

Legal Issues Relating to GMO Safety in China

by Wang Mingyuan

Editors' Summary: The genetically modified organism (GMO) safety regime in China is steadily evolving, with national, regional, and local government departments vying for regulatory power. The process is leading toward a reallocation of responsibilities among governmental departments overseeing science and technology, agriculture, public health, and environmental protection. The results of this power struggle inside the government will exert direct influence on the progress of legislating and implementing GMO safety. In this Article, Dr. Wang Mingyuan explores the historical evolution and system framework of the existing legislation on the safety of GMOs in China, the basic policies on GMO safety administration, and the problems and challenges China faces in refining its GMO policies. He argues that while the legal structure and administrative system relating to the safety of GMOs in China are beginning to solidify, they have lagged dangerously behind the development of biological technology and industry. He advocates a speedy resolution to the current power play within the government, and comprehensive solutions to the problems still evident in China's GMO safety regime.

I. Introduction

In order to ensure food safety, optimize agricultural diversity, and improve human health, China is promoting the research, development, and application of modern biotechnologies. The Eleventh Five-Year Plan for the Development of National Economy and Society sets forth that "by implementing specialized projects of biological industry, [we] strive to realize new breakthroughs in research and development of key technologies and important products of the biological industry." The Outline of the Mid- to Long-Term National Plan for Science and Technology Development lists biotechnology as one of the five strategic priorities of science and technology development in China over the next 15 years. For the past 20 years, the Ministry of Science and

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- 1. The Eleventh Five-Year Plan for the Development of National Economy and Society (promulgated by the Nat'l People's Cong., Apr. 14, 2006), XINHUANET, Mar. 16, 2006, available at http://news.xinhuanet.com/misc/2006-03/16/content_4309517_4.htm.
- 2. Outline of the Mid- to Long-Term National Plan for Science and Technology Development (promulgated by the St. Council, Feb. 9, 2006), available at http://www.gov.cn/jrzg/2006-02/09/content_183787_2.htm.

Technology has prioritized biotechnology as a part of national science and technology development. Early in 1983, the China Biotechnology Development Center was established. The State High-Tech Program, also called Program 863, started in 1986. In the Eleventh Five-Year Plan period, the Ministry of Science and Technology will lend even more support to the research, development, and application of biotechnology in state science and technology development plans, such as Major Specialized Science and Technology Research Projects, Program 863, and Program 973. Moreover, the National Development and Reform Commission (NDRC), the Ministry of Education, the Ministry of Public Health, the Ministry of Agriculture, the State Food and Drug Administration (SFDA), the Chinese Academy of Sciences (CAS), and other departments and institutions are adopting important measures to speed up the development of biotechnology and the bioindustry, including creating working plans, increasing investment, and training new scientists. Local governments are also enthusiastic about developing biotechnology and the bioindustry. Beijing, Guangzhou, Hu'nan, Shanghai, Shenzhen, Tianjin, and other local governments are adopting various measures to stimulate development of biological industrialization.³

Biotechnology is one of the fields presenting the fastest growth, the greatest potential, and the narrowest gap between China and developed countries. Today, the field has finished the phase of technical accumulation and come into

3. Wu Zhongze, Speed Up Development of Biotechnology and Breed New Growing Point of Economy, http://www.863.org.cn/863_105/news/news_bio/200610170005.html (last visited June 1, 2007).

a new period of research and industrialization progressing simultaneously. The development target, as stipulated by the Ministry of Science and Technology, is to accelerate scientific and technological achievements, to cultivate new biological industries, to raise the bioindustry as a pillar within the national economy, and to make China's biotechnology and bioindustrialization ranked among the world's most advanced—all within the next 15 years.⁴

China began to plant genetically modified (GM) crops in 1997. At present, approved commercially cultivated crops include cotton, wild *Cerambycidae* (longhorn beetles), tomatoes, and pimento. China imports even more GM products than it produces domestically. In recent years, China has imported more than 20 million tons of foodstuff, including GM soybeans from Argentina, Australia, Canada, and the United States.⁵ Other imported GM foods are maize and rape.⁶

As is well known, China, with a large population and less per capita plowland than many developed countries, has great incentive to develop and apply agricultural biotechnologies. According to a report issued by the International Service for the Acquisition of Agri-Biotech Applications (ISAAA) on January 27, 2007, of the 10.3 million farmers in more than 22 countries who planted GM crops in 2006, 6.8 million of those farmers were in China. China is ranked sixth in absolute area planted with GM crops. It is expected that a large portion of the millions of small-scale farmers expected to turn to GM crops over the next 10 years will be in China, with China expected to reach a leading level in agricultural biotechnology application during that time.⁷ Domestic experts assess the overall level of China's agricultural biotech research as follows: advanced in Asia, leading in the Third World, but still having a rather long way to go compared with advanced countries in the West. At present, China exports no living modified organisms (LMOs) or LMO products. In the long term, China is expected to export some such products to the Third World, including livestock bacterin and GM seeds.8

China has laid a foundation for the development of biotechnology and the bioindustry and may have a prosperous future. But because genetically modified organisms (GMOs), particularly GM rice and other major grain crops, invite controversy with respect to public health and ecological safety, the Chinese government needs to attach high importance to improving legal systems and management, carefully deal with GM products, and enhance administrative

- Yang Wenli, Biotechnology Industry of Our Country Comes Into the Phase of Development, http://www.sdkjb.com.cn/market/fenxi/ medicine/20061122/13396.html (last visited June 1, 2007).
- Chinafeed, The Development of GM Food Technology in China, http://www.chinafeed.org.cn/cms/_code/business/include/php/ 177881.htm (last visited June 1, 2007).
- Hong Tao, Analysis of the Policies on GM Food and Their Effects, http://www.hnagri.gov.cn/rdgj/read_xx.asp?id=139 (last visited June 1, 2007).
- 7. Huang Chaowu, Future Decade: The Application of Agricultural Biotechnology in China Will Reach Advanced Level, http://www.agri.gov.cn/jjps/t20070208_771043.htm (last visited June 1, 2007).
- Liu Xu, Status of Agricultural Biotechnology and Bio-Safety and the Countermeasures, http://agri.0437.gov.cn/html/shiyongjishu/ shengwujishu/2006/0612/6139.html (last visited June 1, 2007).
- Tong Guanglai, Should GM Rice Be Placed on the Dining Tables or Not?, http://www.biotech.org.cn/news/news/show.php?id=28427 (last visited June 1, 2007).

management to actively promote the development of biotechnology. ¹⁰ This Article will explore the legal issues relating to safety, supervision, and administration of GMOs, particularly agricultural GMOs, in China.

