CLAYTON YEUTTER INSTITUTE OF INTERNATIONAL TRADE AND FINANCE

The Future of U.S. Agricultural Biotechnology and Trade: Summary of a Roundtable Discussion

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Introduction

The United States is one of the largest and highest-yield agricultural producers and exporters in the world. But the world's population is growing, and growing conditions themselves are changing. Farms face shifting weather patterns, more frequent and severe storms, floods, and drought, and changing pest and disease pressures. What farmers plant and how they plant it are evolving to keep pace with these changes. Future global food security, sustainability, and U.S. leadership in agriculture will depend on the domestic and international policy and regulatory landscapes for agricultural biotechnology innovation.

The Clayton Yeutter Institute of International Trade and Finance at the University of Nebraska-Lincoln convened a roundtable on March 2, 2023, conducted under the Chatham House Rule, to discuss the pressing issues around the future of U.S. agricultural biotechnology and trade. This was a unique opportunity to bring together expertise from the farm, the field, the lab, industry, and the policy arena. Participants included high-level government officials from the current and previous administrations, farmers, academics, and practitioners in plant genetics and agricultural sciences. This report summarizes that discussion.

Points of widespread agreement among participants include:

1. Sustainability and food security require innovation. The world's population continues to grow, growing conditions are changing, and our land and water resources are finite. We need to increase yield and there is no way to do this without innovation.

2. There are three agencies responsible for regulating genetically engineered (GE) crops in the United States—the U.S. Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), and the U.S. Environmental Protection Agency (EPA). (GE here includes both genetically modified and gene edited. We will use the broader term GE in this report.) Each agency has developed its own specific rules and regulations within the confines of the statutes, but different statutes govern each agency, which has resulted in "stovepipes that are crooked and turned in different buildings." The U.S. regulatory regime for agricultural biotechnology needs to be streamlined, otherwise investors could go elsewhere like Brazil.

3. There is a fundamental misunderstanding in the United States about how our food is grown. Consumer labeling is helpful, but there is frustration that consumers are being oversold on the value of genetically modified organism (GMO)-free labels. The need for clear, science-based communication applies across the entire supply chain—farmers, processers, packagers, marketers, and grocers.

4. Transparency and science-based regulatory approaches by our trading partners are often as important as traditional market access. The World Trade Organization (WTO) Sanitary and Phytosanitary (SPS) Agreement has withstood the test of time, and the U.S. should work to defend it. SPS provisions are important because they incorporate the science and risk analysis provisions. The U.S.-Mexico-Canada Agreement (USMCA) was the first U.S. trade agreement to include agricultural biotechnology provisions, and that agreement and even the U.S.-China Phase One agreement are good examples of the way forward, although even stronger and bolder provisions could be sought in future agreements.

5. The importance of agricultural biotechnology innovation is not lost on China, and government leaders have a top-down plan to dominate in agricultural seeds and innovation. "Seeds are the 'chip' of agriculture," said Han Wenxiu, deputy director of the Office of the Central Economics and Financial Affairs Commission, referring to semiconductors and the U.S.-China technology race.

1. Sustainability and food security require innovation: a growing population, changing growing conditions, and finite resources means we need innovation.

When the Trans-Pacific Partnership (TPP) was launched in 2005, the world population was 6.5 billion. By the time the United States joined negotiations in 2009, it was 6.9 billion. When USMCA launched in 2017, it was 7.5 billion. Today, the world's population is 8.1 billion.

But the amount of land, water and resources is finite. In fact, USDA data show acreage devoted to agriculture in the United States is not increasing—though productivity per acre has increased.

We need to grow more food to keep up with the growing population. According to estimates compiled by the United Nations Food and Agriculture Organization, by 2050 we will need to produce 60 percent more food to feed a world population of 9.3 billion. Agricultural producers simply cannot do this without fertilizers, biotechnology, and innovation.

Roundtable participants emphasized that issues surrounding agricultural biotechnology are no longer about food safety. The National Academy of Sciences and others have asked and answered that question. That book has closed. Feeding the world's population, improving farmers' livelihoods, and securing sustainable production for the future are now the focus of U.S. policymakers and industry in this arena.

