is the Vice President of Scientific Affairs and Policy for the American Seed Trade Association. Remember to keep your microphones muted, my fellow colleagues, because it works a lot better that way, unless you are recognized. So, without further ado, Dr. Fan-Li Chou, we look forward to hearing your comments this morning, and you have 5 minutes, and the clock will begin on your opening statement.

STATEMENT OF FAN-LI CHOU, PH.D., VICE PRESIDENT FOR SCIENTIFIC AFFAIRS AND POLICY, AMERICAN SEED TRADE ASSOCIATION, WASHINGTON, D.C.

Dr. CHOU. Thank you. Good morning, Chair Plaskett, Chairman Costa, Ranking Member Thompson, Ranking Member Baird, Ranking Member Johnson, and the Members of the Subcommittees. I am so pleased to be here representing ASTA's nearly 700 member companies at today's hearing. Our members produce everything from grass and turf seed, to row crop seed, to vegetable and ornamental seed, to true potato seed for conventional, genetic engineered, and organic seed markets. ASTA has been around since 1883, so as we consider the current advances in agricultural biotechnology, and look forward to the applications in the 21st century, I think it is worthwhile to reflect on the common thread that runs from 1883 to now, and that common thread is plant breeding.

So plant breeding has been around since our ancestors domesticated crops, but in the last several decades plant scientists and plant breeders have accumulated an impressive collection of tools to unlock the genetic potential of plant crops, and using these tools, we have safely and reliably introduced into the food system hundreds of thousands of new plant varieties over the last century. In the 21st century we are all facing critical challenges to our agricultural food system. Climate change, a rapidly growing global population, environmental degradation. The need for new, improved plant varieties is more pressing than ever. But thankfully, plant breeders have an unprecedented number of tools to drive solutions. The most exciting of late is gene editing.

So in agriculture, gene editing is an enabling tool. It supports, rather than supplants, the fundamentals of plant breeding. It enables our plant breeders to leverage the decades of accumulated scientific discoveries and understanding of plant genetics to increase the accuracy, the precision, and the efficiency of plant breeding. Gene editing has been used across all crops, including specialty crops, and by breeding programs of all sizes, including public universities and small companies. We are using gene editing to work within the plant's genetic family, similar to what is done in conventional breeding, or can occur in nature.

So let me share a few examples. Some non-browning varieties are being developed for fruits and vegetables, like potatoes, avocados, and lettuce. For potatoes alone, non-browning varieties could eliminate 1.5 billion pounds of wasted potatoes. We are working on water efficient crops, from lettuce, to wheat, to rice. We are using gene editing to discover cover crops that can be cash crops, bringing both environmental and economic benefits. It is used to encourage healthy eating, modifying soybeans so it is heart healthy, to make berries more consistent and more available to consumers. And many of these examples are based on public and private partnerships. But whether these examples, and others like them, and the tremendous benefit they can provide, becomes widely available would depend in part on research investment, and more notably, on the policy and regulatory environment in the U.S., and around the world.

At ASTA, we commend the regulatory improvement that USDA has made in its final rule for biotech regulation that was published in May 2020. That final rule recognizes the longstanding safety record associated with plant breeding, and extends to certain types of plants that could have been done through conventional breeding, or occur through nature, and we look forward to working with USDA to implementing the various elements of that final rule. We also appreciate the proposed rules by EPA, and we look forward to the leadership by EPA's Administrator in getting that rule to the finish line. Finally, we are awaiting clarifying guidance from FDA. It is critical that these three agencies are consistent and coordinated in their policy approach.

In closing, the 21st century is looking right at us. We are in the middle of it. We have the tools to develop solutions to the challenges facing our food system. But to ensure those tools are widely accessible across all crops, across operations of all sizes, production methods, and geography, it is important to maintain strong investment in plant breeding research, and for domestic and international policies to be clear, risk-based, risk-proportionate, science-based, and harmonized. Otherwise, innovation would be limited to a very few crop varieties, and the benefits would never be fully realized across the broad agricultural sector. I really appreciate the opportunity to share my thoughts with you today, and I will be happy to take any questions, and I look forward to the discussion. Thank you.

[The prepared statement of Dr. Chou follows:]

PREPARED STATEMENT OF FAN-LI CHOU, PH.D., VICE PRESIDENT FOR SCIENTIFIC AFFAIRS AND POLICY, AMERICAN SEED TRADE ASSOCIATION, WASHINGTON, D.C.

Good morning, Chair Plaskett, Chairman Costa, Ranking Member Baird, Ranking Member Johnson, and Members of the Subcommittees. I am Fan-Li Chou, Vice President of Scientific Affairs and Policy at the American Seed Trade Association (ASTA). Prior to joining ASTA, I served for over a decade at USDA, including as the Agricultural Biotechnology Advisor to the Office of the Secretary and in positions with the Foreign Agricultural Service and the Animal and Plant Health Inspection Service. I am pleased to be here today to discuss *Agricultural Biotechnology: 21st Century Advancements and Applications.*

Founded in 1883, the ASTA represents nearly 700 member companies involved in seed production and distribution, plant breeding, seed treatment and related industries in North America. The U.S. seed industry is highly specialized and diversified with hundreds of varieties per crop species. ASTA's member companies produce everything from grass and turf seed to row crop seed, to vegetable, ornamental and flower seed, to true potato seed—for conventional, genetically engineered, and organic seed markets.

My remarks today will focus on plant breeding's impact to each of us, to our economy and to our environment. The importance of plant breeding innovations, including agricultural biotechnology such as genome editing; and actions needed to fully realize the real-world benefits of plant breeding innovation.

Plant breeding is not new, it dates back thousands of years to when people first domesticated wild plant varieties. Over time, plant breeders have accumulated an impressive collection of tools, such as cross breeding, selection, hybridization, induced mutagenesis, biotechnology and molecular markers to unlock the genetic potential of plant crops. Using these breeding tools, the plant breeding community, both the public and private sides, have safely and reliably introduced to the food system hundreds of thousands of new plant varieties over the past century. To be commercially released, new plant varieties, regardless of the breeding tools used, are subjected to strict, multiyear, multi-location evaluation and assessment for quality and performance.

We have all benefited from, and continue to benefit from, the innovations of plant breeding. The food we eat, the clothes we wear, the fuel that powers our cars—all these things and more start with a seed in the ground. New plant varieties have enriched our lives, by increasing our food choices, for example seedless grapes, easy-peel citrus, tastier tomatoes of all sizes and shapes, and snackable peppers; by beautifying our landscapes with ornamental varieties adapted to all seasons and geographies.

New varieties developed from plant breeding allow our farmers to produce more using fewer inputs. According to USDA Economic Research Service's report on Agricultural Productivity in the U.S., since 1948, domestic agriculture productivity nearly tripled. While some of the gains can be attributed to better management practices, some experts estimate that improved varieties account for more than a 50 percent productivity gain. This is because new varieties are bred to be more productive, more disease and pest resistant, and better adapted to environmental stresses such as drought and excess water.

Our economy has benefited and continues to benefit from plant breeding. The U.S. seed market was valued at $14.51 billion in 2020, which is about 25% of the global seed market. In 2020, U.S. planting seed exports exceeded $1.6 billion to 144 countries. Our industry enjoys the global reputation of providing seed with the highest quality assurance standards and the most innovative technologies and genetic resources.

In the 21st century, we are facing the convergence of critical challenges to the agricultural food system: climate change, rapidly growing global population, expansion of the global middle class, environmental degradation, and biodiversity loss. The need for improved plant varieties is more pressing than ever. Thankfully, plant breeders have an unprecedented number of tools to work with. The most exciting of late is gene editing.

In agriculture, gene editing is an enabling tool, supporting, rather than supplanting, the fundamentals of plant breeding. Gene editing enables plant breeders to leverage the decades of accumulated scientific discovery and understanding of plant genetics, its natural variability, and its interaction with the environment, to increase the accuracy, precision, and efficiency of plant breeding. One of the most exciting developments around gene editing and agriculture is that we see it being used across all crops, including specialty crops, and by breeding programs of all sizes, including the public- and private-sectors. Plant breeders are using gene edit-

ing to create genetic variability within the plant's own genetic family, similar to what could be achieved with conventional breeding or could occur in nature.

Let me share a few examples of how gene editing could be used in plant breeding to help drive solutions to the growing pressures of climate change, food and nutritional security, and sustainability.

Bruised and browning produce are a top contributor to food waste in restaurants and grocery stores. Research shows shoppers avoid purchasing bruised produce, even if the vegetables are perfectly healthy and taste fine. And in restaurants, produce prepped before the dinner rush often need to be thrown out at the end of the night because of their brown color. Using innovations like gene editing, plant breeders are unlocking the code to make potatoes more resistant to bruising and browning. The new non-browning characteristic could eliminate 1.5 billion pounds of wasted potatoes, translating to resources saved. The same application is being applied to other produce, from mushrooms to apples and avocadoes.

With 70% of the world's freshwater used for agriculture, reducing the amount of water needed to grow food could have a significant environmental impact. Plant breeders are using gene editing to develop new, water-efficient varieties of crops. For example, lettuce struggles in the heat. But promising research is showing that gene editing can be used to develop lettuce varieties that have the same heat tolerance as certain wild relatives, with the same taste and nutritional value as the lettuce we enjoy today. Drought tolerant varieties are also under development for wheat and rice.

Gene edited is being employed to develop plant varieties that can better support carbon capture. Gene edited crops with stronger, deeper roots can capture carbon and sequester it in the soil for longer periods of time. Gene editing and plant breeding will also expand farmer choices in cover crops, as well as developing cover crops as a source of income for farmers. With funding from the USDA National Institute for Food and Agriculture, a consortium of university researchers from Illinois, Minnesota, Ohio, and Wisconsin, as well as start-up company CoverCress, have used gene editing to develop a cover crop, pennycress, with edible oil and meal, bringing environmental, as well as economic, benefits to the farmers.

Gene edited plants can support healthy eating. Calyxt, company that was founded by a University of Minnesota professor, commercialized a variety of soybean that has been gene edited so that its oil is heart healthy, with a similar composition to olive oil. The same company is working on wheat varieties with higher protein and fiber, and less gluten. Pairwise, a startup food and tech company that uses gene editing to develop new varieties of fruits and vegetables, is part of a collaboration with USDA ARS and others to identify and characterized genetic diversity in berries. The outputs from this collaboration will be used to bring new and better berries to producers, and to make berries more consistent and more available to consumers.

The 21st century is an exciting time for plant breeding and for plant breeders and plant scientists. We are faced with unprecedented challenges, yet we are equipped with extraordinary tools and scientific understanding to find solutions. A continued and robust investment in public sector agriculture research is needed. The work of the public- and private-sectors complements each other. The public sector's role is critical in fundamental research, germplasm collection and maintenance, addressing emerging plant diseases and pests, and training of our future breeders and scientists. The strength of the seed industry is taking a promising concept to market, to shoulder the expensive and time-consuming process of delivering high performing plant products to farmers around the world.

In addition to these groundbreaking examples of public-private partnerships in gene editing, a long-standing example of public-private-sector collaboration is the Germplasm Enhancement of Maize project, or GEM. GEM is a cooperative effort of the USDA ARS, land-grant universities, and the seed industry. Similarly, on the specialty crop side, the close collaboration between seed companies and University of California Davis (UC Davis), has resulted in identifying key pre-commercial research priorities. Seed Central at UC Davis provides a networking forum that facilitates the public-private collaborations often needed to shift these pre-commercial research priorities to commercial applications.

As I previously mentioned, plant breeding innovation, like gene editing, is currently being researched and used across a vast array of plants, including fruits, vegetable, and ornamentals, what we consider specialty or small acreage crops. Whether these crops—and the tremendous benefits they can provide—will become widely available will depend in part on research investment and more notably on the policy and regulatory approach.

Numerous Administrations, across more than 3 decades, have consistently agreed on the foundational principles and policies for effective and efficient regulatory oversight. These principles were articulated in the 1993 Executive Order (EO) *Regu-*

latory Planning and Review and reiterated in the 2011 EO *Improving Regulation and Regulatory Review.*[1]–[2] Specifically, for emerging technologies such as agricultural biotechnology, the foundational principles of effective and efficient regulatory oversight were reaffirmed in the 2011 Memorandum *Principles for Regulation and Oversight of Emerging Technologies,* the 2015 *Memorandum Modernizing the Regulatory System for Biotechnology Products,* and the 2019 EO *Modernizing the Regulatory Framework for Agricultural Biotechnology Products.*[3]–[5]

In advancing innovation in agriculture, the stated policy goals are that regulatory oversight must "ensure the fulfillment of legitimate objectives of protection of safety, health, and the environment" and "avoid unjustifiably inhibiting innovation, stigmatizing new technologies, or creating trade barriers".[3] Regulatory agencies are to, among other things:

- Identify and consider all regulatory alternatives, including the alternative of not regulating.
- Regulate only when there is a significant problem that is best solved by regulation, and where the benefits of regulation justify the costs.
- If regulation is warranted, it should be commensurate with the risk, and "avoid arbitrary or unjustifiable distinction across like products developed through different technology".
- Base regulatory decisions on the best available scientific and technical information.
- Provide sufficient flexibility to accommodate new evidence and learning, and review regulations on a regular basis to ensure they continue to meet the regulatory objectives in the least burdensome way.
- Use clear language and provide opportunity for stakeholder and public involvement.
- Promote interagency coordination and harmonization; avoid interagency duplication and inconsistency.
- Promote international coordination to minimize trade impacts.

With regards to products of plant breeding innovation such as gene editing, I also note the commitments for agencies to provide regulatory clarity in the 2016 *National Strategy for Modernizing the Regulatory System for Biotechnology Products* and the 2019 EO *Modernizing the Regulatory Framework for Agricultural Biotechnology Products.*[1–2]

ASTA commends the regulatory improvements USDA made in the Final Rule for biotechnology regulation, published in May 2020. The Final Rule reflects the over 30 years of regulatory experience accumulated by USDA, recognizes the longstanding safety record associated with plant breeding, and exempts types of plants that could be developed through conventional breeding or occur in nature. As USDA proceeds in implementing the various elements in the Final Rule, we believe it is imperative for the plant breeding community to be consulted to assure a smooth transition to the new processes and to mitigate against unintended barriers to smaller organizations and public sector institutions involved with the development of new crop varieties, especially specialty crops.

ASTA appreciates the proposed rule published by the Environmental Protection Agency in December 2020, proposing exemptions of certain plant-incorporated protectants derived from newer technologies that are like those developed through conventional breeding. We look forward to Administrator Regan's leadership in shepherding the proposed rule revision to finalization and implementation.

We eagerly await clarifying guidance on food derived from plant breeding innovation such as gene editing by the Food and Drug Administration. It is critical that these three agencies are consistent and coordinated in their policy approaches.

One of the exciting things about gene-editing tools is the potential for widespread access across breeding programs of all sizes, including the public- and private-sectors, across all crops, and across farming operations of all sizes, production methods, and geographies. Federal and global policies will play a huge role in access to these products. It is important that policies be clear, and risk- and science-based; it's also important that there is harmonization across global policies—otherwise, innovation will be limited to very few crop varieties, and the benefits will never be fully realized across the agriculture sector. Appropriate policies can incentivize investments

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[1] *https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/biotech_national_strategy_final.pdf.*

[2] *https://www.federalregister.gov/documents/2019/06/14/2019-12802/modernizing-the-regulatory-framework-for-agricultural-biotechnology-products.*

in plant breeding innovation, such as gene editing, creating new jobs and market opportunities, and boosting sustainability throughout the agriculture and food value chain.

In conclusion, the 21st century food and agriculture system faces unprecedented challenges, from climate change to a growing population, and rapidly evolving pests and diseases. In order to maintain the U.S.' position as an economic world-leader in innovation, and to enable long-term economic, social and environmental sustainability, we must make strong investments in plant-breeding research and ensure the alignment of science-based policies, at the domestic and global levels. Thank you for the opportunity to testify before you today. I'll be happy to take your questions.

[Endnotes]

[1] *https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf.*

[2] *https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review.*

[3] *https://obamawhitehouse.archives.gov/sites/default/files/omb/inforeg/for-agencies/Principles-for-Regulation-and-Oversight-of-Emerging-Technologies-new.pdf.*

[4] *https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf.*

[5] *https://www.whitehouse.gov/presidential-actions/executive-order-modernizing-regulatory-framework-agricultural-biotechnology-products/.*

Mr. COSTA. Thank you very much, Dr. Fan-Li Chou, and I like your screensaver, it is a nice background. But we now move on to our next witness today, Dr. Elena Rice, Chief Scientific Officer for Genus plc. And Dr. Rice, please begin with your opening statement—the time clock there. We look forward to hearing from you.

STATEMENT OF ELENA RICE, PH.D., CHIEF SCIENTIFIC OFFICER, GENUS PLC, DEFOREST, WI

Dr. RICE. Chairman Costa, Chair Plaskett, and Ranking Members Thompson, Johnson, and Baird, and Members of the Committee, my name is Dr. Elena Rice, and I am the Chief Scientific Officer of Genus plc. I also serve on the Board of the Biotechnology Innovation Organization's Agriculture and Environment Government Board. I am honored to testify before you today to discuss how innovation in animal breeding will help to protect our food supply, feed our growing population, and feed more healthy and sustainable food system.

Genus plc is a world-leading animal genetics company. We are breeding better pigs and cattle so farmers can produce high quality meat and milk more efficiently and sustainably. Genus has a long history of leadership in research, development, and delivering porcine and bovine genetics, and we apply new ideas using gene editing, reproductive biology, and other breeding technologies to improve genetics for sustainable production in healthy and disease-resistant animals. Genus's R&D and ABS, our global bovine business, have headquarters in DeForest, Wisconsin, and PIC, our global porcine business, has headquarters in Nashville, Tennessee. Our firm belief is we need more science to improve animal health and welfare, and continue America's leadership in meeting global protein demand. Additionally, as climate change and zoonotic diseases present even greater risk today to animal and human health, and to our economy, more science is urgently needed to find mitigating solutions. I appreciate the opportunity to appear today because the innovative work being done by Genus, and others in the biotechnology and livestock industry, is so critical.

Due to science and technology, we see livestock genetics, along with industry practices, reducing animals' carbon footprint. For ex-

ample, the amount of feed needed for a pig to build body weight has fallen by nearly 60 percent over the last 50 years. In dairy, 30 percent fewer cows today are producing 76 percent more milk. Put simply, the animal footprint in the United States is going down, and in large part this is due to improved knowledge and application of innovative animal practices science and technology.

Beyond these benefits, we see even great opportunity in the prevention of disease. Through Genus's gene editing program we have an opportunity today to eradicate Porcine Reproductive and Respiratory Syndrome, or PRRS virus. PRRS is a global endemic disease which causes animal death and suffering, which impacts the livelihood of all farmers. We are excited to share that, through small deletion in one gene, and not a single addition to the pig genome, in our research trials PRRS-resistant pigs showed complete resistance, and I mean 100 percent resistance, to the PRRS virus. The product is currently going through regulatory review by the FDA. As this Committee notes, in your letter to—an efficient risk and science-based regulatory system is imperative to capitalizing on this solution, and we agree.

For Genus, our ethical commitments guide our efforts, including our commitment to partner and comply with all global government regulations, including testing and safety requirements. However, to bring these solutions to commercial reality, we need practical, less expensive, risk- and science-based regulatory system that provides a safe and predictable path to market. We believe a regulatory framework for animals should create certainty for innovators, investors, producers, and consumers. And it should be practical in allowing the benefits of the technology to be efficiently and safely realized, while at the same time cementing the U.S. as a pioneer in innovation in this sector. We also need a coordinated global regulatory framework to avoid trade disruption, allowing producers and farmers to embrace these solutions.

In closing, as we look to the future, we truly believe new technologies can lead to eradication of animal diseases, provide the opportunity for less use of antibiotics, produce more protein from fewer animals, resulting to less environmental impact. If these innovations are stifled, society will miss out on huge solutions for improving the sustainability of our food system. Thank you, I look forward to your questions.

