

USDA Foreign Agricultural Service

GAIN Report

Global Agricultural Information Network

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY
USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT
POLICY

Required Report - public distribution

Date: 7/13/2012

GAIN Report Number: CH12046

China - Peoples Republic of

Agricultural Biotechnology Annual

2012

Approved By:

Melinda Meador

Prepared By:

Joshua Emmanuel Lagos and Ma Jie

Report Highlights:

China is currently the sixth largest producer of biotechnology enhanced plants (primarily Bt cotton) based on total acreage (3.9 million hectares in 2011). The central government plans to actively foster the agriculture biotech industry as an emerging strategic sector.

Section I. Executive Summary:

Current trends suggest that China will remain a significant importer of biotech products and may become an exporter of biotechnology in the medium to long term. China is currently the sixth largest producer of biotechnology enhanced plants based on total acreage (3.9 million hectares in 2011), and the central government is actively fostering the agriculture biotech industry as an emerging strategic sector for the country. China's Ministry of Agriculture issued bio-safety certificates for Chinese developed biotech rice and corn in November 2009, the first time for a staple food crop for domestic cultivation.

China's regulatory infrastructure is still developing, and includes biotech regulations that present market access impediments. The barriers include asynchronous approval, which requires that a product must be fully approved from an exporting country before an application can be filed for approval in China, inadequate protection for intellectual property rights, a restrictive low level presence threshold of 0 percent, and no clear policy on stacked events. Moreover, Chinese biotech regulations and application procedures for new products lack transparency, and currently no foreign biotech crops for domestic commercial production have been approved.

From late 2011 to early 2012, the Chinese government issued many 12th Five-year Plans that focus on developing key industries/sectors, which includes agricultural biotechnology. These major plans are: 1) *"12th Five-Year Plan on National Economic and Social Development"*; 2) *"12th Five-Year Plan for National Agriculture and Rural Economic Development"*; 3) *"12th Five-year Plan for Development of Biotechnologies"*; and 4) *"12th Five-year Plan (2011-2015) on Agricultural Science and Technology Development."*

To increase consumer education, Chinese government public outreach efforts and other media are explaining the benefits and development of agricultural biotechnology products. Despite these efforts, consumer opinion appears somewhat mixed, as some prefer to believe rumors spread by scholars, non-governmental organizations, and others who may not be very supportive of agricultural biotechnology.

Section II. Plant Biotechnology Trade and Production:

Biotechnology Crop Production

According to a report by the International Service for the Acquisition of Agro-biotech Applications (ISAAA), China is now the sixth largest producer of agricultural biotechnology crops in the world by acreage at 3.9 million hectares in 2011. China has commercialized six genetically modified plants since 1997 (cotton, tomato, sweet pepper, petunia, poplar, and papaya). However, almost all of these GM plants are not currently being produced because their biosafety certificates expired and were not renewed (lack of a commercial market). Insect-resistant (Bt) cotton is the single largest biotechnologically enhanced product produced in China. In 2011, more than 71.5 percent of the 5.45 million hectares of all cotton planted in China is produced with Bt cotton varieties. A virus resistant papaya is still produced in Guangdong on approximately 3,500 hectares. In addition, in 2002 the State Forest Administration (SFA) deregulated and commercialized 2 genetically modified forestry plants, insect resistant poplar 12 and poplar 741, which are planted on 333 hectares.

A list of biotech products that have been approved for commercial production in China is available on MOA's web site at <http://www.stee.agri.gov.cn/biosafety/spxx/>. A full list is not provided in this report. SFA provides no public reports on its deregulated products. For MOA, although over 200 varieties are approved, almost all of the approvals are Bt cotton varieties. Three ecological areas are eligible for the cultivation of Bt cotton, but this does not apply to other biotech crops which must apply on a provincial basis. For Bt cotton, the ecological areas include 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).

