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China Moving Towards Commercialization of Its Own Biotechnology Crops

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Report Highlights:
China is the world's largest importer of genetically engineered (GE) crops and one of the largest producers of GE cotton in the world, but it has not yet approved any major GE food crops for cultivation. As a part of its rule revision plan, in 2016, the Chinese Ministry of Agriculture (MOA) released the "Revised Administrative Measures for Safety Assessment of Agricultural Genetically Modified Organisms" (MOA Decree 7 [2016]). The "13th Five-Year Plan for Science and Technology Innovation" aims to push forward the commercialization of a new domestic type of Bacillus thuringiensis (Bt) corn, Bt cotton, and herbicide-resistant soybeans by 2020. At the same time, delays in import approvals continue to worsen, causing unpredictability for traders and delaying the adoption of needed new varieties in exporting countries such as the United States.

Executive Summary

Biotechnology is designated as a strategic emerging industry in China, and the government invests heavily in biotechnology research.

The 13th Five-Year Plan for National Science and Technology Innovation (13th FYP) issued by the State Council in August 2016 revealed that China will push forward the commercialization of key products, including the new generation Bt cotton, Bt corn, and herbicide-tolerant soybeans. The 13th FYP also pledges to establish the technical system for biosafety evaluation to guarantee safety of GE products. Echoing this, several domestic companies are eagerly waiting for biosafety certificates for their events in the MOA approval pipeline for domestic cultivation.

In 2016, MOA revealed a roadmap for the commercialization of GE crops in China, starting with cash crops "not for food use"; followed by crops for input for feed and industrial use; food crops; and finally staple food crops (rice, wheat, and soybeans).

In September 2014, the government released remarks by President Xi Jinping affirming official support for biotechnology research, but calling for a cautious approach to commercialization. He also said that foreign companies should not be allowed to "dominate the agricultural biotechnology product market." This was the first time remarks by President Xi on biotechnology have been made public. In February 2015, the Chinese Communist Party pledged in its annual high level policy paper on agriculture to strengthen research, safety management, and public outreach on biotechnology (see GAIN Report CH15010).

The government of China is in the process of revising laws and regulations governing biotechnology. In July 2016, the Ministry of Agriculture (MOA) released the "Revised Administrative Measures for Safety Assessment of Agricultural Genetically Modified Organisms" (MOA Decree 7 [2016]), which was earlier notified to the WTO SPS Committee (SPS notification 881). The regulations defined in MOA Decree [2016] No.7 revises MOA Decree [2002] No. 8, the previous regulations governing biotechnology. The amendments remove timelines for approvals, extend the National Biosafety Committee's term from three years to five years, and emphasize that entities engaging in GMO research and experiments are accountable for safety management. On several occasions, MOA officials have revealed that they are revising labelling requirements for GMO products and plan to establish minimum threshold levels for labelling, which is expected in the next two or three years. In 2015, MOA reported that it is exploring the feasibility of establishing a public solicitation mechanism to enhance public involvement in the agriculture biotechnology review and decision making process.

China has not approved any GE food or feed crops developed by foreign biotechnology firms for domestic commercial production. When foreign companies have asked to submit an application for domestic cultivation, MOA informed them that China's foreign direct investment restrictions prohibit them from doing so.

There have been increasing reports of farmers in China planting unapproved insect resistant varieties of corn and rice to cope with rising pest pressures, but it is unclear how widespread this trend is.

MOA approved three events for import in February 2016 (see Appendix II). These were the first new approvals since December 2014. Trade in corn and distiller's dried grains with solubles (DDGS) remain weak. Trade in other products, such as alfalfa, suffers from biotechnology-related trade disruptions. Despite these challenges, China is expected to remain a significant importer of GE products, notably soybeans. In September 2016, China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) released the protocol for sugar beet pulp imports from the United States. The first batch of sugar beet pulp is expected to arrive in China before the end of the year.

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PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT: Despite years of public research, China has not yet commercialized any genetically modified grains or oilseeds.

In 2009, MOA granted the first biosafety certificates for food and feed crops to two Chinese developed insect-resistant rice varieties and one high-phytase corn variety (which were renewed at the end of 2014). However, MOA did not issue final approval for planting.

In 2016, MOA revealed a roadmap for commercialization of GE crops in China, starting with cash crops "not for food use;" followed by crops for input for feed and industrial use; then, food crops; and finally staple food crops (rice, wheat, and soybeans).

MOA does not publish information on ongoing domestic biotech research and development. According to MOA publications on deregulation, the following major crops are undergoing field trials (either in the intermediate experimental or environmental-release stages) including insect-resistant corn, high-lysine corn, insect-resistant soybeans, and wheat that is less prone to pre-harvest sprouting. There has been significant research into GE wheat, including eleven stress-resistant events and four high-protein events are under development.

As noted above, China has heavily invested in biotech research and seed development, primarily through publicly funded research institutes and universities. In 2008, China approved a special research program to develop new GE varieties over 15 years through the

Key Scientific and Technological Grant of China for Breeding New Biotech Varieties. Total funding totaled 24 Billion Yuan (approximately $3.6 billion), half of which came from central and local governments, and the remaining half from private industry investment. According to the Long and Mid-term National Development Plan for Science and Technology (2006-2020), the program will focus on crop (rice, wheat, corn, and cotton) and animal (swine, cattle, and sheep) research. The target is to develop varieties with new traits, such as insect, disease, and stress resistance. A list of the 585 new biotech breeding projects funded by the grant is available at the National Science and Technology Report Service, which provides the project name, project undertaker and report abstract.

Private sector research and development in agricultural biotechnology is limited and highly regulated. Foreign investment in research and production of biotech plants, livestock, and aquatic products is prohibited. Foreign investment is allowed in conventional/hybrid seed production, but restricted to minority shares in joint ventures with Chinese companies.

COMMERCIAL PRODUCTION: China is the sixth largest producer of agricultural biotechnology crops in the world by area according to a 2015 report by the International Service for the Acquisition of Agro-biotech Applications (ISAAA). Although China has commercialized six genetically modified plants since 1997 (cotton, tomato, sweet pepper, petunia, poplar, and papaya), only papaya and cotton are in production today due to difficulties in bringing the products to commercialization.

