



Voluntary Report - public distribution

Date: 12/17/2000

GAIN Report #CH0046

China, Peoples Republic of
Trade Policy Monitoring
Current Status of Chinese GMO Development and
Regulation
2000

U.S. Embassy

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Report Highlights:

China has formulated regulations for evaluating and monitoring GMOs in agricultural production. Research and development continues for a wide range of commodities. However, regulations, which have yet to be formulated, particularly on food safety, make China's ultimate stance on GMOs unclear.

Summary

As the world's largest agricultural producer, China's position on GMOs is of great interest to everyone. Groups both inside and outside the Chinese government have raised concerns about GMOs similar to those raised in other parts of the world. Many have also talked of the benefits of eschewing GMOs in order to gain export share in Europe and Japan. However, China is a developing country and it may be very difficult for it to forego the increased efficiency in agriculture production arising from GMOs. Regulations are in place in China allowing the production of GMOs, albeit after a lengthy safety testing program. Significant use of GMOs in cotton and tobacco production already exists. Also, if current levels of research are any indication, widespread use of GMOs in Chinese feed and food production may soon be possible as well. However, the government is still working on questions of food safety, labeling, and the environment. It is still quite possible that unduly restrictive regulations in this area could thwart widespread commercial production and hinder imports. A process of defining a universal position is just beginning and it could be a long time before China comes out with a consistent and definitive policy.

Current Research and Development

Chinese research on agricultural biogenetic engineering began in the early 1980s but recently development has accelerated. Now more than 90 research institutes are engaged in research in this field. By the end of 1999, work had been done on at least 90 recipient organisms. Despite the high level of activity, some researchers have indicated that trade protectionism, and weak intellectual property rights, reduce the incentive to extend research on GMOs, particularly for foreign companies.

Research can be divided into three categories: plants, animals and microorganisms.

Plant Genetic Engineering

Reportedly, 49 GMO plant varieties are currently in research and development involving 103 different kinds of genes. The following table shows the species of these plants as of the International Workshop on Biology Safety Administration and Practice held in Nanjing, November 1998.

<u>Category</u>	<u>Number</u>	<u>Commodities</u>
Grain	7	rice, wheat, corn, potatoes, sorghum, millet, sweet potatoes
Cash and oilseeds crops	9	cotton, soybeans, tobacco, rapeseed, beets, peanuts, sugarcane, sesame and others
Vegetable and fruits	22	tomatoes, cabbage, green peppers, Chinese cabbage, carrots, cauliflower, apples, citrus, papaws, water melons, sweet melons and others
Others	11	poplars, alfalfa

According to the minutes of that workshop, at that time “pilot experiments” were being conducted on 11 species of plants, the second stage of the required government safety evaluation. (See following section.) These included rice, wheat, corn, soybeans, tomatoes, Chinese cabbage, papaws, sweet melons, peanuts, cotton, tobacco, and one kind of herb. The main traits of these GMO plants are insect resistance, disease resistance, salt tolerance, cold resistance and spoilage resistance. The research on genetically modified rice is centered in Hunan province and probably attracts the most attention of any ongoing GMO research. This research promises the development of a type of rice with significantly higher yields than non-GMO varieties.

More recently, MOA officials report that up to 12 species of plants have been approved for “environmental release” which is the third stage in the safety evaluation process. Commodities that have reached this stage include cotton, rice, corn, soybeans, wheat, tobacco, potatoes, tomatoes, green peppers, papaws, and morning glories. The desired traits mentioned for this group are similar to those mentioned in the workshop with the notable addition of herbicide resistance.

Animal Genetic Engineering

More than 30 varieties of GM fish and domesticated animals are under research. The research on some GM fish has entered the “pilot experiment” stage. Some results show that the rate of growth of GM fish is 20 percent faster than that of ordinary fish. Other GMO research on hogs, cattle, sheep, and domestic rabbits is making progress. Scientists have also started research using GM animals to produce medical protein.

Agricultural Microorganism Genetic Engineering

GM microorganism research is being conducted on 31 microorganism varieties, involving 56 kinds of genes. According to the Ministry of Agriculture, by the end of 1999, 4 species of microorganisms had been approved for “environmental release.” These microorganisms are being developed for use in the production of feed additives, vaccines, and pesticides.

GMOS in Commercial Production

In terms of land sown to GMO varieties, China ranks fourth in the world. Four species of plants have been approved by MOA for commercial production. These are pest-resistant cotton, two varieties of tomatoes, disease-resistance green peppers, and short-straw morning glories. GMO tomatoes and green peppers are apparently still not financially viable, perhaps in part because uncertainty about food safety regulations (see next section) makes investors wary. In 1999, the area sown to BT cotton reached 300,000 hectares, mostly in Hebei and Shandong provinces. In addition to those four species, GM tobacco, which accounts for 60 percent of total tobacco planted area, entered into commercial production in 1993, well before the safety administration regulation was issued in 1996.

Policy and Regulation

Oversight of GMOs in China is complicated. Five government agencies, the National Science and Technology Committee (NSTC), the Ministry of Agriculture (MOA), the Ministry of Public Health (MPH), the State Environmental Protection Administration (SEPA) and the State Administration for Entry-Exit Inspection and Quarantine (CIQ) are in charge of formulating relevant laws and regulations.