Domestic Biotechnology Crop Development

On November 27, 2009, the Ministry of Agriculture (MOA) granted biosafety certificates to two Chinese developed insect resistant rice varieties and a high phytase corn variety. This was the first time the Chinese government has granted biosafety certificates to major food and feed crops. In addition to the biosafety certificates, both products must also complete the seed variety registration process before they can be officially commercialized (see Seed Variety Registration). MOA has mentioned that because these are GM crops, the seed variety registration process may take up to 5 years or possibly longer.

Private sector research and development in agricultural biotechnology is limited and highly regulated. Chinese biotech seed development is conducted by public research institutes and universities funded by various parts of the Chinese government. Marketing is often done by affiliated private companies. 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 is restricted to minority shareholders in joint ventures with Chinese companies.

MOA and SFA do not publish information on ongoing Chinese research and development. According to MOA publications on the deregulation process, major crops undergoing the field trial stage of development (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.

Post believes that the central government's primary interest in biotechnology is to address food security. Almost all biotech research and development is carried out by public-funded research institutes and universities. China has heavily invested in biotech research, but has not successfully developed many biotech products that can be commercialized. In July 2008, the State Council approved a special research program on the development of new biotech varieties with an investment that could total as much as USD \$3.5 billion (funding to be allocated by central and local governments as well as investment by companies) over the next 12 years. It is reported that the investment in the special research program has already exceeded \$4.0 billion by the end of 2010. 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.

Depending on the opinions of the new leadership on agricultural biotech (who will be appointed by late autumn 2012 (and formally in place by March 2013))¹, this may affect how China continues to strategically develop the biotechnology industry.

Section III. Plant Biotechnology Policy:

Regulatory Framework

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) and implemented by MOA under Ministerial Decrees 8, 9 and 10. Other decrees (*Measures on the Safety Evaluation Administration of Agricultural GMOs*, *Measures on the Safety Evaluation Administration of Agricultural GMO Imports*, and *Measures on Agricultural GMO Labeling Administration* (See Gain Report CH7053)) govern domestic approval, import approval, and labeling, respectively. SFA also released its *Review and Administration Measures on Conducting Activities Related to Genetically Engineered Forestry Wood Products* (Details can be downloaded at SFA website <http://www.forestry.gov.cn/portal/main/s/26/content-204704.html>).

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 has recently developed a guideline for biosafety assessment (environmental and food safety) to streamline the processes. The guideline can be downloaded at <http://www.moa.gov.cn/ztl/zjyqwgz/sbzn/201202/P020120203390882017249.pdf>.

Ministerial Responsibilities

MOA is mainly responsible for the approval of biotech agricultural crops for import and domestic production, as well as creating biotech 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. The Ministry for Environmental Protection (MEP) (formerly the State Administration of Environmental Protection (SEPA)) is the lead agency for the negotiation and implementation of the Biosafety Protocol (BSP), which China ratified on April 27, 2005. The General Administration of Quality, Inspection, and Quarantine (AQSIQ) and its local inspection and quarantine offices (CIQs) are responsible for the nationwide management of inspection and quarantine for the entry and exit of all biotech products. AQSIQ’s Ministerial Decree 62 (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

¹ The 18th National Congress of the Communist Party of China is expected to be held in Beijing in October or November 2012. It is widely speculated that Xi Jinping (currently vice president) will succeed Hu Jintao as the CPC leader. In March 2013, the Presidency and Premiership will be formally approved at the National People's Congress.

Organisms

The Joint-Ministerial Conference for Biosafety Management of Agricultural Genetically Modified Organisms (GMOs) 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: the Ministry of Agriculture (MOA), National Development and Reform Commission (NDRC), the Ministry of Environmental Protection (MEP), the General Administration on Quality and Supervision, Inspection and Quarantine (AQSIQ), the Ministry of Science and Technology (MOST), the Ministry of Commerce (MOFCOM), and the Ministry of Health (MOH).

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 the potential threat of the organism to human or animal health and the environment. MOA Decree 9 (See Gain Report CH7053) outlines the different 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 biotech biosafety certificate from MOA's Division of GMO Biosafety and IPR. 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.

