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China Considering Major Revisions to Biotechnology Regulations

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Report Highlights:

China is one of the largest producers of biotech cotton in the world. It is also the world's largest importer of biotech crops, but it has not yet approved any major biotech food crops for cultivation. The Chinese government is in the process of revising its biotechnology regulatory system and is reportedly preparing to push ahead with the commercialization of biotech corn. Several domestic companies are reportedly preparing to submit Bt corn events for approval for domestic cultivation; the approval process is expected to take 3-5 years. 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. In May 2015, the Ministry of Agriculture (MOA) released a draft revision to its regulations governing biotechnology that would remove timelines for approvals and add economic and social factors to the approval process for the first time.

Section I. Executive Summary:

The government of China is in the process of revising laws and regulations governing biotechnology. In May 2015, the Ministry of Agriculture (MOA) released a draft amendment to the Administrative Measures for Safety Assessment of Agricultural Genetically Modified Organisms for public comments, which was later notified to the WTO SPS Committee (SPS notification 881). The amendment would remove timelines for approvals and add economic and social factors to the approval process for the first time (see [GAIN Report CH15021](#)). MOA also [recently reported](#) that it is considering creating a procedure for soliciting public opinion on biotechnology applications to enhance public involvement in the agriculture biotech review decision making.

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

According to recent news reports, several domestic companies are preparing to submit Bt corn events to MOA for approval for domestic cultivation. It is expected to take 3-5 years before these events are commercialized. China has not approved any foreign biotech food or feed crops 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 two new soybean and one corn variety for import in December 2014 (see Appendix II). These were the first new approvals since June 2013. The increasingly slow and unpredictable approval process resulted in large-scale trade disruptions. Corn trade remains weak after the approval of the corn event MIR 162, while DDGS trade witnessed a recovery. Trade in other products, such as alfalfa, have also suffered from biotech related trade disruptions. Despite these challenges, China is expected to remain a significant importer of biotech products, notably soybeans. The United States, as well as many other countries, has continued to press China to adhere to a science-based policy on biotechnology approvals.

Section II. Author Defined:

1. Government Policy

Biotechnology is designated as a strategic emerging industry in China, and the government invests heavily in biotechnology research. While the total amount of Chinese government expenditures on biotechnology is unknown, it is believed to far exceed public sector investment in biotechnology in any other country, including the United States ([see the GAIN Report 13033](#) for additional details).

In February 2015, the Chinese Communist Party pledged in the 2015 No. 1 Document 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 built on the comments President Xi Jinping made on biotechnology during a major policy speech on agriculture in December 2013 (see below).

The No. 1 Document and speech help 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 corn and rice, 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.

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.

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.

There are increasing reports that the unwritten policy against approving major GE food crops will soon come to an end. In summer 2015, two leading Chinese seed companies, Da Bei Nong and Origin, revealed that they have finished production trials for their Bt corn varieties, and are now ready to submit applications to MOA for biosafety certificates. The approval process for cultivation is expected to take three to five years, although they could be expedited. There have been increasing reports of farmers in China planting unapproved Bt varieties of corn and rice to cope with rising pest pressures, but it is still unclear how widespread this trend is.

Domestically developed varieties of biotech 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 for 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 developing 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 slow approvals for many biotechnology crops has slowed the development of the biotechnology sector 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 biotech cotton seeds from international companies initially held large share 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. Public opinion is one factor that is considered when deciding whether to approve a genetically engineered (GE) crop for import or cultivation, along with safety, environmental, and economic considerations. A lack of public acceptance was directly cited by MOA in July 2014 as the sole reason for delaying an import approval application for a GE soybean variety.

Public Acceptance

The government is increasing its public outreach efforts to address public misperceptions to help develop China's domestic biotechnology industry. 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 plans outreach to provincial agricultural officials, students, and the general public. Provincial authorities are being asked to assist in these efforts.

Many people in China still have limited knowledge about biotechnology, and rumors and misinformation is widespread. A common and persistent misperception is that consumers in biotechnology producing countries, such as the United States, do not themselves consume genetically modified food. (In reality over 90 percent of corn and soybeans in the United States come from GE varieties and are used in many food products.) The emerging media, such as the MicroBlog, WeChat, and on-line forums are often used by opponents of agricultural biotechnology.

