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Global Agricultural Information Network

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Report Highlights:

China is expected to 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 (primarily Bt cotton) based on total area. The central government plans to continue fostering 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. China is the sixth largest producer of genetically engineered (GE) plants based on total area (four million hectares in 2012) and may become an exporter of biotechnology in the medium to long term.

The central government supports the agriculture biotech industry as an emerging sector of strategic importance and is developing its biotech regulatory structure. Some current regulations present market access impediments and include:

- Asynchronous approval, which requires that a product be approved from an exporting country before an approval application can be filed in China,
- Inadequate protection for intellectual property rights,
- A restrictive low-level presence threshold of zero percent
- No clear policy on stacked events, and
- Chinese biotech regulations and application procedures for new products lack transparency

Despite Chinese government public outreach efforts to explain the benefits and development of agricultural biotechnology products, consumer opinion remains mixed and cautious toward biotech products. Under such circumstances, Ministry of Agriculture (MOA) is slow to approve new events (other than cotton) that are in the pipeline. In June 2013, MOA issued safety certificates permitting import as processing materials for five new events, including three soybean, one cotton and one corn event, which had been pending since March 2012. Four new events (two soybean, one corn, one canola) were approved for field trials.

In November 2009, MOA issued bio-safety certificates for Chinese-developed biotech rice and corn; however, the two events have not yet been commercialized. Currently, China has not approved any foreign biotech crops for domestic commercial production.

Section II. Plant Biotechnology Trade and Production

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

China is the sixth largest producer of agricultural biotechnology crops in the world by area at four million hectares, according to the 2012 report by the International Service for the Acquisition of Agrobiotech Applications (ISAAA). Although China has commercialized six GE 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.

Currently, insect-resistant (Bt) cotton is the single largest biotechnologically enhanced product grown 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. Although 2012 data is not available, both the percentage of Bt cotton and cotton planted area are expected to increase. 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 allowed commercialization of two GE forestry plants, insect resistant poplar 12 and poplar 741, which are planted on 450 hm².

On November 27, 2009, the Ministry of Agriculture (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. After obtaining the biosafety certificates, these products must complete the seed variety registration process before they can be officially commercialized (see Seed Variety Registration in the Part B Policy). MOA has mentioned that, due to the GE nature of these crops, the seed variety registration process may take up to 5 years or possibly longer.

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.

China has heavily invested in biotech research and seed development, primarily through publicly funded research institutes and universities, but has not successfully developed many commercial biotech products. In July 2008, the State Council approved a \$3.5 billion special research program to develop new biotech varieties (funding to be allocated by 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.

On the other hand, 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.

b) COMMERCIAL PRODUCTION

Yes, China cultivates GE crops. MOA provides a list of biotech products approved for commercial production in China on its web site at http://www.moa.gov.cn/ztl/zjyqwgz/spxx/201306/t20130618_3495755.htm. Although over 300 varieties have obtained safety certificates for production, almost all of the approvals are Bt cotton varieties.

China does not publish statistics of GE seed production.

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).

c) EXPORTS:

China exports cotton so it is possible that some components of these exports are products of GE crops. As there is no data on percentage of biotech products in total exports, the data below are provided strictly for reference.

China does not grow GE wheat, corn or rice, so no exports of the products are GE products.

Cotton

In 2012, China exported 17,558 tons of cotton, mainly to Bangladesh, Hong Kong, North and South Korea.

China Export Statistics Commodity: Cotton,							
Year To Date: January - December							
Partner Country	Unit	2010		2011		2012	
		USD	Quantity	USD	Quantity	USD	Quantity
World	T	9208090	6453	78732768	25698	36799017	17558
Bangladesh	T	278374	150	12027737	3678	9938943	5041
Hong Kong	T	0	0	0	0	6944139	3369
Korea North	T	3755104	3859	8791154	5631	6700148	3205
Korea South	T	2381862	1129	5234180	2100	4256954	2140

Source of Data: China Customs

d) IMPORTS:

China is a large importer of cotton, corn, and soybeans. However, China does not import GE seeds for growing.