[The prepared statement of Dr. Rice follows:]

PREPARED STATEMENT OF ELENA RICE, PH.D., CHIEF SCIENTIFIC OFFICER, GENUS PLC, DEFOREST, WI

Chairman Scott, Chairman Costa, Chair Plaskett, Ranking Member Thomp[s]on, Ranking Member Johnson, Ranking Member Baird, and Members of the Committee, my name is Dr. Elena Rice, Chief Scient[i]fic Officer for Genus plc. I also serve on the Biotechnology Innovation Organization's (BIO) Agriculture and [Environment] Section Governing Board.

I am honored to testify before you for today's hearing on "*Agricultural Biotechnology: 21st Century Advancements and Applications*" and discuss how innovation in animal breeding will help to protect our food supply, feed our growing population, and create a more healthy and sustainable food system to help nourish the world.

First, and most importantly, let me acknowledge and thank the strong support from the House Agriculture Committee in the recent letter[1] Subcommittee Chair Plaskett and Ranking Member Baird led calling on the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) to modernize these efforts and improve the regul[a]tory approach to meet the challenges our food supply and society are facing.

Introduction

Let me tell you a bit more about my company. Genus plc is a world-leading animal genetics company by breeding better pigs and cattle so farmers can produce high quality meat and milk more efficiently and sustainably. We do this by accurately analyzing animals' DNA and look for markers we know are linked to desirable [characteristics], and select animals with desirable characteristics to breed subsequent generations which help farmers raise healthier and more sustainable animals.

With 1,300 employees in the United States, Genus' long history of leadership in animal breeding and innovation is focused upon developing improved genetics, healthier and disease resistant animals and improving the sustainability of agriculture.

Research and development is at the forefront of Genus' focus of applying new ideas in the industry using gene editing, reproductive biology and other traditional breeding technologies and approaches.

Genus's global porcine and bovine genetics businesses, PIC and ABS, then deliver leading genetics to tens of thousands of small and large farmers globally by focusing on addressing farmers's biggest needs, which are production efficiency, healthy and robust animals, and data and information to manage the farms.

PIC is hea[d]quartered in Hendersonville, Tennessee and ABS is headquartered in DeForest, Wisconsin.

We work on all these needs and demands by improving feed efficiency, meat and milk quality, and health traits through genomic science and breeding, achieving more production with less [environmental] impact. We also provide data such as genotypes to farmers helping them to manage their own breeding programs and improve [quality] and productivity of their animals..

Global Challenges

We believe more science and technology, not less, is required to meet the nourishment needs of a projected global population of 9.5 billion and the ability to meet a doubling of demand for animal-derived protein by 2050.[2]

We believe in our efforts to continue America's unsurpassed leadership in an innovative and sustainable food and fuel system, more science and technology is necessary, not less.

And we believe more science and technology, not less, is necessary as zoonotic diseases become more prevalent and present greater risks to animal and human health and to our economy.

Beyond addressing the challenge of global food and health security, we also recognize many consumers are not familiar with animal agriculture, what breeding methods are in use today, and what science and technology can offer in ensuring a healthy and sustainable food system in the future.

For example, proposed state ballot initiatives in Colorado and Oregon which restricts traditional animal husbandry practices such as the use of artificial insemination, will impact practices used by [veterinarians] to care for livestock, impact ranchers ability to improve herd genetics which can make agriculture less sustainable by driving up carbon emissions, and impacting the cost of food production by disrupting supply chains.

We also hear more and more concern about greenhouse gas emissions, the use of land, water management and opportunities for regenerative farming practices, where often these discussions lack any scientific basis or misrepresent the facts, where in fact, improved livestock genetics is reducing the carbon footprint per animal.

Even though we're an animal genetics and breeding company, as consumer's are increasingly making food choices based on personal values in addition to nutrition, taste and cost, we have spent the last several years [engaging] with, and listening to consumers and other food and industry leaders to understand their interests and views, and to have a dialogue on the role of animal breeding as part of a healthy and sustainable food system.

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[1] *https://baird.house.gov/news/documentsingle.aspx?DocumentID=201.*
[2] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5532560/.*

The good news is through this effort we have learned we share aligned values around the role of science, technology and animal genetics towards public and animal health and welfare, disease prevention and environmental concerns, and animal genetics is a missing piece of the puzzle for a more healthy and sustainable food system.

Solutions with Innovation

As shared earlier, research and development is at the forefront of Genus' vision of pioneering animal genetic improvement to help nourish the world, through better understanding and innovative strategies through genomics of farm animals, and ground-breaking efforts like advanced reproductive technologies, the use of big data to drive new genetic insights, gender skewed semen, and gene editing which help customers produce animal protein more effectively and efficiently, enhancing nutrition, and making animals healthier and reducing animal suffering.

Examples of our efforts include:

- Genetic improvement using genomic science and breeding enables us to produce more protein more efficiently than ever before. For example, in pigs, the feed conversion ratio—the amount of food needed to build bodyweight (lbs of feed/lbs of edible protein at slaughter)—has fallen 58% since 1970, resulting in over 1.5 times a pig's body weight in feed being saved.
- In the dairy industry, over a 40 year period, 13% fewer cows are producing 76% more milk—another massive improvement in the sustainability of protein production. While improved genetics is not responsible for all of this staggering improvement, genetics has been the major driver. Based on industry studies and our own analysis, we estimate 50–60% of the improvement has been driven by better genetics.
- Developing pigs through gene editing which are fully resistant to PRRS (Porcine Reproductive and Respiratory Syndrome) virus, a global, endemic disease impacting the pig industry, that causes animal death and suffering as well as the loss of billions of dollars in farm production worldwide. Addressing this disease not only protects the livelihood of farmers small and large, it offers an opportunity for a reduction in the use of veterinary drugs to alleviate the symptoms of the disease. This product is currently going through regulatory approval process led by the FDA.
- Over the last 7 years Genus has invested in our proprietary beef genetic program, NuEra Genetics, that allows us the flexibility to create the genetic improvement needed for a more sustainable beef animal, which is increasingly demanded by the beef supply chain. The NuEra genetics program is making faster genetic improvement than competing programs and has demonstrated a reduction in carbon footprint per animal by selecting for a balanced portfolio of traits related to production efficiencies and outcomes.
- Another approach we are developing is utilization of NuEra terminal line for Beef on Dairy progeny production which substitutes higher efficiency beef genetics for unwanted dairy genetics and provides increased production of beef while maintaining lactation in dairy cows.
- We use genotyping to understand the links between DNA and animal characteristics and how to positively influence them. This enables us to make the right breeding decisions much earlier and much more precisely thus enabling faster genetic i[mpr]ovement.
- We have created a semen sorting technology platform, IntelliGen Technologies, which helps with screening and processing to select semen that carries only female or male gender. The female gender is essential for dairy farmers in replacing their heifers and eliminating production of not needed male animals. The male gender is desirable by beef farmers as it allows to reduce amount of feed needed to reach required [carcass] weight.
- Creating embryos using *in vitro* fertilization, which allows us to combine the best male and female genetics and rapidly accelerate genetic improvement of the farmer's heard.

And finally, as important to our innovation, are our Ethical Commitments[3] to the use of innovative research. Both in today's research and tomorrow's potential commercialization, Genus R&D prides itself on an extensive testing system to make

[3] *https://www.genusplc.com/rd/innovation-technologies/gene-editing-ethical-commitments/*.

sure all animals resulting from Genus' genetics are safe and healthy and produce safe and nutritious meat and dairy products.

USA Regulatory Framework

We know it is important to U.S. consumers that new technologies comply with all government regulations related to testing and safety. We also know it is important to provide information to our customers, partners and consumers about our use of innovative breeding technologies, such as gene-editing, and to collaborate with food system partners to create a process that makes information transparent to the public.

Further, in our work with key export markets, the USA stamp-of-approval sends a very strong signal to the safety of U.S. food and animal-products, critical for expanding global exports of U.S. products, and the livelihood of U.S. farmers, ranchers and the food industry.

Yet, we also believe the current U.S. regulatory approach for animals is not fit for purpose. We believe the U.S.'s oversight of animal biotechnology needs to be consistent with efforts to streamline biotechnology regulations, and empower American research, job growth and innovation.

We are encouraged by recent comments from USDA Secretary Tom Vilsack these new technologies should be used to address critical issues, such as climate and animal health issues, saying "it won't happen" if we don't take advantage of science, and about the importance of speeding up the FDA process for animals, which should look forward and not backwards.

Broadly, in order to foster innovation, we believe the U.S. safety assessment of animal biotechnology needs to be grounded in the spirit of the Coordinated Framework for Regulation of Biotechnology by focusing on the characteristics of the product and not the process, and be done as part of an open, transparent and integrated effort across U.S. agencies.

Ultimately, a fit-for-purpose regulatory framework for animals should consider what is most practical for the advancement of animal technologies, allowing the benefits of the technology to be realized to ensure animal health, safety, and welfare. This includes:

- Product-based, with risk and science-based criteria, and clarity and predictability is necessary to drive innovation and have access to these solutions. Specifically, Genus believes product specific safety reviews should be performed on a case by case basis considering the principles of the complexity and familiarity of the intended change, and whether the change made is replicating what could have occurred naturally or could possibly be created using the conventional breeding and mutagenesis approaches. These principles were highlighted as part of the 2017 U.S. Government report *Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology;*
- Familiarity and degree of complexity of the edit should inform the regulatory pathway, so that when an animal with a precise change has been shown to be safe, further regulatory oversight is not necessary and it should not be treated any differently in the food value-chain. Today, irrespective of the nature of the genome edit, it is being treated as drugs in the U.S. This may result in unnecessary complexity of production and prevent it from entering the market. At a minimum, FDA should conduct a thorough review of its premarket review process and post-market-oversight system and implement specific changes to improve its decision-making, transparency, and timelines to ensure that its oversight does not unintentionally disincentivize innovation and market adoption;
- Providing clarity to developers and producers on regulatory pathways, data requirements and timelines for approval is critical for informing key business and development decisions, such as [financial] investments, approval timing, product commercializations and pathways towards global regulatory adoption, and finally;
- A simpler, transparent regulatory approach, which assures safety and efficacy of edits and the safety of food, allows entrepreneurs and technology developers—academic institutions, small companies, and large corporations—to continue to bring innovation to U.S. agriculture.

Global Regulatory Frameworks

Given the importance of global trade to U.S. producers, farmers and ranchers, we also work closely with key customers and livestock organizations to monitor and engage in the development of global regulatory frameworks in critical export markets.

For key global export markets, the regulations and agencies generally cover both plants and animals, and in some countries, such as Japan, Brazil and Argentina, and draft legislation in South Korea, the produ[c]ts are first asses[s]ed whether they fall outside of scope of standards for traditional GMO products. In China, existing GMO frameworks are being used for product safety assessments.

In Japan, both the Ministry of Health Labor and Welfare (MHLW) and the Ministry of Agriculture, Forestry and Fisheries (MAFF) request product developers consult with them to determine if the product needs a safety review as a genetically engineered (GE) product. If MHLW or MAFF determine the product does not need to undergo the GE safety review, then developers need to complete a notification process defined by each agency and when completed, MHLW and MAFF publishes information provided by the developer about the product.[4]

Canada defines and regulates the commercial use, registration and licensing of any biotechnology derived animal products as novel foods, which is viewed as an alteration to the food that would result in food having characteristics outside of the accepted limits of natural variation in regard to its composition, structure, and nutritional quality.[5]

One critical export market of concern, however, is Mexico, where they have yet to develop a regulatory approach to gene edited agricultural products and so consequently, we are moving forward without the benefit of regulatory clarity in this critical market.

We are encouraged by the commitments made by the USDA Secretary Vilsack and U.S. Trade Representative Katherine Tai to use bilateral and multilateral efforts to work with Mexico, though time is increasingly of the essence and the need for regulatory clarity is absolutely critical.

And, finally, thank you for your efforts so far in supporting U.S. Government engageme[n]t with Mexico Government officials, as well as encouraging the Administration to consider the use of enforcement tools available within the USMCA if necessary to ensure fair trade of biotechnology products for U.S. farmers and ranchers.

Consumer Acceptance and Use

After decades of providing superior bovine and porcine breeding genetics to livestock producers, we find ourselves in a place where the opportunities of the rapid advances in science and technology are inte[r]secting with the consumer desire to know how their food is produced.

We know we need to tell our story about the how genetic improvement of animal protein contributes to a more sustainable food system, and with BIO we are working with and engaging a wide variety of food value-chain stakeholders and key opinion leaders about the use of new breeding innovation technology in food and agriculture, and building trust and acceptance of genetic technologies.

As noted earlier, we have committed to be transparent and clearly show the rigorous safety testing and commitments we live by when using technology, and our Ethical Commitments guide our use of new breeding approaches, such as gene editing, in today's research and tomorrow's potential innovations and products. These commitments range from transparency, regulatory compliance, focus on disease, environmental stewardship, and monitoring for unintended consequences.

Conclusion

As we continue to look to the future, new innovations in animal breeding, particularly harnessing our growing knowledge of genetics and data, can lead to things like:

- Eradication of animal diseases and suffering;
- Less use of antibiotics;
- Less production of methane;
- More protein from fewer animals resulting in less environmental impact (less food, water, waste);
- Ensuring our animals are resilient to climate change while meeting the needs of local geographical needs like climates and cultures.

However this will require an efficient, risk and science-based regulatory system that can create a safe, predictable path to market. It will also require working with

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[4] USDA, Foreign Ag Service, Report Number: JA2021–0106, "MHLW and MAFF Update Policies and Procedures for Genome Edited Food and Agricultural Products", July 09, 2021.

[5] USDA, Foreign Ag Service, Report Number: CA2020–009, "Agricultural Biotechnology Annual", January 5, 2021.

all the stakeholders we discussed earlier, from producers to investors, employees to consumers, and legislators to regulators.

Sustainability is the heart of what Genus is all about. There is an opportunity to drive a more sustainable food system with better breeding and if these technologies are dismissed, they remove huge solutions for improving the sustainability of our food system and meeting broader food industry sustainability goals.

The act of genetic improvement fundamentally enables more animal protein to be produced with fewer resources, and technology and innovations can be part of the solution if we will allow it.

Mr. COSTA. I want to thank you, Dr. Rice, for your concise testimony, informative testimony, and both witnesses for staying within the timeline. That is always appreciated. I now defer to our Subcommittee Chair, Chair Plaskett, to introduce our third panel member. Subcommittee Chair Plaskett, the floor is yours.

Ms. PLASKETT. Thank you very much, Mr. Chairman. Our third witness today is Mr. Jack Bobo, who is the Chief Executive Officer of Futurity. Thank you so much, Mr. Bobo, for being a part of the hearing today, and for sharing your expertise and knowledge, and supporting the work of our Subcommittees. Thank you, and you have 5 minutes now.

STATEMENT OF JACK A. BOBO, CHIEF EXECUTIVE OFFICER, FUTURITY, POTOMAC, MD

Mr. BOBO. Good morning. Thank you, Chair Plaskett, Chairman Costa, Ranking Member Baird, Ranking Member Johnson, and Members of the Subcommittee for having me here today. As was mentioned, I am Jack Bobo, the CEO of Futurity, a food foresight company, however, I previously served for 4 years as the Chief Communications Officer for Intrexon Corporation, a synthetic biology company. While you may not be familiar with the Intrexon name, you are likely familiar with some of the company's products, which included the non-browning Arctic apple, genetically engineered mosquitoes, animal clones. I also served on the Board of AquaBounty Technologies. Before that, I served for 12 years with the U.S. Department of State as the Senior Advisor for Global Biotechnology under four Secretaries, and during two Administrations.

I am pleased to be here today to talk about agricultural biotechnology, 21st century advancements and applications. There can be no more important topic than the future of agriculture, because the future of the planet depends on the food we eat, and the choices we make about that food over the next 3 decades. The impact of agriculture on the planet is enormous in terms of land, water, and climate change, and, unfortunately, as was already mentioned, things are going to get worse before they get better because we need to produce 50 to 60 percent more food by the year 2050. Transforming the food system to be more sustainable and resilient provides one of the best opportunities to make change for the better. My remarks here today focus on agricultural biotechnology in contributing to a more sustainable, just, and nutritious future not because it is a silver bullet, but because it is an important tool.

Let me share a couple of examples. The most popular fruit in the world today is the banana, however, the most common variety, the cavendish, is at risk of extinction from plant disease. Biotech research currently underway in the United States and overseas, has the potential to save this variety, and it is critical that these prod-

ucts be able to make it to market. They also have impacts on small holder farmers around the world. Similar benefits will accrue from the deployment of animal biotech products such as the AquAdvantage salmon, which would add jobs domestically, and reduce U.S. dependence on $3 billion of salmon imports.

Globally, the picture is quite diverse. We see some countries forging ahead with deployment of genetically engineered and gene edited products, while others continue to put in place regulatory barriers to adoption. In Asia, Japan has traditionally taken a cautious approach to ag biotech, however, the country took a great leap forward this year with the placing on the market of the first plant and animal gene edited product, a tomato with a healthier nutrient profile, and a meatier fish. Japanese regulations allow such products to be marketed without the regulatory hoops required of a genetically engineered food product, though they must be registered with the Ministry of Health. Unfortunately, consumer acceptance of ag biotech continues to lag behind the global consensus among regulators in the safety of products currently on the market, as well as confidence in the technology from the scientific community.

The United States has long held a comfortable lead in the development and application of new biotech products, but that leadership is now in doubt. This can be seen in the recent advances in Japan, in the case of gene editing. It is also on display in other areas of food technology, such as cell culture and cell cultivated meat, with governments in Singapore and Israel giving the green light to products ahead of U.S. regulatory agencies, despite the long history and the long lead time in terms of technology development here in the United States.

In conclusion, innovation is the only way to produce 50 percent more food using less land and water, and while dramatically reducing emissions. Agriculture has a long history of reducing impact while increasing output. In order to see even greater gains over the next 30 years, we must prioritize investments in agriculture and development of policies that promote more sustainable outcomes. This will ensure that the United States remains the global leader in technology development, and, most importantly, provides leadership to the rest of the world to follow suit. Thank you for providing me the opportunity to discuss this critical topic. I look forward to the questions.

[The prepared statement of Mr. Bobo follows:]

PREPARED STATEMENT OF JACK A. BOBO, CHIEF EXECUTIVE OFFICER, FUTURITY, POTOMAC, MD

Good morning, Chair Plaskett, Chairman Costa, Ranking Member Baird, Ranking Member Johnson, and Members of the Subcommittees. I am Jack Bobo, CEO of Futurity, a food foresight company. Prior to joining Futurity, I served for 4 years as the Chief Communications Officer and Senior Vice President for Global Policy for Intrexon Corporation, a synthetic biology company, which has since rebranded as Precigen. While you may not be familiar with the Intrexon name, you are likely familiar with some of the company's subsidiaries which included Okanagan Specialty Fruits, developer of the non-browning Arctic Apple, Oxitec developer of the genetically engineered mosquitoes that targeted the vector for zika and yellow fever, Viagen, the market leader in animal cloning, and Trans Ova Genetics, a market leader in animal genetics. I also previously served on the board of AquaBounty Technologies, which developed the AquAdvantage salmon.

Prior to joining Intrexon I served for 12 years as the senior advisor for global biotechnology at the U.S. Department of State under four Secretaries and during two

Administrations. I also ran the Department's Biotechnology Division in the Economic Bureau. During that time, I traveled to approximately 50 countries meeting with ministers, parliaments, executives, scientists and students to discuss biotechnology policy and regulations. I also participated in and/or led numerous biotech trade negotiations. In 2015 I was recognized by Scientific American as one of the one hundred most influential people in biotechnology.

In my current role as CEO of Futurity I work with food technology startups and big food brands to help them understand what the future of food looks like and where consumer attitudes are going so they can navigate an ever more complex world. Earlier this year I published the report: 'The role of innovation in transforming the global food system.'[1] Most recently I published the book, 'Why smart people make bad food choices.'

I am pleased to be here today to discuss *Agricultural Biotechnology: 21st Century Advancements and Applications.*

There can be no more important topic than the future of agriculture because the future of the planet depends on the actions we take about the food we eat over the next 3 decades. Agriculture will either save the planet or destroy it.