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 National People's Congress Consultative Committee. A Chinese lawyer filed a case against MOA claiming that MOA violated the public information disclosure requirements after his request for information was rejected. The lawyer requested disclosure of information related to 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. MOA responded that the approved events, the labelling requirements and the safety review documents have been disclosed on MOA's official website and that the other issues do not fall within the government information disclosure scope. In July 2015, the Beijing High Court made the final ruling in favor of

MOA. Such cases against the government in China are unusual.

2. Production

China is the sixth largest producer of agricultural biotechnology crops in the world by area according to a 2014 report by the International Service for the Acquisition of Agro-biotech Applications (ISAAA).

Cotton accounts for almost all of the 4 million acres of biotech crops grown in China. Although China has commercialized six genetically modified plants since 1997 (cotton, tomato, sweet pepper, petunia, poplar, and papaya), few are in production today due to difficulties in bringing the products to commercialization.

In 2014, 7.1 million Chinese farmers planted 3.9 million hectares of biotech cotton. While cotton acreage decreased from 4.6 million hectares in 2013 to 4.2 million hectares in 2014, the percentage of cotton acreage planted with GE seeds increased by three percentage points to 93 percent.

Approximately 8,500 hectares of virus resistant papaya were planted in Guangdong, Hainan Island, and, beginning this year, in Guangxi. Virus resistant papaya acreage increased by 50 percent from 5,800 hectares in 2013 to 8,475 hectares in 2014. There have been reports of farmers in China planting unapproved varieties of Bt corn and rice to cope with rising pest pressures, but it is unclear how widespread this trend is.

Biotech products approved for commercial production in China can be found on [MOA's website](#). In general, biotech crop cultivation is approved on a province by province basis. However, the vast majority of the safety 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. China does not have a co-existence policy.

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. MOA does not publish information on ongoing domestic biotech research and development. According to MOA publications on deregulation, major crops undergoing field trials (either the intermediary experiment or environmental release stage) include 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, and eleven stress-resistant events and four high quality 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 July 2008, China approved a \$3.5 billion special research program to develop new biotech varieties over 15 years through the Key Scientific and Technological Grant of China for Breeding New Biotech Varieties. Funding comes from central and local governments as well as investment by companies. 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. The 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.

3. Trade and Marketing

China is a large importer of biotech soybeans, cotton, corn, and soybeans for feed and processing. It has also recently become a large importer of dried distillers grains with soluble (DDGS), a corn by-product from ethanol production commonly used in animal feed. It accounts for roughly two-thirds and one half of global soybean and DDGS imports, respectively, most of which are produced from biotech varieties. China is also a large exporter of cotton products, many of them made with Bt cotton (biotech cotton at an adoption rate of 93% in 2014). China does not allow the import biotech seeds for commercial cultivation.

China's increasingly slow and unpredictable approval process and lack of a low level presence (LLP) policy has resulted in a large increase in rejected shipments and trade disruptions. Corn trade remains weak after the approval of the corn event MIR 162, while DDGS trade has generally recovered. Trade in other products, such as alfalfa, have also suffered from biotech related trade disruptions.

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 biotech food crops, so all the food aid is comprised of non-biotech crops.

Labeling

China's revised Food Safety Law, which takes force on October 1, 2015, will incorporate existing regulations on biotechnology labeling into law ([see GAIN Report CH15016](#)). China's labeling regulations, governed by MOA Decree 10 (see 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, rape oil, and rape meal
4. Cottonseed
5. Tomato seed, fresh tomato, and tomato paste

In addition to these labeling requirements, China also recently enacted new policies to prevent misleading 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 “healthier” or “safer.”

Testing

Testing of biotechnology products is carried out primarily by MOA, AQSIQ and the Ministry of Environmental Protection (MEP) through their affiliated testing institutes. AQSIQ tests imported products for unapproved biotechnology events, MOA tests domestic crops and conducts safety assessment experiments, and MEP tests for environmental safety assessments.

