Howard Minigh
President & CEO

TESTIMONY OF MR. HOWARD MINIGH

President & CEO, CropLife International

Provided to the U.S.-China Economic and Security Review Commission Hearing on "China's Agricultural Policies: Trade, Investment, Safety, and Innovation"

26 April 2018, Washington, DC

Chairman Cleveland, Vice Chairman Goodwin, and distinguished Members of the Commission, thank you for the opportunity to submit written testimony to this hearing on China's Agricultural Policies: Trade, Investment, Safety and Innovation. We appreciate the Commission's recognition of the plant science industry as a valuable contributor to the discussions today and we hope that you find our input useful as you develop policy recommendations for consideration by Congress.

I represent the seven funding members of CropLife International – the largest global companies engaged in research, development and commercialization of innovative crop protection products, seeds and plant biotechnology traits. CropLife International champions the role of agricultural innovations in crop protection and plant biotechnology to support and advance sustainable agriculture worldwide. Our members bring innovative agricultural solutions to the world marketplace that allow farmers to grow more crops, on less land, using fewer resources. The world needs farmers, and farmers need plant science. CropLife International and its far-reaching global network is proud to be at the heart of helping farmers grow and engage in international, national, and local dialogues that support sustainable farming.

Situational Overview

China is the largest importer of agricultural biotechnology products in the world. At the same time, import approvals for agricultural biotechnology products in China take longer than any other country worldwide, and the timelines associated with these approvals continue to lengthen. For many years, and despite numerous unfulfilled commitments by senior leadership in China and advocacy by CropLife International, its value chain partners and governments of all major grain exporting countries, China's regulatory system for plant biotechnology has remained unpredictable and unworkable. The unprecedented and unpredictable delays in regulatory decisions impede adoption of needed agricultural innovations, deprive growers in the United States and other cultivating countries of new technologies to improve productivity, and have the potential to disrupt global trade.

At present, CropLife International members have ten agricultural biotechnology products in the final stage of import approval for use as food or feed in China, with initial regulatory submissions dating back to 2011 to 2013. All ten products have many approvals in other major import and cultivation markets (a minimum of nine other countries), all of which were obtained in a fraction of the time the products have been pending in China. All ten products have been fully deregulated in the United States, not only for use as food and feed, but also for cultivation. Compounding the long delays, China does not allow new product applications to MOA until there is an approval (or deregulation, in the case of the United States) in the country of origin. This adds at least another two years to the overall timeframe in China. For the ten currently pending products, this means they have been in the regulatory process in China for an average of 7 years and 4 months (88 months) - orders of magnitude longer than the timelines associated with the majority of countries around the world.

The impact of these approval delays in China is keenly felt by CropLife International members because, as part of our commitment to product launch stewardship, our members commit to obtaining regulatory approvals for new products in major import markets prior to commercialization. Our members made this commitment to support the smooth flow of commodity trade around the world, but it is dependent on the regulatory systems of those major markets being functional systems that lead to decisions in predictable timeframes.

China's Ministry of Agriculture (MOA) approved two new agricultural biotechnology products for import as food and/or feed in June 2017 and two in July 2017. There has been no movement on approvals since July 2017. In fact, there has not been a meeting of the National Biosafety Committee (NBC), the administrative body that reviews regulatory submissions for agricultural biotechnology products, since June 2017. CropLife International members watch and wait as the months pass, with no action to schedule an NBC meeting and no news on when they can expect this meeting to happen - all while the planting season in the United States starts without allowing farmers access to these new products that remain held up because of the delays in China's agricultural biotechnology approval system.

Delays in approvals of these products mean delays in marketplace competition that would benefit U.S. farmers and consumers by providing choice and diversity. The persistent delays undermine global agriculture by limiting the production tools available to farmers around the world, jeopardizing market access for agricultural products imported into China, and reducing long-term private sector investment in agricultural production technology. As the world's largest importer of agricultural commodities, it is vital that China responsibly administer its biotech regulations, and fulfil the requirements set out in their own legislation to avoid continued delays.

