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Approved by:
William Westman
AgBeijing

Prepared by:
Mark Petry and Wu Bugang

Report Highlights:
In July 2008, the Chinese Premier Wen Jiabao made an announcement of an additional $3 billion in state support for the development of agricultural biotechnology over the next 15 years. This signals China's intent to use biotechnology as a key means to address food security and re-affirms its position that the technology can be used safely. This strong pro-biotech policy suggests that major food crops may soon break free from a long regulatory limbo and be permitted for planting. A change to permit the planting of biotech food crops (rice, corn, and soybeans, in particular) could significantly alter Chinese production and rural economy in the coming years. However, concerns still remain about transparency in China's biotechnology regulatory and approval system and its ability to evolve with this rapidly changing technology.

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SECTION I. EXECUTIVE SUMMARY

China is currently the sixth largest producer of biotechnology enhanced plants based on total acreage (3.8 million hectares in 2007) and China recently announced that biotechnology will play an even more important role in its future agricultural development. Moreover, China is the largest export market for U.S. crops produced with the aid of biotechnology. Despite a lack of transparency in the development and application of regulations, U.S. biotech soybeans and other products are selling at record levels and are forecast to continue doing well in the future.

The State Council recently approved a special science and technology fund with up to 20 billion yuan (US$ 2.9 billion) for research of new varieties of biotech crops from 2006-2020. Xinhua news agency said that the program aims to "gain genes of great commercial value whose intellectual property rights belong to China and develop high-quality, high-yield, and pest-resistant GM crops." The agency further noted that the council stressed the importance of the program and called upon relevant authorities to "waste no time implementing it".

While China has made notable progress in its regulatory infrastructure, outdated biotech regulations and a lack of transparency still pose market access impediments. The barriers include requirements that a product must be fully approved in the originating country before an application can be filed for approval in China, redundant testing for products already approved in other countries, inadequate protection for intellectual property rights, and the lack of regulatory guidelines for stacked events.

Several internal and external factors influence China's biotech policy. These contradictory and competing political concerns have so far prevented China from commercializing any food and fodder crops, including rice or corn. First, though there is a strong interest in maintaining self-reliance in grains, biotechnology has not been used as a tool to boost production due to uncertainty over consumer reaction.

The Ministry of Agriculture (MOA) is the country's primary governing body over agricultural biotechnology issues. MOA Ministerial Decrees 8, 9 and 10 create the legal framework under which these products are regulated. Other government agencies, such as the General Administration on Quality Supervisions Inspection and Quarantine (AQSIQ) and the Ministry of Environmental Protection (MEP), are also involved on certain issues.

SECTION II BIOTECHNOLOGY TRADE AND PRODUCTION

Biotechnology crop production in China

China has commercialized six genetically modified plants since 1997 (cotton, tomato, sweet pepper, petunia, poplar, and papaya) and, according to an International Service for the Acquisition of Agro-biotech Applications (ISAAA) report, China is now the sixth largest producer of agricultural biotechnology crops in the world by acreage, (behind the United States, Argentina, Brazil, Canada, and India) at 3.8 million hectares in 2007. Insect-resistant (Bt) cotton is the single largest biotechnologically enhanced product produced in China. It is estimated that nearly 69 percent of the 5.5 million hectares of all cotton planted in China is produced with Bt cotton varieties. Other crops approved for commercial production are either not being produced (a delayed ripening tomato and a virus resistant sweet pepper) or are in relatively small production (a virus resistant papaya on some 3,500 hectares).

Biotechnology crop development in China

The Chinese government has granted safety certificates for commercial production of four biotech crops, including insect resistant cotton, virus resistant papaya, virus resistant sweet pepper, and delayed ripening tomato. Transgenic plants like poplar and petunia are also

approved for production. China does not regularly publish lists on products undergoing research and development. Among the hundreds of biotech products under development, insect resistant rice (Bt63), bacterial blight resistant rice (Xa21), and high oil content canola have been approved for productive testing. According to a recent publication by the Ministry of Agriculture, other major crops under filed trials include insect resistant corn, high lysine content corn, wheat resistant to pre-harvest germination, and insect resistant soybeans.

