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China Moves Forward in New Technologies

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Biotechnology and Other New Production Technologies

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Report Highlights:
China has emerged as a pivotal force in advocating the use of new technologies in agriculture. The Chinese Government has made plant and animal biotechnology a fundamental part of their strategy to modernize agriculture. This report highlights the status and current development of plant biotechnology, genetically engineered animals, and cloning within the People's Republic of China.

General Information:

Executive Summary

New technologies are expected to play an important role in meeting agricultural challenges and consumer needs of the 21st century. These new agricultural technologies consist of a range of tools, including genetically modified plants, genetically modified animals, cloning, nanotechnology, and advanced breeding techniques, that alter living organisms for a specific

agricultural use. For over a decade, biotech plants have been used to make both insect pest control and weed management safer and easier while safeguarding crops against disease. While currently not in commercial use, biotech animals offer the opportunity to introduce new traits in livestock that increase production, quality of meat, creates bioreactors for medicine, and other uses. Cloning allows farmers to speed up the reproduction times in conventional breeding in order to meet the demands of an ever growing world population. The application of these technologies in agriculture is expected to provide a range benefits to farmers, producers, and consumers. China has made the support of this technology and its safe use a cornerstone of its future rural development (GAIN CH9061). This report reviews the current regulatory environment for plant and animal biotechnology and animal cloning and describes ongoing research in these fields.

Biotechnology Regulatory structure - 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 biosafety management of agricultural products of biotechnology (both plant an animal). The conference consists of seven government agencies under the State Council, including: Ministry of Agriculture (MOA), National Development and Reform Commission (NDRC), the Ministry of Environmental Protection (MEP), the General Administration on Quality, 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 mainly responsible for approval of biotech products for import and domestic production. MOA has also taken over from MOST the management of central government funds distributed to Chinese institutes and universities for research and development of biotech crops and animals. MEP (formerly State Administration of Environmental Protection (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 goods that utilize methods of agricultural biotechnology.

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 the 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 is a significant development that allows applicants to have more flexibility to file their applications prior to 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, the seed market, and labeling.

Regulatory Framework – Plant Biotechnology

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 eight-year-old regulations to cope with the rapidly 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 another application window for accepting applications for biotech products for 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.

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 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 safety certification. Importantly, approvals are sought at the provincial level. After completing the five steps, products are eligible for safety certificates. The Division of GMO Biosafety and IPR delegates' evaluation of the application is sent 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.

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 plant biotech products is summarized as follows:

- Intermediary experiment (2,500 yuan each)
- Environment release (3,000 yuan each)
- Productive testing (5,000 yuan each or 3,000 yuan for additional imports as processing materials)

- Test of GMO survival and competiveness (83,000 yuan each)
- Test of ecological risk of gene flow (92,000 yuan each)
- Test of GMO impact on non-target organisms and biodiversity (96,000 yuan each)
- Anti-nutrient test (1,000 yuan per item)
- 90-day rat feeding study (120,000 yuan each)

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

- MOA open window: accepts applications

Contact: Mr. Lian Qing
Tel: 5919-1811

- Biosafety Management Division at the Center for Science and Technology Development (CSTD): reviews and submits the application to National Biosafety Committee (NBC)

Contact: Mrs. Li Ning
Tel: 5919-5089

- NBC: plenary sessions in March, July and November to hear preliminary views about applications and decides what tests need to be done.
- Division of GMO Biosafety and IPR processes import permit for field trials and feed study based on NBC approvals

Contact: Ms. Sun Junli
Tel: 5919-3059

- Detection and Testing Division at the Center for Science and Technology Development: designates testing institutes and locations for field trials and feed study; works with applicants and designated testing institutes on development of testing methods and positive samples.

Contact: Mr. Song Guiwen
Tel: 5919-5096

- Provincial Agriculture Bureaus: endorse field trials in the province based on approvals from the Division of GMO Biosafety and IPR;
- Testing institutes for field trials and feed study: draft reports after the field trials and feed study are complete.
- Biosafety Management Division of CSTD: reviews the report and submit to NBC
- NBC reviews the reports about field trials and feed study at the three meetings;
- Division of GMO Biosafety and IPR issues safety certificate to applicant based on NBC decision.