Overall, Chinese farmer acceptance of GE cotton has increased as expanding adoption rates translate into economic gains for primary and secondary beneficiaries. Although, in 2015, China's total cotton planted area dropped by 600,000 hectares to 3.8 million hectares since last season, the rate of GE cotton adoption has increased by 3 percentage points to 96 percent in 2015. In 2015, China planted approximately 3.7 million hectares of GE cotton. An estimated 6.6 million or more farmers in China plant GE cotton and directly benefit from the insect-resistance traits of Bt cotton. An additional 10 million corn, soybean, and vegetable farmers cultivating also realize reductions in cotton bollworm (*Helicoverpa*) infestations. In total, more than 17 million farmers benefit from GE cotton. At the farm-level from 1997 to 2014, the estimated realized economic gains from Bt cotton is $17.5 billion and $1.3 billion in 2014 alone.

About 7,000 hectares of virus resistant papaya were planted in Guangdong, Hainan, and Guangxi provinces. For virus-resistant papaya, while the adoption rate has remained high at approximately 90 percent, plantings fell by 1,475 hectares to 7,000 hectares in 2015 due to over-supply in the 2014.

GE crops approved for commercial production in China can be found on MOA's website. In general, GE crop cultivation is approved on a province-by-province basis. However, the vast majority of the biosafety certificates for cultivation are for domestically developed varieties of Bt cotton which are approved for three ecological areas. The government has not approved any foreign developed biotech food or feed crops for cultivation.

b) EXPORTS: China is a large exporter of cotton products, many of them produced with Bt

cotton.

c) IMPORTS: China is a large importer of GE cotton, corn, and soybeans for feed and processing. In 2015, China imported over 80 million tons of soybeans. Imports of corn remain weak, and imports of DDGS have faced significant trade disruptions due to government interventions and imports of unapproved GE corn events. In September 2016, AQSIQ released a protocol for sugar beet pulp pellet imports from the United States. In the 2009/10 marketing year, genetically-modified sugar beets accounted for about 95 percent of the planted sugar beet crop in the United States. The first vessel of U.S. sugar beet pulp pellets is expected to arrive in China before the end of the year.

China's unpredictable approval process and lack of a low level presence (LLP) policy have resulted in rejected shipments and trade disruptions, such as rejection of alfalfa shipments that containing unapproved GE alfalfa events and the rejection of DDGS shipments containing unapproved GE corn events.

China does not allow the importation of biotechnology seeds for commercial cultivation.

d) FOOD AID: China provides substantial amounts of food aid to North Korea as well as smaller amounts of food aid to other countries. China has not approved any major GE food crops, so all the food aid is comprised of non-GE crops.

e) TRADE BARRIERS:

PART B: POLICY

a) REGULATORY FRAMEWORK: Biotechnology is designated as a strategic emerging industry in China, and the government invests heavily in biotechnology research. The total amount of Chinese government expenditures on biotechnology is estimated to be 12 billion Yuan (approximately $1.9 billion) since 2008, with a matching investment from private industry. The amount far exceeds public sector investment in biotechnology in any other country including the United States (see GAIN Report CH15032 for additional details). Sources expect that Chinese government expenditures on agricultural biotechnology will accelerate in the near term.

The 13th FYP for National Science and Technology Innovation issued by the State Council in August 2016 revealed that China will push forward the commercialization of key products, including the new generation Bt cotton, Bt corn and the herbicide-tolerant soybeans. The 13th FYP also pledges to establish a technical system for biosafety evaluation to guarantee the safety of GE products.

In January 2016, the Chinese Communist Party pledged in the 2016 No. 1 Document to "reinforcing agricultural biotech R&D and oversight, promote (GMO) in a cautious manner on the basis of guarantee its safety." In the previous, No. 1 Document announced in February 2015, China also pledged to "strengthen research, safety management and public education on biotechnology" (see GAIN Report CH15010). (The No. 1 Document gets its

name from being the first policy document issued by the Chinese Communist Party each year. It is reserved for important issues, such as agriculture.) The document is built on the comments President Xi Jinping made on biotechnology during a major policy speech on agriculture in December 2013.

Biotech is a new technology, and a new industry with bright prospect. As a novel issue, biotechnology attracts social disputes and doubts, which is normal. For this issue, I want to emphasize two aspects, one is guaranteeing safety and the second is indigenous innovation. That is, we shall be bold in research, but cautious in commercialization. The industrialization and commercialization of genetically modified crops shall strictly follow the technical procedures provided by Chinese regulations; the industrialization and commercialization of genetically modified crops shall be steady and make sure no problem occurs, and all safety-related factors shall be considered. The research and innovation shall be bold, so we can take the commanding heights in biotechnology, and not let large foreign companies dominate the agricultural biotechnology product market.

Xi Jinping, December 23, 2015

Unofficial translation of remarks by President Xi Jinping made on December 23, 2013 at the Central Conference on Rural Work by the Central Committee of the Communist Party. They were first made public in September 2014.

The No. 1 Document and President Xi's speech help to partially explain what had appeared from the outside to be a confusing and somewhat contradictory set of government actions on biotechnology: slowing or stalled approvals for non-Chinese developed traits, stalled commercialization of domestically developed biotech crops, and strong support for biotechnology research and seed companies. Sources suggest that these policies may be aimed at limiting foreign competition while China's domestic biotechnology industry develops.

There are increasing reports that the unwritten policy against approving major GE food crops will soon come to an end. Several domestic companies revealed that they have submitted biosafety certificate applications for their events to MOA for domestic cultivation. The approval process for cultivation is expected to be completed in one or two years to fulfill the goals set in the 13th FYP.

Domestically developed varieties of GE rice and corn received biosafety certificates in 2009 and these were renewed in December 2014. None of these varieties were granted variety registration, the last step needed for commercialization. To date, China has not approved any foreign biotech food or feed crops for domestic commercial production.

The approval for cultivation of GE corn would be a major breakthrough for China's biotechnology industry. The lack of a clear path to commercialize major biotechnology crop varieties (other than cotton) has limited incentives for local seed companies to invest in biotechnology. It has also encouraged public labs to focus on basic research rather than develop commercially viable seeds. Inconsistent protection of intellectual property and the

fragmented nature of China's seed industry further discourage private sector investment in biotechnology. The government is working on developing a new seed law to try to improve variety protection (see GAIN Report CH14035).