2. The U.S. regulatory process threatens to hold up innovation: a cumbersome regulatory structure can result in duplicative reviews and is a costly burden on innovators.

Three agencies have primary responsibility for regulating GE crops and food in the United States: USDA, FDA, and EPA. Each agency has developed its own regulations, procedures and policy documents on biotechnology products within the confines of the statutes under which the agencies operate. This complex regulatory structure can result in duplicative reviews and is a costly burden on innovators.

The decision was announced in 1986 not to pursue a new statute for GE agricultural products, possibly due to difficulties of getting it through Congress, but rather to work within the current statutes and develop agency regulations. As a result, bringing a new product to market requires regulatory authorization from multiple regulatory agencies. Under the U.S. Coordinated Framework for the Regulation of Biotechnology, each agency has a totally different set of rules and procedures because they have different regulatory responsibilities. This complex regulatory structure can result in duplicative reviews and burdens on innovators. One participant referenced the book Farmers vs. Foodies, by Ray Starling, which described the current system as "stovepipes that are crooked and turned in different buildings."

Gene editing techniques can be used to develop seeds that produce fruits, vegetables or crops that are functionally the same as those that are produced through conventionally bred seeds. The gene editing technique is usually faster and can be scaled more easily, but in certain jurisdictions gene edited seeds are subject to an entirely different regulatory approval process that is more expensive and lengthier to navigate. For example, consider a lettuce that is resistant to a certain virus and suppose this lettuce could be achieved through conventional breeding or with gene editing. In the United States, there is no mandatory pre-market review for the conventionally bred lettuce seed. But gene edited lettuce seed, even though it has the same outcome as the conventional breeding process, must go through separate regulatory processes in USDA and EPA. Participants said that regulations should focus on the outcome of the breeding process, not the process itself.

Innovators would benefit from U.S. regulatory agencies working together to streamline the process.

USDA and EPA recently released new rules and rule revisions that carve out some GE seeds (by plant, trait, and mode of action, like soybeans, glyphosate-tolerant, GE method) such that once they are approved, they do not have to be re-regulated or go through the entire regulatory process again. Each agency, however, carved out a different set of seed traits. So, while this was a helpful move by the two agencies, it was not helpful that each chose a different set of carveouts.

The time-consuming and costly regulatory regime can negatively impact the industry, especially innovators in public academic institutions and small companies that have smaller budgets. To incentivize innovation and resilient food systems, regulatory processes should be streamlined to reduce redundancies and minimize the cost.

What is GM and GE?

Participants noted how the terms genetically engineered (GE) and genetically modified (GM) are often used interchangeably. Below is a helpful set of definitions by North Carolina State University.

Genetic modification or GM refers to a range of methods used to alter the genetic composition of a domesticated plant or animal to achieve a desired result.

Genetically engineered or GE is one type of genetic modification that involves the intentional introduction of a targeted change in a plant, animal, or microbial gene sequence to achieve a specific result.

Source: "What is the difference between genetically modified and genetically engineered foods?" CES, North Carolina State University

3. Understanding the science and how we talk about food

There is a fundamental misunderstanding in the United States about how our food is grown. The language people use is important because it can influence how people think about something. Roundtable participants agreed on the value of consumer labeling, but there is frustration that consumers are being over-sold on the value of genetically modified organism or GMO-free.

There are many "GMO-free" labels on products even when there are no GE products on the market for any of the ingredients. Trigger words like "pesticide-free," "non-GMO," or "organic" are showing up on labels and wrappers that capitalize on consumers' lack of knowledge and fear. The need for clear, science-based communication applies across the entire supply chain—from farmers, processers, packagers, marketers, to grocers.

Discomfort, distrust, and uncertainty continue to fuel concerns over GE foods. A 2018 survey by the International Food Information Council Foundation reported that 46 percent of U.S consumers said they actively avoid bioengineered ingredients, compared with 15 percent in 2007. Yet the majority of Americans are consuming GE foods and processed products using GE ingredients, including cornstarch, corn syrup, corn oil, soybean oil, canola oil, sugar, fresh fruit, and vegetables. The Grocery Manufacturers Association reports that approximately 75 to 80 percent of conventional processed foods in the U.S have genetically modified ingredients.