II. Background

A. Historical Evolution of China's GMO Safety Legislation

From the 1980s to early 1990s, China's biosafety research and practices lagged far behind biotechnology development. In the early 1990s, around the time of China's implementation of the Convention on Biological Diversity (CBD), 11 government agencies started to adopt measures to address biosafety, such as allocating funds for research, formulating laws, rules, regulations, and guidelines, and establishing administrative institutions. 12

With respect to legislation and policies, in order to enhance GMO safety administration, the State Council and relevant agencies have formulated a series of regulations, rules, and policies concerned with GMO safety.

On December 24, 1993, the former State Science and Technology Commission (today's Ministry of Science and Technology) promulgated the Measure on the Safety Administration of Genetic Engineering, China's first rule relating to administration of GMOs. The measure is applicable to all genetic engineering work underway in Chinese territory, including experiments, pilot tests, industrial production, GMO releases, and utilization of finished GM products. GMOs imported from outside China to be used in genetic engineering work in China are also subject to this measure.¹³

Pursuant to the Measure on the Safety Administration of Genetic Engineering, the Ministry of Agriculture promulgated the Safety Administration Implementation Measure on Agricultural Biological Genetic Engineering on July 10, 1996, and amended it on December 25, 1997. This measure set up concrete provisions on safety administration relating to agricultural biological genetic engineering, classified the safety grades of genetically engineered organisms, and prescribed specific administrative measures, in particular, the procedures and rules for registration and safety assessment of agricultural genetic engineering. The Ministry of Agriculture established a Genetic Engineering Safety Administration Office to implement the measure, as well as the Agricultural Biological Genetic Engineering Safety Committee to implement safety assessment on restricted field testing and commercialized production of agricultural biological

- 10. Zhong Xin, China Actively But Prudently Promotes Research, Development, and Use of GM Agricultural Product, Jilin Animal Sci. & Veterinary Med., 2006/2007, at 66.
- 11. On November 7, 1992, the Standing Committee of the National People's Congress ratified the CBD, which was originally signed by the Chinese Government on June 11, 1992. The Decision of the Standing Committee of the National People's Congress to ratify the Convention on Biological Diversity (promulgated by the Standing Comm. Nat'l People's Cong., Nov. 7, 1992), available at http://www.npc.gov.cn/zgrdw/common/zw.jsp?label=WXZLK&id=2807.
- 12. Liu, supra note 8.
- The Measure on the Safety Administration of Genetic Engineering (promulgated by the St. Sci. & Tech. Comm'n, effective Dec. 24, 1993) (P.R.C.), available at http://www.biosafety.gov.cn/gjzcfg/ flfg/200401/t20040115_88044.htm.

GMOs and GM products.¹⁴ On March 20, 2002, the Administration Measure on Safety Assessment of Agricultural GMOs entered into force, and the Safety Administration Implementation Measure on Agricultural Biological Genetic Engineering was abolished at the same time.¹⁵

On March 26, 1998, the State Tobacco Monopoly Bureau promulgated the Management Measure on Tobacco Genetic Engineering Research and Application. ¹⁶

On June 10, 1998, the Interim Measure for the Administration of Human Genetic Resources, formulated by the Ministry of Science and Technology and the Ministry of Public Health, was passed as approved and transmitted by the State Council. The measure is applicable to those actions related to gathering, collection, research, development, trade, import, and export of Chinese human genetic resources, stipulating that the state should carry out classified administration of human genetic resources. All units and individuals that find or possess important genealogy and specialized regional genetic resources should report to the relevant agencies immediately. Without approval, no one should gather, collect, buy, sell, export, or import such resources. According to the measure, the relevant departments of science, technology, and public health of the State Council should establish the Chinese Human Genetic Resources Administrative Office to take responsibility for the administration of the country's human genetic resources. 17

On April 22, 1999, the former State Drug Administration promulgated the Measure on Examination and Approval of New Biological Products, which entered into force on May 1, 1999. ¹⁸ The measure establishes guidelines for clinical research and the production of new biological products, including GM drugs.

The Seed Law was passed by the 16th Conference of the Standing Committee of the National People's Congress on July 8, 2000. Article 14 of the Act requires that seed selection, experimentation, examination, and commercialization of GM plant varieties should go through safety assessment and strict safety control measures, with specific methods to be stipulated by the State Council. The third clause of Article 35 clearly prescribes that "[e]vident marks must be used in the sale of the seeds of GM plants and safety measures in use should be displayed." ¹⁹

- The Safety Administration Implementation Measure on Agricultural Biological Genetic Engineering (promulgated by the Ministry of Agriculture, effective Dec. 25, 1997) (P.R.C.), available at http://www.biosafety.gov.cn/gjzcfg/flfg/200401/t20040115_88043.htm.
- The Administration Measure on the Safety Assessment of Agricultural GMOs (promulgated by the Ministry of Agriculture, Jan. 5, 2002, effective Mar. 20, 2002) (P.R.C.), available at http://law.chinalawinfo.com/newlaw2002/SLC/SLC.asp?Db=chl&Gid=38583.
- The Management Measure on Tobacco Genetic Engineering Research and Application (promulgated by the St. Tobacco Monopoly Administration, Mar. 26, 1998, effective Mar. 26, 1998) (P.R.C.), available at http://www.05791.com/tools/policynlaw/09/09062.htm
- The Interim Measure for the Administration of Human Genetic Resources (promulgated by the Gen. Office of the St. Council, effective June 10, 1998), available at http://health.sohu.com/2004/07/01/05/article220810587.shtml.
- The Measure on Examination and Approval of New Biological Products (promulgated by the St. Drug Administration, Apr. 22, 1999, effective May 1, 1999) (P.R.C.), available at http://www. chinapharm.com.cn/html/zcfg/20000411095243.htm.
- The Seed Law of the People's Republic of China (promulgated by the Standing Comm. Nat'l People's Cong., July 8, 2000, effective

On October 31, 2000, the Eighteenth Conference of the Standing Committee of the National People's Congress amended the Fishery Law, adding, "the introduction of GM aquatic seeds and fingerling fish must undergo safety assessment. Specific administrative regulations should be implemented according to related provisions of the State Council."²⁰

On December 21, 2000, the State Council promulgated the Outline of National Ecological Environmental Protection, requesting "to enhance bio-safety administration and establish an import/export control system and risk assessment system of GMOs and their products."²¹

On May 23, 2001, the State Council promulgated the Regulation on the Safety Administration of Agricultural GMOs. As the most important Chinese legislation on GMO safety to date, the regulation stipulates the safety administration structure and legal system for agricultural GMOs.²²