The Chinese government's decision to restrict participation of foreign seed technology companies, ban foreign investment, and delay approvals for many biotechnology crops reduces incentives for investments in research and development and regulatory compliance of agricultural biotechnology in China. In 2011, foreign investment in biotechnology was moved from the "restricted" to the "banned" category, meaning that foreign companies could no longer conduct agricultural biotechnology research in China. Some Chinese government officials have expressed concern that international seed companies would dominate the seed market in China if they were allowed to commercialize their biotechnology seeds. The example of cotton, where international companies were allowed to commercialize seeds, suggests these fears may be misplaced. While GE cotton seeds from international companies initially held large shares of the market, locally developed varieties quickly arose and now dominate the market for biotech cotton seeds in China.

Government officials cite lack of public acceptance as an important factor behind the slow pace of biotechnology commercialization in China. Although public opinion is not listed as a factor to be considered when deciding whether to approve a GE crop for import or cultivation, it plays an important role in approval reviews.

There have been increasing reports of farmers in China planting unapproved Bt varieties of corn and rice to cope with rising pest pressures. In 2015 and 2016, Chinese and foreign media reported illegal planting of GE crops (mainly corn and rice) in Liaoning, Xinjiang, Gansu, and Hainan provinces. MOA has taken enforcement actions and removed the detected GE crops. In response, Chinese authorities have tightened supervision over field trials, variety registration, and seed production to address the issue.

Regulatory structure

The biotechnology regulatory system for agriculture is outlined in State Council regulations "Food and Agricultural Import Regulations and Standard" and "Agricultural Genetically Modified Organisms Safety Administration Regulations 2001" (See GAIN Report CH1056). They are implemented by MOA under Ministerial Decrees 8, 9 and 10. Domestic approval, import approval, and labeling are governed by Measures on the Safety Evaluation Administration of Agricultural Genetically Modified Organisms (GMOs), Measures on the Safety Evaluation Administration of Agricultural GMO Imports, and Measures on Agricultural GMO Labeling Administration respectively (see GAIN Report CH7053).

The Chinese government is currently revising regulations for agricultural biotechnology. In July 2016, the Ministry of Agriculture (MOA) released the "Revised Administrative Measures for Safety Assessment of Agricultural Genetically Modified Organisms" (MOA Decree 7 [2016]), which was earlier notified to the WTO SPS Committee (SPS notification 881). The amendments remove timelines for approvals, extend the National Biosafety Committee's term from three years to five years, and emphasize that entities engaging in

GMO research and experiments are accountable for safety management. To comply with the revised regulations, MOA is expected to publish revised guidance for safety reviews of plant, animal, and micro-organisms for animal nutrition shortly.

On several occasions, MOA officials have revealed that they are revising labelling requirements for GMO products and plan to establish minimum threshold levels for labelling, which is expected in the next two or three years.

On July 24, 2015, in response to an inquiry from members of China's National People's Congress Consultative Committee, MOA reported that it is exploring the feasibility of establishing a public solicitation mechanism to enhance public involvement in the agriculture biotechnology review and decision making process. No additional details or a final decision have been announced regarding this proposal.

Ministerial Responsibilities

MOA has primary responsibility for the approval of biotechnology crops for import and domestic production, as well as the creation of agricultural biotechnology policy. It also manages and distributes central government funds to Chinese institutes and universities for the research and development of biotechnology crops. This responsibility was formally under the Ministry of Science and Technology (MOST). The State Forestry Administration (SFA) is responsible for the approval of forestry products for research, domestic production, and import, and also creates its own biotech regulatory policies. The Ministry of Environmental Protection (MEP) (formerly the State Administration of Environmental Protection) is the lead agency for the negotiation and implementation of the Biosafety Protocol, which China ratified on April 27, 2005. The General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) and its local inspection and quarantine offices (CIQs) are responsible for the nationwide management of inspection and quarantine for the entry and exit of all biotech products. AQSIQ's Ministerial Decree 62 governs the steps that should be taken at customs when importing or exporting biotech goods (see GAIN Report CH4017).

The Joint-Ministerial Conference for Biosafety Management of Agricultural Genetically Modified Organisms

The Joint-Ministerial Conference for Biosafety Management of Agricultural Genetically Modified Organisms meets irregularly to discuss and coordinate major issues in the biosafety management of biotech agricultural products. The conference consists of seven government agencies under the State Council that include: MOA, MEP, AQSIQ, Ministry of Science and Technology (MOST), National Development and Reform Commission (NDRC), Ministry of Commerce, and the National Health and Family Planning Commission (former Ministry of Health). The conference has little decision- making authority, and mostly is a forum used for coordination purposes in case a biotech policy affects multiple ministries.

Ministry of Agriculture Import Approval Procedure

The Ministry of Agriculture is responsible for approving imported biotechnology products. The approval process varies depending on the product's intended use (research, processing, or production), safety levels, and potential risk to human or animal health and the

environment. MOA Decree 9 outlines the requirements for importing biotech products (see GAIN Report CH7053). For the importation of products as processing materials, Decree 9 states that a foreign seed developer must apply for an agricultural biosafety certificate from the Administrative Examination and Approval Office, the MOA office which administers the review process for applications and issues responses to applicants). The regulations require applicants to provide a variety of materials and certification that the exporting country has allowed the use and sale of the product in its domestic market, and that it has undergone tests showing no harm to animals, plants, or the environment. MOA also requires authorized domestic institutions to conduct environmental safety (field trials) and food safety (animal feeding) tests to verify data provided by the seed developer. All these documents, including reports generated from verification tests, must be reviewed by the NBC before MOA can issue a biosafety certificate.

Pursuant to the Administrative Measures for the Safety of Agricultural GMO Imports (MOA Decree 9), MOA should respond to an application for a biosafety certificate within 270 days. However, the approval processes varies from crop to crop depending on its intended use and potential impact on human or animal health and the environment. On May 22, 2013, MOA released a notice containing seven regulations for review of agricultural GE-related applications (see GAIN Report CH13030). These regulations clarify the MOA review process for approved entry of GE materials, safety certificates, labeling, etc., and the timelines for each step. This is the first time MOA publicly released written application review procedures for biotechnology products.

