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## *Agricultural Biotechnology: Facilitating Trade for Food and Feed*

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I am delighted to speak to you about stewardship and sustainability in agriculture, especially as they relate to the element of international trade. The Office of the US Trade Representative (USTR) is a small government agency. We are responsible within the Executive Office of the President for developing the government's trade policy, negotiating trade agreements, and enforcing trade agreements.

Sustainability is like a stool with three legs, the environmental, social, and economic, and too often the economic leg gets left behind. And even when they are investigated, the economics of trade in the products of agricultural biotechnology are not always fully incorporated. A part of the job that I do every day is to help the US government, our ag stakeholders, and Congress understand the trade impacts of domestic issues and regulations such as insect resistance, herbicide resistance, because we have to take those into account for international trade. It is critical that we consider international trade impacts of new products coming to market and consider their stewardship necessary.

Opening and maintaining markets for US agricultural products, including those derived from agricultural biotechnology, is a top priority for the US government. We have a multi-agency, interagency process that works on these goals; USTR, USDA, the State Department, and all the US regulatory agencies cooperate in these efforts and coordinate to make sure that the use and trade of biotechnology products help US farmers compete in the global marketplace and help make US agriculture more sustainable.

With over \$40 billion in US exports of food and agriculture products, and that is just under 25% of our total agricultural exports, derived from biotechnology, and over 90% of all US corn, cotton, soybeans, and sugar beets, not to mention large percentages of papaya and alfalfa, as well, our and other countries' regulatory approaches to biotechnol-

ogy are critical components of our trade agenda. So for today what I want to do is lay a foundation for discussions you will have for the next day and a half.

By way of background, 28 countries already are growing biotech crops—an estimated 18,000,000 farmers—and more countries are going to be added. I recently met with representatives of Vietnam, which is now conducting field trials and has new regulations in place. Adoption rates globally for the main commodities are high: 82% of soybeans are biotech, 68% of cotton, 30% of corn, 25% of canola. The growth over the last 20 years has been phenomenal, particularly for soybeans and to a lesser extent corn. And it is not just the United States. In 2012 developing countries surpassed developed countries in planted acreage. So what does that mean for trade? Some have calculated the percentage of local trade times the major biotech crops. For soybeans, nearly 100% of global trade is biotech, for corn and cotton it is about 70%, and canola is over 80%.

Keeping all that in mind, let us add in some additional complications and look at it in a slightly different way. I want to show you how trade has changed over the past 40 years. In the 1970s, regional trade agreements were originally primarily focused in South America and Europe. In 1995, which is right about when biotech was being cultivated and started to be traded, there is a substantially increased amount of regional trade agreements, but they were still within a region, within the Western Hemisphere—in Europe, Africa, and South America. By 2014, however, these regional trade agreements had crossed regions and become global.

Now let us look at the United States more specifically. We exported about \$10.6 billion worth of corn to 71 different countries in 2014. That does not include any products made with corn, such as high-fructose corn syrup, just straight feed corn. And 93% of that corn is biotech. In the case of soybeans, including soybean meal and oil, we export about \$30.5 billion to 110 different countries, of which 94% is biotech. In the case of cotton it is about \$4.4 billion worth of exports to 68 different countries. That is 93% of our production and it is biotech.

When you add in the complications of what is coming down the road, it is no longer just herbicide tolerance and insect resistance. There is drought tolerance, higher yield, nitrogen use efficiency, insect resistance, and all the stacked combinations being developed. In the pipeline of products for soybeans there are feed efficiency, new oil profiles, disease resistance, and drought resistance.

With all those complexities, all those new products, the vast expanse of our trade obviously makes us a little concerned about what the future holds for trade issues. I will focus on some of our current issues on trade within the US government.

1. First, there is the lack of science-based regulation, particularly in developing countries. Peru, Kenya, India, Turkey are all major export markets for us. In these countries, our export markets don't have science-based regulations, and if those regulations don't function, it is obviously hard to get products authorized, which puts our exports at risk.
2. There is a second category of regulations that we call "asynchronous authorizations." By this we mean that different countries take different periods of time to

review and authorize the cultivation and import of new products or events. The poster child for asynchronous authorizations is China. China will not accept a dossier for consideration until after a product is already authorized in the country of export. We haven't quite figured out what that means for stacked products yet, since we don't always have authorizations here in the United States for stacks, depending on what the different events are. That means that China already has at least a three-year delay in their system for approving new products, products that US farmers could grow before they could be legally exported to China. The implications of this asynchrony are enormous and result in high risk, particularly as experienced last year by our corn growers and traders.

