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## **China - Peoples Republic of**

### **Agricultural Biotechnology Annual**

### **Agricultural Biotechnology Annual**

**Approved By:**

Philip Shull

**Prepared By:**

Andrew Anderson-Sprecher and Ma Jie

**Report Highlights:**

The Chinese government has prioritized the development of a domestic biotechnology industry and is investing heavily in basic research. Commercialization of biotech varieties has been limited to date due to concerns over public opinion and the strength of the domestic seed industry. The biosafety certificates issued to Chinese developed biotech rice and corn expired in August 2014 without MOA completing the final step needed for commercialization. Delays in import approvals have created large scale trade disruptions in corn and corn products and impacted other crops such as alfalfa. Despite these challenges, China is expected to remain a significant importer of biotech products, notably soybeans. The United States has continued to press China to adhere to a science-based policy on biotechnology approvals.

## **Executive Summary:**

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.

Despite major investment and high level support for biotechnology research, the approval process for agricultural biotechnology cultivation and import has become increasingly slow and unpredictable. After lengthy delays, the Ministry of Agriculture (MOA) approved two new soybean and one corn variety for import in December 2014. These were the first new approvals since June 2013.

In July 2014, MOA cited public acceptance as the basis for delaying approval of one of the two recently approved soybean varieties. This is the first time MOA exclusively cited non-scientific concerns in refusing to approve an import application. MOA also chose to allow the biosafety certificates issued to Chinese developed biotech rice and corn to expire in August 2014 without completing the final required registration step needed for commercialization.

The development of China’s agricultural biotechnology sector has been challenged by the lack of a clear path to commercialization, inconsistent protection of intellectual property, foreign investment bans, and the fragmented nature of China’s seed industry. Chinese seed companies are still working on developing biotech seeds, and some hope to be able to commercialize domestically developed varieties of biotech corn in the next three to five years. To date, China has not approved any foreign biotech food or feed crops for domestic commercial production. There have been reports of farmers in China planting unapproved insect resistant varieties of corn and rice to cope with rising pest pressures, but it is still unclear how widespread this trend is.

China’s increasingly slow and unpredictable approval process resulted in large-scale trade disruptions in 2014. Over the past year the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) has rejected over one millions tons of corn and DDGS due to detections of MIR 162; the trait was approved in the United States in 2010, but not approved for import into China until December 11, 2014. According to industry, these trade disruptions have resulted in hundreds of millions of dollars in losses. 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 has continued to press China to adhere to a science-based policy on biotechnology approvals.

## **1. Government Policy**

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

Despite the government's record of supporting biotechnology research, President Xi Jinping's views on this sector were unclear until recently. This changed in September 2014 when the government released a collection of speeches by President Xi, including a speech he gave at the Central Conference on Rural Work held on December 23, 2013. In this speech President Xi affirmed official support for biotechnology research, but he was much more cautious about commercialization and the participation of foreign companies.

*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.*

These comments shed some light on what had appeared from the outside to be a confusing and somewhat contradictory set of government actions on biotechnology: slowing or stalled approvals for foreign development 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.

However, China's well-funded but nascent biotechnology industry faces a number of challenges. The government's decision not to commercialize major biotechnology crop varieties (other than cotton) limits incentives for local seed companies to invest in biotechnology. It also encourages public labs to focus on basic research rather than developing commercially viable seeds. As mentioned above, MOA allowed the only three biosafety certificates issued to Chinese developed biotech rice and corn to expire in August 2014 without completing the final required registration step needed for commercialization. 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 limit participation of foreign seed technology companies through restrictions and bans on foreign investment, as well as a lack of approvals for many biotechnology crops, is also slowing the development of the biotechnology sector in China by restricting the ability of international companies to partner with Chinese companies. 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 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 concerns over public acceptance as an important factor behind the slow pace of biotechnology commercialization in China. According to Ministry of Agriculture officials, public opinion is one factor among others that is considered when deciding whether or not to approve a 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 genetically engineered (GE) soybean variety.

The public in China, lacking accurate knowledge about agricultural biotechnology, tend to be influenced by rumors and misinformation. 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 frequently used to spread false information about agricultural biotechnology. A former Chinese talk show host self-funded an online video on biotechnology in 2014, heightening online debate. The video was seen by a large audience in China, but was criticized by the scientific community as biased.