Despite producing more food than ever, there are still nearly 800 million people undernourished and over two billion people facing moderate to severe food insecurity. The situation has grown more severe as COVID–19 has led to increasing unemployment, which disproportionately impacts lower income communities. Meanwhile, about two billion people are overweight or obese, contributing to a growing incidence of food related diseases. At the same time, an estimated ⅓ of all food produced globally is lost or goes to waste.

Climate change is creating more challenges to food production due extreme weather conditions, such as droughts, floods, and fires around the world. However, our global food system is also a part of the problem. The footprint of agriculture is enormous in terms of land, water, and climate change.

In fact, [f]orty percent of all the land on earth that could be used for agriculture is being used for agriculture today. The amount of cropland is the size of South America and the amount of pasture land is the size of Africa. In terms of water, there is nothing more important than agriculture as well. Seventy percent of all freshwater is used for agriculture. The Colorado River, the fifth largest river in America no longer flows to the sea, largely because of agricultural withdrawals. Ten to fifteen percent of greenhouse gas emissions come from agriculture and another ten to fifteen percent from deforestation, eighty percent of which is caused by agriculture. As if that weren't bad enough, eighty percent of biodiversity loss is also caused by agriculture.

Unfortunately, the situation is likely to get worse before it gets better. The global population is expected to increase by an additional two billion people by 2050. Demand for food is expected to rise even faster as a result of increasing incomes. As a result, we will need fifty to sixty percent more food by 2050.

Despite this incredible challenge, there is also reason for hope. Over the last 50 years the global food system has managed to increase production faster than the growth in global population, leading to significant reductions in hunger as a percent of population. If we were farming today using 1960s technology, we would need an additional 1 billion hectares of land to produce the food we do today, which is more than a quarter of the 3.6 billion hectares of forest remaining on the planet.

Transforming the food system to be more sustainable and resilient provides one of the best opportunities to make change for the better. Counterintuitively, agriculture is both the biggest driver of deforestation and the biggest protector of forests through productivity gains. An improved food system will not only promote rich biodiversity and ecosystems, but people who are resilient and empowered as well.

Many organizations are waking to these challenges and calling for changes to how food is produced, processed, and consumed, from the United Nations to the World Economic Forum. By considering the food system as a whole, we are better positioned to understand problems and to address them, in a more connected and integrated way.

Decisions about how and what to grow inevitably result in tradeoffs. Over the last fifty years, advances in farming practices and technologies, such as the Green Revolution, dramatically reduced global hunger as well as deforestation, but they also had negative consequences, including eutrophication of waterways, reduced soil fertility, soil erosion and toxicity, diminishing water resources, and pollution of ground water. The alternative, of course, was greater hunger and starvation, which would have also had negative impacts on the environment.

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[1] *https://www.agshowcase.com/the-role-of-innovation-in-transforming-the-global-food-system*.

To address the very real challenges faced by people and the planet we need all tools at our disposal. Initiatives aimed at transforming the food system cannot succeed in delivering the benefits desired without acknowledging the role innovation played in the past and ensuring that it plays an equally robust role in the future. This includes advances in food production that regenerate soil and sequester carbon, but also innovations that allow more food to be produced on the same land using fewer inputs.

My remarks today focus on the role of agricultural biotechnology in contributing to a more sustainable, just, and nutritious future, not because it is a silver bullet, but because it is an important tool. We could as easily spend our time discussing the critical importance of cover crops, field margins and intercropping, but those are topics for another day and other subcommittees.

My fellow panelists will provide more detailed examples of the contributions of plant and animal biotechnology to sustainability and health, but I would like to illustrate the importance with a few examples.

Thirty to forty percent of all food produced in America is wasted. Food waste exacts a terrible toll in terms of the environment. Potatoes and apples are the second and third most wasted food items (bread is number one). Non-browning versions of these products are already available. Wider adoption of these varieties would benefit the environment and consumers, as well as the bottom line of producers. Similar benefits will accrue from the deployment of animal biotech products such as the AquAdvantage salmon, which could add jobs domestically and reduce U.S. dependence on $3 billion in Atlantic salmon imports.

Globally, the picture is quite diverse. We see some countries forging ahead with deployment of genetically engineered and gene-edited products, while others continue to put in place regulatory barriers to adoption.

In Asia, Japan has traditionally taken a cautious approach agricultural biotechnology. However, the country has taken a great leap forward this year with the placing on the market of the first plant and animal gene-edited products—a tomato with a healthier nutrient profile and a meatier fish. Japanese regulations allow such products to be marketed without the regulatory hoops required of a genetically engineered food product, though they must be registered with the Ministry of Health.

On the other hand, the European Union took a step in the other direction last week with the Parliament's adoption of the Commission's Farm to Fork Strategy (FtF), which would move gene editing regulations in the direction of genetically engineered food products rather than regulating them like their conventional counterparts. This outcome occurred despite a concerted effort on the part of academic and research communities in Europe to limit the regulatory hurdles for these products to promote innovation and accelerate adoption.

Studies conducted on the impact of the FtF Strategy by the USDA,[2] HFFA Research,[3] the Joint Research Centre of the EU (JRC),[4] Kiel University as well as Wageningen University and Research (WUR)[5] all conclude that this strategy would have several significant negative impacts in terms of emissions, imports and hunger.

For example, the JRC study anticipates that the decrease of between 40 and 60 percent of GHG emissions from European agriculture from the implementation of Farm to Fork targets will lead to outsourcing European agricultural production, including its agricultural footprint (and emissions) to third countries. The Kiel University study projects that Europe could become a net food importer, in direct contradiction to the European Commission's expressed strategic goals. Finally, the USDA study concludes that the targets set out in the Farm to Fork strategy could lead to food insecurity for 22 million people.

Consumer acceptance of agricultural biotechnology continues to lag behind the global consensus among regulators in the safety of products currently on the market as well as confidence in the technology from the scientific community. Over the last decade public discourse about the technology has become muted as consumer groups have focused on other issues such as highly processed foods.

Despite the lack of understanding among the general population about the science behind agriculture biotechnology, vague concerns about the technology remain and are reflected in consumer purchases of products labeled non-GMO. This is similar to consumer behavior around many other food ingredients, nutrients and chemicals

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[2] *https://www.fas.usda.gov/newsroom/economic-and-food-security-impacts-eu-farm-fork-strategy.*

[3] *https://hffa-research.com/wp-content/uploads/2021/05/HFFA-Research-The-socio-economic-and-environmental-values-of-plant-breeding-in-the-EU.pdf.*

[4] *https://publications.jrc.ec.europa.eu/repository/handle/JRC121368.*

[5] *https://grain-club.de/fileadmin/user_upload/Dokumente/Farm_to_fork_Studie_Executive_Summary_EN.pdf.*

found in food, from the stigma of gluten to synthetic pesticides, which are based in fear rather than an assessment or understanding of actual risk.

What will it take for the U.S. to remain a leader in the field?

The United States has long held a comfortable lead in the development and application of new agricultural biotechnologies, but that leadership is now in doubt. This can be seen in the recent advances in product development and regulatory approval of products in Japan in the case of gene editing. It is also on display in other areas of food technology such as cell-cultured or cell-cultivated meat with governments in Singapore and Israel giving the greenlight to products ahead of U.S. regulatory agencies despite the long head start by U.S. technology developers.

Agricultural biotechnology, including genetic engineering and gene-editing tools, offers tremendous opportunities to develop new products from a wide range of public- and private-sector actors around the world to address some of the global challenges mentioned previously. The policies adopted and implemented in the United States will set an example for the rest of the world, which will ultimately determine the extent to which these technologies contribute meaningfully to a more sustainable food system.

Appropriate policies can incentivize investments from public- and private-sector stakeholders as well as promote consumer trust in the food system. It is critical both that the U.S. pursues a transparent, predictable and science-based regulatory approach that is risk-based and that the Federal Government works closely with the global scientific community and other nations to promote harmonized policies around the world. The United States must also invest heavily in agricultural research, which currently lags far behind investments in medical research despite the fact that food-related illnesses are one of the major drivers of healthcare costs.

In conclusion, innovation is the only way to produce fifty percent more food using less land and water and while dramatically reducing emissions. Agriculture has a long history of reducing emissions while increasing output. For example. a bushel of corn today results in 35 percent fewer greenhouse gas emissions and requires 40 percent less land, 50 percent less water, and results in 60 percent less erosion than a bushel produced in 1980.

In order to see even greater gains over the next 30 years we must prioritize investments in agriculture and development of policies that promote more sustainable outcomes. This will ensure that the United States remains the global leader in technology development and, more importantly, provides leadership to the rest of the world to follow suit. If we are successful then agriculture will indeed save the planet.

Thank you for providing me this opportunity to discuss this critical topic. I'll be happy to take your questions.

Mr. COSTA. Thank you very much, Mr. Bobo. Our fourth witness, that will complete our panel, and we will begin the 5 minutes for each Member for questions and comments, is Dr. Jon Oatley, who is the Associate Dean of Research, and the Professor of the School of Molecular Biosciences, and Director of Functional Genomics Initiative, College of Veterinary Medicine, at Washington State University. Dr. Oatley, that is a mouthful, but clearly Washington State is one of our premiere universities in the country, and your leadership as the Associate Dean is well respected, and we look forward to hearing your comments.

STATEMENT OF JON M. OATLEY, PH.D., ASSOCIATE DEAN OF RESEARCH, PROFESSOR, DIRECTOR, FUNCTIONAL GENOMICS INITIATIVE, SCHOOL OF MOLECULAR BIOSCIENCES, COLLEGE OF VETERINARY MEDICINE, WASHINGTON STATE UNIVERSITY, PULLMAN, WA

Dr. OATLEY. Good morning, Chairman Costa, Chair Plaskett, Ranking Members Johnson, Baird, and Thompson, Congresswoman Schrier from Washington State, and other Members of the Subcommittees. My name is Jon Oatley. I am the Associate Dean of Research, and a Professor in the College of Veterinary Medicine at Washington State University. My testimony will reflect how I see the current state of biotechnology in animal agriculture, in par-

ticular the potential for gene editing technologies to improve how the human population is fed now, and in the coming decades.

The lens I see this area through has been shaped by an array of experiences. Beyond serving as a research administrator for a Tier I land-grant university, I am also a scientist working at the ground level to develop gene editing applications in farm animals. I have also gained an academician's perspective on early stage navigation of the current regulatory approval process for biotechnology in animals, and I served as a member of the recent task force on gene editing and livestock that was established by the American Association of Veterinary Medical Colleges and Association of Public and Land-grant Universities.

As has been mentioned several times already, food security is a global issue. At present, nearly one billion people are malnourished and in starvation conditions, and, based on historic trend, the human population is estimated to reach ten billion by the year 2050. That is a 28 percent increase from where we are today. Although opinions vary, most scientists agree that a significant increase, somewhere in the neighborhood of 60 percent, will be needed in agricultural production, both plant and animal, and that is just to maintain today's nutritional standards for feeding the future in 2050.

The farm animal of the future will need to be more efficient in converting inputs, such as feed and water, into outputs for human consumption, and it will need to do this in increasingly harsher environments, while having less impact on the climate. We will need to tailor food animals for feeding more with less, and now is the time to start the process, not years from now. Humans have been engineering the genome of domesticated animals for thousands of years by way of selective breeding, but it is really the last 10 years of scientific discovery where they have been a game changer, through advent of gene editing as a molecular tool for precision genome engineering in creating dramatic positive impact on production traits.

We are already starting to see applications be advanced from the research lab into commercial channels, including strategies to make PRRS-resistant pigs that were developed by scientists at the University of Missouri and the Roslin Institute, and surrogate sires breeding technology that was developed at Washington State University that is designed to amplify the impact of desirable or elite genetics across the spectrum of livestock production. Global adoption of innovation for producing agricultural animals can significantly strengthen the food supply and positively impact economic prosperity. Applications of gene editing to enhance traits is the present and the future of innovation in livestock production.

For the promises to be realized in feeding the future, processes for Federal regulatory approval and monitoring must be rooted in science, and aligned to the pace of development. The current U.S. Federal regulatory framework that governs processing of intentional genetic alteration of animals was designed for molecular technologies of more than 3 decades ago, and is not well-aligned with state of the art gene editing. A modernization is needed that likely includes re-envisioning of agencies that approve and monitor applications in food animals. To this end, I believe the advance no-

tice of proposed rulemaking on the regulation of animals developed by genetic engineering that was released by the USDA in 2020, and the MOU created in 2021 by officials of the USDA and HHS that calls for collaboration between the FDA and USDA in establishing a coordinated framework to assess genetic alteration of food animals, and streamline the approval and monitoring processes, are both steps in the right direction.

I urge Congress to consider modernizing the Federal regulatory framework of gene editing in food animals, and to be judicious with enacting it. We have the tools at our disposal for designing the farm animal of the future that will feed more with less. We now need a Federal regulatory landscape that is conducive for making material gains in advancing discoveries from laboratory to the public domain.

I would like to close by paraphrasing a quote from George Washington that was written in a letter in 1794: I know of no pursuit in which more real and important services can be rendered to any country than by improving its agriculture and its breeding of useful animals. That statement was relevant 227 years ago, and I believe it still rings true today in guiding the next frontier of animal agriculture, and that will undoubtedly involve applications of gene editing. Thank you for the opportunity to testify before this panel, and I would be glad to try to address any questions.

[The prepared statement of Dr. Oatley follows:]

PREPARED STATEMENT OF JON M. OATLEY, PH.D., ASSOCIATE DEAN OF RESEARCH, PROFESSOR, DIRECTOR, FUNCTIONAL GENOMICS INITIATIVE, SCHOOL OF MOLECULAR BIOSCIENCES, COLLEGE OF VETERINARY MEDICINE, WASHINGTON STATE UNIVERSITY, PULLMAN, WA

Introduction

Good morning, Chair Plaskett, Chairman Costa, Ranking Member Baird, Ranking Member Johnson, Congresswoman Kim Schrier from Washington State and Members of the Subcommittees. My name is Jon Oatley and I am the Associate Dean of Research and a Professor in the College of Veterinary Medicine at Washington State University.

WSU is Washington State's land-grant university and a public research university committed to its mission and tradition of service to society. With six campuses across the State of Washington and a presence in every county through its Extension system, WSU has an enrollment of 31,159 students statewide. In FY 2020, WSU's total research and development expenditures exceeded $350 million. The College of Veterinary Medicine at WSU is a flagship program for the university that houses five departments with a cadre of stellar faculty and staff studying an array basic and applied life and health sciences topics.

My testimony today will reflect how I see the current state of biotechnology applications in animal agriculture, in particular the potential impact of gene editing technologies for improving how the human population is fed now and in the coming decades. The lens I see the animal biotechnology arena through has been shaped by an array of experiences. Beyond serving as a research administrator for a tier 1 land-grant university, I am a scientist and developer of gene editing applications in farm animals. In addition, I have gained an academician's perspective on early-stage navigation of the Federal regulatory approval process for biotechnology in animal agriculture through interaction with the Food and Drug Administration (FDA). I also worked with the American Association of Veterinary Medical Colleges (AAVMC) and Association of Public and Land-grant Universities (APLU) to establish the recent task force on gene editing in livestock and subsequently served as a core member.

A genome is the complete set of genetic information contained within DNA that is present in a cell or organism. Genetic engineering can be defined simply as the manipulation of an organism's genome by way of human intervention. With food animals (*e.g.,* livestock such as cattle, pigs, chickens, sheep, *etc.*), humans have been

engineering the genome for thousands of years via selective breeding as an effort to improve how protein products are generated. This ancient practice is still used today and impacts, both positive and negative, can be observed in all livestock sectors. While opportunity still exists for making gains in traits of livestock to feed the growing global human population that is projected to reach nearly ten billion by the year 2050, the pace and precision needed to ensure the future of food security is not achievable with this strategy alone. Application of cutting-edge technologies such as CRISPR gene editing offers a new frontier for tailoring the traits of livestock for optimized growth, resiliency, and climate smart performance in a variety of environments and within a timeframe of months to years rather than decades and generations that selective breeding requires.

Global adoption of innovation in production of agricultural animals can significantly strengthen the food supply and positively impact economic prosperity of the U.S. Applications of gene editing to enhance the traits of animals is the present and future of innovation in livestock production. For the promises of this groundbreaking technology to be realized in feeding the future, processes for Federal regulatory approval and monitoring must be rooted in science and aligned to the pace of development. A modernization of the U.S. Federal regulatory framework governing applications of genetic modification in animals, including gene editing, is needed for streamlined and cost-effective approval and monitoring. In doing so, the science of gene editing can be advanced from research laboratory to the public domain in a safe and effective manner never before seen in the U.S., thereby addressing the real-world challenges with food security now and over the next 100 years.

Background on Feeding the Human Population through Animal Products

The origins of animal genome engineering by humans are ancient, being traced to over 10,000 years ago following domestication of various species which led to the practice of selective breeding that is still in use today. The central purpose of this intervention has been to shape the traits of animals that generate products (*e.g.,* meat, milk, and fiber) for human consumption. The demand for animal sourced protein in the human diet has always existed and continues to rise as more people are added to the planet every day. According to statistics from the United Nations Food and Agricultural Organization (FAO), the global demand for animal protein increased by ~80% between the years of 1970 and 2000; this trend is expected continue in lockstep with human population growth.[1]

Food security is a critical global issue. The United Nations Population Division projects that there will be 9.8 billion people on [E]arth by the year 2050. Providing food at sufficient quantity and nutritional quality for this number of people will require major improvements in production efficiency for both plant and animal agriculture so that outputs for human consumption are generated from minimal inputs and accomplished in a climate smart way.

The intrinsic element of both plants and food animals that significantly influences traits for resiliency and production of products for human consumption is the genetic makeup or genome. Although the conventional practice of selective breeding has had major impact on physical traits of food animals since the dawn of domestication, advances are often incremental and take decades to manifest. In addition, the lack of precision and need for multiple generations to achieve material gains through use of selective breeding carries an inherent risk of creating unintended negative genetic combinations that reduce the welfare, resilience, and production efficiency of a food animal. For these reasons, the common livestock production practice of selective breeding is not sufficient to meet the demands of food security that arise from an exponentially expanding human population.

The future of food animal production must align to a goal of feeding more with less. As arable land and water resources continue to decline globally, production of animal sourced protein through livestock production will need to increase with use of fewer inputs. In addition, although agriculture accounts for only 10% of greenhouse gas emissions in the U.S.,[2] livestock production is still considered a major contributor to global warming and climate change. The farm animal of the future will need to be resilient in ever changing and often harsher climates while contributing a reduced carbon footprint; farming practices and livestock will need to evolve to be climate-smart.

The science of gene editing holds major potential to address global food security now and for the future. As a biotechnology, gene editing applications in animals are subject to approval and monitoring at the Federal level. As gene editing strategies

[1] *https://www.fao.org/documents/card/en/c/cb4474en.*
[2] *https://www.epa.gov/ghgemissions/sources-greenhouse-gas-emissions.*

such as CRISPR technology are evolving to dramatically expand the toolbox for precision agriculture, so must the Federal regulatory framework.

Overview of Biotechnology Approaches to Shape the Genome of Animals

The science of animal biotechnology has held great promise for decades as a modern-day complement to selective breeding for the shaping production traits of livestock. Indeed, the diverse field of biotechnology is regarded as a major component of the ongoing fourth industrial revolution. Although much of the animal side of the biotechnology sector is still in a research and development phase, the advent of gene editing technologies and their rapid deployment as tools in the animal research arena has led to several applications in livestock that are poised for entry into the marketplace.

A first generation of approach for genetic engineering of livestock is the science of transgenesis. This conventional biotechnology involves the use of recombinant DNA for integration of genetic information found in other organisms into a target animal's genome. As such, genetic changes made by way of transgenic technologies could not arise in nature and have resulted in livestock possessing them being labeled "genetically modified organisms" or GMOs.

Unlike conventional approaches to genetic engineering of animals such as transgenesis, gene editing technologies can precisely target specific sites in the genome to bring about favorable changes using natural processes within a cell or organism. Importantly, many gene editing applications do not involve integration of recombinant or foreign DNA into the genome of an animal. Rather, the gene edit is simply created by breaking DNA at a precise spot in the genome and relying on the repair of that break to bring about a change. This process of DNA breaking and being repaired in a different way is inherent to mammalian cells and occurs constantly in animals. Gene editing simply directs where a DNA break and natural repair change will happen.