— I want to start first on the soybean side, because half of US soybean exports go to China. US soybean farmers are very careful about what biotech products they plant here and make sure that China has approved those new products before they are cultivated in the United States. But that means that our farmers are losing out on the benefit of new technology if they are having to wait four, five, seven, eight, nine years for new weed control mechanisms.

— In the case of corn, US corn exports to China, until recently, were not terribly significant. In 2008 they were under a million dollars. That is not a lot in our ag trade world. So farmers and traders took the risk of exporting corn. Then China decided they needed more corn and they bought a lot of corn from us, reaching over about \$1.3 billion in 2012. China wanted the corn so much that they ignored the fact that maybe some of those new corn events weren't approved yet in China. Then in 2014, China decided they didn't want our corn anymore, that they had enough. And lo and behold, their inspection authorities found some events that were not authorized in China yet, and that resulted in a \$3 billion disruption in US exports to China.

3. The third area is what we call "low-level presence." LLP can happen when an event is approved in a country of export but not yet in the country of import. This low-level presence will occur particularly in cases of asynchronous authorization. So there is a connection between the two. In 2008, the Codex Alimentarius Commission issued guidance on who would do food safety assessments for LLP situations. All three of our US regulatory agencies also already have policies in place for LLPs. But there is a lot of work going on right now, domestically as well as globally, to consider LLP, and Dr. Michael Schechtman will be discussing that in more detail tomorrow.
4. The fourth area is labeling. The US takes a science-based approach to mandatory labeling for biotech products. Here it is in simple terms: If the GE product is compositionally different from the conventional product, then the FDA requires that the difference must be on the label. However, other countries require labeling even if there is no difference in the product. And some countries, such as EU members, require labeling even if there is no novel protein left in a food product

because of the way it is processed. The prime example of trade disruptions resulting from labeling came in around 2000, when the EU imposed labeling and significantly cut off our soybean oil exports. Because European food companies were afraid of boycotts, they decided to source soybeans from non-GE countries.

5. The fifth example is a little bit more limited. In order for some countries to do the scientific reviews, they require that the technology developers do field trials in the country. China, again, is the example. If field trial permits are not granted, and currently China is not making those decisions in a timely manner, that means the technology developers can't get the science together in order to get authorizations.
6. Another issue we deal with is liability, and here the poster child is Turkey, where the liability is so severe for unapproved events or missed information from the technology developer that US technology developers aren't even submitting dossiers for approval in Turkey. Again, that disrupts our exports of corn, soybean, or cotton if we can't get these products authorized in the countries of export.
7. And then finally I must talk about the latest proposal from the European Union—what they call an opt-out provision—whereby even if the European Commission has determined that a particular event is perfectly safe, member states can decide on their own not to allow that particular event to be used in their country. This proposal undermines the common market of the European Union, and we fail to understand how a product that is determined to be safe by the European Commission cannot be allowed in individual countries. This is very important for Europe's livestock producers, who rely on biotech corn and soybeans for animal feed.

The US government focuses on opening up markets to US exports. In the case of biotechnology, we focus on promoting science-based and timely regulatory decisions. We do this in a number of different ways, what we call the sustained working level. This involves primarily the regulatory agencies and USDA's foreign agricultural service. For example, they will work to release individual shipments that have been held or work with individual countries to make sure that regulations are science based as they are being developed. In another area we work bilaterally with countries. That is often focused, as in the case of China, on starting a dialog on scientific innovation. One of our objectives is to work with China to help promote science-based regulatory decision making.

We also work with groups of countries "plural-laterally," where several organizations, including USDA, provide leadership in promoting, again, science-based regulatory approaches. We have what we call our Like-Minded Group, which we established in 2010. These are countries that also produce biotechnology, and we work together primarily in Brussels to raise concerns about European approaches and concerns, whether it is on opt-out or other issues.