On January 5, 2002, the Ministry of Agriculture promulgated three administrative rules matching the Regulation on the Safety Administration of Agricultural GMOs: the Administration Measure on the Safety Assessment of Agricultural GMOs²³; the Safety Administration Measure on the Import of Agricultural GMOs²⁴; and the Administration Measure on the Labeling of Agricultural GMOs.²⁵ The Ministry of Agriculture amended these three measures on July 1, 2004.²⁶

On March 12, 2002, the Ministry of Agriculture promulgated the Announcement on the Provisional Measures on Safety Administration of GM Agricultural Products. These measures stipulated that overseas companies exporting GMOs into China can submit effective safety assessment documents issued by competent institutions of their own government to the GMO Safety Administration Office of the Ministry of Agriculture, which would then issue "provisional certificates" within 30 days if the applicants are determined to be qualified. The importers can bring the provisional certificates from the overseas companies to go

- Dec. 1, 2000) (P.R.C.), *available at* http://law.chinalawinfo.com/newlaw2002/SLC/SLC.asp?Db=chl&Gid=29407.
- 20. Article 17, cl. 2., The Fishery Law of the People's Republic of China (promulgated by the Standing Comm. Nat'l People's Cong., Oct. 31, 2000, effective Dec. 1, 2000) (P.R.C.), available at http://www.agri.gov.cn/xzsp_web/bszn/t20031105_133967.htm.
- The Outline of National Ecological Environmental Protection (promulgated by the St. Council, effective Nov. 26, 2000) (P.R.C.), available at http://www.people.com.cn/GB/channel1/907/20001222/358911.html.
- The Regulation on the Safety Administration of Agricultural GMOs (promulgated by the St. Council, effective May 23, 2001) (P.R.C.), available at http://law.chinalawinfo.com/newlaw2002/SLC/SLC. asp?Db=chl&Gid=35608.
- 23. The Administration Measure on the Safety Assessment of Agricultural GMOs, *supra* note 15.
- 24. The Safety Administration Measure on the Import of Agricultural GMOs (promulgated by the Ministry of Agriculture, Jan. 5, 2002, effective Mar. 20, 2002) (P.R.C.), available at http://www.agri.gov.cn/zcfg/bmgz/t20060123_540863.htm.
- The Administration Measure on the Labeling of Agricultural GMOs (promulgated by the Ministry of Agriculture, Jan. 5, 2002, effective Mar. 20, 2002) (P.R.C.), available at http://agri.gov.cn/gzgf/zlm/ t20030710 99082.htm.
- 26. Decision of the Ministry of Agriculture on Revising the Agricultural Administrative Regulations and Regulatory Documents (promulgated by the Ministry of Agriculture, effective July 1, 2004) (P.R.C.), available at http://law.chinalawinfo.com/newlaw2002/SLC/SLC.asp?Db=chl&Gid=53639.

through the formalities of application for examination and marking the goods according to the provisions of the Administration Measure on the Labeling of Agricultural GMOs. The validity of these provisional measures ended on December 20, 2002.²⁷

On October 11, 2002, the Ministry of Agriculture decided to prolong the validity of the Provisional Measures on Safety Administration of GM Agricultural Products to September 20, 2003. ²⁸ On March 10, 2003, the Ministry of Agriculture announced it would prolong the validity of the provisional measures on safety administration of imported GM agricultural products, including soybeans, to April 2004. ²⁹ Thereafter, the Ministry of Agriculture would implement ordinary administration on the imported agricultural GMOs according to the Regulation on Safety Administration of Agricultural GMOs, Administration Measure on the Safety of Import of Agricultural GMOs, and the Administration Measure on the Labeling of Agricultural GMOs. ³⁰

On March 4, 2002, the State Council approved the Inventory of Industries Guiding Foreign Investment and the Appendix, which was publicized by the former State Planning Commission, the former State Economic and Trade Commission, and the former Ministry of Foreign Trade and Economic Cooperation, and put into force on April 1, 2002. The production and development of GM plant seeds was listed in the Catalogue of Industries in which Foreign Investment is Prohibited.³¹

On April 8, 2002, the Ministry of Public Health promulgated the Measure on Administration of GM Food Hygiene,³² which entered into force on July 1, 2002. The measure contains provisions on food safety and quality assessment, production or import examination and approval, labeling, and supervision of GM foodstuff.

On December 28, 2002, the Standing Committee of the Ninth National People's Congress amended the Agriculture Law at the 31st Conference, adding, "with respect to research, experiment, production, processing, operation, and other application of agricultural transgenic organisms, all

- The Announcement on the Provisional Measures on Safety Administration of GM Agricultural Products (promulgated by the Ministry of Agriculture, effective Mar. 12, 2002) (P.R.C.), XINHUANET, Mar. 13, 2002, available at http://news.xinhuanet.com/zhengfu/2002-03/13/content_314126.htm.
- Ministry of Agriculture, Validity of the Safety Measures on GMOs Renewed for Another Nine Months, http://www.china.com.cn/ chinese/PI-c/217151.htm (last visited Sept. 6, 2007).
- Yang Qing, Validity of the Provisional Agreement on the Trade of GM Soybean Prolonged to April 2004, http://news.xinhuanet.com/ fortune/2003-03/12/content_773717.htm (last visited Sept. 6, 2007).
- 30. The Announcement of the Ministry of Agriculture of the People's Republic of China, No. 349 (promulgated by the Ministry of Agriculture, Feb. 20, 2004, effective Apr. 21, 2004) (P.R.C.), available at http://www.agri.gov.cn/xzsp_web/bszn/t20040223_168682.htm.
- Reply of the State Council on Relevant Issues Concerning the Inventory of Industries Guiding Foreign Investment and the Appendix (promulgated by the Gen. Office of the St. Council, effective Mar. 4, 2002) (P.R.C.), available at http://www.falvfagui.com/fagui/Class 1167/200611/1070226.html.
- The Measure on Administration of GM Food Hygiene (promulgated by the Ministry of Public Health, Apr. 8, 2002, effective July 1, 2002) (P.R.C.), available at http://www.china.org.cn/chinese/PIc/138299.htm.

the safety and control measures shall be enforced strictly in accordance with the regulations of the State."³³

On May 24, 2004, the State Bureau of Quality Supervision, Inspection, and Quarantine promulgated the Measure on Inspection and Quarantine Administration of Entry-Exit GMO Products,³⁴ which stipulated the administration of the entry-exit and transboundary inspection and quarantine of GMO products.

On July 1, 2004, the Law on Administrative Licensing entered into force. The law stipulates that administrative regulations can formulate specific provisions on licensing only within the scope of administrative licensing affairs as defined by higher level legislation.³⁵ Therefore, the content of the Measure on the Safety Administration of Genetic Engineering promulgated by the former State Science and Technology Commission on December 24, 1993, and other administrative rules conflicting with this law, particularly the parts relating to administrative licensing, need to be adjusted according to the Law on Administrative Licensing.