The government has begun to conduct public outreach to address public misperceptions and rumors in order to allow China’s domestic biotechnology industry to develop. Soon after President Xi’s speech was published, MOA launched a campaign to train and educate local agricultural officials and the public about biotechnology. It is working to explain China’s biosafety regulatory work using a traditional and social media. MOA plans outreach to provincial agricultural officials, students, and the general public. Provincial authorities will also be called on to assist in outreach efforts.

## **2. Production**

China is the sixth largest producer of agricultural biotechnology crops in the world by area at four million hectares, according to the 2013 report by the International Service for the Acquisition of Agrobiotech Applications (ISAAA). 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. Biotech products approved for commercial production in China can be found on [MOA’s website](#). The vast majority of the safety certificates for cultivation are for domestically developed varieties of Bt cotton. The government has not approved any foreign developed biotech food or feed crops for cultivation. There are no public statistics on GE seed production in China.

In general, biotech crop cultivation must be approved on a provincial basis. However, Bt cotton

cultivation is approved in three ecological areas including: the Yangtze River Reaches (covering Sichuan, Chongqing, Hubei, Hunan, Jiangxi, Zhejiang, Jiangsu (not including Xuzhou), Huainan of Anhui, and Nanyang and Xinyang of Henan), Yellow River Reaches (covering Huaibei of Anhui, Shandong, Xuzhou of Jiangsu, Henan (not including Nanyang), Hebei, Beijing, Tianjin, Shaanxi, and Shanxi), and the Northwestern inland area (covering Xinjiang, Gansu, Ningxia, and Inner Mongolia). There is no policy on co-existence of GE crops with non-GE crops (including organic agriculture) in China.

Insect-resistant (Bt) cotton is the most widely planted genetically enhanced product grown in China. While precise statistics are not available, it's estimated that around half of all cotton planted in China is produced with Bt cotton varieties. Other genetically modified crops in China include a virus-resistant papaya (approximately 6,700 hectares) and an insect resistant variety of poplar trees (approximately 450 hectares).

Despite large amounts 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. However, MOA failed to issue final approval for planting before the safety certificates expired in August 2014. The future of these domestically developed varieties is now unclear. There have been 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 and the State Forestry Administration (SFA) do not publish information on ongoing domestic biotech research and development. However, according to MOA publications on deregulation, major crops undergoing field trials (which is either the intermediary experiment or environmental release stage; see Approval for Domestic Production section) include insect resistant corn, high lysine corn, resistance to pre-harvest germination wheat, and insect resistant soybeans.

As noted above, China has heavily invested in biotech research and seed development, primarily through publicly funded research institutes and universities. In July 2008, the State Council approved a \$3.5 billion special research program to develop new biotech varieties (funding comes from central and local governments as well as investment by companies) over 12 years. 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.

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.

China does not import biotech seeds for cultivation. It accounts for roughly two-thirds of global soybean imports and close to half of global DDGS imports, much of which is produced from biotech varieties. China is also a large exporter of cotton products, many of them made with Bt cotton.

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. Since October 2013, AQSIQ has rejected over one million tons of corn and DDGS due to detections of MIR 162. According to industry, these trade disruptions have resulted in hundreds of millions of dollars in losses. MIR 162 was commercialized in the United States in 2010 and is widely planted in North and South America, but was not approved in China until December 11, 2014. Alfalfa imports into China have also been affected, as China has yet to approve any GE varieties of alfalfa.

### ***Labeling***

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 draft Food Safety Law, released for comment by the National People's Congress in late December 2014, will make legally mandate GE labeling rather than referring to relevant regulations as is currently the case. The draft law states that producers will be punished if GE products are not properly labeled. 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 labeling. On September 28, 2014, China Central Television Station issued a notice to advertising agents notifying them that State Administration of Industry and Commerce (SAIC) will strengthen regulatory oversight over advertisements involving GMO and non-GMO products. This move was taken after MOA contacting SAIC with concerns about misleading labeling.

The new regulations prohibit advertising crops and products as "non-GMO" if no GMO variety of that crop has been approved in China (e.g., rice and peanuts). Foods made of crops where GMO varieties exist, such as soy and rapeseed, must provide evidence that they are GMO-free before they can be advertised as such. In addition, the regulations ban the use of misleading statements claiming that non-GMO foods are healthier or safer than GMO varieties.