The government has not approved any biotech staple food crops for commercialization, even though it has made significant investment in research and development of agricultural biotechnology in this area. However, the progress of domestic research, slow productivity growth, and food inflation may have contributed to a renewed interest in permitting the release of a broader array of crops. 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 US$2.9 billion (funding to be allocated by central and local governments) over the next 15 years. The program, outlined in the Long and Mid-term National Development Plan for Science and Technology (2006-2020), will focus on research of crops (rice, wheat, corn, and cotton) as well as animals (swine, cattle, and sheep). The target is to develop new varieties with traits such as insect and/or disease resistance, stress tolerance, high yields, and high efficiency. Experts suggests that the plan reflects the central government's intention to use biotechnology as one of the key tools to address food security in China and as a signal that commercialization of staple food crops will be permitted in the near future. Many in Chinese industry anticipate the government will grant safety certificates for locally-developed transgenic corn within a year.

According to the European Union, unauthorized biotech rice (Bt63) has recently been detected in the rice shipments from China to European countries. This has triggered the European Commission to adopt emergency measures that require imports of rice and rice products originating or consigned from China be certified as free of the unauthorized genetically modified organism "Bt63" as of April 15, 2008.

There is essentially no private sector development on biotechnology in China. Biotech seed development in China is conducted by public research institutes and universities funded by various parts of the Chinese government, though marketing is often done by affiliated private companies. Foreign investment on research and production of biotech plants, breeding poultry and livestock, and breeding aquatic products is prohibited. Foreign investment is allowed in conventional seed production, but is limited to minority shareholders in joint ventures with Chinese companies.

Importation of biotech crops

China has approved four biotech products for import as processing materials (soybeans, corn, canola, and cotton) and is a significant importer of U.S. biotech products. The first batch of safety certificates were granted to imported biotech improved crops in 2004. The current list of biotech events approved for import as processing materials follows:

Biotech crops approved for import as processing materials (updated July 15, 2008)

Crop	Trait	Event	Developer	Safety certificate validity
Cotton	Insect resistance	531	Monsanto	02/20/2004-02/20/2009
Cotton	Herbicide tolerance	1445	Monsanto	02/20/2004-02/20/2009
Cotton	Insect resistance	BollgardII	Monsanto	07/20/2006-07/20/2011
Corn	Insect resistance and herbicide tolerance	59122	DuPont & Dow AgroSciences	12/20/2006-12/20/2009
Soybean	Herbicide tolerance	GTS40-3-2	Monsanto	12/20/2006-12/20/2009
Canola	Herbicide tolerance	GT73	Monsanto	12/20/2006-12/20/2009
Canola	Herbicide tolerance	Ms1Rf1	Bayer CropScience	12/20/2006-12/20/2009
Canola	Herbicide tolerance	Ms1Rf2	Bayer CropScience	12/20/2006-12/20/2009
Canola	Herbicide tolerance	Ms8Rf3	Bayer CropScience	12/20/2006-12/20/2009
Canola	Herbicide tolerance	T45	Bayer CropScience	12/20/2006-12/20/2009
Canola	Herbicide tolerance	Topas19/2	Bayer CropScience	12/20/2006-12/20/2009
Canola	Herbicide tolerance	Oxy-235	Bayer CropScience	12/20/2006-12/20/2009
Corn	Insect resistance	MON863	Monsanto	12/20/2006-12/20/2009
Corn	Insect resistance	MON810	Monsanto	12/20/2006-12/20/2009
Corn	Insect resistance and herbicide tolerance	Bt11	Syngenta	12/20/2006-12/20/2009
Corn	Insect resistance and herbicide tolerance	Bt176	Syngenta	12/20/2006-12/20/2009
Corn	Herbicide tolerance	GA21	Monsanto	12/20/2006-12/20/2009
Corn	Herbicide tolerance	T25	Bayer CropScience	12/20/2006-12/20/2009
Corn	Insect resistance and herbicide tolerance	TC1507	DuPont & Dow AgroSciences	12/20/2006-12/20/2009
Cotton	Herbicide tolerance	LLCOTTON25	Bayer CropScience	12/20/2006-12/20/2009
Soybean	Herbicide tolerance	A2704-12	Bayer CropScience	12/20/2007-12/20/2010
Corn	Herbicide tolerance	NK603	Monsanto	12/20/2007-12/20/2010
Corn	Insect resistance & herbicide tolerance	MON88017	Monsanto	12/20/2007-12/20/2010
Cotton	Herbicide tolerance	MON88913	Monsanto	12/20/2007-12/20/2012