Although the regulation states that MOA should respond to an application for a biosafety certificate within 270 days, the approval processes varies from crop to crop depending on its intended use and potential impact on human or animal health and the environment. In general, the process of getting a biosafety certificate for imported biotech food crops for processing (like soybeans) will last about two 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.

Approved Imported Biotechnology Crops

MOA has approved the importation of five biotech crops/products for processing or feed use

(soybeans, corn, canola, cotton and sugar beets). SFA has not approved any imported biotech trees. In 2011, the United States exported more than USD \$12.7 billion (22.35 million MT) of soybeans and USD \$2.94 billion (0.98 million MT) of cotton to China, most of which were biotech varieties. In 2004, China granted its first biosafety certificates to import foreign products. The current import list of biotech events approved for processing is listed below:

Biotech crops approved by MOA for import as processing materials (as of March 2, 2012)

Event	Developer	Bioafety certificate validity
Herbicide tolerance Flex cotton MON 88913	Monsanto	Dec. 20, 2007 - Dec. 20, 2012
Insect resistance cotton 531	Monsanto	Aug.28, 2008 - August 28, 2013
Herbicide tolerance cotton 1445	Monsanto	Aug.28, 2008 - August 28, 2013
Herbicide tolerance soybean GTS40-3-2	Monsanto Far East Ltd.	Dec. 20, 2009 - Dec. 20, 2012
Insect resistance corn 59122	Du Pont/Dow AgroSciences	Dec. 20, 2009 - Dec. 20, 2012
Insect resistance corn TC1507	Du Pont/Dow AgroSciences	Dec. 20, 2009 - Dec. 20, 2012
Insect resistance corn MON810	Monsanto Far East Ltd.	Dec. 20, 2009 - Dec. 20, 2012
Insect resistance corn MON863	Monsanto Far East Ltd.	Dec. 20, 2009 - Dec. 20, 2012
Insect resistance corn BT176	Syngenta Crop Protection	Dec. 20, 2009 - Dec. 20, 2012
Insect resistance corn BT11	Syngenta Crop Protection	Dec. 20, 2009 - Dec. 20, 2012
Herbicide resistant Canola Topas19/2	Bayer CropScience	Dec. 20, 2009 - Dec. 20, 2012
Herbicide resistant Canola Ms1Rf1	Bayer CropScience	Dec. 20, 2009 - Dec. 20, 2012
Herbicide resistant Canola Ms1Rf2	Bayer CropScience	Dec. 20, 2009 - Dec. 20, 2012
Herbicide tolerance Canola GT73	Monsanto Far East Ltd.	Dec. 20, 2009 - Dec. 20, 2012
Herbicide resistant soybean A2704-12	Bayer CropScience	Dec. 20, 2010 - Dec. 20, 2013
Herbicide tolerance corn NK603	Monsanto Far East Ltd.	Dec. 20, 2010 - Dec. 20, 2013
Insect resistance and herbicide tolerance corn MON88017	Monsanto Far East Ltd.	Dec. 20, 2010 - Dec. 20, 2013

Herbicide resistant soybean 356043	Du Pont	Dec.30, 2010 - Dec. 30, 2013
Herbicide resistant soybean MON89788	Monsanto Far East Ltd.	Aug.29, 2011 - Aug. 29, 2014
Insect resistance corn MON89034	Monsanto Far East Ltd.	Dec.30, 2010 - Dec. 30, 2013
Insect resistance cotton 15985	Monsanto Far East Ltd.	Jul.21, 2011 - Jul.21, 2016
Herbicide resistant cotton GHB614	Bayer CropScience	Dec.30, 2010 - Dec. 30, 2015
Insect resistance corn MIR604	Syngenta Crop Protection	Aug.2, 2011 - Aug. 28, 2014
Herbicide resistant corn GA21	Syngenta Crop Protection	Aug.2, 2011 - Aug. 28, 2014
Herbicide resistant cotton LLCotton25	Bayer CropScience	Dec. 20, 2011 - Dec. 20, 2016
Insect resistance and herbicide tolerance corn Bt11×GA21	Syngenta Crop Protection	Nov. 3, 2011 - Nov.3, 2014
Herbicide resistant corn T25	Bayer CropScience	May 8, 2012 - May 8, 2015
Herbicide resistant Canola Oxy-235	Bayer CropScience	May 8, 2012 - May 8, 2015
Herbicide resistant Canola T45	Bayer CropScience	May 8, 2012 - May 8, 2015
Herbicide resistant Canola Ms8Rf3	Bayer CropScience	May 8, 2012 - May 8, 2015
Herbicide resistant sugar beet H7-1	Monsanto Far East Ltd., a German seed company	May 8, 2012 - May 8, 2015
Quality improvement soybean 305423	Pioneer	Nov. 3, 2011 - Nov.3, 2014

