U.S.-CHINA ECONOMIC SECURITY REVIEW COMMISSION
HEARING ON "CHINA'S AGRICULTURAL POLICIES: TRADE, INVESTMENT, SAFETY, AND INNOVATION"
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TESTIMONY OF JOSEPH DAMOND, EXECUTIVE VICE PRESIDENT, INTERNATIONAL AFFAIRS, BIOTECHNOLOGY INNOVATION ORGANIZATION

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to provide testimony to the hearing on "China's Agricultural Policies: Trade, Investment, Safety, and Innovation." We hope our contribution will assist the U.S.-China Economic Security Review Commission's efforts to advise Congress on the impact of Chinese policies and regulations on U.S. agricultural interests.

BIO is a non-profit organization with a membership of more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in almost all 50 States and a number of foreign countries. BIO's members research and develop health care, agricultural, industrial, and environmental biotechnology products. The U.S. life sciences industry, fueled by the strength of the U.S. intellectual property (IP) system, has generated hundreds of drug products, medical diagnostic tests, genetically engineered crops, and environmentally beneficial products such as renewable fuels and bio-based plastics. BIO's members engaged in the research, development and commercialization of crops derived from biotechnology are negatively impacted by a regulatory system in China that is not timely, transparent, predictable, or science-based. The impact of the Chinese regulatory system is felt not only by BIO members, but by their farmer customers and other downstream segments of the supply chain.

OVERVIEW OF REGULATORY CHALLENGES FOR BIOTECHNOLOGY DEVELOPERS

U.S. agriculture is a critical component of the U.S.-China bilateral trading relationship, representing over 15 percent of total U.S. exports to China, and is among the few sectors with a positive trade balance. For U.S. grain and oilseed exports – over 12 percent of total U.S. exports to China - the timing and predictable implementation and enforcement of existing Chinese laws, regulations, and official guidance with respect to the GMO approval process is vitally important to ensuring a functional and rules-based trading relationship.

Biotechnology traits are synonymous with modern agriculture. Since the first commercial traits were introduced in 1996, the technology has allowed farmers to realize higher yields, particularly for corn and soybeans, while simultaneously requiring fewer inputs. Over the past 22 years U.S.

adoption of biotechnology has soared to over 90 percent of total corn and soybean acres, a testament to the value and importance of the technology to the agricultural production community. With over 30 percent of U.S. soybean production exported to China, and the volatile Chinese demand for U.S. corn and corn products, regulatory approval for biotechnology traits directly impacts market access for these products.

Agricultural commodity trade is commonly handled in bulk, and aggregated as commodities move through the supply chain. U.S. grain and oilseeds are traded globally and because agricultural biotechnology is heavily regulated around the world, biotechnology companies begin the international regulatory approval process several years prior to the commercial launch of a new agricultural biotechnology product in the United States.

The goal of U.S. biotechnology firms is to synchronize international import authorizations. However, current Chinese practice mandates that the Chinese approval process cannot begin until the product has been deregulated in a country of origin. This precondition creates a significant gap between authorizations in cultivation countries and China, as well as between most other importing countries and China. As a result, biotechnology companies often delay the commercial launch of a new biotechnology trait in the United States, so to reduce the potential for grain shipments to China from being rejected.

BIO members are committed to the stewardship of agricultural biotechnology products, including attaining regulatory approvals for novel agricultural biotech traits in export markets prior to commercialization. Our members endorse this practice in order to allow for the smooth functioning of the global grain trade. This system only works when the regulatory regimes of major importers, such as China, are functional[1].

Over the past few years China's regulatory approval process has become increasingly asynchronous and a choke point in bilateral trade. The process is opaque and mounting delays require high-level political intervention to advance approvals. The biotechnology industry is concerned that these delays are not based on science, but rather are being influenced by factors outside the risk assessment process. Whatever the cause, the impact on the U.S. value chain is substantial and widespread.

There are currently 10 products awaiting final approval in China, with an average wait time of 5 years and 4 months from the time the products were submitted in China, or about 7 years and 4 months from the time the products were submitted for approval in the cultivation country. Each

[1] A "functioning" regulatory system is science-based, with clearly defined timelines and processes for regulatory review and decision-making, and for appropriate protection for proprietary information and data. In a "functioning" regulatory system, the regulatory and decision-making processes must be predictable and not subject to undue political influence. The term "predictable" includes, without limiting the definition, that the regulatory system accepts submissions in the ordinary course without preconditions related to the regulatory status in other countries, and the regulatory process for import authorization is completed routinely within 30 months or less. Since regulatory systems continue to evolve and change globally, countries' systems may become functional or dysfunctional. Over time, a country should develop a track record of systematic authorizations with consistent and predictable timelines and processes. (BIO Product Launch Stewardship: https://www.bio.org/sites/default/files/Product-Launch-Stewardship-11272012.pdf).