SECTION III BIOTECHNOLOGY POLICY

Ministerial Responsibilities

The Joint-Ministerial Conference for Biosafety Management of Agricultural Genetically Modified Organisms (GMOs) is a loose mechanism that meets irregularly to discuss and coordinate on major issues in biosafety management of agricultural products of biotechnology. The conference consists of seven government agencies under the State Council, including 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).

MOA is chiefly responsible for approval of biotech agricultural crops for import and domestic production. MOA has taken over from MOST the management of central government funds distributed to Chinese institutes and universities for research and development of biotech crops. MEP (formerly State Administration of Environmental Protection or SEPA) is the lead agency for negotiation and implementation of the Biosafety Protocol (BSP), which China ratified on April 27, 2005. AQSIQ and their local inspection and quarantine offices (CIQs) are responsible for the nation-wide management of the inspection and quarantine for entry and exit of all biotech products. AQSIQ's Ministerial Decree 62 (CH4017) governs the steps that should be taken at customs when importing or exporting biotechnologically enhanced goods.

China has established a system of technical experts to support the regulatory system on agricultural biotechnology. The National Biosafety Committee (NBC) consists of 74 experts with multidisciplinary backgrounds from nine ministries, nine research institutions, and nine universities. The Ministry of Agriculture announced that NBC will increase the number of yearly meetings from two to three a year beginning 2008, likely in March, July, and November, to evaluate applications for safety certificates for biotech products for different uses as submitted by domestic and foreign seed developers. The new arrangement allows applicants to have more flexibility to file their applications before NBC meetings. The Committee is divided into three expert groups responsible for: biotech plants, animals and microorganisms, and food and feed.

The National Technical Committee for 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 assessment, testing, and detection.

There are 49 MOA-authorized centers across the country, which undertake environmental safety testing, food safety testing, and detection of agricultural GMOs.

The agricultural departments at provincial levels are responsible for monitoring field trials of biotech products, facilities processing GMO products, seed market, and labeling.

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"* (CH1056) and largely implemented by MOA under Ministerial Decrees 8, 9 and 10. These 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* (CH7053)) govern domestic approval, import approval, and labeling, respectively.

The Chinese government is currently revising these seven-year-old regulations to cope with the rapid evolving technology. 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 safety assessment (environment safety and food safety) to streamline the application and safety assessment processes. The guideline can be downloaded at http://www.stee.agri.gov.cn/biosafety/zhbd/t20070913_782803.htm.

The Ministry of Agriculture has added an additional application window for accepting applications for biotech products of various intended uses. The deadlines to accept the application materials are March 1, July 1, and September 1 of each year. The evaluation decisions will be released 45 days after each deadline. MOA used to have only two windows (deadlines on March 31 and September 30) to accept the applications.

Import approvals

The Ministry of Agriculture is responsible for approving biotechnology products that are intended for import into China. The approval process varies depending on the product's intended use (research, processing material, or production), safety levels, and the potential threat of the organism to human or animal health and the environment. MOA Decree 9 (CH7053) outlines the different requirements for importing biotech products with different purposes.

For importation of products as processing materials, Decree 9 states that a foreign seed developer must apply for an agricultural biotech safety certificate from MOA's Agricultural GMO Biosafety Office. The regulations require applicants to provide a variety of materials and to have certification that the exporting country has allowed use and sale of products in its domestic market and that they have undergone tests there 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 safety certificate.

Although the regulation provides that MOA should respond to an application for a safety certificate within 270 days, the approval processes and timelines of issuing a safety certificate vary from crop to crop depending on the product's intended use and potential impact on human or animal health and the environment. In general, the process of getting a safety certificate for imported biotech food crops as processing materials like soybeans will last about two years because it involves steps of varying length, such as import of testing materials, field trials and/or feeding study, and evaluation by the NBC.

