Statement by Richard Wilkins, Treasurer
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before the
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Good afternoon, Mr. Chairman and Members of the Committee. I am Richard Wilkins, a soybean producer from Greenwood, Delaware, and Treasurer of the American Soybean Association (ASA). ASA is a national trade association with over 24,000 farmer members in 28 states and represents all U.S. soybean producers on national and international issues important to the soybean industry. ASA works closely with other producer groups, the grain trade, and technology providers on cross-cutting biotechnology issues. We appreciate the opportunity to present our views today on the role of enforcement in addressing challenges to exports of U.S. agricultural commodities and products derived from biotechnology. This issue is particularly important in the case of trading partners which do not follow or enforce their own rules, leading to serious trade disruptions which hurt not only exporters but also their own industries.

The Priority of Biotechnology Trade

Biotechnology is a key tool in our effort to satisfy the world's needs for food, feed, fiber and fuel, and to meet the challenge of a global population that is projected to reach 9.2 billion by the year 2050. Since the introduction of the first biotech soybean and corn traits in 1996, acreage planted to crops engineered via biotechnology to express agronomic and quality characteristics has expanded to encompass the majority of U.S. row crop production. In 2013, 93 percent of soybeans, 90 percent of corn, 90 percent of cotton, 93 percent of canola, and 98 percent of sugar beets grown in this country were genetically modified. As a result, timely approval of new biotech traits in importing countries directly impacts global market access for these crops.

Regulatory delays in importing countries have costly impacts on the entire U.S. value chain. For biotechnology companies, they can lead to delaying commercial launch of a new trait to avoid disrupting trade. Such delays erode patent terms, directly affecting investment in research and development of new traits. For growers, delays that impact commercial launches keep new seed technology out of U.S. farmers' hands and reduce U.S. farmer competitiveness. And for the grain trade, regulatory delays increase the cost, uncertainty and risk of trading grain and oilseeds globally and may cause trade to be disrupted.

The U.S. value chain has been a global leader for biotechnology advocacy for many years. ASA and 14 other major national trade associations have joined together as the U.S. Biotech Crops

Alliance (USBCA), which is working to find consensus on how to address asynchrony in international biotech regulatory approvals. Our members include farm organizations representing growers who depend on biotechnology-improved crops, companies whose advanced seed technologies we rely on to remain competitive, and companies which process and export our products to markets overseas.

In addition, opportunities are emerging with key countries such as Argentina, Brazil, Paraguay, and Canada which, combined with the U.S., produce and export an overwhelming majority of the world's crops derived from biotechnology. Both the soybean and corn industries have established international grower-based groups focusing on how our producers and countries can work together to expand trade and overcome trade barriers—the International Soy Growers Alliance (ISGA) and MAIZALL.

These multilateral partnerships are essential to efforts to achieve global food security. But they won't be enough. We are asking the Administration to make trade in biotech commodities and products a top trade policy priority, to engage other governments on biotech trade issues at the highest level, and to ensure that our trading partners honor their obligations under international trade rules. Only with high level, multi-ministry engagement will we be able to overcome current regulatory challenges, minimize the potential for trade disruptions, and strengthen competitive access for U.S. agriculture. Our objective is to facilitate market access for U.S. agricultural commodities produced through biotechnology through bilateral and multilateral trade negotiations, including negotiations underway in the TPP and TTIP. Enforcement tools through the World Trade Organization exist, but we strongly believe increased focus on working with important trading partners to remove barriers to trade through negotiation could help us resolve problems without resorting to litigation.

Regulatory Challenges to Biotech Exports

As a relatively new and groundbreaking means for increasing yields and enhancing quality of crops which provide food, feed and fiber, agricultural biotechnology faces challenges in the different ways in which importing as well as exporting countries have chosen to regulate it. In the U.S., the Coordinated Framework agreed to by USDA, EPA and FDA in 1986 established the principle that, once a commodity with a biotech trait is determined to be safe for food, feed, and the environment, it is deregulated. This determination is grounded in science-based decision making. In the years prior to and following the introduction of biotech crops, study after scientific study by credible academic, regulatory and scientific bodies in the United States and around the world have determined that crops produced through agricultural biotechnology are as safe as their conventional counterparts. Indeed, some biotech crops have improved nutritional profiles, while others reduce environmental impacts by facilitating conservation tillage and reducing herbicide or pesticide applications.

Other countries have adopted criteria for approving the production, import and use of biotech crops and products. However, these decisions are subject to regulatory systems which differ significantly, and which can result in lengthy delays between approval in the country which

produces the biotech crop and approval in countries which import the commodity. This is a key concern because, until an importing country approves a new biotech trait, the presence of even a trace amount of that trait in a cargo can result in its rejection, causing major losses to the shipper. This "zero tolerance" policy makes addressing asynchronous regulatory approvals a critical priority in maintaining and expanding trade in biotech commodities and products.