## **4. 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.

MOA, AQSIQ and MEP have developed national and industry standards for biotech testing, all of which use polymerase chain reaction (PCR) testing methodologies. While they are voluntary, they are believed to be generally adhered to within in 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. 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); and  
MOA Public Notice 1861 (six standards).

#### ***MEP Developed Standards***

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

One of the challenges facing imports is a lack of consistent practices on detection limits. 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 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 creates the risk that shipments will be rejected due to cross contamination from a reused shipping container or pollen blown 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.

#### **4. Approvals**

MOA approved three new traits for import on December 11, 2014: 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.

#### **5. Regulatory structure**

The biotechnology regulatory environment 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 (see Report CH7053) respectively. SFA also issued the Review and Administration Measures on Conducting Activities Related to Genetically Engineered Forestry Wood Products (details are available on the [SFA website](#)).

The Chinese government is currently revising its biotech regulations. Details about the revision and timing of publication of the revised regulations are not publically available. The National Biosafety Committee developed a guideline for biosafety assessment (environmental and food safety) to streamline the processes. The guideline is available on MOA’s [website](#).

##### ***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). 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 (See Gain Report CH4017) governs the steps that should be taken at customs when importing or exporting biotech goods.

##### ***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 if 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 threat to human or animal health and the environment. MOA Decree 9 (see Report CH7053) outlines the requirements for importing biotech products.

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 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 (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 rights (IPR) protection amongst seed companies as MOA would not sign a material transfer agreement. It is unclear why MOA needs

China lacks a "stacked" event policies. Realizing the future need, MOA is conducting research and working with stakeholders to develop regulations on biosafety assessment of stacked events.

### ***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. 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 decisions are generally released 45 days after each meeting.

On May 23, 2013, MOA issued the Working Rules of the Committee for Safety of Agricultural GMOs (see report CH13031). The rules not only explain the function and composition of the Committee, but also for the first time, establish ethical requirements for the Committee members. The members of the fourth BioSafety Committee were released 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 the country which undertake environmental safety testing, food safety testing, and detection of GE agricultural. 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 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 may begin in step 3 or “production testing (see below).

Registration involves field trials and other testing requirements, some of which may be duplicative of 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 June 2014, MOA released the Guideline on Green Channel Test for National Variety Certification of Rice and Corn (see GAIN report [CH14035](#)). 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 (see GAIN report [CH14035](#)). 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***

In the past the process to obtain a biosafety certificate for an imported biotech food crop for processing (like soybeans) took around two years, although it has become substantially slower in recent years. It involves steps of varying length, such as importing testing materials, field trials and/or a feeding study, 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 Examination and Approval Office, MOA: accepts applications.
2. Biosafety Management Division at the Center for Science and Technology Development (CSTD) reviews and then submits the application to the NBC.  
*Contact: Ms. Li Ning*  
*Tel: 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.  
*Contact: Ms. Sun Junli*  
*Tel: 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.

*Contact: Mr. Song Guiwen*

*Tel: 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.

#### ***State Forestry Administration Domestic Production and Import Approval Procedure***

SFA regulates research, production, and the import and export of GE trees intended for forestation and wood processing. This does not include trees that grow fruits, nuts, or other consumable products (these plants fall under the jurisdiction of MOA). The SFA deregulatory process is similar to MOA's.

Depending on transgenic tree risk levels, SFA will give approval for developers to conduct lab research. The deregulation of a biotech tree includes 3 stages: intermediary trial, environmental release, and product testing. After a domestic developer completes each stage, they must submit a document containing all the data and material from the study to SFA, who will provide a determination within 20 working days on whether the deregulatory process can continue to the next stage. If SFA believes that more testing is needed, the time-frame between stages may be longer. After all the stages are successfully completed, a biosafety certificate will be issued, which is valid for 2 years. However, before the product can be commercialized, the biotech tree must also undergo a seed variety registration process (similar to MOA), which may include an additional assessment by experts from the government, academia, and private industry. This process takes about one year for non-GE products, but may take longer for GE products since additional field trials may be needed.

Imported biotech tree products intended for production and processing are not required to undergo field trials. However, in order to acquire approval for import, foreign developers must provide documentation that the product has been deregulated by a third country that will certify that the product is 100 percent safe for humans, plants, animals, microorganisms, and the environment. Because no authority can certify that a product is 100 percent safe, no foreign GE forestry product has entered China's market to date. A biotech tree intended for domestic cultivation must undergo the seed variety registration process.