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 Division of GMO Biosafety and IPR (this office was merged with other

offices and was formerly name the 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; it involves steps of varying length, such as importing testing materials, field trials and/or feeding study, and evaluation by the NBC.

Status of the Industry – Plant Biotechnology

China maintains a vibrant plant biotechnology research community, primarily based at the public university level using central and provincial government funding. China has reviewed the safety and approved over 200 varieties of 8 types of crops, including: cotton, corn, rice, petunia, sweet peppers, papaya, tomato, and poplar. In addition to the broad array of products that have already been de-regulated by MOA, there are a number of advanced trials currently going on within China.

Chinese researchers are currently developing a wide variety of biotech crops, ranging from maize to chili and cabbage. Using the European Union Joint Research Centre's report on biotechnology in China as the primary corroborating source, below is a list of biotech crops believed to be under advanced development in China. Out of the 17 listed biotech crops, rice is the crop undergoing the most research. Nine crops have an insect or virus resistance trait, while the remainder has resistant to an abiotic stress. Over half of the crops are in the commercial stage of development, eight are in the regulatory stage and six are in the advanced research and development stage. It should be noted that nearly all of the biotech crops in the advanced research development stage have not disclosed the specific trait undergoing modification. Due to domestic reporting and permitting requirements, there is presumably a longer list of plants and products in the early experimental stage, but MOA does not release this list publically.

Table 1.1 GM Crop Development

GM crop	Place of Development	Developer	Product Name	Event name/ genes	Trait	Unique identifier
Soybeans	Commercial and regulatory	n/a (China)	n/a	Gna	Insect resistance	n/a
Maize	Regulatory	n/a (China)	n/a	Cry1A	Insect resistance	n/a
Maize	Regulatory	n/a (China)	n/a	n/a	Crop composition (phytase enzyme)	n/a
Maize	Regulatory	n/a (China)	n/a	n/a	Crop composition (high lysine content)	n/a
Cotton	Commercial	CAAS (China)	SGK321	Cry1A + CpTI	Insect resistance (to lepidopterans)	n/a
Cotton	Commercial	CAAS (China)	GK19	Cry1Ab-Cry1Ac	Insect resistance (to lepidopterans)	n/a

Rice	Commercial and regulatory	n/a (China)	n/a	KMD1	Insect resistance	n/a
Rice	Commercial and regulatory	n/a (China)	n/a	Xa21	Disease resistance (against leaf blight)	n/a
Rice	Commercial and regulatory	n/a (China)	n/a	Bt63	Insect resistance	n/a
Rice	Advanced R&D	n/a (China)	n/a	Bar68-1	Herbicide tolerance (to glufosinate)	n/a
Potatoes	Regulatory and advanced R&D	n/a (China)	n/a	n/a	n/a	n/a
Papaya	Commercial	n/a (China)	n/a	n/a	Virus resistance	n/a
Sweet Pepper	Commercial	n/a (China)	n/a	n/a	Virus resistance	n/a
Tomato	Commercial	n/a (China)	n/a	n/a	Virus resistance	n/a
Tomato	Commercial	n/a (China)	n/a	n/a	Crop handling (longer shelf life)	n/a
Wheat	Advance R&D	n/a (China)	n/a	n/a	n/a	n/a
Chili	Advance R&D	n/a (China)	n/a	n/a	n/a	n/a
Peanuts	Advance R&D	n/a (China)	n/a	n/a	n/a	n/a
Cabbage	Advance R&D	n/a (China)	n/a	n/a	n/a	n/a

Source: European Union Joint Research Centre. "Growing Number of Genetically Modified Crops Worldwide Could Disrupt International Trade," September 2009.

Regarding plant biotechnology, it is important to note that approvals are authorized on a provincial level. This means that a biotech product can only be grown in the province(s) authorized by the Ministry of Agriculture. In addition to a safety certificate for commercial production and the provincial restriction, biotech seed developers must seek registration of the biotech seed variety at the provincial agricultural department as required by the Seed Law. The process takes another 2-3 years and is essentially the same for conventional and biotech seeds. (Note: in some provinces, this process may begin in step 4 of "production testing" and, therefore, can save one year).

Animal Biotechnology

As in plants, animal genetic engineering is the deliberate modification of the animal's genome using recombinant DNA (rDNA) technology to introduce new traits. Genetic engineering can be used for various purposes, including creating or introducing: (1) pharmaceutical traits in animals for human or animal use; (2) resistance to disease; (3) useful agricultural traits, such as faster growing animals or leaner meats; or (4) reduce impact on the environment. Genetically-engineered animals have been in existence in laboratory research since the mid 1980s.