Public attitudes to genetically modified organisms have tended to be negative. In the U.S., the 2019–2020 Pew Research Center's International Science survey reported that 27% of Americans thought GMOs were generally safe to eat, 38% responded they were unsafe to eat, and 33% said they did not know enough about the topic to say.[3] This negative perception of food derived from GMOs has presented a major impediment for advancing biotechnology applications to improve livestock production in the public domain.

Currently, the leading edge of biotechnology application for genetic engineering of livestock has moved from the conventional and often time imprecise nature of transgenesis to precision approaches of gene editing. Importantly, the technical science and intended outcomes of gene editing in livestock are substantially different compared to transgenesis. Thus, a "one box fits all" model for regulatory statutes in the U.S. should not be applied to genetic engineering of livestock. A model that allows for fluidity to adapt with contextual categorizing of the genetically altered animals and applying logic-based decision making, while still ensuring safety, is needed.

In contrast to inherent randomness and dependence on the possibility of admixture of favorable versions of genes that conventional breeding is based on, gene editing offers a precise and efficient means for introducing favorable genetic elements into the genome of animals that will drive beneficial traits for improving the production of meat, milk, or fiber for human consumption. Applying gene editing to create lines of livestock with unique and enhanced genotypes is an efficient way to help ensure food security. To realize this potential, global regulations and policies must be framed to allow for facilitated deployment of the technology into production systems and the widespread dissemination of gene edited animals into the food chain, while still ensuring the safety of the food from these animals, as well as the welfare of the animals and the environment.

Leading Edge Applications of Gene Editing in Farm Animals

With the advent of gene editing technologies for mammalian cells nearly a decade ago, a new frontier was opened for the application of biotechnology to improve food animal production. Over the last 5 years, several applications of gene editing in livestock have been devised and advanced to the brink of being useful for U.S. farmers and ranchers. The leading edge of gene editing applications in production animal agriculture can be defined as improving growth efficiency, disease resistance, welfare, and reproductive capacity. Recent reports of gene edits in pigs that confer re-

[3] *https://www.pewresearch.org/science/2020/12/10/biotechnology-research-viewed-with-caution-globally-but-most-support-gene-editing-for-babies-to-treat-disease/*.

sistance to Porcine Reproduction and Respiratory Syndrome Virus,[4–5] and produce surrogate breeding strategies for a range of livestock[6] and poultry[7] to advance genetic gain are poised to make significant impacts on food animal production in the U.S. and globally. At present, none of these gene editing applications have fully navigated the U.S. Federal regulatory approval process and are therefore unable to be capitalized on by America's farmers and ranchers to enhance the food supply and economic prosperity of the agriculture sector.

Reproductive capacity is a staple of livestock production. The flow of genetic information between generations occurs through sperm and eggs. Thus, the basis of selective breeding that has been used for thousands of years to shape the traits of animals is directing the combination of sperm from choice males and eggs from choice females. Most genetic change in livestock production is made through selective use of males because millions of sperm are made every day for directed breeding purposes. This principle of selected use of breeding males has had enormous impacts on shaping what the world's livestock populations look like today, but the impact was kept primarily on a regional scale until the 1950s when artificial insemination technology was developed. This breeding strategy allows for collecting of sperm from what are deemed elite or genetically desirable males and shipping around the world for artificial introduction into females that would result in pregnancies. Effective application of artificial insemination in livestock production requires freezing of sperm and then artificially introducing it into the reproductive tract of a female during a specific window of time in her reproductive cycle. Therefore, sperm freezing and accurate detection of the window of female receptivity are crucial. These nuances are conducive for intensive livestock production systems such as the dairy industry in which >80% of dairy cattle are bred by artificial insemination. Indeed, the impact of this breeding approach on genetic makeup of dairy cattle in the U.S. has been a major contributor to the quadrupling of milk production per cow between 1950 and today.

In beef cattle production, use of artificial insemination has been limited, with only ~7% of animals being bred with the technology because of logistical disconnects. Most beef cattle are managed in range or pasture-based systems which do not allow for tracking the window of receptivity in females nor are they conducive with workforce needed to artificially inseminate large numbers of females. Natural breeding is the primary approach of most beef cattle production.

In swine production, although ~70% of pigs are bred using artificial insemination to influence genetic gain, survival of pig sperm during freezing is poor, thus the influence of elite genetics is regionally limited to regions and global dissemination is a challenge.

For all other livestock populations, such as goats and sheep, artificial insemination is not utilized widely due to need of specialized techniques; thus, introducing new genetics to improve production traits of populations worldwide has been marginal.

There has been lost opportunity to improve production traits for many livestock production sectors due to limited innovation in breeding technologies over the past several decades. Surrogate Sires technology was developed at Washington State University to address the unmet need of a novel tool that can be effectively applied in a natural breeding context to disseminate elite genetics in all livestock populations on a worldwide scale. The premise of the technology is transfer of stem cells that are responsible for continual sperm production from an elite male into the testicles of a battery of recipient males that lack their own sperm producing cells. The recipient males are then able to produce sperm containing the donor male's genetics and are used throughout the world in natural breeding schemes. This capability would provide the benefits of selective utilization of elite genetics without the need for intensive management practices or sperm cryopreservation. Moreover, the tool would be conducive with modern beef cattle, swine, and sheep/goat production practices.

Surrogate Sires technology relies on creating male livestock that lack their own sperm producing cells is to use CRISPR based gene editing to knockout a gene called NANOS2. The only known function of NANOS2 in all mammals that have been studied to date is for production of sperm producing cells. Therefore, gene edited NANOS2 knockout males are ideal Surrogate Sires. Importantly, recent peer-reviewed science has shown that following transplantation of donor sperm stem cells into testicles of a NANOS2 knockout male, sperm production commences, and all

[4] *https://pubmed.ncbi.nlm.nih.gov/29925651/*.
[5] *https://pubmed.ncbi.nlm.nih.gov/26641533/*.
[6] *https://pubmed.ncbi.nlm.nih.gov/32929012/*.
[7] *https://pubmed.ncbi.nlm.nih.gov/31575742/*.

possess the non-edited genome of the donor. Thus, the offspring produced via natural breeding of the Surrogate Sire would not possess the gene edits created by CRISPRs. Moreover, the edits in the NANOS2 gene of the Surrogate Sire are mutations that could arise in nature.

Washington State University has established Investigational New Animal Drug (INAD) files with the Food and Drug Administration (FDA) for NANOS2 gene editing in multiple farm animal species to begin navigating the current U.S. Federal regulatory approval process.

History of Regulatory Framework on Genetic Engineering of Food Animals in the U.S.

Established by the White House Office of Science and Technology Policy (OSTP) in 1986, the Coordinated Framework for Biotechnology lays out the U.S. Federal regulatory policy for how products derived from biotechnology are developed and introduced into the public domain. Composition and intended use are the basis of the Framework and a 1992 update reaffirmed that regulation should be based on the product and not the process by which the product was derived. The Framework does not assign biotechnology products to individual regulatory agencies or a single governing statute and as such, has evolved over time to assign primary jurisdiction of biotechnology oversight to the Food and Drug Administration (FDA), United States Department of Agriculture (USDA), or Environmental Protection Agency (EPA). Acts governing how agricultural biotechnology products are assigned to these Federal agencies were established well before the advent of gene editing technologies. Thus, there is need to modernize the Coordinated Framework for Biotechnology in a manner that aligns with the state-of-the-art for how this area of science is being applied to livestock production today and into the future.

Within the U.S., multiple Federal agencies have directives for regulatory jurisdiction over different aspects of livestock and the products they produce that could be impacted by the application of gene editing. As a means to mitigate the spread of diseases that affect livestock, the Animal Health Protection Act (AHPA) of 2002 established regulatory authority with the USDA Animal and Plant Health Inspection Service (APHIS) to oversee the importation and interstate movement of live animals in the U.S. Likewise, authority for monitoring safety of livestock products that are intended for human consumption has rested with the USDA Food Safety and Inspection Service (FSIS). Additionally, under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA), the FDA has authority for the safety of non-meat food and feed products derived from animals.

At present, as assigned by the FFDCA, regulatory oversight of genetically modified animals in the U.S. rests with the FDA. Through interpretation of this authority, substances other than food that affect the structure/function of an animal are considered to be a drug. As such, the molecular elements such as DNA that alter the genome of an animal are considered a drug. In this manner, gene editing approaches are channeled into a regulatory approval process that is not well matched for how the technology alters the genome, is transmitted to subsequent generations, or the intended purposes. At present, developers of a gene editing application in livestock must undergo an Investigation New Animal Drug (INAD) process during early-stage proof-of-concept and the full New Animal Drug Application (NADA) process in order to achieve commercialization and use in the public domain. Both these processes were designed for development of actual drugs and not for hereditary changes in the genome.

A Need for Modernization of Regulatory Framework

In 2017, draft Guidance for Industry (GFI) #187: Regulation of Intentionally Altered Genomic DNA in Animals was issued by the FDA for framework that regulates approval and oversight function of genetically altered livestock.[8] GFI #187 considers gene editing technologies as animal drugs and does not discriminate from genomic changes that could arise in nature (*e.g.,* insertions, deletions, rearrangements, and single nucleotide polymorphisms) *versus* those that are novel and generated only through a genetic engineering process (*e.g.,* use recombinant DNA and transgenesis). Of note, the long-standing practice of selective breeding results in the creation of genomes by way of human intervention and therefore can be considered as intentional genomic alterations in animals. Yet, this common practice in animal breeding is not regulated by the FDA or any other Federal agency.

In 2021, the USDA and officials of the Department of Health and Human Services (HHS) signed a Memorandum of Understanding (MOU) for the FDA and USDA to

[8] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-187-regulation-intentionally-altered-genomic-dna-animals.*

collaborate on shaping a modernized Federal regulatory framework that would streamline a cost-effective approach to approving and monitoring gene editing in domestic animals.[9] Under authority of the AHPA and Federal Meat Inspection Act, the MOU proposes that the USDA would establish a rulemaking process for premarket evaluation and post-market monitoring of safety concerns related to both human and animal health for genetic engineering applications, including gene editing, in agricultural species. The MOU also lays out how the FDA would retain jurisdiction of intentional genomic alterations in animals intended for purposes other than agricultural use. Moreover, the MOU calls for collaboration between the USDA and FDA in fully vetting safety and health concerns that are not clearly addressable by the streamlined USDA evaluation process. I fully support this MOU and the accompanied Advanced Notice of Proposed Rulemaking (ANPR) on regulating the movement of animals modified or developed by genetic engineering posted by the USDA in 2020.

Because the science and technology of genetic engineering and potential applications in domestic animals is complex, ranging from generation of novel biomedical models to gene therapy to enhancing traits for the improvement of animal agriculture, assigning Federal regulatory jurisdiction to a single agency is challenging and could [stymie] innovation. The current state for Federal evaluation, approval, and monitoring of intentionally genetically altered animals in the U.S. are based on processes established for transgenic technologies which do not align well with the state-of-the-art gene editing technologies. In addition, these processes are viewed by many developers of genetic engineering applications in livestock as ambiguous, glacial in pace, and cost prohibitive.

The House Committee on Agriculture has recognized the importance of navigating this regulatory process with the recent letter signed by many Members of the Subcommittees asking Secretary Vilsack and Commissioner Woodcock to address this issue with a timely improved regulatory process. Thank you for your leadership.

A Call to Action by the AAVMC/APLU Task Force on Gene Editing of Livestock

In 2020, a task force on gene editing of livestock was assembled by joint efforts of the AAVMC and APLU as an effort to generate a blended, yet cohesive, perspective on how applications of gene editing in livestock could be regulated within the U.S. WSU leadership worked with colleagues in the AAVMC and APLU to establish the task force and charge it with addressing mutual interests of the developer, Federal regulatory entities, animal, and consumer. To this end, a group of academicians with international reputation as experts in the science of animal genetic engineering, commercial sector representatives, engagement specialists, and animal bioethicists were assembled as a thinktank. The task force was effective in melding of perspectives voiced by these groups into a series of recommendations that were provided to Federal regulators for consideration when envisioning what a modernized and progressive framework for the regulation of gene edited livestock in the U.S. should be.[10]

Conclusion

George Washington once wrote that, "I know of no pursuit in which more real and important services can be rendered to any country than by improving its agriculture, its breed of useful animals, and other branches of a husbandman's cares". This statement was relevant 200 years ago and still rings true today. The U.S. has been providing leading edge innovation in animal agriculture for nearly 100 years and the next frontier in devising strategies to effectively feed a growing global human population will be defined by gene editing technologies. Harmonization of the regulatory processes beyond the U.S. is key and the regulatory community across the globe look towards the U.S. for stewardship and leadership. For the U.S. to remain as a world-wide leader in shaping how livestock products are produced in sufficient quantity to be cost-effective sources of high-quality protein in the human diet, the Federal regulatory landscape for approving and monitoring of genetic engineering applications must evolve and align with the interests of the developer and consumer. To this end, a coordinated assessment and approval process between the USDA and FDA will be essential in establishing a framework that is streamlined, cost-effective, and ensures safe food, with the decision-making process anchored on logic and science-based fact. Humans have been consuming animal products with mutations in DNA that arose naturally and were propagated by way of selective breeding for thousands of years. Thus, developing a regulatory channel

[9] *https://www.aphis.usda.gov/biotechnology/downloads/mou-usda-fda.pdf.*
[10] *https://www.aavmc.org/wp-content/uploads/2021/07/AAVMC-Gene-Editing-Report-12.pdf.*

for approval of animals possessing gene edits that could have arisen in nature as safe for human consumption should be considered.

Thank you for the opportunity to testify before this panel today and I would be glad to address your questions.

Mr. COSTA. Thank you, Dr. Oatley, for that informative testimony, and I think President George Washington was correct in his observation then, and I think that is instructive for us today. Now we are at that opportunity, having completed the testimony, where Members will be recognized for any questions or comments they wish to make in order of seniority, alternating between the Majority and Minority Members, both between the Subcommittee on Livestock and Foreign Agriculture and the Subcommittee on Biotechnology, Horticulture, and Research. And I want to once again thank our Subcommittee Chair Stacey Plaskett for her graciousness, and her efforts with her staff, to, in a very challenging sort of way, pull together these two Subcommittees for this joint hearing in a completely Zoom environment. This is not a hybrid. It is all, obviously, virtual.

But, realizing that, I will, as best as I know—and please, for all the Members that are participating, please let your staff know, to the—our Subcommittee staff, I will recognize you in the order that the staff passes me the cards, in terms of the times that you have been there, trying to recognize Majority and Minority Members on an alternating basis. And, again, the suggestion that we be careful about having our microphones muted when we are not having our 5 minutes to ask our questions. With that said, I will recognize myself for 5 minutes, and let me begin.

Mr. Bobo, you talked about how biotechnology can help solve environmental problems. In my home State of California, with a strong environmental ethic, we have seen the challenges both in droughts and fires. As a matter of fact, we say we no longer have a fire season, we have a fire year. What can be done to help improve crops, given the extreme drought conditions we are facing in the West, and other parts of the world? Would you please comment?

Mr. BOBO. Yes, I will, and I am sure that Dr. Fan-Li Chou has a lot to say on this as well. But I think, certainly, drought tolerance is something that we need to begin breeding, well, we have been breeding in, but needs to be more of a focus. We need to not—ensure that it doesn't have any kind of a yield drag, because it is not enough that we are able to create crops that are good when years are bad, but they also have to——

Mr. COSTA. We are trying to produce more with less, right?

Mr. BOBO. Yes, and they have to be able to perform when conditions are good, as well under the drought conditions. And so I think that there needs to be an effort on that, but also, in terms of—it is not just the biotechnology, but it is also in the agricultural practices, to ensure low, minimal drip, and irrigation, and other things. So it is going to be a combination.

Mr. COSTA. Well, we have done a lot of that in many parts of American agriculture. Dr. Fan-Li Chou, do you have anything to add to that?

Dr. CHOU. Sure. I was just in California a few weeks ago, and just talked to some of the farmers on the ground. I think, from our

perspective at ASTA, seed is one thing you cannot replace, right? No matter whether you are going to have better fertilizers or better water use, you have to start with the seed. So for the genetics—the best seed to be able to germinate under drought conditions, or under less water conditions, is super important. And once that seed germinates a plant, how it uses water efficiently is very, very important.

There is lots of research that is happening at UC Davis on lettuce, which is grown very widely in California, and which I think every single one of us probably eats every day, or if we don't, we should. So I think there is a lot of research been working, and rice. So there is lots of excitement around this, because water is one of the most—both limited and expensive inputs, if we are talking about California, into agriculture, and how we can limit that, if this would be useful not just for agriculture, but across the board.

And I think too, as you are thinking about increased precision of water usage, increased precision of herbicide or fertilizer, plant breeding and plant genetics can help with that, right?

Mr. COSTA. And on that point, the partnership—you talked about UC Davis, which is one of the premiere land-grant universities in the country on ag science, how do we best utilize the public-private partnerships today, from a standpoint of innovation?

Dr. CHOU. So for public and private, it is the foundation of U.S. agriculture. It is been around for a long time. The public universities take on fundamental research. It trains our scientists, it trains the next generation workforce. The private-sector takes on the burden of the long regulatory process, the long process of investment, of financial burden, to take a very promising product to the commercial space, and they have the resources, both financial and long-term horizon, to do that. Universities do not have the time to do that, or money.

Mr. COSTA. Correct, and I would like talk to you more about that, in terms of the time. My time is expiring, so I want to make sure I get my questions in here. Mr. Bobo, we talked about phytosanitary standards, and both Mr. Johnson and I commented upon a level playing field. The farm to fork strategy that we see in Europe, which has important goals, but is it well thought out, and its application around the world, and possibly here in the United States? I would like to get your thoughts.

Mr. BOBO. So the farm to fork strategy is focused on reducing the impacts of agriculture, which means that they are going to be producing less food in Europe. As a result, they are going to be exporting their agricultural footprint to the rest of the world. The country that sends the most food to Europe right now is Brazil, the largest deforester on the planet, so that is going to create challenges for the rest of the world. In some respects it is an opportunity for the United States, because if they can't produce the food themselves, somebody else has to produce it, but it is actually challenging for the rest of the world if Europe, one of the largest producers, chooses low productivity in a world in which we actually need to be producing more food.

Mr. COSTA. Well, thank you. And I would like to—Dr. Oatley, you talked about gene editing, and provide more food with less inputs. You want to be—tell us where the—I mean, we have same-

sex semen, we have genetics in dairy that are allowing us to produce more lactates and nutrition portions of milk products that we have never seen before. My time has expired, but I would like you to comment on that at a later date, if you could think about that, and I want to defer now to my Ranking Member, Representative Johnson from South Dakota.

Mr. JOHNSON. Thank you, Mr. Chairman. I suspect all of our panelists know that Mexico recently published a decree announcing their intention to phase out a number of different important agricultural technologies, and included in that announcement was that they wanted imports of biotech corn for human consumption to be eliminated in Mexico by 2024. This is in contravention of the bulk of scientific evidence, and it is in violation of USMCA, and we are seeing more and more of this kind of maybe protectionist, or maybe overly cautious approach toward innovation and technology, so we have a mixed panel here.

So for folks who know a lot about crops, I want specifically for them to share with us what Congress should do, given this threat from Mexico, and then for the folks who know more about livestock, tell us to what extent we are seeing similar behavior in the international marketplace on the livestock and animal side, and what Congress should do about that. Let us go in the order of the presenters who spoke, so, Dr. Fan-Li Chou, you are first.

Dr. CHOU. Thank you, Congressman Johnson. I think the USMCA actually has a chapter on agricultural biotechnology, and it is not just plant-focused, even though most of our trade right now is in plants, but it is—it can be used across the board, so I think it is really important for us to enforce that chapter. It creates a mechanism to settle trade disruption, it creates a mechanism to minimize trade disruption, and it also creates a mechanism for us to talk about the future technologies that we are going to use in agriculture, so it is full of current-looking and forward-looking. So I think it is important for this Administration to really use that biotechnology text, because it is actually the first time that we had a biotech text in a trade agreement, and I think that is great precedent for us to use that in other forums as well.