On December 5, 2012, MOA issued the "Announcement on Submission Requirement of GMO Sample and Technical Information," requiring that viable seeds be submitted with import applications for detection testing purposes. Although no final rule has been issued, MOA indicated that the rules are now being enforced. The rule created concerns about intellectual property rights protection among seed companies, because MOA would not sign a material transfer agreement. It is unclear why MOA needs viable seeds for detection purposes.

Ministry of Agriculture Domestic Production Approval Procedure

To produce biotech crops domestically in China, technology providers must pass a biosafety evaluation by the NBC and obtain a biosafety certificate issued by the MOA's Division of GMO Biosafety and IPR. The approval process for biotechnology products for domestic cultivation involves five steps: (1) research, (2) intermediary experiments, (3) environmental release, (4) productive testing, and (5) biosafety certification. In addition to national level review approvals are also required at the provincial level. After completing these five steps, products are eligible for biosafety certificates.

National Biosafety Committee (NBC)

The NBC, established by MOA, is a regulatory body that evaluates domestic and foreign applications for biosafety certificates for biotech products. According to the "Revised Administrative Measures for Safety Assessment of Agricultural Genetically Modified Organisms" (MOA Decree 7 [2016]), the term for NBC members was recently extended from three years to five years.

In 2016, the Fifth NBC was established with 75 members from different research institutions and universities; they have diverse areas of expertise including, biotechnology research, agricultural production, agricultural processing, plant and animal inspection and quarantine, and environment protection. Government officials no longer hold positions on the Committee. The members of the Fifth NBC were announced by MOA in April 2013, and are available on its website.

The NBC is divided into three expert biotechnology review panels: plants, animals and microorganisms, and food and feed. The MOA Decree 7 [2016] stipulates that the NBC hold no less than two meetings per year, and removes the application period for submitting applications for biosafety certificates. NBC's final recommendations are generally released 45 days after each meeting.

In May 2013, MOA issued the Working Rules of the Committee for Safety of Agricultural GMOs. These rules explain the function and composition of the NBC, and establish ethical requirements for NBC members.

Other agencies
The National Technical Committee for the Standardization of Biosafety Management of Agricultural GMOs consists of 41 experts and administrative officials, and is responsible for drafting and revising technical standards for biotech products, including standards for safety assessments, testing, and detections. There are 49 MOA-authorized centers across China that conduct environmental safety testing, food safety testing, and detection. MOA provincial-level departments are responsible for monitoring field trials of biotechnology products, GE plant processing facilities, the planting seed market, and labeling.

Application Processes

MOA Import Approval Application Process
The process to obtain a biosafety certificate for an imported GE food crop for processing (like soybeans) has recently become substantially slower. New regulations include steps of varying lengths, such as importing testing materials, field trials, feeding studies, and an evaluation by the NBC.

The following is a rough outline of the import approval application process for biotechnology products. The names of institutions and contacts are provided where available.

1. MOA, Administrative Services Hall: accepts applications.
Tel: 86-10-5919-1811/1805

2. Biosafety Management Division, Development Center for Science and Technology (DCST): reviews and submits applications to the NBC.
Tel: 86-10-5919-9389

3. NBC plenary sessions: held at least two times each year, timing is unknown.

4. Division of GE Biosafety and IPR: processes import permits for field trials and feed studies based on NBC recommendations.
Tel: 86-10-5919-3059

5. Detection and Testing Division, Development Center for Science and Technology (DCST): designates testing institutes and locations for field trials and feed studies. DCST also works with applicants and designated testing institutes to understand the applicant's testing methods and sampling procedures. Testing institutes may or may not use the same procedures or methods to independently conduct tests.
Tel: 86-10-5919-9385

6. After completing field trials and feed studies, designated testing institutes will draft reports.

7. Biosafety Management Division, DCST reviews and submits a final version of all analysis to NBC.

8. NBC reviews the field trial and feed study reports, and provides a recommendation for approval.

9. Division of GMO Biosafety and IPR considers NBC's recommendations before issuing a biosafety certificate to the applicant.

According to the revised Regulations on the Safety Evaluation of Agricultural GMOs (MOA Decree [2016] No.7), applicants no longer need the provincial agriculture bureaus' approval to conduct field trials in the region.

Costs
According to a joint notification by NDRC and the Ministry of Finance to MOA, the fee schedule for safety evaluation and testing of GE agricultural materials is as follows:

Safety review fees paid to the DCST, MOA:
1. Intermediary experiment (2,500 Yuan per item [$362])
2. Environment release (3,000 Yuan per item [$435]);
3. Production testing (5,000 Yuan each [$724] or 3,000 Yuan [$435] for additional imports as processing materials).

Note: research institutes or academies are subject to favorable rates.

Fees paid to MOA designated institutes for testing

1. Environmental safety testing
   a) GMO Survival and Competiveness Test (83,000 Yuan per item [$12,030])
   b) Ecological Risk of Gene Flow Test (92,000 Yuan per item [$13,333])
   c) GMO Impact on Non-target Organisms and Biodiversity Test (96,000 Yuan per item [$13,913]).

2. Food safety testing
   a) Anti-nutrient Test (1,000 Yuan per item [$145])
   b) 90-day Rat Feeding Study (120,000 Yuan per item [$17,391]).

b) APPROVALS: In February 2016, fourteen months after the last approval, MOA granted import approvals for three products: Monsanto Soybean MON87708, Monsanto Soybean MON87769, and Syngenta Cotton COT102. MOA also issued renewals for a dozen of traits set to expire at the end of 2016.

   To date, MOA has approved imports of five biotech crops for processing or feed use, including, soybeans, corn, canola, cotton and sugar beets. The first biosafety certificate for imports of foreign products was issued in 2004. A full list of biotech crops approved for import for feed or processing material is included in this report in Appendix 2.

c) STACKED EVENT APPROVALS: China does not have a specific policy for approving stacked traits. When reviewing varieties with stacked traits, MOA requires applicants to submit information on each individual trait present in the variety.

d) FIELD TESTING: China allows field trials of GE crops, but does not provide data on the number of field trials taking place, types of crops or traits being tested, or the estimated time to commercialization.

