

China's Agri-Biotech Policy, Regulation, and Governance

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China's agri-biotech crop cultivation ranks as 6th in the world after the United States, Brazil, Argentina, Canada, and India. Policy and regulatory issues become most important for agri-biotech crops' development in China and the rest of the world. With its new leadership established in the 18th National Congress of the Communist Party of China in November 2012, the State Council released its Biological Industrial Development Plan one month later in December 2012. Along with other significant policies, this document reveals China's policy developments related to biotechnology, which is influencing the county and the rest of the world. While reviewing these latest policy developments, this study looks into China's agri-biotech-related regulations and programs, as well as reviews its governance institutions. Focusing on a policy and institutional analysis, the study looks into China's challenges with its bureaucratic system in a global context.

Key words: Agri-biotech, China, policy, regulations, institutions.

Introduction

As one of the significant biotech players, China has the world's largest population with a great demand for agricultural and food products. By December 31, 2013, China's population was 1.36 billion (National Bureau of Statistics of China [NBSC], 2014). Its gross domestic product (GDP) growth rate in 2013 was almost the same as 2012 at 7.7%, compared with 10.4% and 9.3% in 2010 and 2011, respectively (Figure 1).¹ It is forecasted to be roughly 7% in 2015 (Organisation for Economic Co-operation and Development [OECD], 2015); it was 7.4% in 2014. This is still one of the fastest growing nations within emerging markets. In terms of GDP per capita, it is about US\$6,747² in 2013, compared to \$6,094 in 2012 (International Monetary Fund [IMF], 2014),³ which ranks relatively low at about 90th in the world. China's agricultural sector contributed about 10% of its total GDP in 2012 (The World Bank, n.d.[a]). The share of employment in the agricultural sector was about 40% in 2011, according to the World Bank (n.d.[b]). China's major agriculture and agri-food pro-

duction includes rice, wheat, cotton, oilseeds, fruits, and vegetables and it ranks 1st or 2nd in terms of global production (NBSC, 2013).

China's agri-biotech crop cultivation ranks at the 6th in the world (James, 2012)⁴ after the United States, Brazil, Argentina, Canada, and India (Figure 2). There are about 4.2 million hectares producing mainly genetically modified (GM) cotton, representing an adoption rate of about 90%.⁵ In addition, a virus-resistant papaya is still produced in Guangdong on approximately 3,500 hectares. The State Forest Administration commercialized three GM forestry plants on about 333 hectares. For other approved GM plants such as tomatoes, sweet peppers, and petunias, almost all are not currently planted because their biosafety certificates either have expired or have not been renewed due to a lack of commercial

1. While the numbers for 2012 and 2013 are from the NBSC, the numbers for 2010 and 2011 are from the World Bank (n.d.[c]). As a comparison, Canadian GDP growth rate was 3.2% and 2.5% for 2010 and 2011, respectively (IMF, 2012).
2. Unless otherwise specified, all figures are in US dollars.
3. To compare, the GDP per capita of the United States was about US\$48,442 in 2011 and ranked about 18; Canadian GDP per capita was US\$50,565 in 2011 and ranked 12.

4. In this study, agri-biotech refers to agricultural biotechnology, which focuses on modern GM technology with its application in the agricultural sector, especially GM crops research, industrialization, commercialization, and international-trade-related issues. In terms of China's agri-biotech development, generally speaking, the Chinese policy makers and scientists are quite positive and active, while the Chinese consumers (or citizens) are quite concerned. Many overseas scholars argue that China's agri-biotech policies lack transparency and directive to the domestic media.
5. In terms of global agri-biotech crop cultivation, there were 170 million hectares in 2012, which was a 100-fold increase compared to the 1.7 million hectares in 1996 when commercialized agri-biotech crop cultivation started in the world.

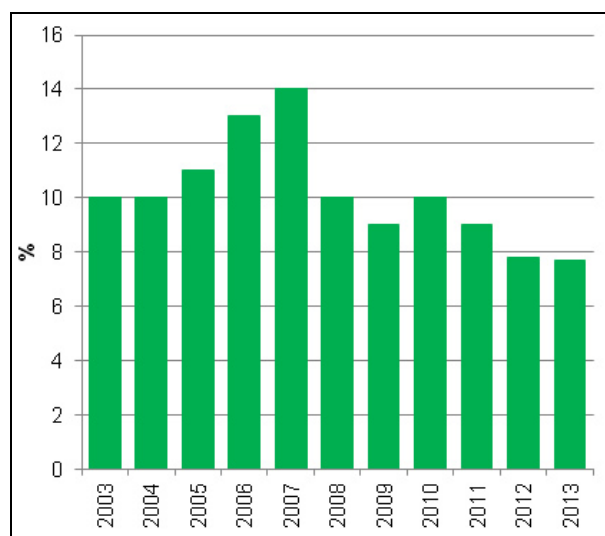


Figure 1. GDP growth in China (%).

Source: Authors' collection

market (US Department of Agriculture [USDA], Foreign Agriculture Service [FAS], 2012).