China has a zero tolerance for unapproved biotechnology traits in imports. In practice, labs have varying testing sensitivities and capabilities, although all use highly sensitive polymerase chain reaction (PCR) testing. This means that the import tolerance can range from 0.1 percent to 0.01 percent, or even less. The variability, high testing sensitivities, and lack of a set threshold for positive results create the risk that shipments will be rejected due to cross contamination from a reused shipping container or pollen blown in from another field. It can also result in cases where a shipment tests negative for unapproved events in the exporting country but tests positive when it arrives in China.

MOA, AQSIQ and MEP have developed national and industry standards for biotech testing, all of which use PCR testing methodologies. Although the standard numbers suggest they are voluntary, they are believed to be *de facto* mandatory and are adhered to within China. AQSIQ developed standards tend to focus on specific crops, while 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)

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)

4. Approvals

As of the date of this report, MOA has not approved any new varieties in 2015. The last approvals were on December 11, 2014, when MOA granted import approvals for Syngenta MIR 162 corn, Bayer Liberty Link soybeans, and a Pioneer high oleic soybean variety (305423×40-3-2). These were the first new import approvals issued by MOA since June 2013. MOA also issued renewals in 2014 for a number of traits set to expire in 2014 and 2015.

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

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.

5. 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 its biotech regulations. In May 2015, MOA released a

draft amendment to the Administrative Measures for Safety Assessment of Agricultural Genetically Modified Organisms (also known as Decree 8) for public comments (see [GAIN Report CH15021](#)). The draft amendment was notified to the WTO SPS Committee in June 2015 (SPS notification 881).

The amendment, if implemented, would remove the timelines provided for in existing regulations, giving MOA greater flexibility and increasing uncertainty for applicants. The amendment would also add “economic and social factors” to the approval process (see below). This has raised questions and concerns from other governments and agricultural groups regarding how the revisions will be implemented, what standards will be used to assess economic and social factors, and why they are included in a scientific evaluation.

Unofficial translation of Article 16 in the draft revised regulations:

The accepted applications shall be submitted to National Biosafety Committee (NBC) for safety assessment. After the Ministry of Agriculture receives the safety assessment result, a decision on the application shall be made according to the Administrative License Law of People’s Republic of China and the Regulations on Administration of Agricultural Genetically Modified Organisms Safety (promulgated by State Council Decree No. 304 in 2001), with scientific, economic and social factors being comprehensively taken into consideration.

MOA is also considering creating a procedure for soliciting public opinion on biotechnology applications to increase public involvement in the agriculture biotech review decision making. This information was [released on July 24th, 2015](#) in response to an inquiry from members of China’s National People’s Congress Consultative Committee. No details or final decision have been announced regarding this proposal.

Ministerial Responsibilities

MOA has primary responsibility for the approval of biotech agricultural 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 biotech 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. 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. 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, 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 (MOA's window office accepting applications and issuing 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 National Biosafety Committee 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 process 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 (GAIN report CH13030). These regulations clarify steps MOA will take in reviewing agricultural GMO-related applications for entry of GMO materials, safety certificates, labeling, etc., and the time needed for each step. This is the first time MOA established written GMO-related application review procedures.

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 right protection amongst seed companies as 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 National Biosafety Committee and obtain a biosafety certificate issued by the MOA's Division of GMO Biosafety and IPR. As outlined below, the approval process for biotechnology products for domestic cultivation involves five steps: research, intermediary experiment, environmental release, productive testing, and biosafety certification. Approvals are also sought at the provincial level in addition to national level review. After completing the 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. The Committee consists of 44 experts with diverse backgrounds from different Chinese ministries, research institutions, and universities. The NBC is divided into three expert groups: biotech plants, animals and microorganisms, and food and feed. Since 2008 the NBC has held three meetings per year, usually in early March, July, and November. 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 (see report CH13031). These rules explain the function and composition of the Committee, and establish ethical requirements for the Committee members. The members of the fourth BioSafety Committee were announced by MOA in April 2013, and are available on its [website](#).

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 biotech products, GE plant processing facilities, the seed market, and labeling.