Approval for domestic production

To produce biotech crops domestically in China, technology providers must pass a safety evaluation by the National Biosafety Committee and must be issued a safety certificate by the MOA's Agricultural GMO Biosafety Office. As outlined below, the approval process for biotechnology products for domestic cultivation involves five steps: research, intermediary experiment, environmental release, productive testing, and safety certification. Importantly, approvals are sought at the provincial level. After completing the five steps, products are eligible for safety certificates. The Agricultural GMO Biosafety Office delegates evaluation of the application to the National Biosafety Committee.

In February 2008, the Ministry of Agriculture announced that Bt cotton varieties and their backcross breeding varieties having received safety certificates for commercial production

may apply for production in all ecologically suitable areas. For other biotech crops, a safety certificate is good for the province or region where the original application was made.

In addition to a safety certificate for commercial production, biotech seed developers must seek registration of the biotech seed variety at the provincial agricultural department as required by the Seed Law. The process will take another 2-3 years. (Note: in some provinces this process may begin in step 4 of "production testing" and therefore can save one year).

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

1) Intermediary experiment (2,500 yuan each)
2) Environment release (3,000 yuan each)
3) Productive testing (5,000 yuan each or 3,000 yuan for additional imports as processing materials)
4) Test of GMO survival and competiveness (83,000 yuan each)
5) Test of ecological risk of gene flow (92,000 yuan each)
6) Test of GMO impact on non-target organisms and biodiversity (96,000 yuan each)
7) Anti-nutrient test (1,000 yuan per item)
8) 90-day rat feeding study (120,000 yuan each)

A rough outline of the process of GMO application is listed below. Where available, the names of institutions and contacts are provided.

1- MOA open window: accept applications
Contact: Mr. Lian Qing
Tel: 6419-1811
2- Biosafety Management Division at the Center for Science and Technology Development (CSTD): review and submit the application to National Biosafety Committee (NBC)
Contact: Mrs. Li Ning
Tel: 6419-5089
3- NBC: plenary sessions in March, July and November to hear preliminary views about applications and decides what tests need to be done.
4- GMO office processes import permit for field trials and feed study based on NBC approvals
Contact: Mr. Wei Kai
Tel: 6419-3059
5- Detection and Testing Division at the Center for Science and Technology Development: designates testing institutes and locations for field trials and feed study; work with applicants and designated testing institutes on development of testing methods and positive samples.
Contact: Mr. Song Guiwen
Tel: 6419-5096
6- Provincial Agriculture Bureau: endorses field trials in the province based on approvals from the GMO office;
7- Testing institutes for field trials and feed study: draft reports after the field trials and feed study are complete.
8- Biosafety Management Division of CSTD: review the report and submit to NBC
9- NBC reviews the reports about field trials and feed study at the three meetings;
10- GMO office issues safety certificate to applicant based on NBC decision.

Approved biotechnology products
A list of biotech products that have been approved for commercial production in China is available on MOA's web site at https://www.agri.gov.cn.

Labeling Policy
China's labeling regulations, governed by Ministry of Agriculture Decree 10 (CH7053), requires approved agricultural biotech products be labeled and prohibits 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.

China and the Biosafety Protocol
The State Council ratified the Biosafety Protocol on April 27, 2005 and China participated in MOP-3 discussions in Brazil in March 2006 as a full member.

As the lead authority for the Biosafety Protocol, China's Ministry of Environmental Protection (MEP) is charged with developing implementing regulations. Though MEP has not published any new or revised laws with regard to implementation of the Protocol, MEP has continued to state its intent to develop an overarching Biosafety Law that would take precedence over the Ministry of Agriculture's decrees regulating agricultural biotechnology.

Issues of Concern in the Biotechnology
Below are some of the current issues of concern for foreign countries and companies that export biotech commodities to China.

Product Approval: As noted above, the requirement that any product have complete regulatory approval in the country of development is a significant impediment to the import of products of biotechnology for processing. This system creates a lag time of about two years that prevents the marketing of seeds in the United States or other foreign markets because the resultant products can be marketed in China. As the full spectrum of safety testing is done in China after the finalized approval in the country of origin, this measure does not to appear to provide additional safety but rather eliminate the possibility that a biotech event would be approved in China but not in the country of origin.