of these products have been approved and have been legal to cultivate in the United States, and several other countries, for many years. The products under review are also legal to import for food, feed and processing in other major markets for many years, thus the technology developers are only waiting for import approval from China before full commercialization. These products include beneficial traits for soybeans, corn, canola, and alfalfa that can help farmers increase their productivity and reduce their cost of production at a time of declining farm income. Chinese regulatory delays factor heavily on U.S. farmers planting decisions, as a biotechnology provider may opt to delay commercialization of a new biotechnology seed variety prior to Chinese authorization. Delayed access to new technology limits U.S. competitiveness, reduces investment in U.S. innovation, and erodes patent life and intellectual property protection for U.S. biotechnology companies.

China's Biotech Regulatory Framework

The Ministry of Agriculture (MOA) is the lead agency responsible for the approval of agricultural GMOs for import and domestic production, as well as the formulation of GMO regulations. MOA's authority covers all activities concerning agricultural GMOs, including approval and licensing with respect to the research stage, field trials stage (including intermediate trials/confined field trials, environmental release and production trials), production and processing, distribution, marketing, import and export, and labeling. MOA's National Biosafety Committee is the regulatory body that evaluates domestic and foreign applications for biosafety certificates for biotechnology products. This committee is composed of about 75 experts from a wide variety of backgrounds and various ministries, research institutions, and universities.

The 2001 State Council regulations and the 2002 MOA Import Measures provide that MOA will determine whether to approve an import application within 270 days after receipt of an application. In practice the approval period takes significantly longer, for myriad reason, such as the sequential nature of the process and the fact that MOA routinely requests applicants for additional data that is unrelated to the intended use of the product

MOA's precondition on commencing a risk assessment, protracted pace, and complete uncertainty and lack of clarity with regard to the milestones and requirements of the regulatory system devalues the return-on-investment for agricultural research and development, and prevents American farmers from accessing critical new production tools. Additionally, this system precludes seed companies from being able to accurately plan for product launches, causes the loss of valuable years on patent lifetimes, and leads to excessive costs related to managing stewardship and separate production channels. ***These factors effectively reduce American competitiveness in agriculture, and have an impact on American jobs, the U.S. trade deficit, and the economic viability of rural America.***

Systemic Solution

The Biotechnology Innovation Organization continues to seek a systemic solution to the challenges with China's regulatory system. This means:

1. China should move all products through the regulatory queue; products in the final stage should be approved without delay and other products in earlier stages should advance. China should align current data requirements to international standards, and return to a predictable and timely regulatory process.

2. China should develop scientific rationale distinctions between import approvals and in-country cultivation approvals. For import approvals, the following changes should be made:
    a. No requirement that a risk assessment begin only after the product is deregulated in a major production market - China should accept submissions as soon as the data is generated to conduct the appropriate risk assessment.
    b. The MOA convenes formal National Biosafety Committee (NBC) meetings at least quarterly to consider applications and issue approvals and the MOA provides feedback to applicants within 20 days of an NBC recommendation
    c. In-country environmental trials should only be required if the safety assessment identifies environmental risks. In the case when in-country environment trials are needed, the overall process and timeline should be largely streamlined and shortened.
    d. China should recognize the safety studies conducted outside of China and eliminate the requirement for in-country molecular and food testing.

In the absence of systemic change, farmers will continue to be denied access to beneficial technologies and BIO member companies will be hindered in their capacity to increase investments and increase jobs in the United States.

RECENT HIGH-LEVEL CHINESE COMMITMENTS TO THE U.S. GOVERNMENT

The governments of the United States and the People's Republic of China have engaged in high-level negotiations since 2014 to address these issues. Despite commitments, including Presidential level agreement, commitments remains largely unfulfilled.

In November 2014, during 25th Joint Commission on Commerce and Trade (JCCT), the U.S. and China agreed on the need to intensify science-based agricultural innovation for food security, and committed to strengthen dialogue to enable increased use of innovative technologies in agriculture.

Less than a year later, on the margins of President Xi's State Visit in September 2015, the U.S. hosted the inaugural meeting of the Strategic Agricultural Innovation Dialogue (SAID), in which both countries committed to strengthen cooperation and create an enabling environment for

agricultural innovation in the two countries and the world at large. In addition, China's Minster of Agriculture, Han Changfu, and then U.S. Secretary of Agriculture, Tom Vilsack renewed the Memorandum of Understanding between the Ministry of Agriculture and Rural Affairs of China and the U.S. Department of Agriculture. The objective of the MOU was to promote comprehensive, sustained, and balanced development of agricultural cooperation between both countries.