China Import Statistics Commodity: Cotton,							
Year To Date: January - December							
Partner Country	Unit	2010		2011		2012	
		USD	Quantity	USD	Quantity	USD	Quantity
World	T	5659346119	2839089	9471526988	3365048	11808363460	5137451
United States	T	1998128600	1008609	2939083229	980871	3686912845	1463647
India	T	1737123279	868022	2652752367	1014381	3031900263	1438682
Australia	T	415773118	204895	1549258658	529474	1913079216	818594

Brazil	T	177493687	88247	603786051	215571	816120965	367079
Uzbekistan	T	692556222	344826	505824697	167731	693149923	309753
Mali	T	43610594	23448	104803192	42141	260050380	107401
Burkina Faso	T	116708313	66865	175642838	67986	231121416	96801
Cameroon	T	65192278	35549	90473459	35770	173872421	71493
Benin	T	54725097	30303	66616047	27336	141162106	57037
Mexico	T	47384928	25695	110049322	42346	140389189	66957

Source of Data: China Customs

China Import Statistics Commodity: Corn,							
Year To Date: January - December							
Partner Country	Unit	2010		2011		2012	
		USD	Quantity	USD	Quantity	USD	Quantity
World	T	367220905	1572394	577573578	1752737	1688464677	5206747
United States	T	348371044	1501779	558968649	1685480	1658081264	5113302
Laos	T	9083288	41994	8297186	35168	12974477	52070
Thailand	T	1848934	8700	507	0	5878827	17945
Myanmar	T	2612485	19394	5740265	28403	4710250	18488

Source of Data: China Customs

China Import Statistics Commodity: soybeans,							
Year To Date: January - December							
Partner Country	Unit	2010		2011		2012	
		USD	Quantity	USD	Quantity	USD	Quantity
World	T	25088991256	54786074	29839724131	52634085	34927474254	58379996
United States	T	11330052976	23590386	12660200926	22352878	15374305037	25969657
Brazil	T	8145425474	18586216	11796516553	20621124	14222479377	23889929
Argentina	T	4977793883	11187270	4354740123	7838303	3688066245	5895592
Uruguay	T	600743103	1347079	808016031	1430119	1211913335	1902862
Canada	T	34614743	74226	219067916	387983	401967655	630237
Russia	T	203357	678	1180672	3678	28714601	91614

Source of Data: China Customs

China imports large quantity of dried distillers grains with soluble (DDGS) for feed use, and DDGS is

made from GE corns (MAJIE: Dear Linda, I added statistics of DDGS, which is also a GE product China imports in large quantity.) .

China Import Statistics Commodity: DDGs,							
Calendar Year: 2010 - 2012							
Partner Country	Unit	2010		2011		2012	
		USD	Quantity	USD	Quantity	USD	Quantity
World	T	753102164	3164204	484662441	1685875	774240151	2382070
United States	T	751948480	3162380	484065892	1685588	772640553	2381470
Czech Republic	T	540175	283	402794	92	1246623	230

Source of Data: China Customs

e) FOOD AID RECIPIENT COUNTRIES

China is not a food aid recipient country.

PART B. PLANT BIOTECHNOLOGY POLICY

a) 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 Genetically Modified Organisms (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 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 the creation of 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 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 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 Gain 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 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, the 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.

In general, the process to obtain a biosafety certificate for an imported biotech food crop for processing (like soybeans) takes 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.

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)

MOA established the National Biosafety Committee (NBC), 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 March 1, July 1, and November 1. 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 Genetically Modified Organisms (GMOs)" (GAIN 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.

MOA public notice of April 16, 2013 announced the members of the fourth BioSafety Committee, the full list of the Committee members can be found at:

http://www.moa.gov.cn/zwillm/rsxx/201305/t20130514_3459388.htm

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.

The MOA provincial level departments are responsible for monitoring field trials of biotech products, GE plant 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 GE crops.

Registration Fees

According to a joint notification by NDRC and the Ministry of Finance to the Ministry of Agriculture, a 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); and
8. 90-day Rat Feeding Study (120,000 Yuan per item).

MOA Application Process

A rough outline of the GE application process is listed below. The names of institutions and contacts are provided as available.

1. MOA: accepts applications.

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

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 product 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-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% safe for humans, plants, animals, microorganisms, and the environment. Because no authority can certify that a product is 100% safe, no foreign GE product has entered China's market to date. Other requirements may be needed. A biotech tree intended for domestic cultivation must 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.

b) APPROVAL

Domestic Production

A list of biotech products approved for commercial production in China is available at MOA's web site

at http://www.moa.gov.cn/ztl/zjqwgz/spxx/201202/t20120203_2474245.htm.

On February 21, 2013, MOA solicited public comments on 129 GE insect-resistance cotton varieties to which MOA planned to issue biosafety certificates. The 129 cotton varieties are mainly Chinese domestic varieties for cultivation. A full list of the events can be found at: http://www.moa.gov.cn/zwllm/zqyj/201302/t20130221_3223377.htm

Imports For Processing Or Feed Use

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 2004, China granted its first biosafety certificates to import foreign products.