On April 27, 2005, the State Council approved China's signature to the Cartagena Protocol on Biosafety.³⁶ On September 6, 2005, China became a Party to the Protocol.³⁷ In order to implement the Protocol, the Chinese government also established the State Biosafety Administration Office, National Focal Point and Biosafety Information Exchange, under the State Environmental Protection Administration (SEPA).³⁸ The SEPA also drafted the Law on Safety of GMOs along with relevant departments of the State Council.³⁹

On January 16, 2006, the Ministry of Agriculture promulgated the Measure on Approving Processing of Agricultural GMOs, which entered into force on July 1, 2006.⁴⁰

On April 29, 2006, the Standing Committee of the Tenth National People's Congress adopted the Law on Quality Safety of Agricultural Products at the 21st Conference, which entered into force on November 1, 2006. Article 30 of the Law stipulates: "Agricultural products that belong to ag-

- 33. Para. 2 of Art. 64, the Agriculture Law of the People's Republic of China (promulgated by the Standing Comm. Nat'l People's Cong., Dec. 28, 2002, effective Mar. 1, 2003) (P.R.C.), available at http://news.xinhuanet.com/zhengfu/2002-12/30/content_674382.htm.
- 34. The Measure on Inspection and Quarantine Administration of Entry-Exit GMO Products (promulgated by the St. Bureau of Quality Supervision, Inspection, and Quarantine, effective May 24, 2004) (P.R.C.), available at http://www.biosafety.gov.cn/gjzcfg/flfg/200509/t20050920_70154.htm.
- Articles 14, 15, 16, and 17, the Law on Administrative Licensing of the People's Republic of China (promulgated by the Standing Comm. Nat'l People's Cong., Aug. 27, 2003, effective July 1, 2004) (P.R.C.), available at http://law.chinalawinfo.com/newlaw2002/ SLC/SLC.asp?Db=chl&Gid=49280.
- 36. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 39 I.L.M. 1027.
- 37. Wu Xiaoqing, Protect Biodiversity and Promote Harmonious Development of Man and Nature, http://www.gov.cn/ztzl/2006-05/23/content_288662.htm (last visited Mar. 3, 2007).
- 38. See National Biosafety Office, SEPA, National Focal Point (P.R.C.), http://english.biosafety.gov.cn/gjlld/zzhll/200401/t20040115_28724.htm (last visited Sept. 6, 2007).
- 39. Id
- The Measure on Approving Processing of Agricultural GMOs (promulgated by the Ministry of Agriculture, Jan. 27, 2006, effective July 1, 2006) (P.R.C.), available at http://www.gov.cn/ziliao/flfg/2006-03/02/content_215830.htm.

ricultural GMOs should be marked according [to] the provisions on safety administration of agricultural GMOs."41

Moreover, a number of local governments formulated and implemented local administrative rules on the safety of GMOs. For example, the Agricultural Bureau of Shenzhen City promulgated the Measure of Shenzhen City for Safety Supervision and Inspection of Agricultural GMOs on July 22, 2005. ⁴² The Agricultural Department of Shandong Province passed the Measure of Shandong Province passed the Measure of Shandong Province for Licensing, Examination and Approval of GMO Processing on August 22, 2006. ⁴³

B. Legislative Framework

The safety of GMOs involves sectors such as agriculture, fisheries, forests, industry, and commerce, areas such as economy, trade, science and technology, public health, and environmental protection, and governmental departments such as agricultural, science and technology, public health, food and drug supervision and control, environmental protection, quality inspection, and foreign affairs. Related legislation and policies are numerous and complicated, involving diverse forms, distinct content and tasks, and different levels of government, but all work toward the same mission: promoting and ensuring the safety of GMOs. In general, GMO law and policy should be integrated, with components cooperating and complementing each other.

Today, the system framework of legislation on the safety of GMOs in China takes the following form:

- 1. International treaties and conventions on GMO safety, particularly the CBD and the Cartagena Protocol on Biosafety;
- 2. Provisions on GMO safety contained in domestic laws;
- 3. Administrative regulation by the State Council on the safety of GMOs;
- 4. Administrative rules and measures on the safety of GMOs formulated by relevant departments of the State Council; and
- 5. Administrative rules formulated by local government departments.

III. China's GMO Safety Administration

A. Basic Policies

China's primary objective in biosafety administration is to minimize the potential hazard of modern biotechnology products to biodiversity, the environment, and public health by formulating policies, laws, regulations, systems, and re-

- The Law on Quality Safety of Agricultural Products of the People's Republic of China (promulgated by the Standing Comm. Nat'l People's Cong., Apr. 29, 2006, effective Nov. 1, 2006) (P.R.C.), available at http://www.gov.cn/ziliao/flfg/2006-04/30/content_271633. htm.
- The Measure of Shenzhen City for Safety Supervision and Inspection of Agricultural GMOs (promulgated by the Agricultural Bureau of Shenzhen City, July 22, 2005, effective Sept. 1, 2005) (P.R.C.), available at http://www.lawyee.net/Act/Act_Display.asp?RID=322722.
- 43. The Measure of Shandong Province for Licensing, Examination, and Approval of GMO Processing (promulgated by the Agricultural Department of Shandong Province, Aug. 22, 2006, effective Sept. 1, 2006) (P.R.C.), available at http://law.chinalawinfo.com/newlaw 2002/SLC/SLC.asp?Db=lar&Gid=16885700.

lated technical standards through coordinating and harmonizing the relationship between producers and consumers, research and commercial application, economic development and health and ecology, and domestic trade and foreign trade. Additional goals of biosafety administration are to prevent harm while prioritizing research and development, combining unified supervision with decentralized administration, scientific management, and public participation, and enhancing international cooperation.

The policy on market development of live GMOs and related products is to implement measures on the commercialized production, distribution, and application of different kinds of modern biotech products according to their biosafety classification. Policies encourage the production, distribution, and application of low-risk, modern biotech products, prohibit the production of high-risk GMOs and related products, and minimize potential impacts on production, operation, distribution, and application. In short, China's attitude on GM technology is to research actively, assess scientifically, apply prudently, administrate forcefully, promote steadily, and develop harmoniously.