   In recent years, news media have reported about illegal planting of unapproved GE crops, mainly for testing purposes in several provinces. Accordingly, MOA more tightly controls supervisory authority over local agricultural officials and crop breeding bases.

e) INNOVATIVE BIOTECHNOLOGIES: Chinese scientists with the China Academy of Sciences (CAS) and China Academy of Agricultural Sciences (CAAS) are making impressive progress in the innovative biotechnologies and have published dozens of papers about clustered regularly interspaced short palindromic repeats (CRISPR) technologies. How to regulate the innovative biotechnologies remains uncertain. China has initiated a study to review the regulatory policy for innovative biotechnologies. MOA has established an expert team to analyze whether gene editing is also subject to the existing biotechnology regulatory system.

f) COEXISTENCE: China does not have a co-existence policy.

g) LABELING: China's revised Food Safety Law, which entered into force on October 1, 2015, incorporates the existing regulations on biotechnology labeling into law (see GAIN Report CH15016). China's biotechnology labeling regulations, governed by MOA Decree 10 (see GAIN Report CH7053), require the labeling of approved agricultural biotech products, and prohibit the importation and sale of any unlabeled or mislabeled products. The 2015 Food Safety Law codifies into law existing biotechnology labeling regulations.

   The types of products subject to mandatory labeling include:

1. Soybean seeds, soybeans, soybean powder, soybean oil, and soybean meal
2. Corn seeds, corn, corn oil, and corn powder
3. Rapeseed for planting, rapeseeds, rapeseed oil, and rapeseed meal
4. Cottonseed
5. Tomato seed, fresh tomato, and tomato paste

On various occasions, MOA and scientists revealed that China will establish a threshold for GE labelling, changing the labelling from qualitative to quantitative. It is expected that the new rules will be issued in a few years.

In addition to these labeling requirements, China also recently enacted new policies to prevent misleading advertisements. The Draft Implementing Rules of the Food Safety Law pending for promulgation prohibit the use of "non-GMO" on labels for foods and materials that have not yet been approved by China (Note: such as peanuts and sesame; there are no commercialized varieties of GE peanuts or sesame in the marketplace; therefore, all peanut oil and sesame oil products are non-GE). This elevates requirements for labeling to a higher level to prevent misleading propaganda or advertisements.

In September 2014, China Central Television (CCTV) issued a notice to advertising agents notifying them that State Administration of Industry and Commerce (SAIC) will strengthen regulatory oversight over advertisements including claims or statements regarding GMOs. This move was taken after MOA contacted SAIC with concerns about misleading labeling.

In January 2015, MOA released the *Notice Concerning Guidance for GMO-related Advertisements*, which urged provincial agricultural authorities to work with the local commerce and Food and Drug authorities to reinforce supervision over GMO-related advertisements. The Notice prohibits the use of "non-GMO" in advertisements of products made of crops where no GE version has been approved for sale in China or where no GE version exists. Non-GMO labels can be used for products for which GE versions are available, but the labeling must be accurate and cannot use misleading words such as "heathier" or "safer."

h) MONITORING AND TESTING: Testing of biotechnology products is carried out primarily by MOA, AQSIQ, and MEP through their affiliated testing institutes. AQSIQ tests imported products for unapproved biotechnology events. MOA tests domestic crops and conducts safety assessment experiments. MEP tests for environmental safety assessments.

China has zero tolerance for the presence of unapproved biotechnology traits in imported products. MOA, AQSIQ, and MEP have developed national and industry standards for biotech testing, all of which use PCR testing methodologies. Although all labs use highly sensitive polymerase chain reaction (PCR) testing, in practice, labs have varying levels testing sensitivities and capabilities. This means that the import tolerances can range from 0.1 percent to 0.01 percent, or even less. Low-level presence of unapproved biotechnology traits, due to testing variability, high testing sensitivities, and lack of a set threshold for positive testing results risks causing trade disruptions. For example, a reused shipping container, or wind-blown pollen grains during pollination, or minor variability in sampling at

loading and unloading, can risk market access to China for thousands of metric tons of GE feed grains or oilseeds.

Although PCR testing is voluntary, it is believed that PCR testing is de facto mandatory and imports to China are strictly held to import thresholds. AQSIQ-developed standards tend to focus on specific crops. MOA-developed standards are often targeted at testing for specific events.

The following are a list of the main standards issued by these ministries. These standards are on file with China's Standardization Committee, but may not all be readily accessible.

National Standards

- GMO Product Testing - General Requirements and Definitions (GB/T 19495.1-2004)
- GMO Product Testing - Technical Requirements on Laboratories (GB/T 19495.2-2004)
- GMO Product Testing - DNA Extraction and. Purification (GB/T 19495.3-2004)
- GMO Product Testing - Qualitative Nucleic Acid Based Methods (GB/T 19495.4-2004)
- GMO Product Testing – Quantitative Nucleic Acid Based Methods (GB/T 19495.5-2004)
- GMO Product Testing – Testing Method for Gene Chips (GB/T 19495.6-2004)
- GMO Product Testing - Sampling and Sample Preparation Methods (GB/T 19495.7-2004)
- GMO Product Testing – Testing Method for Protein (GB/T 19495.8-2004)

In May 2016, MOA issued the Public Notice No.2406, announcing ten national standards, most of which are standards for testing methods:

- General Requirements for Safety Management of Agricultural GMO – Laboratory (MOA Public Notice 2406-1-2016)
- General Requirements for Safety Management of Agricultural GMO – Green House (MOA Public Notice 2406-2-2016)
- General Requirements for Safety Management of Agricultural GMO – Test Base (MOA Public Notice 2406-3-2016)
- Food Safety Detection of Genetically Modified Organisms and Derived Product - Protein 7-day Oral Toxicity Study (MOA Public Notice 2406-4-2016)
- Food Safety Detection of Genetically Modified Organisms and Derived Product - Human serum ELISA for exogenous protein allergenecity (MOA Public Notice 2406-5-2016)
- Food safety Detection of Genetically Modified Organisms and Derived Product - Rat nutrition apparent digestibility test (MOA Public Notice 2406-6-2016)
- Component Detection for Genetically Modified Animal and Derived Products - DNA extraction and purification (MOA Public Notice 2406-7-2016)
- Component Detection for Genetically Modified Animal and Derived Products - Qualification PCR method for human lactoferrin (hLTF) Gene Detection (MOA Public Notice 2406-8-2016)
- Component Detection for Genetically Modified Animal and Derived Products - Qualification PCR method for Human α-lactoalbumin (hLALBA) Gene Detection (MOA Public Notice 2406-9-2016)