Biotech crops approved by MOA for import as processing materials (as of July 1, 2013)

No.	Event	Developer	Bioafety certificate validity
1	Insect resistance cotton 531	Monsanto	Aug.28, 2008 - August 28, 2013
2	Herbicide tolerance cotton 1445	Monsanto	Aug.28, 2008 - August 28, 2013
3	Herbicide resistant soybean A2704-12	Bayer CropScience	Dec. 20, 2010 - Dec. 20, 2013
4	Herbicide tolerance corn NK603	Monsanto Far East Ltd.	Dec. 20, 2010 - Dec. 20, 2013
5	Insect resistance and herbicide tolerance corn MON88017	Monsanto Far East Ltd.	Dec. 20, 2010 - Dec. 20, 2013
6	Herbicide resistant soybean 356043	Du Pont	Dec.30, 2010 - Dec. 30, 2013
7	Insect resistance corn MON89034	Monsanto Far East Ltd.	Dec.30, 2010 - Dec. 30, 2013
8	Insect resistance cotton 15985	Monsanto Far East Ltd.	Jul. 21, 2011 - Jul. 21, 2016
9	Insect resistance corn MIR604	Syngenta Crop Protection	Aug.2, 2011 - Aug. 28, 2014
10	Herbicide resistant corn GA21	Syngenta Crop Protection	Aug.2, 2011 - Aug. 28, 2014
11	Herbicide resistant soybean MON89788	Monsanto Far East Ltd.	Aug.29, 2011 - Aug. 29, 2014
12	Insect resistance and herbicide tolerance corn Bt11×GA21	Syngenta Crop Protection	Nov. 3, 2011 - Nov.3, 2014
13	Quality improvement soybean	Pioneer	Nov. 3, 2011 -

	305423		Nov.3, 2014
14	Herbicide resistant corn T25	Bayer CropScience	May 8, 2012 - May 8, 2015
15	Herbicide resistant Canola Oxy-235	Bayer CropScience	May 8, 2012 - May 8, 2015
16	Herbicide resistant Canola T45	Bayer CropScience	May 8, 2012 - May 8, 2015
17	Herbicide resistant Canola Ms8Rf3	Bayer CropScience	May 8, 2012 - May 8, 2015
18	Herbicide resistant sugar beet H7-1	Monsanto Far East Ltd., a German seed company	May 8, 2012 - May 8, 2015
19	Herbicide resistant cotton LLCotton25	Bayer CropScience	Dec. 20, 2011 - Dec. 20, 2016
20	Herbicide tolerance soybean GTS40-3-2	Monsanto Far East Ltd.	Dec. 20, 2012 - Dec. 20, 2015
21	Insect resistance corn 59122	Du Pont/Dow AgroSciences	Dec. 20, 2012 - Dec. 20, 2015
22	Insect resistance corn TC1507	Du Pont/Dow AgroSciences	Dec. 20, 2012 - Dec. 20, 2015
23	Insect resistance corn MON810	Monsanto Far East Ltd.	Dec. 20, 2012 - Dec. 20, 2015
24	Insect resistance corn MON863	Monsanto Far East Ltd.	Dec. 20, 2012 - Dec. 20, 2015
25	Insect resistance corn BT176	Syngenta Crop Protection	Dec. 20, 2012 - Dec. 20, 2015
26	Insect resistance corn BT11	Syngenta Crop Protection	Dec. 20, 2012 - Dec. 20, 2015
27	Herbicide resistant Canola Topas19/2	Bayer CropScience	Dec. 20, 2012 - Dec. 20, 2015
28	Herbicide resistant Canola Ms1Rf1	Bayer CropScience	Dec. 20, 2012 - Dec. 20, 2015
29	Herbicide resistant Canola Ms1Rf2	Bayer CropScience	Dec. 20, 2012 - Dec. 20, 2015
30	Herbicide tolerance Canola GT73	Monsanto Far East Ltd.	Dec. 20, 2012 - Dec. 20, 2015
31	Herbicide resistant cotton GHB614	Bayer CropScience	Dec.30, 2010 - Dec. 30, 2015
32	Herbicide tolerance Flex cotton MONEy 88913	Monsanto	Dec. 20, 2012 - Dec. 20, 2017

33	Alpha-amylase corn 3272	Syngenta	May 21, 2013 – May 21, 2016
34	Herbicide tolerance Soybean CV127	BASF	Jun. 6, 2013-Jun. 6, 2016
35	Drought resistant corn MON87460	Monsanto	May 26, 2013-May 26, 2016
36	Insect resistant soybean MON 87701	Monsanto	Jun. 6, 2013 – Jun.6, 2016
37	Insect resistant soybean MON87701 x MON89788	Monsanto	Jun. 6, 2013 – Jun.6, 2016

c) FIELD TESTING

Although China allows field-testing of GE crops, it does not provide information on the current number of field trails taking place, nor types of crops/traits being tested, estimated time to commercialization, etc.