B. Legal Systems

1. Genetic Engineering

The Measure on the Safety Administration of Genetic Engineering⁴⁵ stipulates that the State Science and Technology Commission governs nationwide genetic engineering safety. A national genetic engineering safety committee has been set up to handle safety supervision and coordination. Relevant administrative departments under the State Council carry out safety administration of genetic engineering work within their own jurisdictions.⁴⁶

According to this measure, the safety administration of genetic engineering work is carried out as safety assessment, class control, and classification approval systems. ⁴⁷ Genetic engineering work is divided into four safety classes according to potential risk levels. ⁴⁸ Institutions carrying out genetic engineering work should conduct safety evaluation to assess potential risk, determine safety class, and work out corresponding safety control methods and countermeasures, ⁴⁹ and should submit applications to relevant administrative departments at different levels according to the products' scope and safety class. ⁵⁰

The Management Measure on Tobacco Genetic Engineering Research and Application⁵¹ requires the State Tobacco Monopoly Bureau (STMB) to establish a Tobacco Genetic Engineering Administration Commission to take responsibility for the administration of field testing, demonstration, popularization, and application of the research and

- Biosafety Clearing-House of China, *Policies for Biosafety*, http://www.biosafety.gov.cn/gjzcfg/zc/200603/t20060323_28615.htm (last visited Sept. 7, 2007).
- 45. The Measure on the Safety Administration of Genetic Engineering, *supra* note 13.
- 46. *Id.* art. 4.
- 47. Id. art. 5.
- 48. Id. art. 6.
- 49. Id. art. 8.
- 50. Id. art. 13.
- 51. The Management Measure on Tobacco Genetic Engineering Research and Application, *supra* note 16.

products of tobacco genetic engineering. The measure requires researchers to apply to the STMB for examination and then report to the National Genetic Engineering Safety Commission for approval. Field testing, demonstration, and popularization of tobacco genetic engineering products require approval of the STMB. M tobacco seeds must undergo safety assessment organized by the Tobacco Genetic Engineering Commission of STMB and must be examined and approved by the National Tobacco Variety Examination Commission before planting on a trial basis. The GM tobacco leaves must be collected, stored, and used separately to prevent mixing with non-GM varieties. No tobacco leaves prepared for export may use GM tobacco seeds. Stored.

2. Agricultural GMOs

According to the Regulation on the Safety Administration of Agricultural GMOs,⁵⁶ the agricultural department of the State Council is responsible for nationwide supervision and administration of the safety of agricultural GMOs, the agricultural departments of governments at and above county level are responsible for the supervision and administration of agricultural GMOs within their respective jurisdictions, the public health departments of the governments at and above county level, according to relevant provisions of the Law on Food Hygiene,⁵⁷ are responsible for the health and safety supervision and administration of GM food,⁵⁸ and the State Council has established an interministry joint conference for agricultural GMO safety. The joint conference is composed of officials from the departments of agriculture, science and technology, environmental protection, public health, foreign trade and economic cooperation, and inspection and quarantine, and is responsible for the decisionmaking and coordination of major issues with respect to the safety administration of agricultural GMOs.59

With respect to the administration measures, the Regulation on Safety Administration of Agricultural GMOs, the Administration Measure on the Safety Assessment of Agriculture GMOs, ⁶⁰ the Administration Measure on the Safety of Import of Agricultural GMOs, ⁶¹ the Administration Measure on the Labeling of Agricultural GMOs, ⁶² and the Measure on the Labeling of Agricultural GMOs, ⁶³ and the Measure on the Labeling of Agricultural GMOs, ⁶⁴ and the Measure on the Labeling of Agricultural GMOs, ⁶⁵ and the Measure on the Labeling of Agricultural GMOs, ⁶⁶ and the Measure on the Labeling of Agricultural GMOs, ⁶⁸ and the Measure on the Labeling of Agricultural GMOs, ⁶⁹ and the Measure on the Labeling of Agricultural GMOs, ⁶⁹ and the Measure on the Labeling of Agricultural GMOs, ⁶⁹ and the Measure on the Labeling of Agricultural GMOs, ⁶⁹ and the Measure on the Labeling of Agricultural GMOs, ⁶⁹ and the Measure on the Labeling of Agricultural GMOs, ⁶⁹ and the Measure on the Labeling of Agricultural GMOs, ⁶⁹ and the Measure on the Labeling of Agricultural GMOs, ⁶⁹ and the Measure on the Labeling of Agricultural GMOs, ⁶⁹ and the Measure on the Labeling of Agricultural GMOs, ⁶⁹ and the Measure on the Labeling of Agricultural GMOs, ⁶⁹ and the Measure on the Labeling of Agricultural GMOs, ⁶⁹ and the Measure on the Labeling of Agricultural GMOs, ⁶⁹ and the Measure on the Labeling of Agricultural GMOs, ⁶⁹ and the Measure on the Labeling of Agricultural GMOs, ⁶⁹ and the Measure on the Labeling of Agricultural GMOs, ⁶⁹ and the Measure on the Labeling of Agricultural GMOs, ⁶⁹ and the Measure on the Labeling of Agricultural GMOs, ⁶⁹ and the Measure on the Labeling of Agricultural GMOs, ⁶⁹ and the Measure of Agricultural GMOs, ⁶⁹ and the Measure of Agricultural GMOs, ⁶⁹ and the Measure of Agricultural GMOs, ⁶⁹ and ⁶

- 52. Id. art. 6.
- 53. Id. art. 8.
- 54. Id. art. 13.
- 55. Id. art. 17.
- 56. The Regulation on the Safety Administration of Agricultural GMOs, *supra* note 22.
- 57. The Law on Food Hygiene of the People's Republic of China (promulgated by the Standing Comm. Nat'l People's Cong., effective Oct. 30, 1995) (P.R.C.), available at http://law.chinalawinfo.com/newlaw2002/SLC/SLC.asp?Db=chl&Gid=13133.
- 58. The Regulation on the Safety Administration of Agricultural GMOs, *supra* note 22, art. 4.
- 59. Id. art. 5
- 60. The Administration Measure on the Safety Assessment of Agricultural GMOs, *supra* note 15.
- 61. The Safety Administration Measure on the Import of Agricultural GMOs, *supra* note 24.
- 62. The Administration Measure on the Labeling of Agricultural GMOs, *supra* note 25.

sure on Approving Processing of Agricultural GMOs⁶³ have together formed the following major legal systems:

- (1) Class-Based Administration and Evaluation System. Agricultural GMOs are grouped into classes I, II, III, and IV according to their potential risks to humans, animals, plants, microorganisms, and the environment. All research, testing, production, processing, and import activities of agricultural GMOs in Chinese territory must go through safety assessment. Safety assessment is divided into three categories: plant; animal; and microorganism. The Ministry of Agriculture shall set up a biosafety committee responsible for safety evaluation of agricultural GMOs. The committee shall be composed of experts involved in research, production, processing, inspection and quarantine, public health, and environmental protection. The Ministry of Agriculture shall also set up an agricultural GMO safety office to carry out this administration.
- (2) Production and Processing Licensing System. A production license shall be obtained for the production of GM seeds, breeding livestock and poultry, or aquatic fry and seeds from the agricultural department of the State Council. Any organization or person engaged in the production of GM plant seeds, breeding livestock and poultry, or aquatic fry and seeds shall keep clear files of the production places, genes and their sources, and methods for genetic modification, as well as the whereabouts of seeds, breeding livestock and poultry, or aquatic fry and seeds. Any organization or person engaged in the production and processing of agricultural GMOs shall obtain approval from the agricultural department of the State Council or the agricultural departments of the provinces, autonomous regions, or municipalities directly under the Central Government. Where farmers raise GM animals or plant GM plants, the organizations selling the seeds, breeding livestock and poultry, or aquatic fry and seeds shall, on behalf of the farmers, go through the examination and approval formalities. Any organization or individual engaged in the production and processing of agricultural GM products with live agricultural GMOs as raw materials shall obtain a License for Processing Agricultural GMOs from the local agricultural administrative department of the government at the provincial level.
- (3) Marketing Licensing System. Any organization or person intending to market GM plant seeds, breeding livestock and poultry, or aquatic fry and seeds shall obtain a marketing license from the agricultural department of the State Council. Any organization or person marketing GM plant seeds, breeding livestock and poultry, or aquatic fry and seeds shall keep clear files of the sources, transportation, storage and the whereabouts of the seeds, breeding livestock and poultry, or aquatic fry and seeds, etc.

^{63.} The Measure on Approving Processing of Agricultural GMOs, *su-pra* note 40.

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(4) Labeling System. Agricultural GMOs listed in the labeling catalog shall be clearly labeled when they are sold in the territory of China. Agricultural GMOs listed in the labeling catalog shall be labeled by the organization or person producing or repackaging the products. Unlabeled products shall not be sold. The organization or person shall relabel the products if the original packaging has been opened for sale. The label shall clearly indicate the names of the main raw materials containing GM ingredients in the product. If there are special requirements on marketing scope, the label shall also indicate the scope, and the product shall be sold only within this scope. The first group of agricultural GMOs included under the labeling system includes 17 varieties in five species: soybean seeds for planting, soybeans, soybean flour, soybean oil, and soybean meal; corn seeds for planting, corn, corn oil, and corn flour; rape seeds for planting, rape seed, rape oil, and rape meal; cotton seeds for planting; and tomato seeds for planting, fresh tomatoes, and tomato sauce.

(5) Import and Export Administration. When introducing agricultural GMOs into the territory of China for research and testing, the introducing organization shall apply to the agricultural department of the State Council. Any company outside the Chinese territory that exports to China GM plant seeds, breeding livestock and poultry, or aquatic fry and seeds shall make an application to the agricultural department of the State Council. This provision also applies to the seeds, breeding livestock and poultry, aquatic fry and seeds, pesticides, animal medicines and biologics, fertilizers, and additives produced with agricultural GMOs or containing ingredients of agricultural GMOs. For those satisfying the required conditions, the agricultural department of the State Council shall approve the importation of testing materials and the implementation of field testing and productive testing. Once the productive testing and relevant safety evaluation are completed, and after obtaining the required safety certificate, the formalities of examination, registration, or evaluation and approval may proceed. Any company outside the Chinese territory that exports to China agricultural GMOs to be used as raw materials for processing shall apply to the agricultural department of the State Council. The agricultural department of the State Council shall issue a safety certificate of agricultural GMOs for those passing the safety evaluation and meeting the conditions. When introducing agricultural GMOs from outside the Chinese territory, the introducing organization shall make a declaration to the exit-entry inspection and quarantine agency at the port with documents of approval and a safety certificate. The introducing organization may make an application to Customs only after the agricultural GMOs pass quarantine. Agricultural GMOs that are imported without relevant documents of approval and safety certificates, or not conforming to the certificate and approval documents, shall be rejected or destroyed. Where agricultural GMOs to be imported are not labeled in accordance with the relevant provisions, they shall not enter the Chinese territory until they have been relabeled. When agricultural GMOs are to be transferred via the territory of China, the owner of the goods shall in advance make an application to the exit-entry inspection and quarantine department of the State. Such transboundary movement may be carried out only after approval and shall comply with the provisions of the relevant laws and administrative regulations of China. When agricultural products are exported outside the territory of China and the foreign party requests a certificate of non-GM agricultural products, the exit-entry inspection and quarantine agency at the port shall undertake inspection and issue a certificate of non-GM agricultural products in accordance with the information on GM agricultural products published by the agricultural department of the State Council.

3. GM Food Hygiene

With respect to the safety administration of GM food, the Measure on Administration of GM Food Hygiene stipulates the following legal systems:

- (1) Safety and Nutritional Value Assessment. The Ministry of Public Health has set up a GM food-stuff experts committee composed of specialists in food safety, nutrition, and genetic engineering to assess the safety and nutritional value of GM food. The safety and nutritional value assessment adopts the principles of risk evaluation, substantial equivalence, and individual treatment. The assessment rules and related standards shall be formulated and stipulated by the Ministry of Public Health.
- (2) GM Food Examination and Approval System. Production and import of GM food should be examined and approved by the Ministry of Public Health.
- (3) GM Food Tracing System. The producers of GM food should keep import/export records of GM food for at least two years for consultation, including information on shipping, destination, and amount.
- (4) Labeling System. Food (including raw materials and processed foodstuff) containing GMOs should be labeled with "GM XX food" or "with GM XX food as raw materials." The GM food made of potential allergens also should be labeled: "with XX GM food, persons sensitive to XX food should be careful." The measures also define the labeling methods and require that the labels must be true and objective.

4. GM Drugs

According to the Measure on Examination and Approval of New Biological Products, China adopts state-level examination and approval systems for new biological products, including GM drugs. All clinical research and production of new biological products must be examined, assessed, and approved by the former State Drug Administration (to-day's SFDA).

IV. Legislation and Implementation Challenges

A. Legislation Challenges

Current Chinese laws and regulations on the safety of GMOs have provided legal basis for administrative action, but the following major problems still exist in the legal system.

1. Lack of Comprehensive Legislation

Current administrative rules on the safety of GMOs were formulated and implemented by administrative departments of the State Council, such as the former State Commission of Science and Technology, the Ministry of Agriculture, the State Tobacco Monopoly Bureau, the Ministry of Public Health and the former State Drug Administration. ⁶⁴ The Regulation on the Safety Administration of Agricultural GMOs was upgraded by the State Council from the administrative rule of the Ministry of Agriculture on the safety administration of agricultural GMOs. Rules by these departments are sector-specific, leaving gaps where comprehensive legislation is needed. ⁶⁵

The Measure on the Safety Administration of Genetic Engineering adopted in 1993 is China's first legislation relating to biosafety administration and became the model and basis of other legislation on the safety of GMOs. 66 But the basic starting point of the measure is technical administration and lack of operability, so there was no opportunity for substantive implementation. After 1994, along with the development of agricultural GM plants and GM breeding animals in China and large amount of import of GM agricultural products including GM soybeans, the Ministry of Agriculture became the chief governmental department responsible for biosafety administration in China. Especially after the promulgation of the Regulation on the Safety Administration of Agricultural GMOs, the Ministry of Agriculture formulated and implemented a series of administrative rules, establishing a fairly comprehensive legal system, but one confined to the agricultural arena.⁶⁷ Without comprehensive legislation on the safety of GMOs that extends beyond agriculture, the current legal system as a whole is short on overall planning, systemization, integration, and coordination, resulting in nonexistent or redundant administration.