A group that was initiated by Canada, Global LLP Initiative, is a slightly larger group of 15 countries that focuses on developing coordinated approaches to LLP. The USDA provides leadership in both North and South America within governments to promote

science-based decision making. Within APEC, the Asia Pacific Economic Corporation, there is a high-level policy dialog for agricultural biotechnology focused on information exchange and consensus building in the Asian Pacific region.

Multilaterally—with other World Trade Organization members—we routinely raise concerns with other countries on sanitary and phytosanitary measures: food safety, animal health, and plant health. We also have a committee on technical barriers to trade, essentially regulations, that are not related to sanitary and phytosanitary issues. And within the Codex Alimentarius the US government has dealt with various biotechnology issues over the years, including having decades-long conversations about labeling, LLP, and how to do food safety risk assessments.

We talk about biotechnology in trade agreement negotiations, most recently the Trans-Pacific Partnership negotiations with its 12 countries, under Canada's leadership. There is work to try to create a forum within TPP for information exchange and collaboration on LLP and asynchronous authorizations.

And finally, in the area of trade and technical capacity building, USDA has many projects working with third-world countries to help them develop sound regulatory systems. AID and the State Department do a lot of outreach as well.

So what is the future, and what are the key items I would like you to think about over the next day and a half? We have many current challenges associated with ag-biotech products, but they are not limited to the use of genetic engineering or recombinant DNA technology. We have new types of biotechnologies that are already here, some of which are referred to as new breeding techniques, including novel approaches such as genome editing, but there is no clear picture of how these new technologies will be regulated here in the United States or around the world. Scientific advances will continue to provide tools to improve crop varieties more precisely and more quickly, and they can help us address the suite of sustainability challenges confronting agriculture around the world. Engagements on emerging technologies will hopefully help create enabling policy environments for innovation and allow products from those innovations to be used and traded globally in a reliable manner. Farmers and businesses need predictability and certainty in the regulatory processes of other countries, and that is a need with which the US government can help. But the US and Canadian governments can't do it all, which opens the door for you to discuss later today and tomorrow the importance of stewardship on the part of technology developers to help facilitate trade for American farmers. Key to that responsible stewardship is ensuring that products are authorized in key export markets before introducing them for cultivation.

**Speaker Profile:** <https://ustr.gov/about-us/biographies-key-officials/sharon-bomer-lauritsen-austr>

## Q&A

**G. Thompson, Penn State:** How much of the embargoes that are slowing things down by the various mechanisms you described might be due to market manipulation as well?

**Lauritsen:** I think that is certainly the case with China. Obviously it is a very centralized government. They very much control how much of which particular product they import. So I would say that is certainly the case with China, but less so in less centrally planned governments.

**S. Pueppke, Michigan State University:** You paint a complex picture of trade and I wonder if this is just the way it is in general or if there is something about food and biotechnology that is different from other items that might be traded?

**Lauritsen:** I wouldn't say that agricultural biotechnology is unique, but that as new technologies are introduced within agriculture, there is a shared complexity, and whether it is agricultural biotechnology or new animal drugs, there is a range of things that our farmers, ranchers, and food processors use that other countries don't or don't have processes to authorize, and that creates problems. My office, and particularly the USTR, spend a tremendous amount of resources trying to deal with trade created by a whole host of new technologies. One of the reasons our approach to China last year was focused broadly on innovation in agriculture was that, on the road to the future as we see it, this is something that is going to grow with the introduction of new technologies.

**R. Hardy, NABC:** About ten years ago, we were very concerned about field testing of genetically modified crops, especially in the university setting. NABC at that time published a document on best management practices. It seems to me what we are talking about here is best management practices for farming. The National Research Council periodically does studies of standards, etc. Might we not fund a National Research Council study, maybe every five years, to investigate best management practices for producing crops?

**Lauritsen:** I'm a big fan of best management practices and I certainly think there is a role for such a study, whether it is on coexistence or trade. How to get that out to the hundreds of thousands of farmers is a question. There is also a role for best practices within the technology developer community, particularly in regard to stewardship. All of those would be welcome.