Up to now, only two regulations have been aimed specifically at biotechnology engineering management. The first is the Regulation of Genetical Engineering Management issued by the NSTC in December 1993. This regulation requires that all GE products must be subject to safety evaluation and safety control measures. According to this regulation, NSTC is in charge of the administration of Genetic Engineering safety. It established the National Genetic Engineering Safety Committee to supervise and coordinate the administration of genetic engineering safety among the different government departments.

The regulation most relevant to the use of GMOs in agriculture production is the Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering (SAGE) issued by MOA in July 1996 (discussed in next sub-section).

Provisions in three other regulations are also relevant to biotechnology, although they do not directly refer to genetic engineering. These regulations are: 1) the Administration Rules for New Resource Food issued by the Ministry of Public Health in 1992 as part of the Food Health Law; 2) the Administration Framework for Biological Safety (AFBS) formulated by the State Environmental Protection Administration; and 3) the New Plant Variety Protection Regulation issued by the State Council in 1997. A newly released Seed Law also contains certain articles concerning GMO seeds. As discussed in the Regulating Food Safety sub-section below, the Ministry of Health is also working on a special GMO law relating to Food Safety.

Regulation of Agriculture Production

The Planning Division of the Department of Science, Technology and Education in MOA is responsible for the administration of GMO research and production. It has established two organizations, the Office of Agricultural Genetic Engineering Safety Management and the Experts Committee on Agricultural Genetic Engineering Safety, to oversee the management of GMO research and production. This regulation is applicable to any agricultural organism whose genome constitution has been altered using GE technologies.

Safety evaluation is the core of this regulation. Any GM organism is subject to safety evaluation beginning at the point of initial research and must pass a safety evaluation before it can be produced commercially. Safety evaluation includes four stages. First, trial or experimental research which can only be carried out in research labs. The second stage is the pilot experiment stage. In this stage trials must be conducted under controlled conditions on one 0.13 hectare plot. Third is the environment release stage. In this stage GMOs are examined on 1.3 hectare plots in, at most, five different locations. The last stage is industrial production in which GMO safety is studied under conditions that replicate commercial production. After successfully passing through this stage the variety can be certified safe.

However, this certification does mean that the organism can go directly into commercial production. GMOs still need to apply for regular product examination and approval according to relevant regulations. It is also stipulated that the institutes conducting GMO safety evaluation must abide by safety control and precaution measures. A pamphlet outlining the regulation in both Chinese and English can be obtained from MOA. Appendices provide detailed safety evaluation measures for different plants, animals and organisms.

A newly Promulgated Seed Law, which will be administered by MOA, also includes special requirements for GM seeds. This law provides for additional safety evaluation and safety control measures. It also outlines a method for introducing foreign GM seeds and stipulates that commercial GM seeds must be clearly labeled as GMOs. More information on this law is contained in Attache Report CH0031.

The State Environment Protection Agency is also concerned about GMO's impact on the environment. Until now it has left most safety concerns to MOA. However, this year China signed the Biological Safety Protocol concerning biological diversity and ecological environment protection. As a result, SEPA is now reportedly formulating additional regulations which it feels are necessary to monitor GMO development and prevent harm to the environment.

Food Safety

The Ministry of Health's (MOH) Regulation on New Resource Food contains testing and approval measures for new foods. It also regulates packaging, labeling, user instructions, and industry standards. However, MOH feels measures in this regulation are not suitable for GMO products. Consequently, a GMO Food Safety Regulation is being formulated. It could be issued as early as the first part of 2001. This regulation, which focuses on examination and approval procedures for GMO foods, will, according to the Government, be based on science and international principles. It will conform with concepts and principles of China's Food Health Law issued in 1992. At the time of the release of the GMO food regulation, a Center of GMO Food Safety Evaluation is slated to be set up in the Ministry of Public Health. This Center will implement safety testing and evaluation and also engage in GMO food safety research.

Trade Regulation

There are no regulations regarding imports or exports of GMO products or products which contain GMO ingredients. In fact, China has imported, and continues to import, large amounts of GMO agricultural products and their processed products from the United States, Canada and other countries. However, China's inspection and quarantine agency (CIQ) says it is might establish GMO inspection methods and is drafting standards in order to monitor GMO product trade. CIQ is also considering special labeling for imported GMO products.

Outlook

Although the Ministry of Agriculture has set up a regulatory framework, and research progresses toward using GMOs in agricultural production, future regulations on food safety, labeling, and the environment could thwart further development of GMOs in China. Also, even though imports of GM products are now common, new regulations could reverse this trend. Still, many in the government, particularly the Ministry of Agriculture, realize the benefits of GMOs to agriculture, particularly for a developing country like China. These people will not easily allow others in the Government to trump ongoing GMO development.

As noted, the National Science and Technology Committee supposedly has overall responsibility for GMO policy, but coordination appears to be lacking. Perhaps foreseeing a potential problem developing, more senior officials in China's State Council, which has authority over all the agencies involved, are reportedly working on a mechanism to come up with a single coherent policy. However this will very likely be a lengthy process, in no small part dependent on how GMOs are eventually accepted in the rest of the world. Therefore, for some time to come, it will be difficult to know definitively what China's overall policy on GMOs will look like in the future.