



**Testimony of Dr. Elena Rice
Chief Scientific Officer
Genus plc
DeForest, Wisconsin**

**Joint Hybrid Subcommittee Hearing
United States House Agriculture Subcommittee on Livestock and Foreign Agriculture
and Subcommittee on Biotechnology, Horticulture, and Research**

Agricultural Biotechnology: 21st Century Advancements and Applications

Chairman Scott, Chairman Costa, Chairwoman Plaskett, Ranking Member Thompsen, Ranking Member Johnson, Ranking Member Baird, and Members of the Committee, my name is Dr. Elena Rice, Chief Scientific 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 letter¹ Subcommittee Chairwoman 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 regulatory 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.

¹ <https://baird.house.gov/news/documentsingle.aspx?DocumentID=201>

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 headquartered 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 2050².

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.

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 seven 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 improvement.
- 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 herd.

And finally, as important to our innovation, are our Ethical Commitments³ 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 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 US 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

³ <https://www.genusplc.com/rd/innovation-technologies/gene-editing-ethical-commitments/>

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 US 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 products are first assessed 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

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

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 engagement 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 intersecting 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);

⁵ USDA, Foreign Ag Service, Report Number: CA2020-009, "Agricultural Biotechnology Annual", January 05, 2021

- 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 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.

**Committee on Agriculture
U.S. House of Representatives
Information Required From Nongovernmental Witnesses**

House rules require nongovernmental witnesses to provide their resume or biographical sketch prior to testifying. If you do not have a resume or biographical sketch available, please complete this form.

1. **Name:** Elena Rice

2. **Organization you represent:** Genus PLC

3. **Please list any occupational, employment, or work-related experience you have which add to your qualification to provide testimony before the Committee:** _____

18 years employment with Monsanto/Bayer company working in different departments including Regulatory Science, R&D, Commercial. Currently, Chief Scientific Officer, Head of R&D for Genus PLC working on breeding technologies including gene editing for development of animal genetics; Member of BIO's Ag & Environment board.

4. **Please list any special training, education, or professional experience you have which add to your qualifications to provide testimony before the Committee:** _____

PhD in Plant Molecular Biology, Working experience includes development of safety assessments of genetically modified crops for Regulatory approvals; establishing gene editing pipeline for crops; developing gene editing approaches for animal application; breeding pipeline for crops and animals, genomics science in application to breeding pipeline in crops and animal; establishing and development of advanced reproductive biology technologies for animals. Over 50 publications in peer reviewed scientific journals; numerous presentations at scientific conferences.

5. **If you are appearing on behalf of an organization, please list the capacity in which you are representing that organization, including any offices or elected positions you hold:**

Chief Scientific Officer, Genus PLC (member of the executive team);
Member of BIO's Ag & Environment board.

**PLEASE ATTACH THIS FORM OR YOUR BIOGRAPHY TO EACH COPY OF
TESTIMONY.**