Farmers need actors across the entire supply chain as well as our educational system to increase transparency around this misconception. Some food manufacturers may be hesitant to do so, perhaps because sellers can charge higher prices and reap greater profit margins on organic and non-GMO foods; that is, it may not be in their commercial interest to increase transparency around the issue. Regardless, the public deserves fact-based conversations and policies about how food is grown, the consumer benefits of that reality, and what that means for sustainability and food security.

The food industry should provide factual information to help allay unfounded consumer fears and anxiety about GE foods and correct misconceptions about organic and old-fashioned farming

being more sustainable. The National Academy of Sciences released a comprehensive and exhaustive report on genetically engineered foods and concluded that there is no evidence of adverse health effects on people from GE foods. The report also concluded that (i) GE crops can benefit people because they reduce cases of insecticide poisoning, (ii) farms that use GE crops tend to be more commercially viable, and (iii) GE crops benefit human health, such as Golden Rice that improves vitamin A intake, which in turn can reduce blindness.

Gene editing techniques can create shortcuts to breeding processes that could occur naturally.

All breeding involves genetic modification of some kind. A farmer selecting seedless berries to plant at scale, a rancher selecting a prize cow to breed, or a plant breeder editing out the mustard-flavor in lettuce to get greens that the whole family will enjoy—it is all genetic modification one way or another. Farmers have been breeding plants and animals with the most desirable traits for decades. Desirable traits are those that will be better for sustainability, the consumer, or the farmer, e.g., an ability to thrive in dry climates, provide better-tasting lettuce or facilitate resistance to disease or pests.

Gene editing techniques can be a shortcut to a breeding process that occurs naturally. It's a scientific way to introduce genetic variability, which farmers have been doing for decades. In fact, plant breeding dates back thousands of years to when people first domesticated wild plants. Rice, potatoes, wheat, and barley were domesticated about 10,000 years ago.

All Americans should know that Norman Borlaug was the American agronomist who developed semi-dwarf, high-yield, disease-resistant wheat varieties in the 1960s. Borlaug was awarded the Nobel Peace Prize in 1970 for his contributions to the world food supply.

One participant noted that Borlaug's extensive and exhaustive cross breeding programs on wheat in Mexico included literally thousands or tens of thousands of crosses made by hand in an era before biotechnology provided the precision and efficiency to improve it. Today, such genetic editing can be done in the lab more easily and far less costly, yet agricultural scientists have the same goal as Borlaug of genetic selection and advancement. Wheat yields have increased, and food security has improved around the world, with large thanks to Borlaug's efforts.

Over the last couple decades, however, many policymakers, food manufacturers, and marketers seem to have gotten stuck on "is this a GMO or not?" Meanwhile, U.S. farmers, the agricultural industry and the technology itself have moved beyond that discussion.

Regulatory agency staff should be sufficiently trained in the evolving science and technology.

Regulatory agencies should ensure that staff are sufficiently trained in the evolving science and technology. Otherwise, as one participant stated, "our regulators are regulating on perceived risk," which can be a contributing factor to the cumbersome regulatory review process.

Countries around the world recognize that food security requires agricultural innovation.

The war in Ukraine, a changing climate, and challenging growing conditions have heightened awareness around food security. Countries seeking food security, especially developing countries, increasingly recognize the need for agricultural innovation. The U.S. government

needs to lead the way on this through our international economic policy discussions, regulatory discussions, and trade negotiations. Nongovernmental organizations can also play a role—for the better or, as in the case of Kenya, for the worse.