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 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)

MOA established the National Biosafety Committee (NBC), which is a regulatory body that evaluates domestic and foreign applications for biosafety certificates for biotech products. The body is

composed of 74 experts from a wide variety of backgrounds who come 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 Ministry of Agriculture announced that the NBC will increase the number of meetings from two to three a year, which usually occur in March, July, and November. Final decisions are generally released 45 days after each deadline.

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 agricultural GMOs.

The MOA provincial level departments are responsible for monitoring field trials of biotech products, GMO processing facilities, the seed market, and labeling.

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 (note: in some provinces this process may begin in step 4 or “production testing” (see below)). Registration involves field trials and other testing requirements, some of which may be duplicative of trials conducted for the National Biosafety Committee 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, although no specific time-frame has been given for GM crops.

Registration Fees

According to a joint notification by NDRC and the Ministry of Finance to the Ministry of Agriculture, a fee charge schedule for the safety evaluation and testing of agricultural GMOs is summarized 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)

MOA Application Process

A rough outline of the GMO application process is listed below. The names of institutions and contacts

are provided as available.

1. MOA open window: accepts applications.
Contact: Mr. Lian Qing
Tel: 5919-1811
2. Biosafety Management Division at the Center for Science and Technology Development (CSTD) reviews and submits the application to the National Biosafety Committee (NBC).
Contact: Mrs. Li Ning
Tel: 5919-5089
3. NBC plenary sessions are held in March, July and November to discuss applications and determine appropriate tests.
4. Division of GMO Biosafety and IPR processes import permit for field trials and a 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 a 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

The State Forestry Administration (SFA) regulates research, production, and import/export of biotech engineered trees that are 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 productive testing. After a domestic developer completes each stage, he/she 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 also must undergo a seed variety registration process (just like MOA), which may include an additional assessment by experts from the government, academia, and/or private industry. This process takes about one year for non-GM products, but may take longer for GM 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 and will certify that the product is 100% safe for humans, plants, animals, microorganisms, and the environment. Because no foreign developer can certify that a product is 100% safe, no foreign GM product has entered China's market to date. Other requirements may be needed. A biotech tree intended for domestic cultivation must also undergo the seed variety registration process.

Ministry of Agriculture: Labeling Policy

China's labeling regulations, governed by the Ministry of Agriculture Decree 10 (CH7053), require the labeling of approved agricultural biotech products and prohibit the importation and sale of any unlabeled or mislabeled products. The types of products subject to mandatory labeling include:

1. Soybean seed, soybeans, soybean powder, soybean oil, and soybean meal;
2. Corn seeds, corn, corn oil, and corn powder;
3. Rape seed for planting, rape seeds, rape oil, and rape meal;
4. Cotton seed;
5. Tomato seed, fresh tomato, and tomato paste.

12th Five Year Plans Related to Biotech Development

From late 2011 to early 2012, China issued many 12th Five-year Plans to develop key industries/sectors, several of which address agricultural biotechnology.

On March 14, 2011, China concluded the Fourth Session of the 11th National People's Congress ("NPC"). In the session, NPC approved the overarching *12th Five-Year Plan on National Economic and Social Development* from 2011 to 2015. Agricultural biotech was identified as a priority in developing the biology industry (one of the seven Strategic Emerging Industries²). The Plan also calls to nurture professionals in various industries including bio-tech and agricultural science and technology.