I think it is very short-sighted of Mexico. We are all not—it—global climate change—it is a global climate change, not a U.S. climate change. They need to produce food, we need to produce food, and you don't want to cut off your arm just to do things with one hand tied behind your back. But I think, as we look forward to gene editing, there is an opportunity that we are all, across the world, looking at. Many governments are taking their GMO position, and rethinking it in light of gene editing, because it is working within the plant's own genetic resources and own genetic gene pool. So I am hopeful that Mexico will take a look at that, and really rethink how they look at the future of the 21st century, and not look backwards.

Thank you.

Mr. JOHNSON. Thank you very much. Dr. Rice?

Dr. RICE. Thank you. Mexico is a key market for our pork producers, and as we invest a lot into PRRS-resistant pigs today, we are facing a very uncertain future for this very important product to come to the market, because if our producers cannot export pork

to Mexico, that will close door for this important product. And, saying that, we also know, because we had a lot of conversations with pork producers in Mexico, that they are very interested in this very critical trade for them. They are facing a lot of diseases, just like every producer everywhere else, and this inability for us, or uncertainty with Mexico, really creates a significant barrier for all trades that we can bring to our producers. So having our government to work on the trade agreements with Mexico is absolutely critical. Thank you.

Mr. JOHNSON. Mr. Bobo, about 45 seconds, and then Dr. Oatley after that.

Mr. BOBO. Sure. Dr. Chou already spoke to the regulatory aspects. I think I would just add that there is also the human impact in terms of food security. This is going to dramatically increase the cost of food in Mexico, but there aren't a lot of other markets for that corn that are not biotech, and so, if they are going to produce dramatically more corn in Mexico, it is going to be with more modern varieties, which is going to eliminate a lot of the land races that are in Mexico which are traditional, and so it is actually going to have an impact on sort of the global center of biodiversity for maize to move in this direction, so there is both an environmental impact, a long-term consequence of food security, and current hunger that I think we will see rise out of this decision.

Mr. JOHNSON. Thank you. Dr. Oatley?

Dr. OATLEY. I agree with everything that has been said so far. I just want to reiterate one point, and that is, on the animal side at least, a lot of the gene editing changes that are being made to the genome of animals can, and likely do, arise in nature at some level, and I think that needs to be taken into account when we are talking about regulation of trade of animal biotechnology products amongst countries.

Mr. JOHNSON. Yes. I think that is all very well said. Thank you to the panelists, and this is a serious threat, and we want to work with the global community to make sure we get this right. Too much is at stake environmentally, too much is at stake from a hunger perspective. We need American leadership now more than ever. Thank you, Mr. Chairman, and I yield back.

Mr. COSTA. I thank the gentleman from South Dakota. Now it is the Chair's pleasure to recognize the Subcommittee Chair from the U.S. Virgins, Chair Stacey Plaskett.

Ms. PLASKETT. Thank you very much, Mr. Chairman, and thank you again to the witnesses who are here with us. This is a question that is directed to Mr. Bobo. I just want to know, are there reasons to be cautious, or to be optimistic, in using agricultural biotechnology as a tool to advance climate change adaption and mitigation in plant and animal agriculture? I just want to know your thoughts on this topic.

Mr. BOBO. Well, in terms of the science, I am actually dramatically hopeful. If we were farming today with 1960s technology, we would need one billion additional hectares of land in order to produce the food we do, which is more than ¼ of all the forests on the planet. So innovation has saved more forest than agriculture has led to the destruction of. I think that it is not a question of can we do it, it is a question of will we choose to do it. Science tells

us what we can do, but the public tells us what we should do, and therefore it is critical that there is transparency and engagement with the public so that they have trust in the companies that are developing these technologies so they will allow us to bring them to market.

Ms. PLASKETT. Thank you. You talk about what science is doing, and the research and the work that is really advancing at a rapid rate. Does the U.S. regulatory system guide or inhibit innovation in agricultural biotechnology, and what improvements, if any, should there be made to support innovation, while at the same time reacting positively and responsibly to the concerns of people as well? And that is for any of the witnesses.

Mr. BOBO. Yes, I can begin. Certainly I think the U.S. regulatory system is recognized around the world as being a leader, however, I do think that we need to ensure that the level of regulation is consistent with the threat that is actually there, or the risk that is there. And with many of these technologies, the risk is not actually much higher than with traditional breeding, and in many cases it is exactly the same, or even less, and so we need to ensure that there is that balance between actual risk, and then there are tradeoffs between the choices that we make. If we choose not to apply these technologies, then we will be living with the consequences of increased climate change, increased hunger, and other things. And so we really need to keep those in check.

And, finally, the United States could be doing a lot more. Much of this has come down to political will, that the regulations, if there is political will, you can move more quickly. Europe's regulations are not all that different than the United States. There is just a lack of political will that allows products to come out the other end of the regulatory system.

Ms. PLASKETT. Thank you. Is there anything, Dr. Oatley, Dr. Chou, that you would like to add?

Dr. OATLEY. Yes, I would like to add that the Federal regulatory framework that exists now is not necessarily a hindrance, it is just it was created for technologies that were developed several decades ago, and gene editing is quite different than conventional transgenesis that uses recombinant DNA. And so I think modernization is needed in order to speed up the process for assessment, as well as monitoring. I think many in the academic world view it as glacial and somewhat ambiguous at the moment, and I think that needs to be improved on as we are developing some of these gene editing applications that, again, can and do arise in nature, and are somewhat more precise than kind of a messy system that is selective breeding. And so I think those things need to be taken into account as we are looking to modernize what the Federal regulatory landscape looks like.

Ms. PLASKETT. Thank you. You talked about gene editing. Dr. Chou, can you talk—at the University of the Virgin Islands, we are doing research in biotechnology application and traditional Caribbean crops. Dr. Oatley just talked about gene editing solutions. Are any emerging technology or gene editing solutions related to staple or specialty crops like these? Is any of that work being done that you are aware of?

Dr. CHOU. Yes. So this is the exciting thing about gene editing in plants, is that it is applicable across all crop varieties. So we are doing—there is lots of work being—happening in fruits in vegetables, in casaba, in African countries that it is a subsistence—sorry, can't say that word—crop, and I think that is the excitement. I was a research scientist, and the seed science seems really fast, but it is quite slow. I am sure Dr. Oatley has been working on his project for years and years, and gene editing and plant breeding has been occurring for years and years. So the speed of regulation seems to be even slower, and we need to kind of speed that up a little bit so that, as the science advancements are getting ready to commercialization, that the regulatory processes are there to meet it.

Ms. PLASKETT. Thank you. Thank you so much. My time has expired. I want to thank you, my fellow Chair, for this opportunity. And, as I am hearing these questions and these answers, yes, there is regulatory work that we need to do on our end, but we really do rely on all of you, as witnesses, and the industry to make the information that you are doing with gene editing palatable, and such that the layman can understand so that our constituency and others are not afraid of what is happening, that they have comfort in the work that you are doing that will then give us some leeway to be able to support your work as well. Thank you.

Mr. COSTA. Well, I thank the Chair, and I think your point is well taken, and, in my own conversations with our counterparts within the European Union, and Members of the European Parliament, I think creating the trust factor, as we try to meet the demands of a growing world population, and understanding that—about biotechnology, and food, and plant science—animal science that we are not going to be able to do this. And we already know that we have almost a billion people that are malnutritioned, and in need of good food, so it is a challenge, and you are correct to point this out. It is more work that we need to do with both Subcommittees, I believe.

Our next witness—excuse me, our next Committee Member to be recognized is the Ranking Member, Mr. Baird, from Indiana, and you will be recognized for 5 minutes.

Mr. BAIRD. Thank you, Mr. Chairman. I really appreciate you having such knowledgeable witnesses testifying today, and I really enjoy these kinds of committee hearings. But I am going to start with Dr. Rice, because I am excited about the work you are doing with PRRS-resistant pigs through gene editing, and I am going to select this question because I think it has an impact not only on producers, but it has an impact on consumers, so it is just one example of what we can do to help promote disease resistance.

PRRS is a threat to hog farmers of all sizes. The disease attacks the pig's reproductive and respiratory systems, and it makes it difficult for them to breathe, as well as to give birth. And it can devastate an entire herd of 1,000 pigs in just 2 short months. I think African Swine Fever may be even faster than that. But, unfortunately, it cannot be effectively prevented or treated by traditional veterinary medicines or vaccines. So could you talk about Genus's technology on developing disease resistant pigs using gene editing?

Dr. RICE. Yes. Thank you for this question. The research on PRRS resistance was done originally by Missouri State and Roslin

University of Edinburgh. So, as a company, we took that challenge to bring this very important product to the market. So it took us quite a few years to develop the right technological approach to make resistance in the pigs, and what—I think most importantly, we started our interaction with the FDA, and entered the regulatory process with the FDA, last year. The gene editing is really—it gives us a really simple tool. We are deleting one very small portion of the gene, and, as a result of that, the virus cannot enter the body of the pigs. So basically pigs become—they don't see the virus anymore. There is no foreign material being inserted in the genome of the pigs. It is really just one small deletion. So pigs continue to grow the same way, they develop the same way. There is absolutely no other differences, except that those pigs cannot get sick from PRRS virus.

So as we entered into the regulatory process last year, we have very good relationship with FDA. We have a lot of discussions. At the same time, the process is very long. Why? Because we need to show and demonstrate different trait—well, confirm our testing across multiple generations of pigs. Because of the life cycle of the animals, it takes quite a few years, so we assume it would be at least 5 years before we can bring this to the market.

Mr. BAIRD. So has this been in the process for 5 years? Is that what I am understanding?

Dr. RICE. Well, we will be finishing all required—by the end of 2023, and we hope that we will get approvals in 2024.

Mr. BAIRD. Okay. Super. Dr. Oatley, given your veterinary medicine background and so on, do you have any thoughts to add to this on disease resistance, and how we might use gene editing and so on?

Dr. OATLEY. Thank you for the question. I think gene editing strategies provide an opportunity to create pigs that are resistant to pathogens like PRRS, even addressing African Swine Fever. One of the interesting things about African Swine Fever is that both domestic pigs as well as wild warthogs are hosts for the virus. However, only domestic pigs are susceptible to the disease, and warthogs are asymptomatic. And so there is potential to identify what is unique about the warthog genome that allows them to be resistant to the virus, and then use gene editing to engineer that into a domestic pig. So I think those are some of the concepts that can come out for getting disease resistance across the spectrum of pathogens that infect and harm our livestock.

Mr. BAIRD. Thank you. And I see I have 12 seconds left, so, Dr. Fan-Li Chou, I appreciate you being here, but I can't ask a question, and same for you, Mr. Bobo, but I appreciate all of your answers. All right, I yield back.

Mr. COSTA. I thank the gentleman from Indiana for his questions, and our next Member to be recognized is Representative Jahana Hayes from Connecticut. You are recognized for 5 minutes.

Mrs. HAYES. Well, thank you, Mr. Chairman, for having this very important hearing today. Genetic engineering is woven throughout Connecticut agriculture and agricultural research. UConn Extension, which is in my district, was among the first in the world to clone animals and have an active hemp and cannabis genetic pro-

gram. Connecticut dairy farmers use genetically modified corn, beet pulp, and soybeans for livestock feed and feed rations.

Another area of genetic engineering research happens in my district as well, and it relates to environmental protection. UConn Extension is researching how they can breed plants to be responsive to climate change. So, Dr. Chou, can you give me a few examples of how gene editing can lead to climate change mitigation, and what applications of biotechnology have proven most effective for addressing climate change in agriculture?

Dr. CHOU. Thank you for the question. Let me just say that climate change is the most pressing issue facing our farmers right now, and it is because of the unpredictability of the climate they have. In California they have been historically dealing with a drought, but then just recently they had a huge bunch of rain, and it is difficult for farmers to adjust to that. I think plant breeding has a lot to contribute to climate change, both from an adaptive perspective, and also from a mitigation perspective.

On the adaptive perspective, we can breed plants that can adapt to drought conditions or to high water conditions, right? From the mitigation perspective, there are scientists that are working on making plants with stronger roots that can sequester carbon for longer. They are creating plants—new cover crops that farmers can plant when the fields are fallow to keep the soil healthy, but instead of just having a non-economic crop, these oil seeds are now gene edited so it can be fed to animals, and that creates a cash crop for the farmers.

So we, as the plant research community, are really excited about these kind of things that could occur, but I think for us it is not just about climate adaptation and climate mitigation, it is all about creating food, and making food, and making that food nutritious and tasty for consumers across the board, right? So we are also looking on nutrition security. So berries is something that everybody likes—I have two small children—but they don't last very long in my fridge. So just thinking about making berries more available, and more shelf friendly, shelf—stay fresh longer for consumers, that will have tremendous benefit, from a nutritional perspective, for us, and for the value chain, so you can stay on market shelves longer.

So these are the things that are really important. And I think the last thing I want to mention is food waste, right? So I have little kids. Every time I cut an apple, if it is brown, they won't eat it. There is nothing wrong with that apple, right? It tastes fine. So there is lots of work working on non-browning apples, non-browning potatoes, non-browning lettuce. So it is not about just producing enough food, but also, like, using the food that we are not producing and not wasting it. Because every time we waste food, we are wasting resources. We are wasting water, we are wasting labor, we are wasting gas. So I think those, across the board, are all the things that we need to do from a climate-friendly perspective in agriculture.

Mr. COSTA. Would the gentlewoman yield?

Mrs. HAYES. Yes. Yes, Mr. Chairman.

Mr. COSTA. Just a quick question, how much food is estimated that we waste in the United States each year?

Dr. CHOU. I don't have that figure off the top of my head, but I would think it is—so for potatoes, it was the—there is a study that demonstrate—if we can just have non-browning potatoes, we will save 1.5 billion pounds of potatoes a year. That is a lot of French fries. So I think if you take that across apples and lettuce—like, just think about all the lettuce we throw away when it gets brown, and we don't finish it by the end of the week. It is a lot. And that is just in our kitchen.

Mrs. HAYES. Thank you, Dr. Chou. I can tell you that you have made my colleague, Representative Schrier—Ms. Schrier very happy, because this is something that she talks about often. I just have one follow-up question. Even with these exciting developments, I have also heard concerns that gene editing may drive reliance on environmentally detrimental herbicides. How do you believe we should balance our efforts with climate change mitigation with those concerns?

Dr. CHOU. I think if you look at the research that is happening right now on how gene editing is used in crop species, and even in animals, it is broader than just herbicide use. We are talking about nutrition, we are talking about water usage, we are talking about things that would allow us to use less inputs. So I think we have to think broadly, and not think about how we use agricultural biotechnology, the 20th century agricultural biotechnology, but thinking more ahead in the 21st century. As we are learning more about plants, we are getting more precise about how we are doing things, and I think that creates a lot of opportunities.

So at ASTA we actually have a website called Innovature that talks about food. It doesn't talk about agriculture, it talks about food, and how plant breeding impacts our lives both from an environmental perspective, but a health perspective. So I really encourage you all to take a look at that, because it is very appealing for foods. I did not start in ag, so I think it is targeted at folks that are not in ag, which really need to understand and appreciate all the efforts we all put into agriculture.

Mrs. HAYES. Thank you so much for being here today, and for working with us on sustainable agriculture. As we look for ways to address food insecurity, that is something that is big for me, so thank you very much for your work in this area. Mr. Chairman, with that, I yield back.

Mr. COSTA. Well, thank you very much, Representative Hayes, for your good questions, and for yielding. I appreciate that. I had Committee staff just send me some numbers that—the amount of food that is wasted in the United States is in excess of—depending upon the different products we are talking about, in excess of 30 percent. It is a very significant number, and we have to figure out a better way to deal with that waste issue.

The next representative that staff has put before me, and that is the order I am going on, is Representative Crawford from Arkansas. Representative Crawford, you are recognized for 5 minutes.

Mr. CRAWFORD. Thank you, Mr. Chairman, I appreciate it, appreciate the hearing and the presenters, and I will throw this out there just to anybody what might want to address this topic. Mr. Baird alluded to this earlier in his questioning, African Swine Fever is a significant threat to our food supply, our economy, our

environment, and it was recently detected in the Caribbean, and has also caused the loss of more than seven million pigs in Asia, Africa, and Europe. I am just wondering if anyone wants to comment on biotech research specific to this disease. What are the prospects of using biotech to protect the nation's swine industry as it applies to African Swine Fever?

Dr. OATLEY. As I mentioned to Mr. Baird about the warthog being a host for the virus, but resistant to the virus, whereas the domestic pig is susceptible to the virus, there has been some research in trying to understand what is unique about the warthog that allows it to be resistant, and hopefully find the genetics to drive that trait, and engineer that, using gene editing, into domestic pigs. I think it is at the very beginning stages of concept, from a research and development standpoint, but I think applications like that hold great promise for us to be able to address big problems like African Swine Fever.

Mr. CRAWFORD. What about biotech that can be developed and used to reduce the need for antibiotics? As you know, antibiotics are, and continue to be, a controversial topic as it applies to animal agriculture. Any comments on that?

Dr. OATLEY. Yes, I can comment on that as well. We heard about gene edited pigs that are resistant to Porcine Reproductive and Respiratory Syndrome virus, and I think those are likely closest to the public domain. If those were in a production setting, there would be less use of antibiotics. Another example is gene editing strategies to make cattle resistant to bovine respiratory disease, one of the major disease problems in feedlot cattle. Considering that one of the causative agents of the disease is bovine coronavirus, I think that studying a disease like bovine respiratory disease, and the viruses that cause it, and devising ways to make cattle resistant to it, we would surely learn more about coronaviruses in general, and that may be a public win for solving COVID–19, or future pandemics as well. So somewhat related to antibiotic use, but studying disease resistance in livestock I think can be a win-win for the public.

Mr. CRAWFORD. And research going on addressing BSE, and FMD, and others?

Dr. OATLEY. Yes, I am not as familiar with where the state of the art is for those diseases, but perhaps others on the panel know more.

Dr. RICE. Yes, I can add few words here. So there is research that we proactively engage on, for example, such diseases as influenza, and in cattle, BRD. And all these diseases, the biggest problem, that producers have to treat sick animals, and very often antibiotics are used as a preventative measure from secondary effects caused by the virus. So it is not directed at the virus, but more of the secondary effect. If we—and we show with research on PRRS—if we can prevent the key reason for the animal getting sick, being affected by the virus, then the use of antibiotics in general will significantly go down.

Mr. CRAWFORD. Let me switch gears a little bit. I am concerned about China and Mexico not fulfilling their biotech trade obligations under the China Phase One agreement and USMCA respectively, and, quite frankly, I have some questions on whether the

Administration is doing anything to address the problem. But I am just wondering what impacts this might have, this flagrant disregard for established trade obligations, what impacts that might have on future research and development in the biotechnology space?

Dr. CHOU. Congressman Crawford, if you will allow me?

Mr. CRAWFORD. Sure.

Dr. CHOU. I think for the research space, we are going to go on doing research. Science is going to move on in the U.S. But from a trade perspective, it had a huge chilling effect. The seed industry is global in nature. We talk about seed movement, so as seed as getting freed, and increase from foundational seed to commercial seed, it is moved across the world many times because of seasonality, and also because of the kind of labor we need for making and developing seed. And then, when our customers grow these seeds, the products that they produce moves across the world. So as other countries are taking on an anti-science approach in their regulation, it is not a good situation for U.S. seed producers or U.S. food producers everywhere.

I think from my perspective, from our perspective, the USMCA and the China Phase 1 agreement has very strong language about biotechnology and science-based, risk-based, regulation across the board that is consistent with international standards, so I think we need to enforce those. But from China's perspective, they just put out their 5 Year Strategic Plan, and in that plan they made a specific point that they are going to modernize their seed system in China. I think it would be really—they cannot achieve that goal without using technology, so my expectation is that in the future the world, regardless of where you are, cannot move forward without really taking on agricultural biotechnology like gene editing on board. And if you look at China's research strategy, they are spending a lot of money on gene editing, so we need to be prepared to be as competitive as we can from a research perspective, but also from an economic perspective.

Mr. COSTA. We thank you for your comments, time has expired, the Chair will now recognize the gentlewoman from Washington State, and she has one of her own university associate professors who is on our panel, and we are pleased to recognize Representative Kim Schrier for your 5 minutes.