- Food safety Detection of Genetically Modified Organisms and Derived Product - Protein Acute Oral Toxicity Test (MOA Public Notice 2406-10-2016, replacing the MOA Public Notice 2031-16-2013)

AQSIQ Developed Standards

- Testing of GMO Plant and Its Products – General Requirements (NY/T 672-2003);
- Testing of GMO Plant and Its Products – Sampling (NY/T 673-2003)
- Testing of GMO Plant and Its Products – DNA Extraction and Purification (NY/T 674-2003)
- Testing of GMO Plant and Its Products –Qualitative PCR Method for Soybean (Testing) (NY/T 675-2003)

MOA Standards for GMO Testing of Specific Events

- MOA Public Notice No. 261 (four standards)
- MOA Public Notice No. 680 (five standards)
- MOA Public Notice No. 869 (14 standards)
- MOA Public Notice No. 953 (27 standards)
- MOA Public Notice No. 1193 (three standards)
- MOA Public Notice No. 1485 (19 standards)
- MOA Public Notice 1782 (13 standards)
- MOA Public Notice 1861 (six standards)
- MOA Public Notice 2122 (16 standards)
- MOA Public Notice 2031 (19 standards)
- MOA Public Notice 2259 (19 standards)

*Some standards were updated by the later notices

MEP Developed Standards

- Guideline for Eco-Environmental Biosafety Assessment of Insect-resistant Transgenic Plants (HJ 625-2011)

i) LOW LEVEL PRESENCE (LLP) POLICY: China has zero tolerance for unapproved biotechnology traits in imports.

j) ADDITIONAL REGULATORY REQUIREMENTS: Not available.

k) INTELLECTIONAL PROPERTY RIGHTS (IPR): China's Seed Law and MOA Administrative Measures for Plant Variety Protection, which governs intellectual property right protection for agricultural biotechnology, were both amended and revised in 2016. Intellectual property right protection in seeds remains a major challenge in China, and misbranding and illegal reproduction of seeds remains rampant despite government efforts to crack down on such practices.

l) CARTAGENA PROTOCOL RATIFICATION: China signed on as a member of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity in 2000 and ratified the protocol in 2005. In 2011, China announced that the protocol would also apply to the Hong Kong Special Administrative Region. China participates in the Global LLP

Initiative as an observer.

m) INTERNATIONAL TREATIES/FOR AND DIALOGUES: Major biotechnology producing countries, including the United States, routinely engage China regarding its slow biotechnology approval system, which can take several years for an approval to be granted. China's slow biotechnology approval system has delayed the global adoption of new varieties.

The United States and China held in-depth discussion on agricultural biotechnology in multiple forums in 2016, including the Strategic and Economic Dialogue (S&ED) held in Beijing in June 2016 and the 27th U.S.-China Joint Commission on Commerce and Trade (JCCT) held in Washington, D.C. in November 2016.

Below are the agreed outcomes on biotechnology from the U.S.-China S&ED.

Strategic & Economic Dialogue (S&ED)
At the June 2016 S&ED, China and the United States agreed to the following outcomes: China and the United States commit to further improve their approval processes for the products of agricultural biotechnology. 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 on 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 regulations upon the completion of assessments by the National Biosafety Committee. The United States commits to prepare a study on the global impact of asynchronous approvals on sustainability, trade and innovation, and present it to the Chinese side by October 2016. The United States and China are to meet to jointly discuss the full range of agricultural biotechnology policy matters by the end of 2016.

U.S.-China Joint Committee on Commerce & Trade (JCCT)
USDA invited MOA to attend the discussion of the report prepared by the Council on Agricultural Science and Technology on "Impact of Asynchronous Approvals for Biotech Crops on Agricultural Sustainability, Trade and Innovation" on side of the 27th JCCT. China said it would provide a reaction to the study by then end of 2016.

n) RELATED ISSUES: Seed Registration Procedures

Amendment to China's Seed Law
On November 4, 2015, China's legislative body, the National People's Congress (NPC) announced the amendment to China's Seed Law. This is the first change to the legislation since it was enacted in 2000.

Major modifications to the variety registration system include:
1. The number of crops subject to variety registration requirements was reduced from 28 to five. The five seed varieties that will still need to be registered are rice, wheat, corn, cotton

and soybean;
2. Variety registration will no longer be required for other crops, such as rapeseed, potato and peanuts;
3. Seed companies no longer need approval to introduce a registered variety to a similar ecological region in another province in China.

The Amended Law states that "the selection, experiment, validation and popularization of transgenic plant varieties shall be subject to safety assessment and strict safety control measures. The administrative departments for agriculture and for forestry under the State Council shall strengthen tracking and supervision, and promptly announce the information regarding the validation and popularization of transgenic plant varieties. Specific measures in this respect shall be formulated by the State Council."

MOA Seed Variety Registration for Cultivation
In addition to procuring a biosafety certificate for commercial production, biotech seed developers must register the biotech variety at the provincial agricultural department (and/or at the national level) as required by the Seed Law. In some provinces, this process begins in step 3 or "production testing" (see below). Registration involves field trials and other testing requirements, some of which may duplicate trials conducted for the NBC review.

Not all varieties can register at the national level. The provincial-level committee decides whether seeds can undergo the national registration process, which means the seed can be planted in any province. This variety registration process can take up to 4 years for conventional varieties. No specific time-frame has been given for GE crops.

In July 2016, MOA released the "Administrative Measures for Major Crops Variety Registration", which provides that "GM Crop Variety (except for GM cotton) Registration Measures shall be developed separately"; however, the measures have not yet be announced.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINONS: The government is increasing its public outreach efforts to address public perceptions of biotechnology to help develop China's domestic biotechnology industry.