Regulatory Framework – Animal Biotechnology

The People's Republic of China Animal Husbandry Law, effective July 2006, contains a section dedicated to the genetic resources of poultry and livestock. Article 45, Chapter II, Article XI of this law instructs the Animal Husbandry and Veterinary Administrative Department of the State Council to set up a committee that is responsible for livestock and poultry genetic resources, identification and assessment. This committee, the National Animal Genetic Resources Committee, monitors all livestock and poultry genetic activities and regularly provides a list of animal resources to the State Council. (2006). However, the Ministry of Agriculture regulates biotech animals under the same framework that was originally designed for biotech plants (described above).

Approval for domestic production

To produce biotech animals 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 Division of GMO Biosafety and IPR. As outlined above, the approval process for biotechnology animals for domestic development involves five steps: research, intermediary experiment, environmental release, productive testing, and safety certification. After completing the fourth steps, biotech animals are eligible for safety certificates. The Division of GMO Biosafety and IPR delegates' evaluation of the application is sent to the National Biosafety Committee. As noted above, the Committee has one sub-committee that specializes in biotech animals.

Experts have noted that the process of review varies more than the plant biosafety review process because animal research is being used in many more different ways than the majority of ongoing plant research. However, the general permitting process includes the following steps:

- Preliminary Research permit from the Ministry of Agriculture;
    a. Includes basic investigative research parameters
- Intermediate scale research permit
    a. Small-scale research conducted mostly in a lab or other very small, isolated research area
    b. Small-scale research usually less than 10 individuals
- Environmental release (mid-scale) research permit
    a. Mid-scale research is also done in a tightly controlled laboratory or confined research area
    b. Mid-scale research is usually less than 100 individuals
- Productive Testing
    a. Production and breeding is carried out on a large specimen group, usually around 1,000 individuals

Following the review of findings, the National Biosafety Committee must be satisfied with the safety of the animal and recommend that the Ministry of Agriculture grant a biosafety certificate. MOA then makes the final determination regarding whether to issue the official biosafety certificate. In terms of biotech animal research, the biosafety certificate is important because it allows the researcher to transport the animal to different locations to begin commercial operations and it is also needed to obtain a breeder's certificate. The breeder's certificate is essential to bring the final product to market.

This procedure applies to the animal itself but does not apply to any drugs, organs, or meat/milk that may be intended for human or animal use. Products intended for human use would then have to go through the existing process used by the Ministry of Health or the State Food and Drug Administration. While the process for approving a drug produced by an animal for human use is the same as for any new drug, no drugs of this nature have yet to be evaluated in China. Food produced from biotech animals would have to be reviewed under novel or functional food regulations (GAIN CH9120).

So far, no biotech animals have completed the full safety review process and have granted a biosafety certificate. Clearly, as a result, there are no products produced using animal biotechnologies that are marketed in China. However, there are a number of animals that are in the final review stages. Several research institutions believe that they have successfully met the safety requirements and will soon be issued biosafety certificates.

However, there are a number of specialized biotech yeasts that have been approved for food use. Many experts believe that

experience in this area will be the basis for the eventual registration and marketing of products from biotech animals.

Beyond the existing published regulatory documents, there have been no public statements from the government or private sector about how these products would be regulated in the marketplace. While Chinese researchers are very active and have a high standing in certain international research fields, the Chinese Government has not been active in international fora on this issue.

Status of the Industry - Animal Biotechnology

Advanced conventional technologies are favored in China due to their lower cost and the fewer regulatory hurdles. Current biotech animal research is concentrated in the laboratory phase at China's universities. There are also some private sector companies, such as Genon Shanghai, that are also active in this area. The current status and trait information of biotech animal development in China is listed below.