## **8. Field Trials**

Although China allows field-testing of GE crops, it does not provide information on the current number

of field trials 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. The Hainan Agriculture Bureau conducted an investigation on 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 starting this year it would conduct 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 grew 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 collecting seeds and leaf samples on Huazhong Agricultural University's experimental fields in Hainan province without permission. Greenpeace claimed they were investigating the safety management of GM crops.

On May 27, 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. Actions to be taken include:

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 labelling. 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*

## **9. Animal Biotechnology**

China has not yet approved commercialization of any livestock clones or GE animals or products derived from animal biotechnologies. It 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. The center aims 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 quite mature and await commercialization, pending MOA's review. Research has mainly focused on medicine production, improving quantity and quality of milk, and improving quality of meat and wool.

The following are examples of ongoing research:

1. Researchers from Nanjing Medical University and Yunnan Key Laboratory of Primate Biomedical Research jointly created genetically modified monkeys using a new method of DNA engineering, CRISPR/Cas9, showing that targeted genome editing is feasible in primates
  - o In 2009, China Agricultural University successfully cultivated cows that have the Prion Protein gene knocked off
  - o In 2010, Inner Mongolia University and a company cultivated cloned cattle that have the Myostatin gene knocked off
2. China Agriculture University developed transgenic cows with either a human Lysozyme (hLY) gene or a human fucosylated sugar transferase gene expression
3. In 2011, China Agriculture University successfully researched GE chicken that is anti-IBV
4. In 2003, Pr. Li Bichun with Yangzhou University in Jiangsu province cultivated a GE chicken, which laid eggs and incubated 2 chicks
5. In 2010, China developed a disease-resistant goat that expressed the TLR4 gene
6. Institutes of Biomedicine and Health under the Chinese Academy of Sciences is focused on research of pigs for meat with rich omega-3 fatty acids and pigs for multi-functional stem cells;
7. The Institute of Hydrobiology of the Chinese Academy of Sciences has developed a fast-growing transgenic triploid carp. This transgenic fish has been approved for field trial.
8. In June 2012, Inner Mongolia University developed a GE cow that produces milk with elevated levels of omega-3 fatty acids (a health benefit), and lower omega-6 unsaturated fat, which has been linked to cancer and heart disease.
9. The Heilongjiang Fishery Research Institute of the Chinese Academy of Fishery Sciences has developed a transgenic carp (utilizes a fish growth hormone gene) that is undergoing a field trial and a mammal feeding study.

Source of the information: *30 Years Practice of Genetically Modified (Technology)* and publicly

available information.

**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**

**Unit: Metric Tons**

Partner Country	Quantity			
	2011	2012	2013	2014 (Jan-Nov)
World	25,698	17,558	6,733	13,121
Bangladesh	3,678	5,041	0	4,391
Vietnam	4,600	790	2,506	2,383
Korea North	5,631	3,205	2,082	1,958

Source of Data: China Customs

**China Cotton Imports**

**Unit: Million Metric Tons**

Partner Country	Quantity			
	2011	2012	2013	2014 (Jan-Nov)

World	3.37	5.14	4.15	2.18
India	1.01	1.44	1.19	0.74
United States	0.98	1.46	1.15	0.50
Australia	0.53	0.82	0.80	0.48

Source of Data: China Customs

### China Corn Imports

Unit: Million Metric Tons

Partner Country	Quantity			
	2011	2012	2013	2014 (Jan-Nov)
World	1.75	5.21	3.26	1.99
United States	1.69	5.11	2.97	1.01
Ukraine	0.00	0.00	0.11	0.57
Thailand	0.00	0.02	0.00	0.29

Source of Data: China Customs

### China Soybean Imports

Unit: Million Metric Tons

Partner Country	Quantity			
	2011	2012	2013	2014 (Jan-Nov)
World	52.63	58.38	63.40	62.87
Brazil	20.62	23.89	31.81	31.83
United States	22.35	25.97	22.26	22.25
Argentina	7.84	5.90	6.12	5.82

Source of Data: China Customs

### China Distillers Dried Grains Imports

Unit: Million Metric Tons

Partner Country	Quantity			
	2011	2012	2013	2014 (Jan-Nov)
World	1.69	2.38	4.00	5.39



United States	1.69	2.38	4.00	5.39
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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-	Bayer CropScience	Dec. 31, 2013 -

	12		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 Bt11×GA21	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 305423×40-3-2	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