When Kenyan President William Ruto took office in September 2022, he moved to lift the ban on genetically modified crops, reversing a decade-old decision as his country has struggled with food security and a deadly drought. President Ruto is a plant ecologist with a botany and zoology background and was well aware of the benefits of modern agriculture. On his first day in office, he said the country would modernize its agriculture sector, and import and cultivate biotech crops to feed its people. Ruto aspired to improve his country's ability to develop and innovate its own biotech crops someday—a movement which could have proven to be a huge step forward in improving the food production environment across the African continent. Soon after the government's announcement, however, the Center for Food and Adequate Living Rights, a nongovernmental organization, sued the Kenyan government.

NGOs have engaged in aggressive marketing campaigns to make GMOs seem dangerous to the developing world.

Meanwhile, Kenya's crops are failing, Kenyan farmers are fighting for the ability to plant GM crops, and the country's fight for food security continues.

Sustainability is about feeding people and the economic viability of farm operations.

Sustainability means many things—a lower carbon footprint, ability to grow food in changing climate conditions, growing enough to feed a growing population, growing food with desirable traits, and farmers making enough money to stay in farming.

According to the National Agricultural Library of the U.S. Department of Agriculture, the legal definition of "sustainable agriculture" (U.S. Code Title 7, Section 3103) is an integrated system of plant and animal production practices having a site-specific application that will over the long-term:

- Satisfy human food and fiber needs.
- Enhance environmental quality and the natural resource base upon which the agriculture economy depends.
- Make the most efficient use of nonrenewable resources and on-farm resources and integrate, where appropriate, natural biological cycles and controls.
- Sustain the economic viability of farm operations.
- Enhance the quality of life for farmers and society as a whole.

4. For international trade policy, transparency and science-based regulatory approaches can be just as important as traditional market access.

The United States has not been engaging in traditional free trade agreements with tariff elimination or reduction for the past few years. Other countries like the EU, Canada, Japan, and Australia have been, though, and this often leaves U.S. exporters at a relative disadvantage.

Notwithstanding, market access is not all about tariffs, especially in agriculture. Technical regulations and SPS barriers can be as restrictive and costly as a tariff.

The WTO SPS Agreement provides a baseline. All WTO members signed on to the WTO SPS Agreement, which encourages governments to establish national SPS measures consistent with international standards, guidelines, and recommendations, and based on science and risk assessments. SPS provisions are important because they incorporate the science and risk analysis provisions. The agreement has withstood the test of time and continues to provide a sound and viable framework for all countries regardless of developing country status. Roundtable participants also agreed that future trade agreements should address new and emerging issues, including as the science advances on the benefits of biotechnology.

USMCA is the first U.S. trade agreement to include agricultural biotechnology provisions (whereas TPP and its successor agreement, the CPTPP, did not). The SPS and biotech provisions in USMCA, and even the U.S.-China Phase One agreement, are examples of how to incorporate modern agriculture issues in new ways that are consistent with the WTO SPS Agreement. Note that it is the SPS provisions of USMCA that USTR is currently disputing with Mexico on corn.

Developing countries don't always have the infrastructure to test or approve biotech products, and some countries have indicated that they will approve a new product only after five other countries have done so. More consistency or at least compatibility in the gene editing regulatory space would facilitate trade.

Europe still maintains relatively strict regulations on biotechnology that can hinder advancements. Participants noted that U.S. and EU officials meet semiannually for U.S.-EU biotech consultations, but some questioned the usefulness of these talks.

The days of FTAs are not necessarily over forever, but in agriculture we need transparency and science-based regulatory approaches as much as we need traditional market access. So, to the extent an FTA is not possible with a particular country or region, then our negotiators can shift the negotiations toward these other key areas and move forward with advocating for transparent, science-based regulatory processes. This is especially advantageous for developing countries that face a more acute need to improve their own productivity to feed their people.

Countries have different laws and rules on what is considered gene edited (e.g., the EU is grappling with the recent European Court of Justice decision on what is to be regarded as a GMO). Roundtable participants agreed that the present challenge is to ensure the durability of key provisions in international agreements. Negotiators must balance the need for language to not be too specific in terms of the technique, but specific enough to address salient issues facing firms today. For instance, if the WTO Agreement on Technical Barriers to Trade had included

language on floppy discs instead of more general language on electronic and digital devices and software, that agreement would have quickly been rendered outdated.