6. Seed Registration Procedures

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.

China is currently revising its Seed Law as part of its effort to develop a stronger domestic seed industry. The Draft Seed Law was published for public comment in May 2015. It is designed to strengthen variety management and intellectual property protections for seeds. As currently drafted, it will also increase restrictions and oversight over international seed companies as well as the transfer of germplasm internationally and within China. See [GAIN report CH14035](#) for more information on seed regulations as well as an unofficial translation of the 2014 Draft Seed Law.

In June 2014, MOA released the Guideline on Green Channel Test for National Variety Certification of Rice and Corn. The new measure established a "green channel" to streamline the cumbersome variety registration process for certain large scale domestic companies. Foreign companies are unlikely to be able to access this channel given the specific requirements.

According to a joint notification by NDRC and the Ministry of Finance to MOA, the fee schedule for

the safety evaluation and testing of GE agricultural materials is as follows:

1. Intermediary experiment (2,500 Yuan per item)
2. Environment release (3,000 Yuan per item)
3. Productive testing (5,000 Yuan each or 3,000 Yuan for additional imports as processing materials)
4. GMO Survival and Competiveness Test (83,000 Yuan per item)
5. Ecological Risk of Gene Flow Test (92,000 Yuan per item)
6. GMO Impact on Non-target Organisms and Biodiversity Test (96,000 Yuan per item)
7. Anti-nutrient Test (1,000 Yuan per item)
8. 90-day Rat Feeding Study (120,000 Yuan per item)

Intellectual Property Rights

China's Seed Law and MOA Administrative Measures for Plant Variety Protection governs intellectual property right protection for agricultural biotechnology. The administrative measure was promulgated in 1997 and revised in 2013. The government is working on developing a new Seed Law to try to improve variety protection. 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.

7. Application Processes

MOA Import Approval Application Process

The process to obtain a biosafety certificate for an imported biotech food crop for processing (like soybeans) used to take around two years, but it has now become substantially slower. It involves 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 as available.

1. Administrative Services Hall of MOA: accepts applications.

Tel: 86-10-5919-1811/1805

2. Biosafety Management Division at the Center for Science and Technology Development (CSTD) reviews and then submits the application to the NBC.

Tel: 86-10-5919-9389

3. NBC plenary sessions are held in March, July and November to discuss applications and determine appropriate tests.

4. Division of GE Biosafety and IPR: processes import permit for field trials and feed studies based on NBC recommendations.

Tel: 86-10-5919-3059

5. Detection and Testing Division at the Center for Science and Technology Development: designates

testing institutes and locations for field trials and feed study, and works with applicants and designated testing institutes to understand the applicant's testing methods and sampling process. The testing institutes may or may not use the same processes or methods while conducting its own tests.

Tel: 86-10-5919-9385

6. Provincial Agriculture Bureaus endorse field trials based on the Division of GMO Biosafety and IPR approvals.
7. Testing institutes draft reports after the field trials and feed studies are completed.
8. Biosafety Management Division of CSTD reviews and submits a final version of all analysis to NBC.
9. NBC reviews the field trial and feed study reports, and provides a recommendation for approval;
10. The Division of GMO Biosafety and IPR takes NBC's recommendation into consideration before issuing a biosafety certificate to the applicant.

8. Field Trials

China allows field trials of GE crops, but does not provide data on the number of field trails taking place, types of crops/traits being tested or estimated time to commercialization. The South China Crop Breeding Base, located in Hainan, attracted national media attention in 2014 following reports of inadequate controls on field trials. This followed an investigation by the Hainan Agriculture Bureau into illegal planting of GE crops in three counties and cities in the province in late 2013. The investigation found 15 samples collected from 13 research institutes tested positive of GE contamination. All the samples were from experimental fields. Nine out of the 15 detected crops were destroyed, and six underwent further testing.