**T. Shelton, Cornell University:** Right now most of the biotechnology is involved with process, with grains, etc. You also mentioned papaya and a number of other crops, and I see this opening up to tremendous complications as we look at vegetables and fruits. I recently attended a seminar where someone was talking about China and how central planning was deciding which crops to grow and which to buy on the world market. Soybeans, which originated in Asia, are a water-intensive crop, and someone in China said they are probably not going to plant much of those, because they are so water intensive, and

that water is needed for the population. They are planning to get away from producing soybeans and just buy them on the world market, in which case they probably are going to have to be much more flexible on the traits they will accept. It is market demand and survival more than rules.

**Lauritsen:** That is absolutely right and that is what we saw with corn last year. When they decided that they had enough corn in storage, they started inspecting and testing the corn and found a scientific reason to stop imports. And you are right, they want soybeans and they are going to buy them from us and Brazil and Argentina—all of us biotech producers. One of the conversations with the Chinese last year was that they need to get their regulatory system functioning because US farmers may decide that they will not hold back on introducing a new technology and will just send their crops someplace other than China. I don't know if that will happen, but there is a lot of grumbling among farmers who want to use new technologies, in particular crops tolerant to different herbicides. The soybean market is too important for us, and our farmers will take the risk right now, but they are certainly starting to rethink this. The other issue with China is they are developing their own biotechnology traits. I remember going to a scientific conference a few years ago, and all the Chinese in the room picked up their cameras and took pictures of all the slides and took them back. So you know they definitely want to develop their own technology—and that is one of the reasons they are slow to approve imports. They are trying to play catch-up.

**S. Shantaram, University of Maryland of the Eastern Shore:** What is your prediction on the opt-out in the EU?

**Lauritsen:** I just had a report from our office in Brussels this morning, where four major political parties in the European parliament requested that the commission take back the opt-out proposal. Those of us in government—and you will appreciate this, it tends to be a joke—know we are doing our job when nobody is happy. When you make both sides unhappy, you know you have done your job right. That's what the commission did. We never thought the NGOs and the biotech industry in Europe would both agree that this proposal was bad. The environmentalists don't like it, and the major European farm organization actually publically criticized it. A French farmer led the protest. So, nobody likes it, and maybe it was their intention to put out something so bad that it would die. We'll see.

**S. Shantaram:** You know I have studied this transatlantic fight over GMOs so long here in the US that it is my very informal nonscientific conclusion that this whole debate is not about safety of the technology, but totally about international money that is being paid off in different arenas. How are they going to tackle this? Most of these decisions are not being resolved. What is the solution?

**Lauritsen:** I will answer that in two ways. It is purely political. If you look at surveys in Europe asking, "What do you look for when you buy your food?", only 5% of the

respondents talk about GMOs. For most European consumers, GMOs are just not at the top of the list. But if you ask Europeans, “Do you care if your food is a GMO?”, most will say they do, or 75% will say, “Yes we care and we don’t want it.” So it is how you ask the question, it is politics. They have a new commission, a new president leaning in that direction. As the US government, we will continue to focus on science-based decision making when we meet with the European food safety agency, and the working-level people there are also very much focused on trying to make science-based decisions. It is the political overlay that causes the problems. At some point in time, European agriculture is not going to be competitive. Without biotech advances, without advances in animal growth—when you travel through France and some of the other countries, you realize that the farmers there are just fine not using new technologies, and our farmers will simply go elsewhere. Europe is no longer the big market it used to be, and we spend less time on European issues—at least we did before we had to start trade negotiations with them—since it has not been as important a market as Asia in particular.

**R. Giroux, Cargill:** I can’t possibly let the USTR leave without asking questions. But first I am going to thank Sharon for all the hard things the USTR does for us as we try to do trade. All markets are important to US agriculture. I’m sure that’s what you needed to hear. Your work helps our farmers prosper here in the United States. Competition and being competitive is the number one priority and should be the number one priority for the department, as I am sure it is. I think what you have highlighted on your slides is very dramatic, it shows how we merge into a global food system. Compared to 1975, in 2015 we really have a developed global food system, and as you have noted, it is about integrating technology, not about innovation. We are innovating very well. There are lots of products. Many of them meet demands by our producers, but it is the integration step, the integration of those technologies into that global food system, that is the problem. And it is through science, it is by understanding what consumers want that we will find those solutions. I think the challenge in front of us, and one you highlighted very well, is to integrate the technology into what has become a global food system, to recognize that it is a global food system not only from a customer, but also from an origin perspective.

**Lauritsen:** Thanks Randy. And thank you.