Ms. SCHRIER. Thank you, Chairman Costa, thank you, Chair Plaskett, for holding this important hearing. And first I want to take a moment to acknowledge Dr. Jon Oatley from Washington State University, in my home state. Thank you for being here, and thank you so much for your invaluable work, and taking the time to appear before my colleagues and me this morning.

Speaking of Washington State University, I want to highlight a terrific example of the results of innovative agriculture research and biotech happening in my district, otherwise known as the apple capital of the world. More than 20 years ago Washington State University's apple breeding program first started developing the cosmic crisp apple to be a perfect balance of taste, texture, and usability. And in 2019, these apples first became available for purchase in grocery stores around the country. It was a much-awaited event. Today, WSU has planted 17 million cosmic crisp trees all in

modern high density trellising, with a focus on the future of possible machine harvesting.

Now, this apple was bred to have high acidity levels and sugar content that preserves the taste throughout harvest, storage, packing, shipping, and sale, and cosmic crisps can stay fresh for a whole year in storage, leading to minimal waste in packing houses. They also don't brown when cut. We have been talking about not browning. This revolutionizes school lunches, after school snacks, fruit salads, and it further reduces food waste, which we have already heard has a very detrimental effect on the environment, in terms of methane. Cosmic crisps are also relatively easy to grow, compared to other apples, because they don't have a lot of physiological vulnerabilities, and these unique characteristics minimize environmental impacts and ensure orchard sustainability, exactly what biotech innovation should seek to achieve.

Dr. Chou, in your testimony you mentioned research being done to develop heat tolerance in lettuce, and, as I am sure you know, the Pacific Northwest was hit with a record-breaking heat wave this summer that dramatically impacted agricultural yield and quality. Can you tell us a little bit more about this research, and other innovative work done to help farmers and ranchers, and maybe even whether that same type of engineering could extend to other crops, like blueberries, and even maybe touch on heat, drought, and wildfire smoke?

Dr. CHOU. Sure, thank you. And I just want to put a plug in for our conservation side of the ASTA members. So for anytime there is—after a wildfire, you need to replant that, our members provide the seedlings and the seed to do that. So every time we make a new highway, and there is this—up on the—highway you can see wildflowers or grass, that is our members, so we don't just do fruits and veg, and soy, and cotton, we do all sorts of things. So I just want to give them a shout-out on that.

Ms. SCHRIER. Thank you.

Dr. CHOU. I think the drought-resistant—it is a very interesting topic, because there are two things that need to happen. When a seed goes into the ground, the water conditions have to be right for the seed to sprout. And then, once the seed sprouted, the drought—the conditions have to be right for the plant to grow. And the plant sweats, I want to say, just like we do, so it opens its pores and closes the pores, depending on weather condition. And scientists are looking at that to see whether they can control that opening and closing of their sweat pores, if you will, to decrease water loss.

And Innovature, the website I keep talking about, actually has a really interesting story about lettuce, because a plant scientist—she was driving around, and there was an abandoned gas station, and there was a wild lettuce that was growing in the cracks, and she was like, this is not getting water. How is it growing? So she took it back to the lab, and there she discovered how it was able to germinate and produce, so now they are trying to move that gene, or that modification, into lettuce that we eat so it is nutritionally—and it tastes better. I am sure wild lettuce does not taste very good.

So this is science, right? Ninety-five percent perspiration, five percent inspiration. But science doesn't happen so quickly. Like,

these scientists have been working on drought-resistant lettuce at UC Davis for 25 years. So gene editing just allow us to make it more efficient, and more accurate, and more effective. It doesn't change the fundamentals of science. It does not change the fundamentals of plant breeding, or making sure that that variety is performing as they need it throughout the years. Before anything heads to market, there are so much quality control that goes into it before it comes—like the cosmic apple, it did not happen overnight, right? And trees take a long time, but the farmers have to make sure that everything is performing adequately before it reaches the consumer, so there are lots of layers of that. So I would really encourage you to check out the Innovature website to learn more about drought-tolerant lettuce.

Ms. SCHRIER. Thank you very much. And I just have to add, in a little joking way, inspiration, perspiration, and then transpiration. Thank you very much.

Mr. COSTA. Thank you very much, Representative Schrier, and thank you for your response to our Member's questions. The next Member that I have before me is Ranking Member Thompson from Pennsylvania, and then that is followed by Representative Rush from Illinois. So, Representative Thompson, you are recognized for 5 minutes.

Mr. THOMPSON. Thank you. Mr. Chairman, thank you so much for a great hearing. I have seen reports in recent years that FDA's cumbersome approach to regulating animal biotechnology is forcing U.S. academics and developers to consider moving research or commercialization of their product to international markets. I have a significant concern with that. Dr. Oatley, have you heard these sorts of concerns, or seen these sorts of moves, among your peers, and if so, what are the implications for domestic research, development, and ultimately access to innovation for our U.S. livestock producers?

Dr. OATLEY. Thank you for the question. To be short, yes, I have heard amongst peers, in various conferences on gene editing and food animals that I participate in, discussions with my colleagues in the space both within the U.S. and outside the U.S. There are always discussions about moving R&D, as well as commercialization efforts, to outside the borders of the U.S., where a regulatory approval and monitoring process may be more streamlined and less costly.

My opinion, this is not a good thing for access to innovation by U.S. livestock producers, nor is it a good thing for scientific discovery and innovation. And I think that scientists are going to follow paths of least resistance on developing their ideas through rigorous experimentation. And so, if they can do rigorous and trustworthy science where the Federal regulation process is more aligned with the pace of development than it is in the U.S., it is always going to be considered as a potential option.

Mr. THOMPSON. Dr. Oatley, thank you. I certainly concur with your opinion. I will say that, whether it is FDA or USDA, United States bureaucrats should be the last to deny, and to be a barrier, to the continued leadership of U.S. agriculture when it comes to science, technology, and innovation. Over the past two Administrations we have seen bipartisan recognition of the importance of mod-

ernizing the nation's biotechnology regulatory framework, however, as many of you made clear in your testimony, work remains to ensure these regulations are based in science, and are competitive globally. Now, whether USDA, FDA, or EPA, can any of the panelists given their opinion on particular areas that are in need of regulatory clarity, improvement, or modernization? And I will leave that to any of the panelists that would like to respond.

Mr. BOBO. I will——

Dr. RICE. I can start—go ahead.

Mr. BOBO. I was just going to say, absolutely there is a lot of room for improvement, in the animal biotech area, in particular, also with gene editing. There are absolutely animals that have—products that have been introduced in Argentina for approval before they were introduced in the U.S., even though the technology was developed here, because they didn't know what the regulatory path was in the United States, and that is still unclear a decade after we have been looking at it. And so we definitely need to clarify those paths to market.

And the reason we are talking about gene editing is because genetic engineering has been so slow to be able to bring more products to market. The technology is capable of doing much more than we are doing, but the regulatory burden and the cost is so high that we have moved on to new technologies.

Mr. THOMPSON. Very good.

Dr. RICE. I think I would like to add that we definitely need to simplify regulations for gene editing where there is no foreign DNA inserted into the genome, and changes can occur naturally. We also need to reconsider multiple generational testing. Considering animal life cycle, it takes many years before the studies can be completed. And, finally, I think today we still consider modified DNA in the animal as a drug, and it is continued to be regulated. I think that is—provides undue burden on producers, and can really limit our ability to bring those products to the market.

Mr. THOMPSON. All right. Very good. Well, thank you for that. And finally, as some of you may know, just last week, very appreciative, this Committee passed legislation to support research efforts on Chronic Wasting Disease, or CWD, that impacts all cervids, a highly contagious prion disease affecting cervids across North America, and in my home State of Pennsylvania in particular. I have been heartened by the development of diagnostic tools to detect increased susceptibility and transmissibility of CWD, and with these types of advancement already in the works, do any of the panelists have thoughts about potential of modern genetic tools to improve CWD resilience? And, actually, I would ask to please consider a written response, because my time has expired. Mr. Chairman, thanks so much. Great job.

Mr. COSTA. Thank you very much, Mr. Chairman—Ranking Member, excuse me, but the gentleman from Pennsylvania is always welcome. And our next Member is the gentleman with a great deal of experience and expertise from Illinois, Representative Bobby Rush.

Mr. RUSH. I want to thank you, Mr. Chairman, and I am so well pleased, Mr. Chairman, that we are having this critical hearing this morning. As a proud Member of the Agriculture Committee, as

well as the Energy and Commerce Committee, I was pleased to join my esteemed colleagues, Chair Plaskett and Ranking Member Barrett, earlier this month in sending a letter on this very issue to USDA Secretary Vilsack, and FDA Acting Commissioner Janet Woodcock.

Mr. Chairman, we must ensure that our regulatory framework is able to work seamlessly across agencies and departments to incentivize innovation through—biotechnology. This is the only way that we will be able to successfully address the challenges, like food insecurity and climate change. That leads to my question this morning.

Mr. Bobo and Dr. Chou, in your testimonies, you both discussed the problem of having limited land and resources for farming. As we increase the use of biotechnology and related innovations in our nation, can you explain what role urban farming can play, and how it can be best utilized for the good of our nation?

Dr. CHOU. Sure. I think urban farming has a huge role to play, not just in producing food, but educating our urban population about agriculture. As we have mentioned here before, we need science, we need regulation, and we need consumer acceptance, and consumer acceptance comes from understanding. So I keep mentioning I have two little kids. When they started learning, they were still reading *Old MacDonald. Old MacDonald* has not changed since I was a child, and farming has changed. They don't have a new Old MacDonald that has AI, drones, electronic tractors. They are still talking about Old MacDonald with the red tractor. So I really think we need to change the way we talk about agriculture, and talk about food, with our urban population as early as we can. So urban farming has a role to play in that, in producing food for the urban population, but also as an educational tool.

From a plant breeding perspective, urban farming, if we are talking about indoor ag, has very different criteria than if I was farming in the field in California, or in Illinois, or elsewhere. So in that perspective, the genetics of the seed that is put in there has to be specific for urban farms, for indoor ag, and that is where the plant breeding comes in, how we can provide genetics. So I can ask Dr. Rice to talk about urban farming from the animal perspective, and Dr. Oatley too.

Mr. RUSH. Mr. Bobo, can you address this also?

Mr. BOBO. Sure. So I would add, in addition to indoor ag, I think community gardens have been growing in many communities, and, as Dr. Chou said, I think this gives communities access to fresh fruits and vegetables, it gives them access to understanding how our food is produced, which gives them a better understanding of what goes into that, and the challenges that go into that. So while it may not be feeding our communities, it is feeding their minds, in many ways even more than their bodies, and I think that is critical for regaining that great relationship and connection to our food source. But it also diversifies our source of food, and I think that is critical, going forward, that we need to be thinking about new ways of producing food, not just doing it the same way we have been doing for 200 years.

Mr. RUSH. Dr. Chou, in addition to making farming more efficient, and reducing food waste, does biotechnology have the poten-

tial to lower the costs of fresh fruits and vegetables to make them more affordable, and how specifically would it impact food insecurity in lower income communities around the country?

Dr. CHOU. Thank you, Congressman Rush, for that question. I think lowering food insecurity in the low-income population of the country is really, really important, and some of that has to do with shelf life. All right, so, we have lots of—I grew up in an immigrant community, so I am aware of the lack of supermarkets in some areas, as we buy our food from the local bodega, if you will. So to stock fresh fruits and vegetables is difficult, because every couple weeks you had to restock because the food doesn't stay fresh, like berries or lettuce. So if we can use gene editing and other technology to increase how food can stay fresher for longer, that will allow some of these stores in these neighborhoods to stock shelves, right? So I think that is super important, from a food security perspective.

But also making food more nutritious, and more tastier, so that we actually eat it. I can put a vegetable in front of my child. Whether she eats it or not is a completely different story. So I think that is also important, is how we address both from the production perspective, but also from the consumption perspective. We can make strawberries all year round, but if it doesn't taste good, then we are not going to eat it. If it cannot stay fresh, we are not going to have it. So those are important things from a food security perspective as well.

Mr. RUSH. Thank you, Mr. Chairman. I yield back. I yield back, Mr. Chairman.

Mr. COSTA. Yes, I am sorry. I was trying to find my mute button. Thank you very much, Representative Rush, the next Member that I have before me to be recognized is another gentleman from Illinois, Representative Rodney Davis, for 5 minutes. Representative Davis?

Mr. DAVIS. Well thank you, Mr. Chairman. Thank you to Chair Plaskett, and also Ranking Member Baird, and even Ranking Member Johnson. I would like to throw him in there too. This has been a great opportunity to actually hear from some of the experts in the field. I do want to make sure that we talk about these biotechnology advancements and applications well into the 21st century that have been mentioned throughout this entire hearing. And as you know, and has been said, research shows that gene editing tools like CRISPR, result in outcomes that could technically be achieved through conventional breeding, which has proved to be a valuable and promising technology in agriculture to enhance the quality, and the yields, and sustainability of crops.

But my question to any of the witnesses right now is whether the Federal Government, or any government around the world, for that matter, should regulate these edited products any differently than their conventionally bred counterparts?

Dr. CHOU. Congressman Davis, I really like the way you put that, regulate them any differently, because all food is regulated, regardless of how it is produced. All different plant varieties are regulated. We have general food safety. So I think the question that everyone—all governments around the world are answering is whether these products, that could have been done through conven-

tional breeding, or occur in nature, but we used advanced technologies to do it, whether they should be differentially regulated, and that differential regulation is what commonly is termed GMO regulation. And internationally there is consensus now, growing consensus, that these products that could have been done through conventional breeding, but the method to get there was different, does not need to be differentially regulated, so it does not need to go through the GMO regulation.

So in the U.S. we don't have such a clear-cut GMO in, GMO out. We have three agencies that have their own regulatory triggers, and their own regulatory policies, and then we have all mentioned how important it is for those three agencies, USDA, EPA, and FDA, to be coordinated and consistent in their policy, both from a scoping perspective, but also from an implementation perspective, meaning they need to make timely decisions together, not separately. We cannot wait on one. It is a three-legged stool that we are sitting on here. So as we are looking into the 21st century, USDA has made some progress, EPA has made some progress, and we are waiting for FDA to join the ranks, so I think there can be better coordination and cooperation between the three agencies.

Mr. DAVIS. Well, thank you. Anybody else want to take that on?

Mr. BOBO. Yes.

Dr. RICE. Yes. I want to add here one thing, today we regulate in technology. I think the right way would be to regulate products. And if products are no different, and not outside of what occur naturally, then they should go through minimal safety testing regulatory process. So I think that small change can make a big difference, not to regulate technology, but to look at the product.

Mr. DAVIS. Okay.

Mr. BOBO. Let me just add onto that, they shouldn't be differentially regulated, however, if different countries do regulate them differently, it is important that governments are aware of the changes, and, therefore, the registry that Japan has is useful for governments because we want to ensure that trade continues to flow as well.

Mr. DAVIS. Great. Thank you all for your responses. One of the priorities of this Subcommittee is agricultural research, and how can we better utilize and leverage any existing Federal research programs under NIFA or AFRI, and hopefully AGARDA also, once funded, to actually enhance technology, and more importantly too, based on my previous question, enhance the public's understanding of it. Do you have any suggestions you want to make about how we can let the USDA and other regulating agencies, know what we expect into the future?

Dr. OATLEY. I think, as a university professor, maybe I can begin to address that. I think it probably comes as no surprise to hear me say that I think research funding in the public-sector really is the heart and soul of innovation for biotechnology within the U.S. Many of the basic and most groundbreaking discoveries happen at our land-grant universities. I think our research programs live and die based on being or not being awarded extramural funding every year. And so every year conducting research at a university becomes more expensive and competitive, and Federal funding for

biotechnology in the animal space has remained largely stagnant, or even reduced.

So being an academic researcher can be quite stressful, in not knowing whether you can keep a lab going from year to year, and it is becoming more and more of a challenge for faculty to convince the next generation of graduate students who are trying to train to follow in our footsteps and become academic researchers. So, in my opinion, I think if the U.S. is going to keep pace with other countries in science and innovation, we need to bolster Federal funding for university research through USDA, NIFA, and AFRE foundational programs. I also think land-grant universities have an aging infrastructure for livestock research, and this needs to be addressed at some point.

Mr. COSTA. Well, Dr. Oatley, thank you for your response and your answers, and I couldn't agree more with your final comments—I think it is important that we make those investments. The next gentleman is a colleague, and good friend of mine, from the Sunshine State we call California, Representative Salud Carbajal.

Mr. CARBAJAL. Thank you, Mr. Chairman, and thank you to all the witnesses joining us today. Dr. Oatley, biotechnology has great potential to help address many of the challenges facing agriculture in our society today. Academic research is essential as we advance these technologies. I have seen incredible progress made through universities in my district, such as Cal Poly San Luis Obispo. With your experience as the Associate Dean of Research at Washington State University, what recommendations would you offer Congress to help improve the ability to deploy or better utilize important innovations happening within our education system?

Dr. OATLEY. Thank you for the question. I think at land-grant universities our funding for doing research is primarily extramurally awarded by agencies, such as the USDA, NIFA, AFRI foundational programs. I think that the funding for the foundational granting mechanisms through the USDA, NIFA, and the AFRI Program, has not kept pace with the cost of doing research. It is more expensive now to do animal research than it was even 5 years ago. It is more expensive for the personnel to do the research. It is more expensive to keep animals on a university campus to do research. It is more expensive to run the research labs, and yet the funding that is available through extramarital grant awards has not kept pace.

Our infrastructure is also aging. The infrastructure that was put in place for conducting livestock research, large animal research, at our land-grant universities, and supported federally, is aging, and now we are looking to how do we improve that infrastructure? Does it come from the private-sector, or is this something that should be supported at the Federal level. I would think it should be supported at the Federal level, being a land-grant university. So I think that a bolstering of the funding available for basic and applied research in the universities, and an improvement to our aging infrastructure is desperately needed.

Mr. CARBAJAL. Thank you very much. Mr. Bobo, finding innovative ways to make our food system more sustainable and resilient is becoming increasingly important, however, global acceptance of

biotechnology products continues to be inconsistent, and I know we touched on this with several of my colleagues' questions earlier. Mr. Bobo, how have uncertainties regarding other countries' approvals of new genetically engineered products affected U.S. seed and biotechnology companies? What can be done to increase acceptance of biotechnology products abroad?

Mr. BOBO. Yes, so there have been dramatic impacts of the decisions that other countries have made. It could be China blocking imports of food, which cause disruptions around the world. It could be slow regulatory approvals in Europe, that cause delays of years in the adoption of products in the United States. So slowing down the adoption, increasing the cost, all of those things have a dramatic impact, and a chilling effect, in other parts of the world, and so there needs to be more investment in other places, not just here in the United States. But, to be clear, we invest 50 to 100 times more in medical health than we do in agriculture, and yet one of the biggest drivers of health impacts is food, and the food choices we make.

And so I think that there is a big opportunity to help other countries to develop technology so that they understand the benefits of these technologies for themselves. Dialogue with Europe, the changes that have happened in Japan, I think are very encouraging, and we need to leverage those conversations with other places like China and Europe. There have been recent developments in the UK. They are opening up to gene editing. Very critical conversations should be happening around that to leverage that movement in order to shape global opinion.

Mr. CARBAJAL. Thank you very much. Mr. Chairman, I yield back.

Mr. COSTA. I thank the gentleman from the great Central Coast for his questions and observations. The next Member that is in the order given to me is representative from Minnesota, Mr. Jim Hagedorn, and that will be followed by the next Member, Mr. Lawson, I believe. I am trying to let Members know in terms of the order, when you are up next. Mr. Hagedorn from Minnesota.

Mr. HAGEDORN. Thank you, Chairman Costa. I appreciate you, and the other Chair and Ranking Members for holding this hearing, and the witnesses for testifying. I really appreciate it. It is a very important subject, and it is one that we should keep addressing. I happen to represent southern Minnesota's 1st District, which has some of the great grain and livestock farmers in our country. We happen to rank number two for hogs, as far as the value, I think number three for the number of hogs produced, and so, pork production is really important to us.