2. Incompleteness of Scope

Current legislation in China on the safety of GMOs is mainly used to regulate the agricultural sector. Along with the rapid development of biotechnology in China, the issues

- 64. See Part II of this Article.
- 65. Shi Xiaoli, Laws and Regulations on GM Technology and GM Products, COMP. LEGAL STUD., Apr. 2003, at 82-83.
- 66. Other such legislation includes the Safety Administration Implementation Measure on Agricultural Biological Genetic Engineering promulgated by the Ministry of Agriculture on July 10, 1996, and the Management Measure on Tobacco Genetic Engineering Research and Application promulgated by the STMB on Mar. 26, 1998.
- 67. Shi, supra note 65, at 81-82.

of GMO safety in the areas of forestry, wild animals and plants also need to be regulated through legislation. Moreover, current legislation regulates only research, testing, popularization, production, processing, import/export, and other activities with relation to GMOs, but ignores the linkages of storage, transportation, waste disposal, etc.

3. Insufficiency of Administrative Instruments

Current legislation in China on the safety of GMOs has established a supervision and administration system with safety evaluation, licensing, and labeling as the core content, but prior informed consent for transboundary movement, public participation, damage compensation, and liability insurance are insufficient or lacking altogether.

4. Lack of Adequate Supervision

The State Council departments have established their status as administrators through the rules they promulgated for themselves, and not through unified State leadership. In the competition for administrative authority on GMOs, the Ministry of Agriculture has taken primary responsibility for safety administration of GMOs. The research, testing, production, processing, import, and other activities relating to GMOs are mainly administered by the Ministry of Agriculture and the agricultural departments of provincial-level governments. At the same time, the departments engaged in science and technology, forestry, public health, commerce, environmental protection, quality inspection, food and drug administration, and foreign affairs, along with the CAS and some other institutions, also take certain responsibility for the safety administration of GMOs within their respective functions and authorities. With the lack of comprehensive laws and regulations on the safety of GMOs, relevant departments have no coordinated and defined functions and responsibilities, resulting in problematic intersection, overlapping, conflict, and vacancy of responsibilities. When introducing comprehensive legislation on GMO safety, legislators need to clarify departmental functions and a coordinating mechanism.

B. Implementation Challenges

Although the Regulation on the Safety Administration of Agricultural GMOs functions as the cornerstone of China's legal regime on GMO safety, the following major problems still exist in the regulation's implementation.

1. Lack of Coordination and Cooperation

GMO safety in China is managed both vertically through central ministries and horizontally across local governments. At present, technological research and development of GM products falls to the Ministry of Science and Technology, while safety administration belongs to the Ministry of Agriculture. The Ministry of Public Health is also involved through its Measure on Administration of GM Food Hygiene. The safety assessment of GM products also relates to the assessment and control of ecological destruction and environmental pollution for which the SEPA is the competent department, while the authority to import and export GM product belongs to the Ministry of Commerce. More-

over, the State Bureau of Quality Supervision, the State Administration of Industry and Commerce, and the SFDA also hold certain responsibilities for the administration of GMOs. Under such conditions, it is difficult to avoid overlap, conflict, and vacancy of functions, such as the contradiction between the "active research" of the Ministry of Science and Technology and the "careful use" of the Ministry of Agriculture. Interdepartmental coordination in the process of signing the Cartagena Protocol on Biosafety had been nearly impossible; since the Protocol is a convention of the United Nations Environment Program, the joint signature should be headed by the SEPA. But because it was challenging to coordinate among different departments, signing the Protocol had been delayed.⁶⁸ Under the current situation, the SEPA lacks information on research, testing, import, and industrialization of GMOs.69

2. Lack of Capacity

Compared to the funds invested in technological research and development, funding devoted to research and administration on GMOs is limited. According to statistics, funding for GMO safety research was about 500,000 yuan in 1997. This amount increased to 9 million yuan by 2001 and to 19 million yuan by 2004, while funding of safety administration was increased to 6 million yuan by 2004, up from several hundred thousand yuan in previous years. The total investment in GMO research amounted to 1.647 billion yuan in 2004.⁷⁰

Moreover, the competency and institutional construction on GMO safety are also quite weak. For example, the Agricultural GMO Safety Administration Office under the Ministry of Agriculture is responsible for nationwide GMO safety supervision, including approval of GM crops, but it is staffed with just a few workers. At the local level, most of the work of the agricultural GMO safety administration is shared by other departments of the provinces, autonomous regions, or municipalities directly under the Central Government.⁷¹

3. Lack of Transparency

The Chinese government lacks transparency and public participation in safety administration of GMOs. Even members of the "think tank" of GMO administration, the State Safety Commission of Agricultural GMO Affairs, were not assigned through public selection, but recommended by specific departments and appointed by the Ministry of Agriculture. Membership on the commission is not open to the public. Materials related to examination and approval of GM varieties can only be accessed by the members of the commission; there is no procedure for opening these processes to public scrutiny. 72

4. Lack of Enforcement

In general, China's policy on GMO commercialization tends to be prudent, while the corresponding examination and approval systems tend to be strict as that administration becomes stronger. Since the first commercial planting of GM pest-resistant cotton in 1999, the Chinese government has not approved any other GM crops for commercial planting.⁷³

However, due to the absence of effective administration of GMOs, there is a common phenomenon of law violation. In the area of research of GM technology, the laboratories of many scientific research institutions cannot meet necessary insurance conditions for the safety of GMOs; indeed, they cannot meet even the basic conditions to conduct GM technological research. With respect to environmental release of GMOs, most research institutions bypass agricultural agencies at the county and provincial levels and report directly to the agricultural department of the State Council. As a result, the county- and provincial-level governments know nothing about the environmental release of agricultural GMOs within their jurisdictions, and thus have no means of supervision and control.