On November 14, 2011, the Ministry of Science and Technology (MOST) released the "*12th Five-year Plan for Development of Biotechnologies*." The Plan says that biotech will play a significant role in developing the agricultural industry and securing national food security by increasing yields and introducing new plant and/or animal varieties. MOST predicts that indigenous innovation for biotech will significantly advance in the next 5 years, and specifically identifies bio-pharmaceuticals, agricultural biotech, bio-manufacturing, bio-fuels, and bio-environmental protection industries as focus areas. The MOST Plan intends to develop the bio-tech industry by: 1) strengthening basic

² In October 2010, the State Council released the "Decision to Accelerate the Cultivation and Development of the Strategic Emerging Industries." The seven strategic emerging industries named in the document are: energy saving/environmental protection, next generation information technology, biology, high-grade equipment manufacturing, new energy, new materials, and new energy vehicle.

research; 2) achieving a breakthrough in essential key technologies; 3) researching and developing key products and technologies; and 4) building an innovation capacity for the biotechnology sector.

On December 30, 2011, the Ministry of Agriculture (MOA) released the “*12th Five-Year Plan for National Agriculture and Rural Economic Development*,” which supplements and provides further detail to the NPC “*12th Five-Year Plan on National Economic and Social Development*.” The MOA Plan proposes to strengthen agricultural science and technology innovation and cultivate future agricultural experts. One of the tasks is to accelerate the development of the agricultural biotech industry by breeding and producing new varieties of animals and plants, bio-pesticides, veterinary drugs, vaccines, bio-fertilizers, and other agricultural materials.

Mid and Long Term Plan and the Grain Law

On December 8, 2011, the NPC released the “*National Mid and Long-term (2010-2020) Plan for Cultivating Bio-technology Talents*,” and states that by 2015 China will: 1) form a national bio-tech research team of scientists and experts with multidisciplinary backgrounds; 2) nurture a group of leading researchers and innovation teams, as well as establish national engineering technology centers and other key national laboratories; and 3) cultivate future senior management in government, universities, research institutes, large bio-pharmaceutical enterprises, and other entities. By 2015-2020, the plan intends to nurture/support 3 to 5 international leading Chinese scientists and 30 to 50 international leading science and technology innovation Chinese experts, and build 5 to 10 international leading national laboratories.

On February 22, 2012, the Legislative Affairs office of the State Council released the draft *Grain Law*. Jointly prepared by the National Development and Reform Commission and the State Administration of Grain, the draft Law aims to ensure grain security by stabilizing grain output and intensifying control and supervision over the market. Regarding biotech, the draft Law stated that scientific research, testing, production, distribution, and imports/exports of GM grain seeds must comply with relevant regulations. It further clarifies that any entity or person shall not utilize GM technology without permission.

Issues of Concern for MOA Biotech Regulations

Biotechnology Issues

- Asynchronous Approval - Current regulations require that biotech events be fully approved from an exporting country before the Ministry of Agriculture (MOA) will accept an application for a biosafety certificate (required before the product can be exported to China). This requirement creates unnecessary delays in marketing and trading new biotech products that are already approved in exporting countries.
- Re-registration of Certificates- MOA biosafety certificates are valid for 5 and 3 years (non-food and food crops). Re-registration is cumbersome and contains certain unnecessary demands.
- Re-registration of Seed Samples – MOA requires seed samples for the renewal of biosafety certificates, even for varieties no longer marketed. This requirement is redundant and creates

an unnecessary burden to maintain seed stocks for products that are no longer commercially sold. If a few quantities of product are still in circulation after the certification expires, this may impede trade since China has a low level presence policy of 0 percent.