Low Level Presence: China maintains a policy of zero tolerance for unapproved varieties. As China imports a broader arrange of products, especially processed products, and develops a broader range of products approved for domestic food consumption zero tolerance has potentially serious repercussions for food distribution systems.

Stacked events: China's regulations currently do not contain guidance on its policy about the evaluation of stacked events. The Chinese Ministry of Agriculture considers stacked events new products and requires a full regulatory review even if the same event has been approved previously. While China has approved cases of stacked events for local cultivation and import, officials have indicated that China will consider approval for importation of products composed of stacked events for processing on a case-by-case basis. Additional transparency regarding China's policy toward plants containing multiple biotech traits would assist registrants.

Investment restrictions: The Chinese investment catalogue puts significant restrictions on investment and/or control over intellectual property (CH7087). Full modernization of the Chinese seed sector and biotechnology research would be greatly assisted by providing foreign companies greater ability to develop seeds specific to the Chinese market using the same technologies open to domestic competitors.

Re-submission of discontinued products: China currently requires periodic re-registration of products that are approved for use (including import for processing), even if they are no longer in commercial seed channels, in order to maintain up-to-date testing methodology. While there is not an issue with the policy per se, companies generally hold very small quantities of discontinued seed and the Chinese required volume of seed is too large and poses safety issues if the plants need to be reproduced for this reason alone.

Intellectual Property Rights: Concern remains that there are potential conflicts of interest within the Chinese system for reviewing applications for biosafety certificates. Many of the domestic laboratories or institutes that actively test products under MOA review are also technology developers.

Import of testing materials: Although current regulations allow import of transgenic organisms for research and experiment purposes, the Ministry of Agriculture is not ready to accept such requests as they are not positive whether and how the testing/experiment results should be used in the safety assessment for the organism once it is has completed the regulatory approval process in the country of initial development and has been submitted by the developer to MOA for an import approval. MOA Decree 9 provides that import approval process can begin only after the biotech crop has been granted approval by the government of the exporting country for the same usage in domestic market.

Revision of biosafety regulations: The Ministry of Agriculture has repeatedly stated that it will modify the current regulations governing agricultural GMOs that were first published in 2002 (CH7053) in a bid to keep pace with the advancement of biotechnology. It is hoped that the modification process will be transparent and the revised version will be notified to the WTO for public comments.

SECTION IV MARKETING ISSUES

Market acceptance issues

China's consumers are by and large open to and accept biotechnology products. Generally, there does not seem to be the negative stigma attached to biotech foods that exists in some other Asian markets. A recent nation-wide study found 60 percent or more of respondents were willing to purchase biotech foods (including soybeans and rice) without any price discrimination. Twenty percent would only buy biotech food products when a price discount was offered. Twenty percent of respondents to the study would not accept biotech foods (with the exception of biotech rice with enhanced nutritional traits) regardless of any discounts in price.

Another study found that Chinese consumers' awareness to biotech foods was low, with about 75 percent having never heard of biotech foods or having heard of them on an occasional basis. The study found that a large majority of Chinese consumers hold a favorable or neutral attitude toward biotech foods, with only 5-15 percent of urban consumers opposed to biotech foods.

These findings are consistent with a recent study by the Asian Food Information Center's study on communicating with consumers on biotechnology that found that a "majority of consumers hold an open-minded position towards biotechnology foods and did not reject them per se."

SECTION V CAPACITY BUILDING AND OUTREACH

U.S. Government funded outreach and capacity building programs

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. Together, these fora have become a constructive means to address issues of common concern. The most recent BWG and TWG were held in March 2008 in Washington D.C. with both sides committed to continued dialogue and collaboration on regulatory and technical exchanges on agricultural biotechnology.

SECTION VI REFERENCE MATERIALS

Reference Materials Subcategory

USDA GAIN Reports: http://www.fas.usda.gov/scriptsw/attacherep/default.asp

The International Service for the Acquisition of Agri-biotech Applications: www.isaaa.org