Table 3.1 Advanced Animal Research

Species	Status	Details
Cattle	Experimental phase	Chlamydophila abortus
Cattle	Experimental phase	ITS-2 ribosomal DNA sequence. Fasciola species
Cattle	Experimental phase	Genetic diversity, Blood protein markers
Cattle	Experimental phase	Mitochondrial DNA, origin and introgression
Cattle	Experimental phase	Other
Cattle	Experimental phase	DNA probes; chlamydophila abortus
Chicken	Experimental phase	Chicken anemia virus (CAV); RT-PCR & sequencing
Chicken	Experimental phase	RFLPs; polymorphisms for B-LII beta (beta 1 exon) locus in some Chinese native chicken
Chicken	Experimental phase	Other
Goat	Experimental phase	DNA probes; chlamydophila abortus
Goat	Experimental phase	hEPO bioreactors, expression of human lactoferrin and lysozyme
Goat	Experimental phase	Microsatellites; genetic relationships
Pig	Experimental phase	Human organ transplant research
Pig	Experimental phase	Blood protein markers; genetic diversity
Water buffalo	Experimental phase	PCR; Sarcocystis cruzi (protozoa: sarcocystidae)
Rabbit	Experimental phase	Other

Source: Food and Agricultural Organization, UN, Biotech in Developing Countries

Cloning

Animal cloning is considered a common practice in universities across China, especially in assisting in biotech animal research. Most of the major species of livestock, including cattle, swine, and goats, were first cloned in the China from 2002-2006. As in the United States, little basic research is being performed in these places since the principle of Somatic Cell Nuclear Transfer cloning already has been proven in most species; and therefore, no longer is of interest to most basic researchers. Some of the main universities that conducted the initial successful cloning experiments of pigs and dairy cattle from 2000-2004 include China Agriculture University, Chinese Academy of Agricultural Sciences, and Northeastern Agricultural University.

Regulatory Framework – Animal Cloning

At the current time, China's regulatory approach to animal cloning is very similar to that of the United States. China conducted a risk assessment on the safety to human and animal health of Somatic Cell Nuclear Transfer (SCNT) cloning. The assessment incorporated the domestically generated safety data on SCNT cloning. In its assessment, China determined that no unique risks can be identified for SCNT cloning and that those risks that have been observed (related solely to animal health) are similar to risks observed in other assisted reproductive technologies (ARTs), such as in vitro fertilization. Furthermore, Chinese experts noted that, as with other ARTs, the frequencies of adverse effects have been shown to decrease with continued use and optimization of the technology. China found no risks to human health from the consumption of food products from cattle, swine or goat clones or from the offspring of any species of clone. Chinese experts also noted that they closely monitored the U.S. situation and evaluated the results of a similar risk assessment conducted by FDA in 2008. The Chinese experts noted that their experience and results compared favorably to that of the U.S. FDA.

As a result, there are currently no restrictions on the use of animal cloning in China. China does not have any type of registration or reporting requirement for researchers or companies that use this technology. There is also currently no regulation of animal products from clones or their off-spring.

Beyond the existing published regulatory documents, there have been no public statements from the government or private sector about how these products would be marketed or whether there would be restrictions or limitations. While Chinese researchers are very active and have a high standing in certain international research, the Chinese Government has not been vocal in international fora on this issue.

Status of the Technology - Animal Cloning

Researchers suggest that the technology is currently only being used widely in laboratory settings and in commercial development. Laboratory usage includes both for traditional government-sponsored animal breeding for extension purposes and to speed reproduction in biotech animal research. Cloning is also being actively pursued by commercial animal breeders, especially in the dairy industry.

Dairy Cattle: China was successful in cloning its first cow in 2002 from frozen somatic cells. The cow was cloned from a highly productive dairy herd under a high-tech program between the Shandong Company and China Agricultural University. Since then, the Shandong Company has cloned 26 additional cattle with the same technology.

Swine: China successfully cloned its first pig in August 2005. This experiment was conducted through the Chinese Agriculture University. Scientists were quoted as stating that cloned pigs would be useful for organ transplants, scientific research and improving the pig production in China. Further experimentation is in the early research stages.

In commercial usage, experts suggest that the products of the progeny of clones are or will soon be on the market. Due to the structure of Chinese animal production, the dairy industry is the only one likely to use this technology in the short run. However, experts suggest that, in the short term, the Chinese dairy industry is not structured to take great advantage of this technology as there are easier efficiency gains to be found in other areas. Though small in volume and as a percentage of production, milk from the conventionally bred offspring of cloned cows or bulls is already or will soon be on the Chinese market. Based on current regulations, as noted above, milk or meat from clones or their offspring is not subject to any special labeling or monitoring.