Chinese Investment in Agricultural Biotechnology

The Chinese government invests heavily in its domestic biotechnology industry, and has identified biotechnology as a strategic emerging industry. Since 2008, the total amount of Chinese government investment in its domestic biotechnology industry is estimated to be RMB24billion (approximately US$3.8 billion), with much of this funding matched by private industry. This significant investment far exceeds public sector investment in biotechnology in any other country in the world, including the United States. The stated priority is to conduct research and development on biotech crops relevant for use within China, and there are significant efforts to develop biotech crops for local cultivation.

In 2016, China's State Council released the 13th Five-year Plan for National Science and Technology Innovation, which sets the goal of commercializing locally-developed Bt-cotton, Bt-corn, and herbicide-tolerant soybeans by 2020. President Xi has referenced these goals in public speeches numerous times, and it remains a clear priority for the country. However, none

of these statements or investments have led to changes in policy, or movement toward public acceptance, or streamlined regulatory systems for agricultural biotechnology crops in China.

China's Approval Process for Agricultural Biotechnology Crops for Import

China's regulatory approach to agricultural biotechnology is outlined in the State Council's "Administrative Rules for Safety of Agriculture GMO" of 2001 (revised in 2017) and is implemented by a number of MOA measures, including, *inter alia*: MOA's Ministerial Decrees 8 [2002] "Administrative Measures on the Safety Evaluation of Agricultural Genetically Modified Organisms", revised in 2016 by MOA Decree 7 [2016]; and, MOA Decree 9 [2002] "Administrative Measures on the Safety of Agricultural GMO Imports". MOA has primary responsibility for the approval of agricultural biotechnology crops for import and domestic cultivation, as well as the development of related policies and regulations.

As indicated above, the first step for new agricultural biotechnology crop import applications in China - before an application can be submitted to MOA – is the product must be approved (deregulated) in the country of origin. No other major importing country has this requirement. After this first step, MOA Decree 9 [2002], which specifies that MOA should respond to an application for a biosafety certificate within 270 days, requires the applicant to submit an application to MOA's "Administrative Examination and Approval Office". The application must include certifications that the exporting country allows the use and sale of the product in its domestic market, and that the product has undergone tests showing no harm to animals, plants, or the environment. The NBC then considers the application for a permit for local studies, including environmental safety (field trials) and food safety (animal feeding) that must take place in China. Once that local study permit is approved, authorized domestic institutions conduct the relevant local studies, using government funding, to verify data provided by the applicant. The NBC then receives reports issued by the domestic institutions and reviews them at the final stage of approval. If the application passes this final NBC review, the applications are then subject to MOA's administrative review before receiving a final approval and biosafety certificate. If the NBC has additional questions or requests additional data, the applicant must resubmit the application with the required data for review at the next NBC meeting.

There is also an overarching law in China called the Administrative License Law [2003, as amended, ALL] that requires government agencies to make an administrative license decision within 20 working days after accepting an application. It also specifies that requests for additional information or materials shall be made in a one-time single request, preventing government agencies from making piecemeal and repetitive requests to delay the process. The effect of the ALL is that any NBC decision must be communicated to applicants within 20 days of passing NBC review and that repeated requests for additional information by NBC members is not permitted. MOA has not been observing the requirements of ALL.