In March 2014, MOA announced that it would start conducting annual inspections of agricultural crops grown in the South China Crop Breeding Base. MOA said some research institutes and seed companies had brought uninspected and unregistered seeds to the breeding base, and that such practices might introduce quarantine pests to Hainan Island and threaten agriculture production safety in the base. On March 20, several days after the MOA announcement, five seed companies were reported to have illegally grown biotech corn in the Breeding Base. The companies included three from Henan province, one from Liaoning province, and one state-owned enterprise; company names were not provided. In April 2014, two Greenpeace activists were caught taking seeds and leaf samples from Huazhong Agricultural University's experimental fields in Hainan province without permission. Greenpeace claimed they were investigating the safety management of GE crops.

In May 2014, MOA released the Public Notice Further Strengthening Supervision of Agricultural GMO Safety. The notice urges local agricultural authorities to include every research institute, school and enterprise in the region that engages in agriculture biotechnology research and development, production, processing and trade into their supervision system. Below is a list of objectives and actions included in the notice:

1. *Strengthen supervision of tests*

2. *Regulate safety assessment experiments*
3. *Strengthen supervision in crop variety examination*
4. *Strengthen supervision in the production and distribution of GMOs, in particular seeds*
5. *Strengthen the management of labeling. Labels shall be provided if the product is subject to the labeling requirements, so the public is fully informed*
6. *Strengthen the supervision over research institutes. Prohibit the illegal spread of GMO materials*
7. *Fulfill regulatory responsibilities*
8. *Provincial and local agricultural authorities shall initiatively carry out their supervisory responsibilities*
9. *The research institutes and developers are the first and primary responsible entities for biosafety*
10. *Guarantee support to the GMO safety regulatory work*
11. *Leaders of the local agricultural authorities shall be the chiefs of biosafety supervision, guarantee funds and staffs for the work*
12. *Strengthen risk monitoring; early detection of risks will enable agricultural authorities to control and solve problems*
13. *Harshly punish violations, such as when involving field trials, breeding in Hainan Province, and transfer of GMO materials*
14. *Educate the public on GMO technology*

9. International Treaties and Dialogue

China signed onto 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 is participates in the Global LLP Initiative as an observer.

Major biotechnology producing countries, including the United States, routinely engage China regarding its slow biotechnology approval system. China is the last major agricultural importer to approve most biotech crops, sometimes by several years. This has delayed the global adoption of new varieties and lead to increased weed and pest pressure in countries like the United States.

The United States and China held in-depth discussion on agricultural biotechnology in multiple forums in 2015, including the State Visit by President Xi Jinping in Washington, DC in September and the Joint Commission on Commerce and Trade in Guangzhou, China in November. Below are the U.S.-China agreed outcomes on biotechnology from these two events.

State Visit by President Xi Jinping Washington, DC, September 2015

China and the United States conducted in-depth discussions on the administration of agricultural biotechnology, and committed to further improve approval processes. 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

**Joint Commission on Commerce and Trade
Guangzhou, China, November 2015**

China and the United States reaffirm the outcomes reached on agricultural innovation in September 2015 at the state visit of President Xi with President Obama. China and the United States have fully exchanged views about agricultural innovation at the JCCT and the Strategic Agricultural Innovation Dialogue; will jointly promote cooperation on agricultural innovation; and will create a favorable environment for agricultural innovation. Both countries reiterated they would work together to further the approval process based on international standards; and reiterated the importance of adopting a timely, transparent, predictable and science-based approval process. China and the United States jointly agreed to strengthen policy and information exchange; share the experiences and practices on research and development, supervision and approval; and consider domestic and international stakeholders' comments when modifying and improving regulations.

10. Outreach Activities

On December 8, 2015 the U.S. Embassy, along with Crop Life China and the Platform of Science Communication for Agricultural Biotechnology, organized a workshop in Beijing, China for countries to share experiences and best practices in risk communication and public outreach on agricultural biotechnology. Speakers included Chinese scientists, journalists, and representatives from the United States, Australia, and Canada. Representatives from several Chinese ministries and other countries also participated in the workshop. Mr. John Cordts, former APHIS regulator, presented at the workshop with support from the U.S. Department of State. Public outreach on biotechnology was identified as a priority in China's 2015 "Number One Document" on rural policy.