Depending on the country, delays in regulatory approvals can be substantial. China, by far the largest market for U.S. soybeans, does not initiate regulatory review of a new trait until it has been approved in the exporting country. This can delay commercialization of a new biotech crop in the United States by over two years. The regulatory process in the European Union has become so politicized that companies have been forced to postpone commercialization of new traits in the United States, sometimes for years.

The Need for a Global Low Level Presence Policy

A system for harmonizing international biotech approvals is urgently needed. The optimal approach would be for countries to agree to synchronize their approval timelines, or to mutually recognize each other's approval decisions. However, given the disparate national regulatory approaches currently in place, these solutions may be many years in the future.

In fact, harmonization should not be so elusive. All major U.S. export markets are WTO Members, and WTO requirements are quite specific. Under WTO rules:

- Regulatory decisions must be based on sound science and a risk assessment;
- Risk assessments must be performed according to standards established by international organizations such as Codex Alimentarius and the International Plant Protection Convention;
- Applications must be processed without undue delay;
- Approval procedures must be transparent and regulators must be responsive to requests for information from the applicant;
- Procedures must exist for reviewing complaints from applicants regarding the approval process and for taking corrective action;
- Data requirements must be limited to what is necessary for the assessment of risks;
- Conditions of approval must be no more trade-restrictive than necessary to meet level of protection.

If our trading partners respected these obligations, the trade barriers we are facing would disappear.

A shorter-term answer would be for the U.S. and other governments to establish a global Low Level Presence (LLP) policy. An effective LLP approach would allow a commercially feasible amount of a biotech trait which has been determined to be safe and approved in an exporting

country but not yet approved in an importing country, to be present in a shipment without resulting in its rejection.

Unfortunately, the global discussion on LLP has not advanced, and we believe U.S. leadership on this issue is critical to bringing other countries to the table. We respectfully urge the Committee to work with the Office of the U.S. Trade Representative, USDA, EPA, and FDA to establish a LLP policy that can serve as an example, and then to work with other major exporting and importing nations to establish workable Low Level Presence policies globally.

Biotechnology Approvals in China

I would like to return to my earlier comment on the importance of China as a market for U.S. biotech commodities and products. China is by far the largest buyer of U.S. soybeans, importing over one-fourth of our annual production. The Department of Agriculture forecasts that China will also become the world's largest corn importer by 2020. U.S. agriculture is a long-term committed partner in working with China to meet its food security needs.

In the past, Chinese officials routinely announced regulatory decisions on new biotech traits three times per year, and their system processed new applications in a 24-30 month timeframe according to China's biotechnology regulations. However, since 2011, Chinese regulatory decisions on new traits have been issued only once a year, and it has been a full year since the last announcement on "new" corn or soybean traits. Delays are increased by requirements that unnecessarily lengthen the approval process. As indicated above, China refuses to accept an application for regulatory review before the product in question has been approved in the exporting country. Moreover, China requires in-country field tests even for products that will be imported only for food, feed or processing rather than cultivation. These requirements cannot be justified scientifically and are therefore clearly WTO-inconsistent.

It is critically important for the Administration to engage the Government of China at the highest level to reach a mutually beneficial understanding on trade in biotech commodities. This engagement should include the Joint Commission on Commerce and Trade (JCCT) and the Strategic and Economic Dialogue (S&ED). China's future food security depends, in large measure, on our ability to commercialize new biotech traits in a timely and predictable manner. We ask for the Committee's support in achieving this understanding between our two countries.

EU Biotech Policies

The U.S. also has serious and longstanding problems with the biotech regulatory approval system in the European Union. While the EU initially approved the first biotech crops in 1996, it has since taken steps to limit their use and to slow approvals of new traits. In 1999 and again in 2004, it adopted laws and rules which require that biotech commodities be able to be traced to their country of origin and that products containing more than 0.9 percent of a biotech ingredient be labeled. Faced with the likelihood of negative reactions by consumers to

pejorative labels, food companies reformulated their products, effectively eliminating biotech-derived foods in EU supermarkets and restaurants.

According to the EU, the purpose of the labeling requirement is to provide information to EU consumers who wish to purchase non-biotech products. The EU could have accomplished the same objective without distorting trade by establishing voluntary labeling standards for non-biotech foods. A WTO Member is obliged to choose a less trade-restrictive measure if one that accomplishes its objective is reasonably available.

The EU also has allowed its process for approving the importation of new traits for food and feed processing to become politicized. A number of Member States routinely vote against import authorizations and thus seriously delay and block approvals, despite positive safety reviews and recommendations of these new traits by the European Food Safety Agency. It then falls on the European Commission to decide whether or not to issue authorizations for the import of commodities and foods containing new biotech traits. However, even Commission decisions have been delayed for months or years due to political considerations. The end result is that the EU routinely fails to meet the approval timeframes established in its own regulations, often by many months or even years. And the situation is getting worse, not better.