In April 2016, MOA held a press conference on agricultural biotechnology related issues. The two speakers, head of the MOA regulators' office and the director of the National BioSafety Committee, answered a wide range of questions, including the status of biotech research, planting of GE crops, governing regulations, safety, and illegal planting of GE crops.

Soon after President Xi's speech was published in September 2014, MOA launched a campaign to train and educate local agricultural officials and the public about biotechnology. Both traditional and social media are being used to explain China's biosafety regulatory work. MOA also launched outreach to provincial agricultural officials, students, and the general public.

MOA is also coordinating with its sister ministries to eliminate misleading claims or statements in product labels and advertisements. The Draft Implementing Rules of the Food Safety Law pending for promulgation prohibit the use of "non-GMO" in labels for foods and materials that have not yet been approved by China (Note: for peanuts and sesame there are no GE varieties in commercialization, therefore, all peanut oil and sesame oil are non GE).

Because of these efforts, false and misleading stories or articles circulating in both the mainstream and new media (MicroBlog, WeChat, etc.) have either disappeared or appear less frequently.

Meanwhile, public opponents of biotechnology have become more vocal and active in challenging the government. There have been a number of requests for MOA to disclose information, including questions from members of the Consultative Committee of the National People's Congress. MOA has been sued several times for violating requirements to disclose public information (including information of agriculture biotech imports, safety review results, and reports for three soybean events imported for food and feed use, reasons for rejecting commercialization of GE crops for staple foods, whether China plans to commercialize GE crops for staple foods, measures to protect domestic agriculture and farmers' interests, as well as implementation of the GMO labeling regulations and punitive measures). Although, the court has ruled in favor of MOA, MOA is reportedly swamped by day-to-day work responsibilities and newly filed court cases.

b) MARKET ACCEPTANCE/STUDIES: There are no widely accepted studies or surveys available on market acceptance.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

China is a leader in animal biotechnology research. The Key Scientific and Technological Grant of China for Breeding New Biotech Varieties launched in 2008 supports the research of GE animals including swine, cattle, and sheep. Despite the heavy investment and advanced research, China has not yet approved commercialization of any livestock clones or GE animals or products derived from animal biotechnologies.

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT: China's Central Government invests heavily in basic research for animal biotechnology. Research institutes can apply to MOA and the Ministry of Finance (MOF) for research funding. The National GE Animal Technology Research Center was established at Inner Mongolia University in September 2012, aiming to improve new livestock variety development and animal breeding in China, and to facilitate public education of GE animal technology. Research has mainly focused on pharmaceutical development, improving dairy production volume and quality, and improving meat and wool quality. A list of the research projects funded by the Key Scientific and Technological Grant of China for Breeding New Biotech Varieties could be found at the National Science and Technology Report Service, which provide the project name, project undertaker and report abstract.

b) COMMERCIAL PRODUCTION: Although there is no definite timetable for commercialization of animal biotech research results, some GE animal projects are currently awaiting commercialization, pending MOA's review.

c) EXPORTS: China does not export GE animals, livestock clones, or products from these animals.

d) IMPORTS: China does not import GE animals, livestock clones, or products from these animals.

e) TRADE BARRIERS: Not available.

PART E: POLICY

a) REGULATORY FRAMEWORK:

Regulation of GE Animals

Animal biotechnology is also subject to the "Agricultural Genetically Modified Organisms Safety Administration Regulations 2001" (See GAIN Report CH1056). However, this regulation lacks implementation rules or specific policies that regulate animal biotech research, production or trade. Like plant biotechnology, MOA starts review of dossiers only after an event is deregulated in an exporting country. To date, there have been no applications submitted in China for a safety certificate for GE animal exports.

b) INNOVATIVE BIOTECHNOLOGIES: Chinese scientists are making continuous progress in research of GE and genome edited animals using the innovative biotechnologies, in particular for medical purposes. However, the government is still considering whether and how to regulate innovative biotechnologies in animals.

a) LABELING AND TRACEABILITY: GE animal labeling is subject to Measures for Agricultural GMO Labeling Administration (MOA Decree 10). However, as China has not yet commercialized GE animals or clones. There are no specific measures for GE animal labeling available at this time.

b) INTELLECTUAL PROPERTY RIGHTS (IPR): GE animals still fall into a legal gap in China's IPR protection regulations. Currently, gene and DNA fragments are subject to protection provided by the Patent Law of China.

c) INTERNATIONAL TREATIES/FORA: China sends officials to high-level conferences for GE animals, but mainly as observers. Scientists at the technical-level maintain frequent and close contact with foreign peers in GE animal researches.

d) RELATED ISSUES: Not Available.

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS: Public concern and underdeveloped links between public research institutes and industry have made commercialization of GE animals difficult in China.

b) MARKET ACCEPTANCE/STUDIES: Although no official survey is available, market/public acceptance towards the sale and use of livestock clones, offspring of clones, GE animals, genome-edited animals, and products is low. The acceptance for such products for medical purposes is more positive.

Appendix 1: China's Trade in Biotech Crops

China Cotton Exports

Partner Country	Quantity (Million Tons)			
	2013	2014	2015	2016 (Jan.-Sep.)
World	7,567	13,184	29,344	5,703
Korea North	2,802	2,577	1,661	1,890
Indonesia	557	1,821	3,417	1,138
Bangladesh	0	4,636	933	1.012
Vietnam	2,333	1,608	16,288	545
United States	0	0	0	506

Source of Data: China Customs

China Cotton Imports

Partner Country	Quantity (Million Tons)			
	2013	2014	2015	2016 (Jan.-Sep.)
World	4.15	2.44	1.67	0.85
United States	1.15	0.55	0.53	0.19
Australia	0.80	0.50	0.25	0.18
Uzbekistan	0.26	0.17	0.175	0.144
India	1.19	0.82	0.33	0.11
Brazil	0.16	0.14	0.15	0.058

Source of Data: China Customs

China Corn Imports

Partner Country	Quantity (Million Tons)			
	2013	2014	2015	2016 (Jan.-Sep.)
World	3.26	2.6	4.73	2.98
Ukraine	0.11	0.96	3.85	2.67
United States	2.97	1.03	0.46	0.21
Russia	0.005	0.026	0.083	0.06