In fall 2015, the U.S. Consulate in Shenyang brought several U.S. farmers and agricultural experts to meet with scientists and managers of large farms in northeast China. The U.S. farmers and experts shared how they use different technologies, including biotechnology, in their operations in the United States. The intent was to exchange best practices in farming and begin a dialogue on ways to improve agricultural sustainability and food security.

11. Animal Biotechnology

China is a leader in animal biotechnology research. However, it has not yet approved commercialization of any livestock clones or GE animals or products derived from animal biotechnologies. It also does not import or export GE animals, livestock clones, or products from these animals. Public concern and underdeveloped links between public research institutes and industry have made commercialization of GE animals difficult in China.

China's Central Government invests heavily in basic research for animal biotechnology. Research institutes can apply to MOA and 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. 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. Researches mainly focused on medicine production, improving quantity and quality of milk, and improving quality of meat and wool. 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.

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.

GE animal labeling is subject to Measures for Agricultural GMO Labeling Administration (MOA Decree 10). However, as China has not yet commercialized any GE animals or clones, no specific measures for GE animal labeling are available.

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.

Appendix 1: China's Trade in Biotech Crops

China Cotton Exports

Partner Country	Quantity (Metric Tons)
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	2012	2013	2014	2015 (Jan.-Oct.)
World	17,558	6,733	13,470	24,214
Bangladesh	5,041	0	4,636	835
Vietnam	790	2,506	2,435	14,226
Korea North	3,205	2,082	2,037	748
Indonesia	507	557	1,821	2,925
Korea South	2,140	169	990	4,173

Source of Data: China Customs

China Cotton Imports

Partner Country	Quantity (Million Tons)			
	2012	2013	2014	2015 (Jan.-Oct.)
World	5.14	4.15	2.44	1.20
United States	1.46	1.15	0.55	0.504
India	1.44	1.19	0.82	0.19
Uzbekistan	0.31	0.26	0.17	0.12
Brazil	0.37	0.16	0.14	0.086
Australia	0.82	0.80	0.50	0.18

Source of Data: China Customs

China Corn Imports

Partner Country	Quantity (Million Tons)			
	2012	2013	2014	2015 (Jan.-Oct.)
World	5.21	3.26	2.6	4.58
Ukraine	0.00	0.11	0.96	3.85
United States	5.11	2.97	1.03	0.43
Bulgaria	0	0	0.134	0.16

Source of Data: China Customs

China Soybean Imports

Partner Country	Quantity (Million Tons)			
	2012	2013	2014	2015 (Jan.-Oct.)
World	58.38	63.40	71.4	65.22
Brazil	23.89	31.81	32	36.97
United States	25.97	22.26	30	17.51
Argentina	5.90	6.12	6	7.84

Source of Data: China Customs

China Distillers Dried Grains Imports

Partner Country	Quantity (Million Tons)			
	2012	2013	2014	2015 (Jan.-Jun.)
World	2.38	4.00	5.415	5.936
United States	2.38	4.00	5.413	5.934
Canada	0	0	0.0005	0.0015