This convoluted approval process invites delays at every stage. First, as indicated above, an approval must be obtained in another country prior to the application being accepted by MOA. This is the first delay of at least 24 months. Second, the NBC typically asks multiple questions during the application process for field trial permits, sometimes requiring resubmission more than once, resulting in additional delays. Third, feedback from the NBC meetings is usually not provided to applicants within the 20-working day timeframe required by the ALL, causing further delays. Then, during the field trial process, applicants rely on Chinese institutes to undertake the field trials and issue required reports in a timely manner, which is also a source of delay. Next, the application for final safety certificate (final approval) goes through the same process of submission, delay in communicating questions to applicants, resubmission, waiting for an NBC meeting to be convened, more questions, resubmission (again). In fact, for the ten products currently awaiting final approval in China, the NBC has reviewed the applications and asked

questions on three of the pending applications five times. Most of the questions concerned data already available to MOA for several years. On top of all these delays, the NBC meets only twice per year, so if questions are asked and resubmissions are required, applicants must sometimes wait six months for the next NBC meeting for responses to be considered.

These delays – requiring a country-of-origin approval, scheduling only two NBC meetings per year, slow communications of NBC meeting results and MOA decisions to applicants, asking redundant questions often unrelated to the intended use of the product - create the cumulative delays that cause CropLife International members to delay bringing innovative new products that increase productivity to American farmers. Global trade could be impeded if new agricultural biotechnology crops are introduced to the global marketplace without import approvals in the world's largest biotech crop importer.

Notably, the government of China recently undertook a restructuring of its government agencies, and the current MOA will be renamed the Ministry of Agriculture and Rural Affairs. The scope of work of the new ministry will incorporate relevant rural affairs and rural investment management responsibilities of the National Development and Reform Commission, Ministry of Finance, Ministry of Land and Resources and Ministry of Water Resources. While there are no stated plans for this new scope of work to have an immediate impact on agricultural biotechnology regulatory oversight, creating more bureaucracy within an already heavily-tasked Ministry will likely draw resources away from this area of work. Minister Han Changfu remains as the Minister of this newly-formed Ministry of Agriculture and Rural Affairs, which leads CropLife International and its members to expect more of the same policy approach overall.

The above is intended to illustrate the lack of predictability, transparency and timeliness of China's biotech regulatory process. Continued recycling of questions is used as "justification" for non-science-based delays in regulatory decisions. This stifles innovation by CropLife International's members and denies farmers in the United States and other cultivating countries access to productivity-enhancing new technologies that have been approved for years in cultivating and import markets around the world.

Regulatory Trends in China

Recently, China's State Council revised various regulations on administrative procedures with the stated intention of streamlining a number of regulatory processes. As part of this effort, the State Council revised the Administrative Rules for Safety of Agricultural Genetically Modified Organisms, originally released in 2001. Despite their stated intentions and commitments to the United States and other major trading partners that this process was for streamlining purposes, the revised regulations create greater uncertainty in the biotech approval process in China. The changes authorize technical institutions in China to conduct field trials and feeding studies on behalf of the applicants. This shifts financial responsibility – and thereby the complete oversight - for the conduct of safety trials from the product developers to the Chinese government. As these changes begin to be implemented, our members are already challenged in complying with these developing changes in the application process.

CropLife International members are concerned that this movement toward greater authority of MOA officials in the conduct of approval reviews creates more opportunity for delay, greater unpredictability in outcomes, and overall a sense that China is moving away from its commitments to streamline regulatory processes.

Intellectual Property

In order to ensure food security, China needs modern technologies. The area of agricultural innovations has significantly expanded in the last twenty years, not only in the field of genetically

modified crops but also in sophisticated methods of plant breeding based on advanced technologies that employ DNA markers and genome sequencing.

Continued investments into agricultural innovation require a system that provides for a reasonable return on investments through effective intellectual property protection. The CropLife International member companies invest heavily in research and development to bring forward new innovations that drive long-term agricultural productivity, environmental sustainability and rural development, ensuring that farmers and consumers have access to these innovations, including in China.

For agricultural innovations, such effective intellectual property protection consists of plant variety protection rights and patent rights. Plant variety protection rights protect the new variety as a whole, but not any specific trait or essential genetic element, which are aimed to be used in a multitude of plant varieties or crops. These specific traits can only be protected by a patent.