Enforcement will always be necessary, but agreements are more likely to stick when trade partners see it is in their own interest.

When our trade partners recognize the benefits of modern agriculture to food security and sustainability, trade and market-based cooperation are easier to achieve. Roundtable participants agreed that we must lead the way on modern agricultural practices and incorporate that into our policy dialogue and trade agreements, which in turn will facilitate U.S. agriculture trade.

There are consumer and producer benefits of modern agriculture. Whether those benefits are realized will depend on regulatory regimes and trade policies.

Consumer benefits of GE crops include growing healthy food that more people will want to eat, e.g., greens without a mustardy bite. Producer benefits of GE crops include innovations that enable growing crops that can thrive in challenging climates like hotter and drier growing conditions and resist new pest pressures as climates change. For example, swaths of America's farmland for lettuce crops are facing longer, hotter, and drier growing conditions and would benefit from seed varieties that can thrive in these conditions.

Other examples include softer and tastier kale, nutrient-rich tomatoes, seedless berries, and fruit with a longer shelf-life. Livestock examples include cattle with shorter and shinier hair coats that make them more comfortable in high-heat environments. Again, such crops and livestock appear naturally, but innovative techniques can make them available to farmers sooner and enable farmers to grow them on a sustainable and larger scale.

There is also an emerging market in climate-smart agricultural products with a lower carbon footprint, including an energy-dense ingredient that can be used in animal feed, feedstock for sustainable aviation fuel, and renewable diesel.

Whether and to what extent consumers, farmers, and agricultural producers in the United States and other countries enjoy these innovations will depend on regulatory regimes and trade policies in the United States and around the world.

5. China has a top-down plan to dominate in agricultural seed technology and innovation.

Seeds are the 'chip' of agriculture," said Han Wenxiu, deputy director of the Office of the Central Economics and Financial Affairs Commission. Han Wenxiu was referring to semiconductors and computer chips, which are center stage in the U.S.-China technology race.

China has a top-down plan to dominate in agricultural seed technology and innovation. China recognizes the importance of seed innovation, and senior Chinese lawmakers have begun to review new laws to stop fake and substandard seeds.

For years, U.S. regulators and trade negotiators have been pushing China to adopt science- and risk-based transparent approaches to approving new traits that U.S. firms have spent hundreds of millions of dollars to develop. But all too often the U.S. side finds out after the fact that China

has had a meeting to evaluate applications, with the result that all domestically produced innovations have been approved while only one or two foreign traits have been approved.

With 1.4 billion people, China is a large and important market for U.S. agriculture. For full commercialization, the U.S. agricultural industry needs China's market, which means that U.S. innovators, producers, and exporters need China to approve U.S. innovations.

Roundtable participants agreed that the biotech section of the China Phase One agreement was good philosophically. But China has not fully implemented those biotech commitments.

The Chinese Communist Party appears to be shifting the narrative away from safety and towards intellectual property. This shift may reflect their own interests as they advance technologically.

Concluding remarks and next steps

Throughout the roundtable discussion, participants voiced widespread agreement on the need for clearer communication on U.S. agriculture across the supply chain from farmers, processors, marketers, and grocers. Farmers and consumers benefit when the discourse around farming, food, and food labels, including how we talk about gene-edited food products, comes from science-based sources (and not fear-based marketing).

Innovation is essential for achieving food security and sustainability in the coming decades. Congress should consider holding hearings on the challenges and opportunities to unleash innovation in service of this goal, including consumer perception and education, genetically modified foods, trade barriers, and the overlapping regulatory environment.

There was shared concern on the cumbersome U.S. regulatory environment that threatens to undermine U.S. global preeminence in the industry. Streamlining the U.S. regulatory regime for agricultural biotechnology would benefit innovators.

Finally, proactive trade policy that works to resolve technical and SPS barriers continues to be essential. Participants agreed that all these points deserve further attention.

This report summarizes a roundtable discussion held on March 2, 2023. Opinions expressed are solely those of the roundtable participants and not the Yeutter Institute or the University of Nebraska-Lincoln.