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China – Law Firms

China's Regulation Of Agricultural Biotechnology

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China is the largest market for genetically modified ("GM") crops from the U.S.¹ As of 2005, China had approved for importation and processing varieties of GM canola, corn, cotton, and soybeans to be insect-resistant, herbicide-resistant, or both.² Since 2002, China has imported 20 million metric tons of U.S. GM soybeans a year, which is half of China's annual consumption of soybeans.

China also is the fifth largest producer of GM crops by acreage.³ China has approved varieties of cotton, petunia, poplar, sweet pepper, and tomato with GM traits including insect resistance, virus resistance, and long shelf life. In 2004, China planted 3.7 million hectares of GM crops, almost all of which were varieties of cotton with *Bacillus thuringiensis* ("Bt") genes for insect resistance.⁴ Bt cotton makes up two thirds of China's annual cotton production.

Over 600 applications are pending to commercialize new GM plant varieties in China, and 41 new GM plant varieties are currently undergoing biosafety testing in China. Also, China is among the largest investors in agricultural biotechnology research. As of 2005, China's Patent Bureau had accepted 146 patent applications for new varieties of GM soybeans.

Laws Governing Agricultural Biotechnology In China

In 1993, the State Science and Technology Commission ("SSTC") adopted China's first biosafety regulation, which required relevant ministries to issue biosafety regulations.⁵ Accordingly, in July 1996, the Ministry of Agriculture ("MOA") adopted the *Agricultural Biotechnology Engineering Safety Administrative Implementation Measures*, which addressed agricultural biotechnology research and led to the creation in 1997 of a National Agricultural Biotechnology Safety Committee ("Ag Biosafety Committee") to provide MOA with expert advice.⁶

In May 2001, the State Council of China adopted a new, general regulation on biosafety, the *Agricultural Genetically Modified Organisms Safety Administration Regulations*, which regulated not only research but also testing, production, pro-

cessing, distribution, import, and export. The State Council's 2001 regulation superseded the SSTC's 1993 regulation and much of MOA's 1996 regulation.

Under the State Council's new framework, MOA adopted Ministerial Decrees Nos. 8, 9, and 10 and implementing regulations on January 5, 2002: the *Measures on Safety Evaluation Administration of Agricultural Biotechnology*, the *Measures on Safety Administration for Import and Export of Agricultural Biotechnology*, and the *Measures on Biological Labeling Administration of Agricultural Biotechnology*. On May 24, 2005, by Ministerial Decree No. 62, China's General Administration of Quality and Supervision, Inspection, and Quarantine ("AQSIQ") adopted new customs requirements, the *Measures on Inspection and Quarantine Administration of Entry and Exit of GM Products*, to complement MOA's new biosafety regulations. On January 27, 2006, by Ministerial Decree No. 59, MOA adopted a fourth biosafety regulation, the *Measures for Biological Processing Review and Approval for Agricultural Biotechnology*, which became effective on July 1, 2006. Thus, agricultural biotechnology is governed primarily by six instruments in China: the State Council's 2001 regulation, MOA's four ministerial decrees and regulations, and AQSIQ's customs decree and regulation.

Authorities Responsible For Agricultural Biotechnology In China

MOA oversees biosafety throughout China and establishes evaluation standards and technical specifications.⁷ The State Council has established a Joint Inter-Ministerial Conference on Agricultural Biotechnology Safety ("Conference") to coordinate key issues related to biosafety, to examine and approve applications to commercialize new GM plant varieties, to determine which GM plants and commodities are subject to labeling, and to establish import and export policies for GM plant varieties and products.⁸ The Conference includes representatives from MOA, the State Development and Reform Commission, the Ministry of Science and Technology ("MOST"), the State Environmental Protection Administration, the Ministry of Health, the Ministry of Commerce, and AQSIQ.⁹

The Ag Biosafety Committee, established by MOA in 1997, includes experts on biotechnology, food safety and sanitation, environmental protection, agriculture product inspection and quarantine, economics, and foreign trade and meets twice a year to review the safety of all new GM plant varieties. In addition, MOA has established an Agricultural Biotechnology Safety Office ("Ag Biosafety Office"), which provides administrative support to the Ag Biosafety Committee, specifically, receives and processes all applications for approval to research, test, produce, or import GM plant varieties in China.¹⁰

In 2005, all 31 provinces in China established biosafety management offices under provincial agricultural bureaus.¹¹ These

offices approve all applications for research, field trials, and commercialization involving GM plants in their provinces.¹² Only cases that are approved by provincial biosafety management offices are submitted to the (national) Ag Biosafety Committee for further assessment.¹³

Process For Commercializing New GM Plant Varieties In China

In China, a company must obtain an Agricultural Biotechnology Safety Certificate ("Safety Certificate") (1) to produce or import GM seeds for domestic cultivation or (2) to import GM plant varieties for processing. When a company applies for a Safety Certificate, MOA assigns the new GM plant variety to a risk category: no risk, low risk, medium risk, or high risk. Any research on a GM plant variety in the medium- or high-risk category requires MOA's prior approval. Any importation or domestic production of a new GM plant variety requires MOA's prior approval regardless of the anticipated risks.