Most importantly for the topic at hand, the U.S. and China, during SAID, conducted in-depth discussions on the administration of agricultural biotechnology, and committed, as part of the Summit communique to further improve approval processes, specifically:

> Both sides reaffirmed the importance of implementing timely, transparent, predictable, and science-based approval processes for products of agricultural biotechnology, which are based on international standards. Both sides committed to strengthen policy formulation and information exchange, share experience in and practices of research and development, regulatory administration, and safety approval of agricultural biotechnology; further revise and improve regulation, based on comprehensive consultations with domestic and international stakeholders; and, enhance capabilities in safety administration and safety approval of agricultural biotechnology products.[2]

Following the SAID, the U.S. and China met again in June 2016 for the Strategic and Economic Dialogue (S&ED), in which both countries reaffirmed and added definition to their commitments at the SAID. To implement its commitment to improve the approval processes for products of agricultural biotechnology, there was agreement that:

> China is to revise the Regulations on the Safety Evaluation of Agricultural GMOs (Decree 8) and related measures. China's revisions are to be consistent with the outcomes of the administration of agricultural biotechnology agreed in September 2015 at the U.S.-China Leaders' Meeting. China is to review applications of agricultural biotechnology products in a timely, ongoing, and science-based manner, and complete final approvals in line with the relevant laws and regulation upon the completion of assessments by the National Biosafety Committee.[3]

Despite efforts by the U.S. to hold China to its commitments, the failure of China to implement a timely, transparent, predictable, and science-based approval process, as evidenced by the numerous products not advancing through the system, necessitated a new approach by the U.S. to incentivize reform in China.

In May 2017, President Trump and President Xi agreed to advance U.S.-China economic cooperation with a 100-day action plan under the framework of the U.S.-China Comprehensive Economic Dialogue (CED). Subsequent meetings led to consensus on addressing issues in areas

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[2] The White House. *FACT SHEET: U.S.-China Economic Relations.* Washington, D.C. September 25, 2015.
[3] U.S. Treasury Department. *2016 U.S.-China Strategic and Economic Dialogue Joint U.S.-China Fact Sheet – ECONOMIC TRACK.* Washington, D.C. June 7, 2016.

including agricultural trade, financial services, investment, and energy. Under agricultural trade, there was agreement that:

> China's National Biosafety Committee (NBC) is to hold a meeting by the end of May 2017, to conduct science-based evaluations of all eight pending U.S. biotechnology product applications to assess the safety of the products for their intended use. No additional information unrelated to safety assessment for intended use is to be requested of the applicants. For any product that does not pass the safety evaluation at the NBC meeting held in May, the NBC is to operate with transparency by providing in writing to the applicants a complete list of requested information necessary to finalize the safety assessment for the products' intended use, along with an explanation of how the requested information would be relevant to the safety of the products' intended use. The NBC is to hold meetings as frequently and as soon as possible after an application is resubmitted in order to finalize reviews of remaining applications without undue delay. For the products that pass the safety evaluations of the NBC, China is to grant certificates within 20 working days in accordance with Administrative License Law of the PRC.[4]

To date, only 4 of the 8 products have received final approval, and China has not held another NBC meeting since June 2017. The objective of the 100-day plan was to establish good faith between the U.S. and China and enter into a one-year plan intended to address systemic issues in the regulatory system. In the absence of approval for all 8 products, the governments were unable to continue the process towards resolving this issue that has challenged U.S. farmers, seed technology companies, and exporters.

During the past four years, and to two administrations, China has made and failed to uphold commitment after commitment to implement a timely, transparent, predictable, and science-based approval process for products of agricultural biotechnology. The impact of which is most felt by U.S. farmers as they are unable to access new technologies that would benefit them in the increasingly competitive global marketplace.

CONCLUSION

In conclusion, the BIO requests the U.S. Government to hold China to its unfulfilled commitments to systemically address the deficiencies in its regulatory system for products of agricultural biotechnology. American seed technology companies, farmers, and exporters need a timely, transparent, predictable, and science-based approval process to unleash American innovation and enhance the competitiveness of U.S. farmers and exporters, thereby creating jobs and reducing the trade deficit with China.

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[4] Department of Commerce. *Joint Release: Initial Results of the 100-Day Action Plan of the U.S.-China Comprehensive Economic Dialogue.* Washington, DC. May 11, 2017.

APPENDIX I: U.S. Agricultural Exports to China, 2007-2016