Long before anybody had ever heard of COVID–19, I was on the House floor, and working in bipartisan fashion with many Members of this Committee to make sure that we could address something called African Swine Fever. And, African Swine Fever is one of those things that we really need to make sure we protect our producers in America against, at the ports with more folks to do inspections, the Beagle Brigade and everything else. And, Mr. Chairman, I would encourage you to—maybe we could bring the USDA and DHS people down to talk a little bit about their plan for how we would address an outbreak of African Swine Fever in

our country, particularly since USDA just found it in the Caribbean. It is getting a little close, and we need to do everything we can. So if we can move on that, that would be terrific, in the near future.

The problem with this disease is that it killed seven million or more hogs in places like China and Vietnam. It would just be devastating if it came into the United States. And it wouldn't just be pork producers. We would be talking about everybody up and down the chain. Seed corn dealers, you are looking at feed mills, implement dealers, packers, truckers, grocers, and, of course, consumers would be harmed the most in the end, probably, with much higher prices and less choice. And all that spills into our rural communities. If pork product in areas like ours is down, that means less people shopping on main street, going to our schools, and everything else.

So I say that this is an issue that we should keep investigating, and I would ask all the witnesses to please chime in. What do you think we can do? If you can, please speak about the biotechnology research for African Swine Fever. What is going on, where do you think it needs to go, how far along are we, that type of thing.

Dr. OATLEY. I can chime in on that question, again, with the need to understand why some wild populations of animals are resistant to things like African Swine Fever, like the warthog. So I think there is biotechnology applications in the form of gene editing to try to address that. But I think there is another angle to work there, and that is also targeting the vector, and that is the tick that is transmitting the virus amongst animals. And so I think there is—it is a two-pronged approach. Probably gene editing of an animal, but also targeting the vector through vaccines, or other strategies to eliminate the ticks that are carrying the virus.

Mr. HAGEDORN. Something like that would be quite a bit down the road, though, right? We are not talking about even next year, it could be a lot longer. So you would recommend that the government do everything possible in order to protect the country, not allow those hogs and hog products to come in our country and disease our population, correct?

Dr. OATLEY. In the short-term, yes.

Mr. HAGEDORN. Any of the other witnesses like to discuss this issue a little bit?

Dr. RICE. I think just recent progress that USDA demonstrated the new vaccine against the—by that vaccine. It seems to be working better than any previous vaccine we have seen, so that is really promising. In terms of biotechnology application, we are at the beginning, and it is going to be a long time before we will find solution. But I want to say that where we are, this other biotechnology trait, might have chilling effect on how much investment would be put toward this. If we cannot even bring product that already showed efficacy to the market, or it takes very long time, and a lot of very expensive process, it does have really chilling on how much investment will be in the future toward ASF and other diseases.

Mr. HAGEDORN. So you recommend common sense regulations, streamlined regulations, working internationally, and everything else, right?

Dr. RICE. Absolutely. And make it faster. That would really help.

Mr. HAGEDORN. I only have about 20 seconds left. I appreciate your answers. This is really a subject we are going to continue to press upon. It would be just devastating to our consumers, and everybody in the hog industry, if we had an outbreak in the United States, so I appreciate everybody supporting this effort. Mr. Chairman, I yield back.

Mr. COSTA. The gentleman yields back his time, and the Chair will now recognize the gentleperson from Florida, Mr. Lawson, for 5 minutes, and that will be followed by Representative Feenstra from Iowa. Representative Lawson, you are recognized.

Mr. LAWSON. Thank you, Mr. Chairman, for this meeting, and Ranking Member, and welcome to all the members of the panel. Dr. Oatley, you spoke a little about how American's negative perception of food derived from the GMOs has presented a major barrier to advancing biotechnology application to improve livestock productions. Now, the critical question is, what are some of the things that can be done, especially by Congress, if we can do anything, to increase public approval?

Dr. OATLEY. Thank you for the question. Yes, I think that the public acceptance of biotechnology applications in food is absolutely critical. We can do the most important and the coolest science in the lab, but if we can't advance it into the public because it is not accepted, then what is it for? I do believe that there is lack a of understanding about science behind biotechnology in the general public domain, and that is because it was a narrative shaped 20 years ago, and has been handed down from generation to generation. I think the science, the application, the importance of the use of biotechnologies to improve food production is very different now.

At Washington State University, we are working towards trying to develop a new public narrative on gene editing of livestock by interlacing science with bioethics. Prior to the pandemic, we were gearing up for a major public engagement campaign that would start locally, hopefully grow statewide, and hopefully find traction nationally. I do think land-grant universities have an opportunity, in serving as a think tank and opinion-makers, to play a role in changing the public narrative on biotechnology and animals. I guess I would encourage Congress to find ways to support that through Federal grants, or other ways to fund the efforts that are going on at land-grant universities to engage at the public level better, even down to having educational programs at our grade school and high school levels about what gene editing is, and how it can help feed the future.

Mr. LAWSON. Okay. Thank you very much. Within the U.S., multiple Federal agencies have regulatory jurisdiction over approval of agricultural biotechnology, as you just mentioned earlier, and traditionally the process for approval is time consuming and burdensome. And this is for the whole panel, in your opinion, what are some changes that need to be made to streamline the process for approval, and to ensure that small- and mid-sized companies can still compete in research, and innovation in agricultural biotechnology? For the whole panel.

Mr. BOBO. Well, I would just jump in and say that the lower the regulatory burden, the more companies will be in the field. It is guaranteed that if we can minimize the red tape, that more compa-

nies will be able to do it, and bring products to market. Second, I would say that we still need more investment, and that would benefit small- and medium-sized companies more than others. And, finally, to the consumer acceptance piece, we need to bring products to market that people want and love. In Japan they are bringing a tomato that lowers blood pressure, and they are selling seeds directly to consumers so you can grow these heart-healthy tomatoes right at home. And so, we need to think about products that are going to be relevant to consumers.

Dr. CHOU. Thank you, Congressman Lawson. I think that that is one of the things, is to have a product that excites the consumers' imagination, right? So we cannot ask consumers to accept technology. I think that is difficult. And we have to ask consumers to think about what is important for them, from a food perspective. So we use Impossible Burgers all the time. It has a huge consumer pull, and it does use GMO soybeans. So I think the future is here, and we have to make a distinction between gene editing, where we are modifying within the animal and the plant's genome that could occur in nature, or through conventional breeding, and I think that is changing the narrative of consumer acceptance not just in this country, but around the world. Dr. Oatley, I am sorry, I cut you off.

Dr. OATLEY. No worries. I was just going to add that I think the current regulatory framework is somewhat unnecessarily cumbersome and expensive for many gene editing applications, and I think the process is potentially too ambiguous for gene editing, and the pace of review is somewhat glacial. So I think if we are going to foster innovation to design that farm animal of the future, that gene edits that can arise in nature, and be propagated by selective breeding, should have limited regulatory oversight.

Mr. LAWSON. Okay. Thank you. Mr. Chairman, I am going to yield back, but, for the record, Mr. Chairman, I want to know what kind of tomato that is going to lower blood pressure? And so if you can get some information back, that will be interesting.

[The information referred to is located on p. 65.]

Mr. COSTA. Well, if I find that tomato, my friend, I will make it mandatory that a case be supplied to every Member of the Agriculture Committee, because we could certainly use that to lower our collective blood pressure.

Mr. LAWSON. Okay.

Mr. COSTA. Which is good health. We will work on that.

Mr. LAWSON. All right.

Mr. COSTA. One of the takeaways of this joint Subcommittee hearing. The next person that we have to recognize, Mr. Feenstra from Iowa, and then that follows by my friend and colleague from California, Mr. Panetta. Mr. Feenstra, you are recognized for 5 minutes.

Mr. FEENSTRA. Thank you, Chairman Costa, Chair Plaskett, and all the Ranking Members, Baird and Johnson. Thank you for having this hearing today, very informative. As many of you know, Iowa's Norman Borlaug, and all his work, contributed extensively to increases in agricultural production using genetics, and gene editing, and things like that. So obviously I am very supportive of the use of genetic innovation to help improve resiliency in our crops,

or flocks, or herds, animal diseases, and everything. As the U.S. continues to develop products through biotechnology, it is important that we streamline the regulatory approval process that we just talked about. We cannot let our own regulatory hurdles get in the way of more productive agriculture and global competitiveness.

With gene editing and biotechnology, a lack of information could also lead to a lack of trust. We are seeing it around the world. Dr. Chou, I just want to ask you, back in your time, during your time at USDA, what was the position at that time, or what do you think the position is today on gene editing of our agricultural food products?

Dr. CHOU. I think the position of USDA when I was there just a few years ago and now has not changed. We need to use all the technology that we have in our toolbox to make our agriculture more sustainable, both productive and also sustainable, and I think the latest Secretary's initiative on that is—it demonstrates that it has not—I think that attitude hasn't changed. But I think it is—what we have been talking about here is potential. It is a dream.

We need a plan, right, to achieve what we need to achieve, and it is both from a regulatory perspective, how we modify and modernize our regulatory system so we recognize this experience we have gained in all these years regulating products, and also the new science and new evidence that is out there. So we are not asking to decrease the regulatory burden unnecessarily, we are asking that regulatory burden to be justified by the risk. So I think that is all we are—that is what we are asking for. So for these new products that could have been done through conventional breeding, both on the animal side and the plant side, there are multiple layers of oversight both from a public perspective and a private perspective that ensure that these products are safe for consumption and for production, so that additional regulatory hurdles on the government side need to be proportionate to the risk we are talking about here.

Mr. FEENSTRA. Yes. Yes.

Dr. CHOU. We also need to recenter investment. I think that is super important as well.

Mr. FEENSTRA. Yes. Yes. Yes, I would agree. I think there is a PR issue, a public relations issue, with the public, and what the public sometimes perceives as concerns. Do you think there is anything that we, or the Department, can do to create better perception in this arena?

Dr. CHOU. I think we all have a role in that. I think, from a regulatory perspective—the job of the regulatory agency to ensure that we have a safe food supply. It is not the job of the regulatory agency to ensure that there is market acceptance. They need to regulate this on real risk, not on perceived risk. It is incumbent on the rest of us in the agricultural community to actually talk about why we do the things we do. I think Jack mentioned this. We can do lots of these things, but why do we do it? We do it from animal welfare purposes, we do it from climate change purposes, we do it from food security and nutritional security purposes, and those are things that matters to consumers, so I think that is where we need to focus our attention.

Mr. FEENSTRA. Yes. Thank you so much for your comments. So, just like my good friend, Representative Hagedorn, I have the largest swine production in my district, and obviously I am very concerned about African Swine Fever and what is happening. Dr. Oatley, does the approach proposed by the USDA in its ANPR make sense for animal innovations, and do you see USDA having a role in the regulation of animal agriculture innovations moving forward?

Dr. OATLEY. Yes, thanks for the question. I absolutely do see a role for the USDA, and I am very much supportive of that advanced notice for proposed rulemaking that was released by the USDA. When it comes to African Swine Fever, as we have talked about several times during this hearing already, I think if we are going to use biotechnologies, it is probably years out before we address that, so we need a quicker solution for addressing the potential threat now. But the long-term solution rests with biotechnology, with gene editing.

Again, I think the pace at which the discoveries can be advanced from concept in a research lab, to developing through a research and development pipeline, and then getting into commercial channels, is influenced greatly by the Federal regulatory landscape. And so some sort of coordinated landscape process that is coordinated between the USDA and the FDA I think is critical, going forward. I think many small businesses, even academic labs, that are trying to develop applications in this space start to just fall off into the margins as the process for monitoring and approval becomes more burdensome and more costly, and that is stifling to innovation.

Mr. FEENSTRA. Yes. Yes. Thank you, Dr. Oatley. I fully agree with you. And we have a lot of private organizations and nonprofits doing that. Thank you, and I yield back.

Mr. COSTA. I thank the gentleman for your questions, and my colleague from California, representing a wonderful part of California's Central Coast, Congressmember Jimmy Panetta. You are recognized for 5 minutes.

Mr. PANETTA. Thank you, Chairman Costa, and thank you, Chair Plaskett, and, of course, the Ranking Members for this joint hearing. I really appreciate this opportunity, and of course, thanks to all the witnesses who showed up today via Zoom. Thank you very much. I want to address just a couple of areas. I know a lot have been already mentioned, so let me just focus on public-private partnerships, one, and I am going to hit Dr. Chou with that question, and then the increasing acceptance of biotech abroad, and I am going to ask Mr. Bobo and Dr. Rice on that.

So, Dr. Chou, obviously, thank you for being here. As you might have heard mentioned by Rodney Davis, my co-Chair of the Ag Research Caucus, we have been able to work pretty well, or at least see the success of public-private partnerships, especially when they leverage the USDA and its resources. And so I was wondering, Dr. Chou, when it comes to biotechnology innovation, can you provide some real world examples of public-private partnerships in action? And if anybody else would like to weigh in, feel free to do it, but I will start with Dr. Chou.

Dr. CHOU. As you look at public-private partnership that is funded by USDA and NIFA, we have to focus on gene editing. Because

of the regulatory burden for traditional GM products, they have never invested in that because it just—they cannot meet that regulatory hurdle. So a couple examples on gene editing that—is cover crops. There is a consortium that is funded by NIFA of public universities all across the Midwest states, including a private company, a small company, a startup company that is gene editing penny crust, that is a cover crop, so that the oils are now edible, and can be used in animal feed. So farmers can plant it, from an environmental perspective, but they also can sell them seasonal for a cash crop perspective. So that is in early commercial stages, and it is very exciting.

And another thing that AFRI has been funding is this consortium with another startup company called Pairwise that is looking at the genetic diversity within berries, and trying to use gene editing to make discovery, but also to implement that so the berries can be thornless, can have better nutrition, so that there is more availability to consumers and to producers.

So those are two things that—where there is specific investment and utility of gene editing. But I think there are some great examples of public-private partnership that goes beyond gene editing and plant breeding, right? UC Davis's strawberry program putting out 60 varieties, a patented variety of strawberries, which is 93 percent of what is being grown in California. A great public-private partnership. The GEM Program, the program for maize, land-grant universities, private companies, bringing—into the U.S. So those are two great examples on the plant side for continued public-private partnerships.

Mr. PANETTA. Great, great. And I have just got some time here, so I want to move on to my next area of questions, and that is the exceptions to the biotech abroad. Obviously we have heard about the challenges that producers and the biotech industry face when it comes to increasing acceptance of biotechnology products, not just here, as I think Representative Lawson talked about, but also abroad. And we know that there are consumers that are very skeptical abroad. Obviously here too, but also abroad. How can our government help those consumers understand the safety and efficacy of those—of these technologies that we have been talking about? And, obviously, it is more pronounced, I think in other nations than in the United States, so what can we do to help those nations come to more of an acceptance? Mr. Bobo or Dr. Rice, do you want to take that question?

Mr. BOBO. Yes, I can begin. This was my job when I was at the State Department for 12 years. I traveled to 50 countries, met with scientists, policymakers, and others. Within the State Department there are outreach funds, so there are PR efforts that are done to hold meetings to do workshops and other things. Similarly, the Foreign Agricultural Service every day is out there having these conversations with other governments about their regulations, about the potential of the technology, advocating for partnerships with U.S. institutions.

But the funding for those outreach programs is about $1 million a year, and when you think about $100 billion industry, one might think that we could be investing a little bit more. Whenever there is a regulatory or disruption it costs hundreds of millions, if not bil-

lions, of dollars, and so we could provide more resources to those agencies that are on the front lines.

Dr. RICE. Yes, I can just add that we have conducted several rounds of consumer research, and what we see out of this research that, for consumers, regulatory approval is extremely important, as well as safety and testing of the product. But also what is important is better communication about the benefits of those products. This is on the top of the mind for consumer acceptance, and simple answer to your question, Congressman, is we need to ensure U.S. regulatory framework is functional, fit for purpose, and information about benefits is broadly available.

Mr. PANETTA. Great. Thank you, Dr. Rice. Thanks to all the witnesses. I yield back. Thank you, Mr. Chairman.

Mr. COSTA. I thank the gentleman for his comments and questions, and staff and I have coordinated with my co-Chair, Representative Plaskett on this, and what we will do, I believe, is—the last Member to ask questions that I have before me is Representative Fischbach, and I am told Barry Moore from Alabama. So it is the Chair's intention to close the joint hearing between the two Subcommittees after the gentleman from Alabama has a chance to ask questions, and then we will allow a brief opportunity for my co-Chair and the Ranking Members, if they have any thoughts that they would like to follow up with so that we can—with the busy schedule that we all have this afternoon and this week, conclude the hearing. So, with that said, Representative Fischbach from Minnesota, you are recognized for 5 minutes.

Mrs. FISCHBACH. Thank you very much, Mr. Chairman. And, I would just like to explore a little bit. I know that Congressman Feenstra was talking to Dr. Oatley a little bit about the FDA process, and I understand you have firsthand experience with that. You used the phrase *coordinated landscape,* which, like I said, you mentioned a little bit earlier. I am wondering if you could potentially expand on that? What kind of things could we do to improve that process? Because I am very, very excited about the use of biotechnology, particularly in the ag field, and I think there are great strides that we can make, but don't want those kinds of burdens in the way of innovation, and we move forward. Can you walk us through the process, and maybe offer improvements, or how you would like to approach that, since you do have the firsthand experience? What can we do to help that process, and potentially even lower those costs to get these products, or to get this innovation moving?

Dr. OATLEY. Thank you for the question. Now, let me first say that my experience with the FDA approval process is at the investigational stage. That is the kind of first line of communication with the FDA, by opening an investigational new animal drug filing, and I do have several of those now. Essentially, this allows for communication with the FDA to share information about what the gene editing application is in a food animal. The FDA has created a few other channels that are less bureaucratic, but really they all converge into this first step of having an investigational new animal drug filing. When you are going from concept, to gene editing application, to trying to get final approval, it would be in the form of an investigational new animal drug filing.

With these filings in hand, a developer like myself can share information about the concept, provide experimental data supporting the concept. At some point, when enough data has been collected, and the concept has been matured experimentally, then the investigation finally gets converted to the next stage, and that is where a more rigorous process kicks in, and eventually leading to a decision-making point.

I think the challenges for developers like myself is the ambiguity in what defines the next steps, the ambiguity in what information is needed to progress along the process, and, in my experience, it seems like it is a show me what you have, and we will tell you whether it is good enough approach, and that is discouraging for early stage investigators. It is also somewhat expensive, if you are not a nonprofit organization. So every year that that investigational new animal drug filing exists, there is a maintenance fee that is rather hefty, unless we get exemptions, by being a land-grant university, from having to pay that fee. But if we were a small business, or a large company, we wouldn't have those same exceptions, and so it becomes quite expensive to maintain those filings, which I think suppresses the small business early stage developers.

I think that having a process where we can streamline the assessment and the approval in such the changes in the DNA that are being made to animals that can, and probably do, arise in nature, are addressed with enforcement discretion, and have limited oversight, because we are probably already eating products from animals that have these changes. We just don't screen millions and millions of animals looking for that rare variant. And so I think there needs to be different sets of criteria, different paces of oversight, different paces of approval, and different costs of those approvals based on the type of gene editing that is being pursued.

Mrs. FISCHBACH. Thank you very much. And I just have less than a minute left, if any of the other panelists wanted to add to that? Well, then, thank you very much, Mr. Chairman, and I yield back.

Mr. COSTA. I thank the gentlewoman for her comments and questions. The next Member of the Subcommittee is Mr. Moore from Alabama, who is recognized for 5 minutes.

Mr. MOORE. Thank you, Mr. Chairman, and I appreciate all the witnesses appearing before the Committee today. I would like to follow up on a few of the questions so far relating to the Federal regulation of biotechnologies. Many countries around the globe have a single regulatory entity that oversees agricultural biotechnologies, but in the United States we have three, the USDA, the EPA, and the FDA. Dr. Chou, for our education, can you provide sort of a brief overview of what role each of these agencies play?

Dr. CHOU. Sure. I will just talk about it from the plant perspective, where three agencies play, and it is based on what the intended product will do. So FDA will regulate food and feed to make sure it is safe for animals and humans to consume. USDA will regulate a product for agricultural purposes so it is safe for planting, and EPA, it regulates products if there is an intended pesticidal effect. It is a little bit in the weeds. So only a specific plant that perhaps is bred to protect itself against pests, EPA will regulate that.