Production or Importation of GM Seeds for Domestic Cultivation

To obtain a Safety Certificate to produce or import GM seeds for cultivation, an applicant must undertake a five-step testing program: (1) experimental (laboratory) research; (2) a "medium test" (small-scale research in a controlled environment); (3) environmental release testing (medium-scale field testing with appropriate precautions); (4) production testing (large-scale, pre-production field testing); and (5) applying for the Safety Certificate itself, which requires reports from the prescribed testing and a report prepared by an MOA-approved safety institute in China.

Starting with the medium test, a company must obtain prior approval from the Ag Biosafety Office. The Ag Biosafety Committee reviews and approves all test reports at and beyond the medium test and also approves progression from one testing stage to the next. For this purpose, the Ag Biosafety Committee collects test reports on March 31 and September 30 of each year and meets twice each year to review the test reports. MOA makes final decisions in individual cases within 20 days of receiving the Ag Biosafety Committee's evaluation report.

Importing GM Plants for Domestic Processing

To obtain a Safety Certificate to import a GM plant variety for processing, an applicant must submit the following to the Ag Biosafety Office: (1) an import safety administrative form; (2) a safety evaluation application letter; (3) proof of the exporting country's approval of the GM plant variety for commercial use; (4) data developed in the exporting country on the GM plant variety's safety; (5) testing from an MOA-qualified laboratory demonstrating the safety of the GM plant variety; and (6) measures taken during export to ensure the GM plant variety's safety. The Ag Biosafety Committee evaluates the applicant's safety data and develops a recommendation, based on which the MOA makes a final decision to approve or deny the proposed importation.

Labeling Of GM Products In China

China has labeling requirements for

agricultural biotechnology products. Labeling is tied to product listings maintained by MOA. Specifically, a product listed in the MOA's agricultural biotechnology catalog must be labeled as a GM product. This requirement applies only to (1) GM crops, (2) GM seeds, and (3) certain commodities that are processed directly from GM crops. Labeling is not required for commodities that are not directly processed from GM crops or that are not listed in MOA's catalog, which currently includes 17 GM crops and commodities:

1. Soybeans: soybean seed, soybeans, soybean powder, soybean oil, and soybean meal.
2. Corn: corn seed, corn, corn oil, and corn powder.
3. Canola: canola seed, canola seed oil, and canola seed meal.
4. Cotton: cotton seed.
5. Tomatoes: tomato seed, fresh tomatoes, ketchup, and tomato sauce.

Accordingly, tofu, soy milk, and soybean sauce, even when processed directly from GM soybeans, do not require labeling, because these commodities are not listed in item 1 of MOA's catalog. Food fried in GM soybean oil also does not require labeling, because, unlike the soybean oil itself, the fried food is not directly processed from a GM soybean variety. Similarly, because cotton seeds are the only cotton commodity listed in MOA's catalog, textiles and garments made with Bt cotton do not require labeling.

Agricultural Biotechnology Research In China

In 2002, China banned outside investment in domestic agricultural biotechnology research.¹⁴ Research funds in China now come from the government (MOST) to State-owned research institutes and universities. The inventor owns the intellectual property rights, however, and is free to license them to third parties, including foreigners.

China spent US\$ 200 million on agricultural biotechnology research in 2004, and one-third of this money went to research on GM rice varieties containing Bt genes for insect resistance. There are more than 100 varieties of Bt rice undergoing research in China.

In 2005, four GM rice varieties nearly obtained commercial approval in China, but Greenpeace released two studies arguing against approval even before the Ag Biosafety Committee had started its evaluation. Eventually, the Ag Biosafety Committee rejected all four applications. Due to the importance of rice to the Chinese diet, extreme poverty in western China, a scarcity of arable land, and problems with water pollution, however, Chinese approval of GM rice varieties is likely within the next two years.

¹ U.S. Foreign Agric. Serv., China, People's Republic of Biotechnology: Agricultural Biotechnology Report 2005 3 (Nov. 21, 2005) (GAIN Report No. CH5009).

² *Id.* at 4-5.

³ *Id.* at 3.

⁴ *Id.* at 3-4.

⁵ Carl E. Pray et al., Costs and Enforcement of Biosafety Regulations in India and China, 2 *Int. J. Technology and Globalisation* 137, 144 (2006).

⁶ *Id.*

⁷ MOA, Measures on Safety Evaluation Administration of Agricultural Biotechnology, arts. 4, 7 (2002).

⁸ Pray et al., supra note 6, at 145.

⁹ MOA, supra note 8, art. 5.

¹⁰ *Id.*

¹¹ Pray et al., supra note 6, at 145.

¹² *Id.*

¹³ *Id.*

¹⁴ U.S. Foreign Agric. Serv., supra note 2, at 4.

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