-d) STACKED EVENT APPROVALS

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.

e) ADDITIONAL REQUIREMENTS

MOA Notice on December 5, 2012, “Announcement on Submission Requirement of GMO Sample and Technical Information” requires viable seeds to be submitted for detection testing purposes with import applications. Although no final rule has been issued, MOA indicated that the rules are now being enforced. The new rule is arousing concern by stake holders about intellectual property rights (IPR) protection.

f) COEXISTENCE

There is no policy on co-existence of GE crops with non-GE crops (including organic agriculture) in China.

g) LABELING

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 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; and
5. Tomato seed, fresh tomato, and tomato paste.

h) TRADE BARRIERS

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.

i) INTELLECTUAL PROPERTY RIGHTS (IPR)

MOA Administrative Measures for Plant Variety Protection shall be referred to for IPR issues of agricultural biotechnology, which was promulgated in 1997, and revised in 2013.

j) CARTAGENA PROTOCOL RATIFICATION

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.

k) INTERNATIONAL TREATIES/FORA

MOA is quite active as an observer. In September 2012, MOA sent officials to attend the LLP forum held in Rosario, Argentina; in June 2013, MOA sent officials to the APEC High Level Policy Dialogue on Agricultural Biotechnology in Indonesia.

l) RELATED ISSUES

Plan for Development of the Biology Industry

On December 29, 2012, the State Council released the Plan for Development of the Biology Industry, which includes the agriculture biology sector. The Plan highlights the biology industry as a strategic emerging industry, while naming ongoing problems, such as market access policies and regulations, a disconnect between research and production, and a lack of competitive, leading enterprises and innovative, small enterprises. The State Council plan estimates that annual agriculture biology output value will reach 300 billion Yuan by 2015. To achieve this goal, the State Council pledges to enhance core competitiveness of biotech breeding and to accelerate industrialization of agricultural biotech products through incentive measures.

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* for 2011 to 2015. Agricultural biotech was identified as a priority in the biology industry (one of the seven Strategic Emerging Industries) as was development of 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*” in which biotech was identified to play a significant role in developing the agricultural industry and securing national food security through increased yields and introduction of 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 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’s “*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.

m) MONITORING AND TESTING

AQSIQ tests all GE products. Importers have expressed concern with the testing effectiveness and consistency, as well as adherence to testing frequency guidelines.

n) LOW LEVEL PRESENCE POLICY

China does not have an LLP policy. The tolerance level is zero.

PART C. PLANT BIOTECHNOLOGY MARKETING ISSUES

a) MARKET ACCEPTANCE

Although some pre-2008 literature and surveys suggest that China’s consumers were by and large open and accepting toward 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.

b) PUBLIC/PRIVATE OPINIONS

The public in China, lacking accurate knowledge about agricultural biotechnology, tend to be influenced by the rumors maliciously circulated in the media. The emerging media, such as the MicroBlog, WeChat, and on-line forum, are fast tunnels to spread false information about agriculture biotech. Lacking of unified voices from scientists and weak risk communication, the public are concerned about safety of biotech products.

In the past year, Post was encouraged to see that Chinese government and scientists are responding to the rumors in a timely manner, including accepting interviews by the traditional media, write articles to explain to the public about agricultural biotech, etc. Although the public opinions cannot be curved in a

day, the measures would help build correct understanding of biotech.

c) MARKETING STUDIES

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 GE 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 researcher's 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 is needed to gain support for GE foods.

PART D: CAPACITY BUILDING AND OUTREACH

a) ACTIVITIES

Dr. Frank Shotkoski Outreach Funded by the State Department

In December 2012, USDA and the State Department supported a visit by Dr. Frank Shotkoski to educate and discuss agricultural biotechnology and risk communication with university faculty, students, government researchers, policymakers, and the media in Beijing and Shenzhen. His visit helped clarify the benefits of agricultural biotechnology to a wide Chinese audience.

Risk Communication Workshop

In August 20, 2012, using USDA funds, IFIC Foundation implemented the China/US Risk Communication Workshop on Agricultural Biotechnology in Beijing. The objective of the workshop was to bring together U.S. risk communication specialists with Chinese biotech scientists to discuss how to communicate information on plant and animal biotechnology to the public.