Source of Data: China Customs

Appendix 2: Biotech Crops Approved for Import as Processing Materials

No.	Event	Developer	Biosafety certificate validity
1	Alpha-amylase corn 3272	Syngenta	May 21, 2013 - May 21, 2016
2	Drought resistant corn MON87460	Monsanto	May 26, 2013 - May 26, 2016
3	Herbicide tolerant Soybean CV127	BASF	Jun. 6, 2013 - Jun. 6, 2016
4	Insect resistant soybean MON 87701	Monsanto	Jun. 6, 2013 - Jun.6, 2016
5	Insect resistant soybean MON87701 x MON89788	Monsanto	Jun. 6, 2013 - Jun.6, 2016
6	Insect resistant cotton 15985	Monsanto Far East Ltd.	Jul. 21, 2011 - Jul. 21, 2016
7	Herbicide resistant cotton LLCotton25	Bayer CropScience	Dec. 20, 2011 - Dec. 20, 2016
8	Herbicide resistant soybean A2704-12	Bayer CropScience	Dec. 31, 2013 - Dec. 31, 2016
9	Herbicide tolerant corn NK603	Monsanto Far East Ltd.	Dec. 31, 2013 - Dec. 31, 2016
10	Insect resistant and herbicide tolerance corn MON88017	Monsanto Far East Ltd.	Dec. 31, 2010 - Dec. 31, 2016
11	Insect resistant corn MON89034	Monsanto Far East Ltd.	Dec.31, 2013 - Dec. 31, 2016
12	Insect resistant corn MIR604	Syngenta Crop Protection	Aug. 28, 2014-Aug.28, 2017
13	Herbicide resistant corn GA21	Syngenta Crop Protection	Aug. 28, 2014-Aug.28, 2017
14	Herbicide resistant soybean MON89788	Monsanto Far East Ltd.	Aug. 29, 2014-Aug.29, 2017
15	Insect resistance and herbicide tolerance corn Bt11xGA21	Syngenta Crop Protection	Nov. 3, 2014 - Nov.3, 2017
16	Quality improvement soybean 305423	Pioneer	Nov.3, 2014-Nov. 3, 2017
17	Soybean A5547-127	Bayer	Dec.11, 2014-Dec.11, 2017
18	Soybean 305423x40-3-2	Pioneer	Dec.11, 2014-Dec.11, 2017
19	Corn MIR162	Syngenta	Dec.11, 2014-Dec.11, 2017

20	Herbicide tolerant Flex cotton MON 88913	Monsanto	Dec. 20, 2012 - Dec. 20, 2017
21	Herbicide resistant corn T25	Bayer CropScience	May 8, 2015-May 8, 2018
22	Herbicide resistant Canola Oxy-235	Bayer CropScience	May 8, 2015-May 8, 2018
23	Herbicide resistant Canola T45	Bayer CropScience	May 8, 2015-May 8, 2018
24	Herbicide resistant Canola Ms8Rf3	Bayer CropScience	May 8, 2015-May 8, 2018
25	Herbicide resistant sugar beet H7-1	Monsanto Far East Ltd., a German seed company	May 8, 2015-May 8, 2018
26	Insect resistant cotton 531	Monsanto	Aug.28, 2013 – Aug. 28, 2018
27	Herbicide tolerant cotton 1445	Monsanto	Aug.28, 2013 – Aug. 28, 2018
28	Herbicide tolerant soybean GTS40-3-2	Monsanto Far East Ltd.	Dec. 20, 2015-Dec. 20, 2018
29	Insect resistant corn 59122	Du Pont/Dow AgroSciences	Dec. 20, 2015-Dec. 20, 2018
30	Insect resistant corn TC1507	Du Pont/Dow AgroSciences	Dec. 20, 2015-Dec. 20, 2018
31	Insect resistant corn MON810	Monsanto Far East Ltd.	Dec. 20, 2015-Dec. 20, 2018
32	Insect resistant corn MON863	Monsanto Far East Ltd.	Dec. 20, 2015-Dec. 20, 2018
33	Insect resistant corn BT176	Syngenta Crop Protection	Dec. 20, 2012-Dec. 20, 2015
34	Insect resistant corn BT11	Syngenta Crop Protection	Dec. 20, 2012-Dec. 20, 2015
35	Herbicide resistant Canola Topas19/2	Bayer CropScience	Dec. 20, 2015-Dec. 20, 2018
36	Herbicide resistant Canola Ms1Rf1	Bayer CropScience	Dec. 20, 2015-Dec. 20, 2018
37	Herbicide resistant Canola Ms1Rf2	Bayer CropScience	Dec. 20, 2015-Dec. 20, 2018
38	Herbicide tolerant Canola GT73	Monsanto Far East Ltd.	Dec. 20, 2015-Dec. 20, 2018
39	Insect resistant and herbicide tolerant cotton GHB 119	Bayer CropScience	Apr.10, 2014 - April 10, 2019
40	Insect resistant and herbicide tolerant cotton T304-40	Bayer CropScience	Apr.10, 2014 - April 10, 2019
41	Herbicide resistant cotton GHB614	Bayer CropScience	Dec. 30, 2015 - Dec.30, 2020