Although in principle, agricultural biotechnology plants are patentable under Chinese patent law, the scope of the granted protection is (too) narrow. In addition, under the current Chinese patent system it is difficult to get homology for gene or protein claims. Furthermore, the patentability of native traits (knowledge of the genetic basis of native traits enables comprehensive screening of a broad base of both well-adapted and exotic genetic diversity and facilitates the introduction of the genetic diversity underlying these traits in order to develop improved varieties), as well as products resulting from gene editing technologies requires further clarification and refinement. CropLife International is of the view that the narrow scope of biotech patents and lack of clarity related to patents on the newest technologies undermines the effectiveness of the patent system as a driver for further innovation, and limits the availability of new products for farmers and consumers in China.

With regards to the issue of biotech piracy, CropLife International would like to point out that product security is an issue and there are several reported cases of germplasm theft. Taking into account that enforcement of trade secrets in this area is very difficult, effective means to act against these illegal activities are currently lacking.

Proposed Recommendations for Congress

CropLife International recommends that any solutions to the issues outlined above must be sustainable and long-term. Our advocacy for reform is focused on fixing the broken regulatory process in China, not one-off transactional approvals of individual products in the long pending queue. Our members have worked for years in an unpredictable, “one-off” situation, whereby pressure from exporting governments mounts until MOA approves one or two pending products at a time, relieving the pressure for those products only, but not providing any longer-term solution to the approval delays. There always remains a substantial backload of applications, with a trickle of approvals each year. This is not a path toward progress, but rather continues our members’ inability to predict when they can bring new innovations to the marketplace. This has a significant negative effect on our members’ economic performance, as biotech research is heavily front-loaded in product development programs that, on average, extend 13 years from discovery to initial commercialization due to years of delay in import approvals in China.

One of the major causes of delays is China’s requirement that an agricultural biotechnology product have an approval in the country of origin before an applicant may submit it for consideration in China. The has the effect of creating a minimum two-year delay for product approvals before the product even reaches a Chinese regulator’s desk. CropLife International recommends that the United States prioritize advocacy with China toward the goal of allowing for review of new agricultural biotechnology products in China at the same time the reviews are

occurring in other major importing countries, which would have the immediate effect of reducing the delays by at least two years.

In addition, significant delays occur in obtaining feedback following NBC meetings, as well as the multiple times questions are asked by NBC members on each application. CropLife International recommends that the United States encourage China to abide by the requirements of the ALL, which would require the NBC to ask all questions at one time. In addition, ALL requires that feedback is provided to applicants within 20 working days of an NBC decision. Following the ALL provisions would therefore significantly reduce approval delays in China.

Lastly, CropLife International recommends that the United States work with China to minimize its requirements for in-country studies to approve import of biotech crops. Our members are applying for import for food and feed only, yet China requires numerous in-country field and animal feeding studies that are not appropriate for such applications. In-country environmental trials should only be required if the safety assessment specifies potential environmental risks. In addition, China should – like many other countries currently do – recognize animal feeding studies conducted outside China and eliminate the need for in-country studies. CropLife International suggests that China's regulatory process should distinguish between import approvals and in-country cultivation approvals. This would greatly clarify the approval process and minimize delays due to duplicative and/or unnecessary in-country testing requirements.

In summary, CropLife International appreciates the Commission's attention to the significant negative impacts that China's agricultural biotechnology import policies have on U.S. farmers, technology providers, value chain members and consumers. I am hopeful that there will be progress in developing approaches and policies that minimize such negative impacts. CropLife International is committed to continuing our work with the United States and other countries that export agricultural commodities to ensure an understanding of the benefits our members' technologies can bring to global food security and sustainability. It is our hope that the United States will work with China to facilitate the acceptance of emerging agricultural innovations, and support market access for these technologies in China and in other markets worldwide. Thank you.

Sincerely,

Howard Minigh
President and CEO
CropLife International