- Biosafety Certificates for Imported Products – Importers are required to obtain a MOA GMO biosafety certificate for all imports with biotech content, which adds an additional cost in shipping the product. The requirement does not provide any additional information to import quarantine officials beyond standard “may contain” shipping documentation. Importers of large-volume, bulk commodities routinely obtain certificates, but this practice varies among processed product importers.
- Low Level Presence (LLP) – Zero tolerance for unapproved varieties. The lack of an effective LLP policy constrains trade.
- Stacked Traits – China has no public policy outlining the approval process for stacked events, and all registrations are considered “case-by-case.” The lack of a public policy creates concern over the long-term flexibility to deal with new generations of technology.
- Variety Based Registration – This current biotechnology registration system applies to both exports and domestically produced products. Variety based registration systems duplicate past safety evaluations and result in a less effective use of resources and a longer approval processes, especially as newer varieties incorporate previously approved technology. That being said, recently, China has started a new application process that allows an applicant to choose to register an event or a variety for domestic cultivation (not import). If a company registers a new event and it is approved through the regular process (3 production trials), a subsequent variety that uses the same event would only need to undergo 1 production trial in lieu of 3. Therefore, the deregulation time is shortened for the registration of a new variety that utilizes the previously registered event.
- Import Testing – AQSIQ randomly tests all products for GMO content. Importers have expressed concern with the testing effectiveness and consistency, as well as adherence to testing frequency guidelines.
- Proprietary Information in Biosafety Applications – During the biosafety application process, reportedly attempts have been made to require companies to provide sensitive, proprietary information. These inquiries appear to ask for more than what may be necessary to test the safety of new events.

Conventional Seed Issues

- Seed Registration – After MOA issues a biosafety certification for production, China requires either national or provincial variety registration before the planting seeds can be commercially sold or distributed nationally or within a specific province, which for GMO seeds may take 5 years or longer. This process is duplicative and non-transparent.

- Plant Variety Protection – China has not acceded to UPOV91. (See GAIN Report CH12009).

Cross-Cutting Issues

- Investment Restrictions – China’s State Council foreign investment catalogue stipulates that foreign investment in the conventional seed industry is a "restricted" activity (limiting foreign ownership of a joint venture to 49%) and foreign company development, production, or marketing of transgenic plants in China is a "prohibited" activity. (See GAIN Report CH7087)
- Intellectual Property Rights Protection - China’s conventional seed and biotechnology regulatory and review mechanisms lack complete IPR protections and contain fundamental conflicts of interest that encourage weak IPR protection. For example, field trials for new products are conducted by Chinese research institutes that sometimes are also competing seed developers. Legal protections provided to applicants’ genetic material appear insufficient to ensure complete confidentiality. Weak enforcement and low penalties for infringement weaken market protection for rights’ holders.

China and the Biosafety Protocol

The State Council ratified the Biosafety Protocol on April 27, 2005 and China participated in the discussion of MOP-3 (March 2006), MOP-4 (May 2008), and MOP-5 (October 2010) as a full member.

The Ministry of Environmental Protection (MEP) is the lead authority in implementing and developing Chinese regulations in compliance with the Biosafety Protocol; however, it has not published any new or revised laws in accordance to the Protocol. MEP continues to state its intent to develop an overarching Biosafety Law that would take precedence over the Ministry of Agriculture's decrees regulating agricultural biotechnology. Reportedly, this exercise was not mandated by the State Council or any higher decision-making body, and was solely initiated by MEP.

Section IV. Plant Biotechnology Marketing Issues:

Market Acceptance of Biotechnology Products

Although some pre-2008 literature and surveys suggest that China’s consumers were by and large open to and accepting of biotechnology products, the acceptance has been mixed in recent years due to lack of education and negative media reports, many of them by non-profit organizations. After China deregulated Bt rice and phytase corn in 2009, debate sparked over biotech food safety, risk communication, and the deregulation process.

One of the most recent surveys published in 2008 by the Asian Food Information Center (AFIC) stated that general Chinese consumer knowledge of biotech products was very low, and approximately only 45 percent of the population knew that GM products could be found in the grocery store. A lack of knowledge without factual support provides opportunity for propaganda to influence consumer beliefs. That being said, because some Chinese researchers question the long term effects of the technology, such as on the environment, some Chinese government officials believe that the greater challenge is not alleviating consumer fears but finding more support within the Chinese scientific community. Regardless, greater efforts from the Chinese government to provide accessible and clear public information on the advantages and safety of biotechnology will be needed to gain support for

GM foods. Otherwise, China may experience difficulty in fully realizing the benefits of biotechnology to help address its food security challenges.