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.

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

From May 21 to 25, 2012, FAS Agricultural Trade Office Guangzhou held seminars 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.

The most recent Biotech Working Group and Technology Working Group meetings were held in April 2013 in D.C.

In the 2013 BWG meeting, Chinese and U.S. regulators probed implementation plans for the Pilot Project for synchronized application of biotech events, and discussed a variety of topics, including enhancing cooperation, risk communication, low level presence, etc.

In the TWG meeting, the two sides have discussions on regulatory updates on reviews of biotech products, containment of GE Plants for pharmaceutical and industrial purposes, USDA APHIS petition process improvement, and GE animals, etc.

b) STRATEGIES AND NEEDS

Some key needs are improvements in risk communication, improvements in new product approval process, and assistance with new product approval applications by Chinese developers in foreign countries.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART E: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

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:

1. In 2009, China Agriculture University successfully cultivated cows that have the Prion Protein gene knocked off
2. In 2010, Inner Mongolia University and a company cultivated cloned cattle that have the Myostatin gene knocked off
3. China Agriculture University has developed transgenic cows with either a human Lysozyme (hLY) gene or a human fucosylated sugar transferase gene expression.
4. In 2011, China Agriculture University successfully researched GE chicken that is anti-IBV
5. In 2003, Pr. Li Bichun with Yangzhou University in Jiangsu province cultivated GE chicken, which laid eggs and incubated 2 chicks
6. In 2010, China developed a disease-resistant goat that express TLR4 gene
7. 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;
8. 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.
9. 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.

10. 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 information publicly available.

b) COMMERCIAL PRODUCTION

China has not yet approved commercialization of any livestock clones or GE animals or products derived from animal biotechnologies.

c) BIOTECHNOLOGY EXPORTS

China does not export GE animals, livestock clones, or products from these animals.

d) BIOTECHNOLOGY IMPORTS

China does not import GE animals, livestock clones, or products from these animals.

PART F: POLICY

a) REGULATION

In China, animal biotechnology is also subject to the “Agricultural Genetically Modified Organisms Safety Administration Regulations 2001” (See Gain Report CH1056,). This regulation though lacks implementation rules or specific policies that regulate animal biotech research, production or trade.

China’s Central Government invests heavily in basic research for animal biotechnology. Research institutes can apply to Ministry of Agriculture and Ministry of Finance for research funding. 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.

Like plant biotechnology, MOA starts review of dossiers only after an event is deregulated in an exporting country. There is currently no application for a safety certificate submitted to China for GE animal exports.

b) LABELING AND TRACEABILITY

GE animal labeling is also 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 is available.

c) TRADE BARRIERS

China does not import nor exports GE animals.

d) INTELLECTUAL PROPERTY RIGHTS (IPR)

GE animal is still a legal gap in the intellectual property rights (IPR) area. Currently, gene and DNA fragments are subject to protection provided by the Patent Law of China.

e) **INTERNATIONAL TREATIES/FORA**

Government of China does not take positions on animal biotechnologies in other international treaties, conventions, or international for a. However, Chinese scientists engage in animal biotech researches are quite active in international forum to closely follow and share latest research advancements.

PART G: MARKETING

a) **MARKET ACCEPTANCE:**

Although no study is available, Post believes public acceptance of GE animal is still lower than acceptance of GE plants.

b) **PUBLIC/PRIVATE OPINIONS:**

There is no study about public/private opinions towards animal biotechnology; however, it is obvious that public is more cautious about animal biotech than towards plant biotech.

c) **MARKET STUDIES:**

There is no study available about this topic.

PART H: CAPACITY BUILDING AND OUTREACH

a) **ACTIVITIES**

FAS and FDA Selected Animal Biotechnology Research Sites Visited in China

In August 2012, FAS and FDA animal biotechnology scientists and regulators visited selected animal biotechnology research institutes in Beijing, Guangzhou and Wuhan, including the Institutes of Biomedicine and Health (under Chinese Academy of Sciences), Institute of Hydrobiology (under Chinese Academy of Sciences), and China Agriculture University.

b) **STRATEGIES AND NEEDS:**

Although commercialization of GE animal is not happening soon, China is working to get itself prepared in both scientific research and regulatory work.

In the 2013 BWG held in D.C., Chinese government shows interest in GE animal regulatory system and research updates in the United States, which could be opportunities for the two sides to have in-depth discussions and cooperation.

Also, Chinese scientists are probing possibilities of getting their mature research results approved in the States. Guidance to them and exchange in the area will be very welcome.