With respect to the commercialized production of GM agricultural products, many institutions, driven by profit to violate the licensing system on production and operation of GM plant seeds, breeding livestock and poultry, or aquatic fry and seeds, conduct related production and operations activities illegally. GM rice, not approved for commercial production, was planted in Hubei Province and entered the market.⁷⁵

With respect to the labeling of GMOs, laws and regulations are not observed by industry and are difficult for the government to enforce, meaning the Administration Measure on the Labeling of Agricultural GMOs exists in name only. For example, in 2002, Greenpeace China (Hong Kong) sampled nearly 60 popular brands of foodstuff in 7 batches throughout Beijing, Guangzhou, Hong Kong, and Shanghai. The results revealed 16 samples containing GM elements, including 6 varieties of Nestle Alimentana SA, McDonald's pizza, and Kentucky Fried Chicken's dehydrated potatoes. In July 2003, in the supervision and random sampling action on the labeling of agricultural GMOs conducted by the Municipal Agricultural Bureau of Beijing, 22 brands of soybean oil and soybean meal from 14 enterprises were inspected and found to be GM products, but none of them was labeled as such. Most consumers are unaware of these labeling problems.⁷⁶

Xu Xiaoying, China Raises Threshold of GM Safety, http://www. businesswatch.com.cn/Html/gov/064511530333389_2.html (last visited Sept. 8, 2007).

Biotech.org.cn, GM Agriculture Keeps Developing With Controversies, http://www.biotech.org.cn/news/news/show.php?id=6819 (last visited Sept. 9, 2007).

^{70.} Xu, *supra* note 68.

^{71.} *Id*.

^{72.} Id.

^{73.} Liu Jianqiang, *Do the Chinese Scientists Have Their Own Private Interests or Not for the Commercialization of GM Rice?*, http://tech.sina.com.cn/d/2004-12-09/0958473277.shtml (last visited Sept. 10, 2007).

^{74.} Zhou Shudong & Cui Qifeng, *The Problems in Administration of GM Agricultural Products in China and Recommendations on Countermeasures*, CHINA SCI. & TECH. F., Jan. 2006, at 61.

Sun Danping, Green Peace Organization Announced That GM Rice Had Been Found in China Market, http://news.xinhuanet.com/ fortune/2005-04/14/content_2826426.htm (last visited Sept. 10, 2007).

^{76.} Wen Yu, *GM Food Is Developing With Standardization*, Global Food Indus., Aug. 2003, at 37.

V. Prospects for Improving Legislation

The Decision of the State Council on Practicing the Concept of Scientific Development and Enhancing Environmental Protection requires that no time should be lost in drafting laws and regulations on genetic resources, biosafety, ozone layer protection, and environmental damage compensation.⁷⁷ According to this requirement, the Cartagena Protocol on Biosafety, and opinions of the Office of Legislative Affairs of the State Council, the SEPA announced that it will join with other departments and institutions like the Ministry of Foreign Affairs, the Ministry of Science and Technology, the Ministry of Finance, the Ministry of Agriculture, the Ministry of Commerce, the State Bureau of Quality Inspection, the General Administration of Customs, the State Forestry Bureau, and the CAS to draft the Law on the Safety of GMOs. As planned by the SEPA, the proposed law would be listed into the legislation program of the Office of Legislative Affairs of the State Council in 2007, to be adopted by the Standing Committee of the National People's Congress in 2008.⁷⁸ The main task of this law is to protect public health and biosafety, promote development of biotechnology and industry, regulate the import and export of GMO technologies and products, implement the international obligations defined by Cartagena Protocol on Biosafety and remedy the defects of current legislation and administrative systems on the safety of GMOs.

In fact, the drafting and formulation of the Law on the Safety of GMOs is a process of readjusting power and obligations among authorities and between authorities and the public. The SEPA attempts to establish its position within the GMO safety administration by leading the drafting of the Law on the Safety of GMOs. This naturally draws resistance from the Ministry of Agriculture, which is presently considered the primary authority on GMOs. It may be a long and tortuous road to adoption of the draft, if it is ever adopted at all. The draft may suffer the fate of other laws that have died in the proposal stage—for instance, a regulation pertaining to GMOs was drafted under the charge of the Ministry of Science and Technology, but it has not been passed because departments are locked in a stalemate on the division of authority and functions. 79 If this comprehensive law on the safety of GMOs cannot be adopted, other attempts to clarify the regulatory regime may be made, such as amending other relevant laws on agriculture, food hygiene, and environmental protection.

VI. Conclusion

Over the past decade, the State Council and its departments, along with local governments, have formulated and enforced a series of regulations, rules, and policies on GMOs. The Standing Committee of the National People's Congress has formulated or amended laws on GMOs. China has also joined the Cartagena Protocol on Biosafety and other international pacts, and the legal and administrative systems on GMO safety have begun to take shape and play a role in protecting public health and the environment and ensuring the development of biotechnology and industry. But in general, biosafety research in China still lags behind the development of biotechnology, and problems and defects in the legislation and enforcement on GMO safety remain. It is still difficult to ensure effective coordination and implementation of complicated policies: active research, scientific evaluation, prudent application, enhanced administration, steady promotion and coordinated development.

In the early 1990s, the state had not stipulated unified and coordinated safety policies on GMOs and had not defined the government's role in supervision and administration system, so the State Council's departments of science and technology, agriculture, and public health tried to establish their own positions in GMO safety supervision and control by formulating their own administrative rules. In 2001, the State Council promulgated the Regulation on the Safety Administration of Agricultural GMOs, which is actually a regulation upgraded from an administrative rule of the Ministry of Agriculture, thus laying the foundation for the Ministry of Agriculture to occupy the leading position in the GMO safety administration system. After China acceded to the Cartagena Protocol on Biosafety, the SEPA tried once again to win the leading position in national GMO safety supervision and administration by drafting the Law on the Safety of GMOs. But because there are disputes among the State Council departments on the division of authority in GMO safety administration, whether this proposed comprehensive law will be passed smoothly is still uncertain.

China's legislation on GMO safety and its enforcement are still evolving. This is not only a process of readjustment of rights and obligations between authorities, industry, and the public, but also a process of reallocation of power and position among related competent governmental departments involved in science and technology, agriculture, public health, and environmental protection. The competition for power and authority among related administrative departments inside the government affects the government's ability to effectively oversee the enterprises and society outside the government. The Chinese government must clarify departmental roles and begin the process of crafting comprehensive legislation and regulations in order to achieve proper governance of GMO safety.

^{77.} The Decision of the State Council on Practicing the Concept of Scientific Development and Enhancing Environmental Protection (promulgated by the St. Council, effective Dec. 3, 2005) (P.R.C.), available at http://www.gov.cn/zwgk/2005-12/13/content_125680.htm.

^{78.} Because the enacting of this law has not been listed into the legislation program, the Ministry of Agriculture will not assign experts to take part in the drafting works at present.

^{79.} Xu, supra note 68.