Section V. Plant Biotechnology Capacity Building and Outreach:

US-China Technical and Biotechnology Working Group

The U.S. and Chinese governments are working closely on several fronts to assist China in its capacity to effectively and fairly handle biotechnology. The U.S. - China High-Level Biotechnology Joint Working Group (BWG) was established in July 2002 as a way to address bilateral biotechnology issues of mutual interest. To supplement the policy discussions, a technical subgroup (TWG) was established in July 2003. The most recent BWG and TWG meetings were held in September 2011 in Beijing.

U.S.-China Biotechnology Inspection and Quarantine Technology Seminar

From May 21 to 25, 2012, FAS Agricultural Trade Office Guangzhou held a seminar in Guangzhou, Shenzhen, and Xiamen to exchange information with various China Inspection and Quarantine officials on biotechnology regulations and management. The program also covered inspection methodologies, detection technologies, and low-level presence (LLP) issues.

Dr. Roger Beachy Outreach

In mid October 2011, USDA and the State Department supported a visit by Dr. Roger Beachy to educate and discuss agricultural biotechnology and risk communication with university faculty, students, government researchers, policymakers, and the media in Beijing and Guangzhou. His visit helped clarify the benefits of agricultural biotechnology to a wide Chinese audience.

Section VI. Animal Biotechnology:

Research and Development of Genetically Engineered Animals in China

Public-funded research institutes or universities have developed or are researching transgenic animals, but none are approved for commercial production. The following are examples of ongoing research:

- 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 under field trial and a mammal feeding study.
- 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.
- China Agriculture University has developed transgenic cows with either a human lysozyme (hLY) gene or a human fucosylated sugar transferase gene expression.
- Shanghai Genon Bio-engineering Co. Ltd has developed a transgenic goat that expresses either a human lactoferrin or lysozyme gene (both are single events). The first has been approved for an enlarged field trial and the latter is under restricted field trial.
- In June 2012, Inner Mongolia University developed a genetically modified (GM) 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.

Section VII. Public Questioning of MOA's Deregulatory Process and Other Risk Communication Outreach:

Public Questioning of MOA's Deregulatory Process

In February 2012, *China Business* (a Chinese domestic newspaper) published an article questioning why MOA issued 8 biosafety certificates to 16 events (one certificate issued to two products) in 2008 and 2009. MOA responded that the biosafety certificates were issued for different purposes (importation vs. cultivation).

In May 2012, *China Business* published another article that challenged MOA's biosafety certificate approval process for GM soybean GTS40-3-2 because reportedly MOA did not release the third party testing reports to the public, which the article argued is required by the "Administrative Rules on GMO Safety." Two weeks later, MOA formally responded that correct procedures had been taken in approving the GTS40-3-2 event, and explained the overall approval process in its statement.

Risk Communication Outreach

On April 27, 2012, *China Food Newspaper* (a widely read and influential newspaper for the food industry and local government bureaus) printed an article based on interviews with MOA officials and top scholars on GMO food safety and management. Although the article provided no new information on GMOs, it presented evidence that GMO food is safe. Similarly, *the Science and Technology Daily*, the official newspaper of the Ministry of Science and Technology (MOST), published a series of articles on agricultural biotechnology, focusing on safety, benefits, and the reliability of the deregulatory process and management of GMO products.

MOA officials, scientists, and other experts and academics wrote a 360-page book entitled, "*30 Years of Practice of Genetically Modified (Technology)*" that provides the history of global GM technology and explains the GMO biosafety management/administration for many countries (including China). It also briefly covers the current research and status of global GM plant, animal, and micro-organisms. The book is pending publication.

In early 2012, MOA published, "*30 Questions about the Magical GM Technology,*" which answers frequently asked questions and concerns by the general public. The text includes charts and pictures to explain complicated issues.