Source of Data: China Customs

China Soybean Imports

Partner Country	Quantity (Million Tons)			
	2013	2014	2015	2016 (Jan.-Sep.)
World	63.40	71.4	81.74	61.19
Brazil	31.81	32	40.13	35.54
United States	22.26	30	28.41	17.5
Argentina	6.12	6	9.44	5.85

Uruguay	2.3	2.44	2.32	1.18

Source of Data: China Customs

China Distillers Dried Grains Imports

Partner Country	Quantity (Million Tons)			
	2013	2014	2015	2016 (Jan.-Sep.)
World	4.00	5.415	6.82	2.698
United States	4.00	5.413	6.818	2.697

Source of Data: China Customs

Appendix 2: Biotech Crops Approved for Import as Processing Materials

No.	Event	Developer	Biosafety certificate validity
1	Quality-Improved Soybean MON 87769 (approved in 2016)	Monsanto	Dec.31, 2015 - Dec.31, 2018
2	Herbicide tolerant Soybean MON 87708 (approved in 2016)	Monsanto	Dec.31, 2015 - Dec.31, 2018
3	Insect resistant cotton COT102 (approved in 2016)	Syngenta	Dec.31, 2015 - Dec.31, 2020
4	Alpha-amylase corn 3272	Syngenta	Dec.31, 2015 - Dec.31, 2018
5	Drought Tolerant corn MON87460	Monsanto	Dec.31, 2015 - Dec.31, 2018
6	Herbicide tolerant Soybean CV127	BASF	Dec.31, 2015 - Dec.31, 2018
7	Insect resistant soybean MON 87701	Monsanto	Dec.31, 2015 - Dec.31, 2018
8	Insect resistant soybean MON87701 x MON89788	Monsanto	Dec.31, 2015 - Dec.31, 2018
9	Insect resistant cotton 15985	Monsanto Far East Ltd.	Dec.31, 2015 - Dec.31, 2020
10	Herbicide resistant cotton LLCotton25	Bayer CropScience	Dec.31, 2015 - Dec.31, 2020
11	Herbicide resistant soybean A2704-12	Bayer CropScience	Dec.31, 2015 - Dec.31, 2018
12	Herbicide tolerant corn NK603	Monsanto Far East Ltd.	Dec.31, 2015 - Dec.31, 2018
13	Insect resistant and herbicide tolerance corn MON88017	Monsanto Far East Ltd.	Dec.31, 2015 - Dec.31, 2018
14	Insect resistant corn MON89034	Monsanto Far East Ltd.	Dec.31, 2015 - Dec.31, 2018
15	Insect resistant corn MIR604	Syngenta Crop Protection	Dec.31, 2015 - Dec.31, 2018
16	Herbicide resistant corn GA21	Syngenta Crop Protection	Dec.31, 2015 - Dec.31, 2018
17	Herbicide resistant soybean	Monsanto Far East	Aug. 29, 2014-Aug.29, 2017

	MON89788	Ltd.	
18	Insect resistance and herbicide tolerance corn Bt11×GA21	Syngenta Crop Protection	Dec.11, 2014 – Dec.11, 2017
19	Quality improvement soybean 305423	Pioneer	Nov.3, 2014-Nov. 3, 2017
20	Soybean A5547-127	Bayer	Dec.11, 2014- Dec.11, 2017
21	Soybean 305423×GTS40-3-2	Pioneer	Dec.11, 2014- Dec.11, 2017
22	Corn MIR162	Syngenta	Dec.11, 2014- Dec.11, 2017
23	Herbicide tolerant Flex cotton MON 88913	Monsanto	Dec. 20, 2012 - Dec. 20, 2017
24	Herbicide resistant corn T25	Bayer CropScience	May 8, 2015-May 8, 2018
25	Herbicide resistant Canola Oxy-235	Bayer CropScience	May 8, 2015-May 8, 2018
26	Herbicide resistant Canola T45	Bayer CropScience	May 8, 2015-May 8, 2018
27	Herbicide resistant Canola Ms8Rf3	Bayer CropScience	May 8, 2015-May 8, 2018
28	Herbicide resistant sugar beet H7-1	Monsanto Far East Ltd., a German seed company	May 8, 2015-May 8, 2018
29	Insect resistant cotton 531	Monsanto	Aug.28, 2013 – Aug. 28, 2018
30	Herbicide tolerant cotton 1445	Monsanto	Aug.28, 2013 – Aug. 28, 2018
31	Herbicide tolerant soybean GTS40-3-2	Monsanto Far East Ltd.	Dec. 20, 2015-Dec. 20, 2018
32	Insect resistant corn 59122	Du Pont/Dow AgroSciences	Dec. 20, 2015-Dec. 20, 2018
33	Insect resistant corn TC1507	Du Pont/Dow AgroSciences	Dec. 20, 2015-Dec. 20, 2018
34	Insect resistant corn MON810	Monsanto Far East Ltd.	Dec. 20, 2015-Dec. 20, 2018
35	Insect resistant corn BT176	Syngenta Crop Protection	Dec. 20, 2015-Dec. 20, 2018
36	Insect resistant corn BT11	Syngenta Crop Protection	Dec. 20, 2015-Dec. 20, 2018
37	Herbicide resistant Canola Topas19/2	Bayer CropScience	Dec. 20, 2015-Dec. 20, 2018
38	Herbicide resistant Canola Ms1Rf1	Bayer CropScience	Dec. 20, 2015-Dec. 20, 2018
39	Herbicide resistant Canola Ms1Rf2	Bayer CropScience	Dec. 20, 2015-Dec. 20, 2018
40	Herbicide tolerant Canola GT73	Monsanto Far East Ltd.	Dec. 20, 2015-Dec. 20, 2018
41	Insect resistent and herbicide tolerant cotton GHB 119	Bayer CropScience	Apr.10, 2014 - April 10, 2019
42	Insect resistent and herbicide tolerant cotton T304-40	Bayer CropScience	Apr.10, 2014 - April 10, 2019
43	Herbicide resistant cotton GHB614	Bayer CropScience	Dec. 30, 2015 -Dec.30, 2020