The EU's College of Commissioners is expected to decide by next month whether to approve eight new biotech events that have gone through the tortuously-slow EU review and approval system, received positive EFSA determinations, but failed to receive approval by Member State representatives at the Standing and Appeals Committee levels. We hope the Commission issues final authorizations for these eight events without further delay.

The EU approval process has already been the subject of WTO litigation. In 2003 a WTO panel ruled that the EU was guilty of undue delay in the processing of applications. In the wake of the ruling, the U.S. government pushed hard for changes in EU practices, and, for a time, the situation improved marginally, as the moratorium on processing applications was removed and the Commission restarted the approval process. However, delays persist, and significant political interference in the risk management process continues. This issue should be among the highest priorities for the Administration within the TTIP, and the agreement should ensure the EU fully complies with its WTO obligations.

The result of the EU's unscientific biotech labeling requirements and politicized import approval process has been a sharp drop in sales of U.S. soybeans and soybean products as well as of other commodities to EU markets. U.S. soy sales fell by more than half, from 9.2 million metric tons in 1995 to 4.5 million tons in 2013. U.S. corn exports remain at near zero as new traits have been commercialized which have been hung-up in the EU approval system.

Compounding the situation, either by accident or by design, the EU has imposed its approach to biotechnology on other countries which export agricultural commodities and foods to EU markets. Many of these are developing countries with longstanding trade ties to EU Member States. Rather than forego exports, they have rejected adoption of biotech crops which would

benefit both their farmers and their consumers. For the same reason, some of these countries prohibit imports of biotech commodities from the U.S. and other exporters.

TTIP Negotiations

An approach currently available for addressing biotech barriers in the EU is through the TTIP negotiations. ASA sent letters and testified on several occasions prior to the launch of TTIP on the need for the negotiations to address the EU's labeling regulations and the fact that it is not meeting its own timelines for making decision on biotech trait applications. However, we have seen statements by EU negotiators that the EU will not consider changing any of its biotech laws or regulations as a result of a TTIP agreement.

This is not an acceptable position. The very nature of trade agreements necessitates the changing of laws and regulations by all parties to implement their provisions. We urge the Administration and Congress to ensure that key EU biotech policies that discriminate against U.S. exports are addressed within TTIP. Specifically, we believe the following changes must be achieved, either within or in advance of a TTIP agreement:

1. The EU must take the steps necessary to comply with its own regulations and timeframes for making science-based decisions on biotech products for import. This should include improved timeliness of EFSA reviews and Member State or Commission decisions on biotech crops intended for import and food and feed processing.

2. Commercially meaningful tolerances must be established for the low-level presence of biotechnology-derived commodities which have been approved by U.S. regulatory authorities but for which reviews have not yet been completed by EU regulatory bodies.

3. Poland's discriminatory and unjustified law which would ban the use of biotech ingredients in animal feed must be removed. Although implementation of the law has been delayed until 2017, it has no basis in science, is trade restricting, and contravenes the EU's WTO commitments.

4. The EU's trade-restricting, mandatory traceability and labeling requirements must be modified or replaced with non-discriminatory rules that allow food manufacturers to market – and consumers to choose – GMO-free products. Such policies have worked well, in both the EU and the United States, to allow food manufacturers to market, and consumers to choose, organic products without stigmatizing all other food products that contain ingredients produced via non-organic, modern or traditional agricultural practices.

Beyond biotechnology, ASA has other objectives that we believe must be achieved within or leading up to a TTIP agreement. These include:

1. Addressing the EU's Renewable Energy Directive, which imposes discriminatory greenhouse gas emissions reduction requirements on U.S. soy-based biodiesel and sustainable production documentation and practices on U.S. soybean farmers;

2. Ensuring that thresholds for important crop protection products used on U.S. crops are not eliminated for non-science based reasons;

3. Ensuring that a new protein-crop subsidy scheme in the latest version of CAP reform does not undermine EU commitments under the WTO; and,

4. Removing non-science based barriers to U.S. livestock products.

We have provided the Administration with information on these issues and would be happy to share this information with the Committee as well.

Conclusion

In conclusion, the U.S. must insist that biotechnology be a top priority in TTIP, TPP, and future trade agreements, including any resumption of the Doha Round. These negotiations should directly address the very real problems we are experiencing in biotech trade, in particular the failure of trading partners to follow their own legally mandated timelines and procedures for biotech authorizations. Only when there are real "teeth" in trade agreements will the U.S. be able to use enforcement tools to protect our interests. If the Administration and Congress do not press our trading partners to address biotechnology in trade negotiations, it will make the task of improving conditions for biotech exports that much harder.

We greatly appreciate the Committee's support in encouraging the Administration to address policies that are inhibiting the growth of agricultural biotechnology exports as well as other trade-restrictive practices.

Thank you again, Mr. Chairman. I will be happy to respond to any questions.