So in this way, to Dr. Oatley's point, if you are a researcher in a university, trying to figure that out is pretty difficult, and so USDA, and FDA, and EPA actually have a joint website now that you can ask a question, says, this is my product, who should I talk to, and they jointly have to respond to and answer. So there are efforts to streamline the process and make it more approachable.

Mr. MOORE. Okay. Thank you, Dr. Chou. I have no further questions, Mr. Chairman. Thank you.

Mr. COSTA. All right. Thank you very much, Mr. Moore, and I believe our last Member to ask questions, or make some comments, is Representative Letlow from Louisiana. You are recognized for 5 minutes.

Ms. LETLOW. Thank you, Chairman Costa, and thank you to the witnesses for your time and testimony here today. Agriculture research and innovation is at the forefront of agriculture resiliency and sustainability across this nation and abroad. Whether it is adopting new practices, implementing new technologies, or mitigating for potential risks, research plays an essential role in the implementation of new biotechnologies.

In my home State of Louisiana the LSU Agricultural Center is one of nine campuses of the LSU system. Its main focus is on research, extension, and teaching, to make advancements that will benefit future generations. Research conducted by the LSU Ag Center examines ways to expand the food and fiber supply, while improving agriculture's valuable contributions to the state's economy. Through Dr. Mike Deliberto's research on production agriculture at the LSU Ag Center, advances in biotechnology have allowed commodity producers to increase output in an efficient manner. One example of this great work is the Rice Breeding Project at the H. Rouse Caffey Rice Research Station in Crowley. Their primary objective is the development of superior varieties, with emphasis on herbicide resistance, in addition to studies examining the direct or indirect contributions of variety development, like milling quality, and mutation breeding.

In 2019 the Food and Drug Administration indicated that it would develop guidance for foods derived from new plant varieties produced using genome editing. However, it is now late 2021, almost 2½ years later, and FDA has not yet published this guidance. To any of the witnesses, how important is it to the research and developer community that FDA clarify its approach to gene editing, and second, does the current lack of guidance have any impact on the consistency of the regulatory approach to gene editing internationally?

Dr. CHOU. Congresswoman Letlow, if you can allow me to start? I am sure everyone has an opinion on this. I think it is really important—as the previous Congressman mentioned, we have three agencies, so the three agencies need to be coordinated not just in a regulatory approach, but in timeline. So right now FDA is not putting out their clarifying policy, it is a bit concerning, all right? So we do need all three agencies to be coordinated.

From an international perspective, it makes it difficult for us to advocate, and from a public-sector perspective, from a government perspective, because our house is quite not in order. So in that way, we need all three agencies to get together to get our house

in order so we can remain leaders not just in research and development, and in commercial production, but also in regulatory science and regulation.

So, in my view, we are really looking towards the three agencies to work better together so that they are putting out policies together, that they are coordinating and collaborating. Not just sharing information, but actually working together to make sure that there is not too much duplicity in the way they regulate, and to be as streamlined as possible, especially for these products of gene editing, where we are working within a plant and animal genome that could have been done through conventional breeding or naturally occurring. I know we keep coming back to that point, but this is really the 21st century advances that we are trying to talk about here.

Ms. LETLOW. Thank you. Would anybody else like to comment?

Dr. OATLEY. May I speak on the animal side, I would say that genetic engineering of animals right now goes through a drug review process at the FDA. That drug review process was set forth by the Federal Food, Drug, and Cosmetic Act, and this assigned regulatory oversight of genetically modified animals to the FDA. Through interpretation of that authority, substances other than food that affect the structure and function of an animal are considered to be a drug, and so those molecular elements, like DNA, that alter the genome of an animal are now considered a drug. And this Act was established during a time of genetic engineering called transgenesis that used recombinant DNA to alter the genome, put something foreign into the genome. That is not the state of the art for gene editing, and so I think continuing to regulate it as a drug in changes to the DNA that can and do arise in nature is not aligned with the state of the art of the science, as well as the pace of development.

Ms. LETLOW. Thank you for that comment.

Dr. RICE. Another point here to bring up that the absence of clarity today between three agencies, the fact that animal gene editing is being regulated as drug, but not plant gene editing, all confuses our consumers. And what we see that—when consumers are confused, they refuse to accept the technology, and products that originate from the technology, and that is what we see as a major issue today, because, at the end, the products only will be available to the market if consumers will accept them.

Ms. LETLOW. Thank you so much. I appreciate those responses. Mr. Chairman, I yield back.

Mr. COSTA. I thank the representative for yielding back. Her time has expired. And now, with the support of both Subcommittees, I would like to bring this hearing to a close. Mr. Johnson has indicated that he has had to leave for other appointments. Mr. Johnson, do you have any closing comment you would like to make? I guess not. Mr. Baird, do you have any closing comment you would like to make?

Mr. BAIRD. Yes, Mr. Chairman. I really appreciate that opportunity, because I want to express how much I appreciated the witnesses today, and the expert work that they are doing, and that it really is encouraging to me that we recognize that biotechnology in agriculture really does represent a true bright spot in the future

for our global economy. And so with that, I just want to say that we also, in the discussion today, recognize that we need to ensure that regulation does not stifle the innovation, and the appropriate agencies regulate the technology of agriculture, and that where interagency cooperation and regulation is unavoidable, that it happens efficiently.

So I can't tell you how much I enjoyed hearing the witnesses today. I could just spend the rest of the afternoon discussing some of these issues, so I want to make sure that we thank them for being here, and I yield back. Thank you.

Mr. COSTA. Okay. Well, we thank you for your enthusiasm and your focus, and I will now yield to our colleague and co-Chair, who, without her participation, and enthusiasm, and focus, and her staff's efforts, this joint Subcommittee hearing would not have been possible. So, Chair Plaskett, for any closing comments you might like to make?

Ms. PLASKETT. Yes, thank you, Mr. Chairman, and thank you so much to my colleagues on both sides of the aisle for what I believe was an extremely informative discussion. And, of course, to the witnesses, whose expertise has been invaluable to us not only understanding what is happening in this field, but supporting us in trying to make decisions about how Congress plays a role in this. As we bring the hearing to the close, I of course want to thank the staff, both mine, yours, Mr. Costa as well, in particular the Committee staff who have made this possible, and our colleagues who took time to be here and ask really pertinent questions.

As the last year has made abundantly clear, it is crucial that we continue to find ways to increase the resiliency of our food and agricultural systems. We need to work with researchers and farmers to accelerate efforts to develop crops and animals that are better suited to adapt to the increasingly severe impacts of climate change, and, paired with improved practices, better help us mitigate climate change. As well, we have learned that there is, in fact, a role both for us as regulators, and to the industry to make consumers feel more comfortable with the strides that science has made, and I can't wait to get to work with my colleague and Ranking Member, Mr. Baird, to see how our Subcommittee, working with you, Mr. Costa, and others, and Mr. Johnson, as well as the full Committee, to make this a reality. Thank you so much, and for the time, and I yield back to Chairman Costa.

Mr. COSTA. Well, thank you very much, Chair Plaskett, for your comments. I couldn't agree with you more, and I too also want to thank the Ranking Members, and I think this has been a good use of time by both Subcommittee Members in working together on what really is an overlap of interests by both of our Subcommittees. The panel experts today provided not only important testimony, but I think did a very good job of answering the questions. I am sure there will be follow-up.

One thing that has struck me in listening to today's testimony is the technological jump that I think is taking place not only in the last decade, but certainly in the next, and it has to be. It has to be, with the population growth that we have all talked about here, by the middle of the century it being almost ten billion people. We are over 7½ now at this point in time, and trying to

produce more food for our nation, and for this planet, with less is, in light of climate change, a tall order, to say the least.

And—so I think it is important that the takeaways from today's hearing is something that both Subcommittees will focus on, and our staff, on how we incentivize innovation in agriculture, deal with some of the larger threats that we are facing in terms of drought, extreme drought conditions that we find ourselves in, dealing with efforts that are—provide threats, and disease-resistant animals, and drought-tolerant crops, two things that are critical to our food supply chain, and technology is going to be a key part of how we make sustainability a greater part of our ability to produce food. Sustainability, frankly, has been a part of our success, but we need to do more. We have to do more.

And I think, as you hear me say regularly, and I think most of the Members of the Committee share this thought, food is not only a national security issue, but a world security issue. Food and fiber that so many folks take for granted, that is on their dinner table every night, cannot happen unless we ensure that we have a robust and sustainable ability to produce that absolutely necessary nutrition for our sustenance, and it is important that, with the global dynamics changing, that we integrate new technologies into agriculture, and that we can prepare for that change.

So once again I want to thank the witnesses, and the researchers, and the advocates that figure out how we can continue to build better efforts in terms of public-private partnerships with our universities throughout the country, and through the private-sector. It has been key on how we have done so well thus far, but obviously we need to do more, and have it scale neutral for new technologies for our agricultural producers. The bottom line is if we do this, we can address the challenges of the future for sustainability in the production of food and fiber not only for our nation, but for the world.

So, with that, under the Rules of the Committee, the record of today's hearing will remain open for 10 calendar days to receive additional material and supplemental written responses from witnesses to any question posed by the Members. So, again, to our witnesses, who did a terrific job today, we may have follow-up questions for you by Members of the Committee, because we really want to ensure that the takeaways from this joint Subcommittees' hearing are something that we can build on, and that is what I hope will take place. So the joint hearing of the Subcommittee on Livestock and Foreign Agriculture and the Subcommittee on Biotechnology, Horticulture, and Research, with the support of my co-Chair, is now adjourned. Thank you very much.

[Whereupon, at 12:43 p.m., the Subcommittees were adjourned.]

[Material submitted for inclusion in the record follows:]

SUBMITTED LETTER BY HON. JIM COSTA, A REPRESENTATIVE IN CONGRESS FROM CALIFORNIA; ON BEHALF OF SARAH GALLO, VICE PRESIDENT, AGRICULTURE AND ENVIRONMENT, BIOTECHNOLOGY INNOVATION ORGANIZATION

October 26, 2021

Hon. DAVID SCOTT,
Chairman,
House Committee on Agriculture,
Washington, D.C.;

Hon. GLENN THOMPSON,
Ranking Minority Member,
House Committee on Agriculture,
Washington, D.C.;

Hon. JIM COSTA,
Chairman,
Subcommittee on Livestock and Foreign Agriculture,
House Committee on Agriculture,
Washington, D.C.;

Hon. DUSTY JOHNSON,
Ranking Minority Member,
Subcommittee on Livestock and Foreign Agriculture,
House Committee on Agriculture,
Washington, D.C.;

Hon. STACEY E. PLASKETT,
Chair,
Subcommittee on Biotechnology, Horticulture, and Research,
House Committee on Agriculture,
Washington, D.C.;

Hon. JAMES R. BAIRD,
Ranking Minority Member,
Subcommittee on Biotechnology, Horticulture, and Research,
House Committee on Agriculture,
Washington, D.C.

Dear Chairman Scott, Chairman Costa, Chairwoman Plaskett, Ranking Member Thompson, Ranking Member Johnson, and Ranking Member Baird and Members of the Committee:

The Biotechnology Innovation Organization (BIO) is pleased to submit a statement for the record to the United States House of Representatives Committee on Agriculture joint hybrid Subcommittee hearing, *Agricultural Biotechnology: 21st Century Advancements and Applications.*

Introduction

BIO represents 1,000 members in a biotech ecosystem with a central mission—to advance public policy that supports a wide range of companies and academic research centers that are working to apply biology and technology in the energy, agriculture, manufacturing, and health sectors to improve the lives of people and the health of the planet. BIO is committed to speaking up for the millions of families around the globe who depend upon our success. We will drive a revolution that aims to cure patients, protect our climate, and nourish humanity.

Agricultural Biotechnology: 21st Century Advancements and Applications

BIO applauds the Committee for examining the role of agricultural biotechnology in the 21st Century.

To meet the challenges of a changing climate and sustainably increasing production to feed a growing world, it is crucial to lead with science and U.S. innovation. We must incentivize the adoption of innovative, sustainable technologies and practices; and streamline and expedite regulatory pathways for breakthrough technology solutions.

Adoption and Acceptance of Agricultural Biotechnology

The adoption of biotechnology in agriculture and the development of biobased technologies has already contributed to food security, sustainability, and climate change solutions. The acceptance of biotechnology has enabled large shifts in agronomic practices that have led to significant and widespread environmental benefits.

Ensuring policies and regulations continue to advance innovative breakthroughs will be critical. Increasing the use and acceptance of these technologies can reduce greenhouse gas emissions throughout agricultural supply chains and strengthen producers' resiliency to climate change while increasing production and helping tackling hunger by bringing more nutritious offerings to all tables.

BIO understands that consumers want to know information about biotechnology in food and agriculture, and our members want to be the driver of that endeavor. A proactive approach to transparency stands to energize understanding, build trust, and foster an environment where innovators, companies, and consumers together can address our most pressing societal and environmental problems. BIO supports increased openness about products being developed and best practices developers use in advancing beneficial products to the commercial marketplace.

The U.S. has led the way in developing these innovations due to thoughtful, bipartisan public policy. This has created a favorable climate in which to undertake the lengthy and risky job of investing and developing the next biotech breakthroughs; allowed producers to use new technologies; and ensured a pathway to market for new products. However, America's continued success and leadership are not guaranteed, and we should not take its global leadership for granted.

COVID–19 has also exposed the vulnerabilities and inequalities in how communities are disproportionately impacted, our capacity to respond to crisis, our ability to maintain our supply chains, and to withstand an economic downturn. These challenges will only grow more prevalent and damaging because of climate change.

To ensure America is able to respond to future challenges in cleaner, more efficient ways, maintain its global leadership, and allow its farmers, ranchers, sustainable fuel producers, and manufacturers to have access to cutting edge technologies, the United States must invest in new technologies and have risk-proportionate regulations that spur biological innovations.

The government should also focus on removing barriers and assisting beginning and socially disadvantaged farmers and ranchers in accessing and utilizing these technologies, so all producers can adapt to the challenges ahead. By accelerating and deploying innovation, American agriculture can be resilient, self-sustaining, and strengthen our economy.

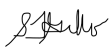
To learn more about these technologies, our companies' innovative breakthroughs, and the policies that can allow American agriculture to thrive in the 21st Century, please see BIO's past comments to the Committee and the U.S. Department of Agriculture (USDA).

- BIO statement for the record to the United States House of Representatives Committee on Agriculture hearing entitled, *Climate Change and the U.S. Agriculture and Forestry Sectors,* [available] *here*.[1]
- BIO comments to USDA's Solicitation of Input from Stakeholders on Agricultural Innovations, available *here*.[2]
- BIO response to USDA's Request for Comments: Executive Order on Tackling the Climate Crisis at Home and Abroad as USDA develops a Climate-Smart Agriculture and Forestry Approach, available *here*.[3]

Conclusion

With science we can return our nation and the world to health and prosperity. BIO is committed to working with the Committee, Congress, and the Administration to establish supportive policies and regulations to foster the rapid development and deployment of agricultural biotechnology to help American agriculture meet the challenges of the 21st Century. We look forward to our continued partnership in this critical endeavor.

Sincerely,



SARAH GALLO,
Vice President, Agriculture and Environment,
Biotechnology Innovation Organization.

SUBMITTED LETTER BY HON. STACEY E. PLASKETT, A DELEGATE IN CONGRESS FROM VIRGIN ISLANDS; ON BEHALF OF AGRICULTURAL RETAILERS ASSOCIATION, *ET AL.*

October 26, 2021

Hon. DAVID SCOTT,
Chairman,
House Committee on Agriculture,
Washington, D.C.;

Hon. GLENN THOMPSON,
Ranking Minority Member,
House Committee on Agriculture,
Washington, D.C.;

Dear Chairman Scott and Ranking Member Thompson,

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[1] *https://www.bio.org/letters-testimony-comments/bio-submits-testimony-first-climate-hearing-new-house-agriculture*.†

References annotated with † are retained in Committee file.

[2] *https://www.bio.org/letters-testimony-comments/bio-submits-comments-usda-ag-innovation*.†

[3] *https://www.bio.org/letters-testimony-comments/bio-submits-comments-usda-highlighting-biotechs-role-tackling-climate*.†

On behalf of our nation's food and agricultural stakeholder community, we write to extend our appreciation for holding today's hearing on "Agricultural Biotechnology: 21st Century Advancements and Applications." Biotechnology is an increasingly vital technology for the future productivity and sustainability of agriculture. As we work to posture these tools for greater future use, we welcome the Committee exploring important facets of the technology, including its underlying science, applications, and relevant policy matters. Moreover, we stand ready to assist the Committee in advancing policy improvements that will help these promising innovations address the challenges facing agriculture and our society.

As mentioned, we believe this technology already has and will continue to play an important role in addressing many challenges facing our society. Historically, plant breeding has helped growers reduce their input needs and protect crops from devastating pests. In the last few decades, biotechnology has helped growers of certain crops, such as corn, soy, cotton, and sugar beets, even further, by facilitating adoption of vital conservation practices. Looking ahead, advancement in breeding innovation, such as genome editing, can play an even greater role in addressing countless issues in a broader variety of products, like specialty crops, cover crops, and livestock. We are already seeing important research and developments taking shape that can reduce food waste and put longer-lasting fresh produce in the hands of consumers; decrease livestock susceptibility to diseases, reducing producer losses and the need for antibiotics; and further cut greenhouse gas emissions and other environmental impacts of agricultural production.

However, we would note that science and innovation are moving swiftly. To realize these important applications and their benefits, we must have Federal policies that are risk and science-based and will permit the meaningful adoption of these products by producers, supply chains, and consumers. For several years, the Federal Government has been involved in regulatory modernization efforts that will better facilitate the future use of these tools. We look forward to supporting continued work on these issues with the Committee and other policymakers to improve our regulatory landscape in a way that will allow these important innovations to come to fruition.

Again, we thank you for your attention to these vitally important tools and stand ready to assist the Committee in efforts to ensure we can maximize the benefits these innovations can offer producers, consumers, and our society.

Sincerely,

Agricultural Retailers Association
American Association of Veterinary Medical College
American Farm Bureau Federation
American Seed Trade Association
American Soybean Association
American Sugarbeet Growers Association
Biological Products Industry Alliance
Biotechnology Innovation Organization
Crop Science Society of America
National Association of State Departments of Agriculture
National Association of Wheat Growers
National Cattlemen's Beef Association
National Corn Growers Association
National Cotton Council
National Council of Farmer Cooperatives
National Milk Producers Federation
National Pork Producers Council
National Potato Council
National Sorghum Producers
National Turkey Federation
Society of American Florists
U.S. Canola Association
USA Rice

SUPPLEMENTARY MATERIAL SUBMITTED BY JACK A. BOBO, CHIEF EXECUTIVE OFFICER, FUTURITY

Insert

Mr. BOBO. . . . In Japan they are bringing a tomato that lowers blood pressure, and they are selling seeds directly to consumers so you can grow these heart-healthy tomatoes right at home. . . .

* * * * *

Mr. LAWSON. . . . Thank you. Mr. Chairman, I am going to yield back, but, for the record, Mr. Chairman, I want to know what kind of tomato that is going to lower blood pressure? And so if you can get some information back, that will be interesting.

A genome-edited tomato produced using CRISPR-Cas9 technology have been sold on the open market in Japan since September 2021. The Sicilian Rouge tomatoes, which are genetically edited to contain high amounts of γ-aminobutyric acid (GABA), are being sold directly to consumers by Tokyo-based Sanatech Seed. The company

claims oral intake of GABA can help support lower blood pressure and promote relaxation.

References

USDA FAS: *Japan Determines Genome Edited Tomato Will Not be Regulated as GE https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Japan%20Determines%20Genome%20Edited%20Tomato%20Will%20Not%20be%20Regulated%20as%20GE Tokyo Japan 12-10-2020.**

GABA-enriched tomato is first CRISPR-edited food to enter market, December 14, 2021, *https://www.nature.com/articles/d41587-021-00026-2.*

Sanatech Seed *https://sanatech-seed.com/en/about-en/.*

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*__Editor's note:__ the report is retained in Committee file.