During its 11th Five-Year Plan from 2006 to 2010, China's biotech output had an average growth rate of 22.9%, with its output value reaching \$308 billion in 2011 (State Council of the People's Republic of China, 2012). In terms of importation, China has, in recent years, approved five biotech crops with 32 events (13 for corn, 7 for canola, 6 for cotton, 5 for soybeans, and 1 for sugar beets) for processing or feed use (USDA FAS, 2012). In 2011, the United States exported more than \$12.7 billion (22.35 million tonnes) worth of soybeans to China, most of them biotech varieties (USDA FAS, 2012). As one of Canada's largest agricultural trade partners, China's imports reached about \$5 billion CAD in 2012—almost double that of the previous year—of which biotech canola and related products accounted for more than 75% (Gilmour & Phillips, 2012).

Policy and regulatory issues are most important for agri-biotech crops' development in China and the rest of the world (James, 2012). With its new leadership established in the 18th National Congress of the Communist Party of China (CPC) in November 2012, the State Council released its *Biological Industrial Development Plan* in December 2012 (State Council of the People's Republic of China [PRC], 2012). Along with other significant documents, this plan revealed China's latest policy developments related to biotech, which is to influence this field within the country, possibly the Asia Pacific region, and the rest of the world. In reviewing its

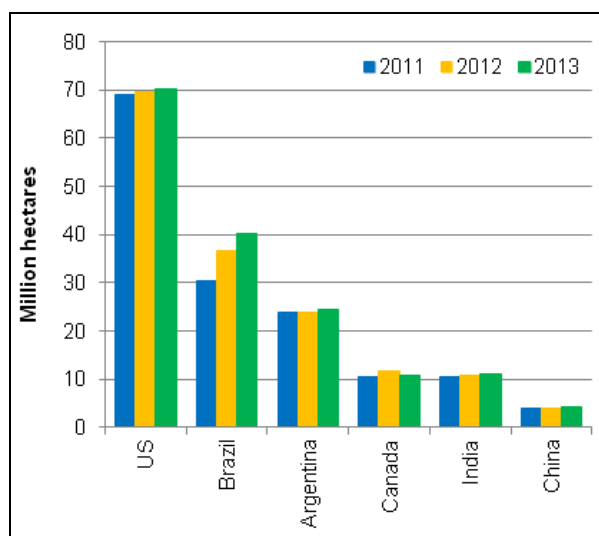


Figure 2. Global areas of biotech crops for top six countries (million hectares).

Source: ISAAA (2012)

latest policy developments, this study looks into China's agri-biotech related policies, regulations, and programs. It also reviews its institutions for the decision-making process. With a focus on its policy, regulations, and institutions, the study analyzes China's challenges with its centralized bureaucratic system.

Biotech Regulations and Policies

General Regulations

As China has a centralized governance system, unlike western governments, it is important to understand Chinese regulations within its institutional framework. In response to development of biotech, China began to establish its agri-biotech policy and regulations from the early 1980s, and further developed them since the 1990s. China has sped up agri-biotech application and industrialization since the beginning of the 21st century.⁶ Agri-biotech regulations in China encouraged relevant research and applications. In the meantime, China's regulatory issues have attracted both domestic and international attention. This section is generally

6. According to Jinkun Huang, Director of the Center for Chinese Agricultural Policy, Chinese Academy of Sciences, the first biotech-related research in China started in 1982, led by the former State Development and Plan Commission (SDPC, and the National Development and Reform Commission [NDRC] since 2008). See Huang and Wang (2002).

looking at those major regulations affecting agri-biotech developments in China.

Since the 1990s, China has initiated a number of regulations governing its agri-biotech research and development. In December 1993, for the first time, the Ministry of Science and Technology (MOST) issued *Measures for the Safety Administration of Genetic Engineering*.⁷ This regulation mainly involved bio-safety related issues, such as safety assessment, biotech application and approval procedure, safety control, and legal concerns. MOST's document provided a framework for developing agri-biotech policies and regulations in China. Based on MOST's regulation, the Ministry of Agriculture (MOA) issued in July 1996 *Implementation Measures for the Safety Control of Agricultural Genetic Engineering*. This covered genetic engineering in plants, animals, and microorganisms related to the agricultural sector.

During the first decade of the 21st century, China developed a number of key regulations to govern the agri-biotech development and applications. In 2001, the State Council amended MOA's 1996 agricultural genetic engineering regulations to include trade and labeling of GM products. The newly released document by the State Council is called the *Regulation on Safety Administration of Agricultural Transgenic Organisms*, which has been in effect since May 2001. As China does not have any other laws governing the agri-biotech practice,⁸ this regulation becomes the main governance directive, focused on five general aspects: research and testing, production and processing, marketing, import and export, and supervision and inspection.⁹

Based on the State Council's 2001 regulation, MOA amended its 1996 regulation for biosafety implementation by issuing three independent regulations effective since March 2002. These are: *Measures of Management of Evaluation on the Safety of Agricultural Transgenic Organism* (Decree 8); *Measures of Safety Administration on Import and Export of Agricultural Transgenic*

Organism (Decree 9); and *Measures of Labelling Administration of Agricultural Transgenic Organism* (Decree 10). The 2001 State Council's regulation, along with MOA's three decrees (8, 9, and 10) for implementing agri-biotech practice, are still the operative policies. These regulations and measurements include a few articles that are becoming dated: for example, in Decree 9, related to the trade of agri-biotech products, there is no clarification of the statement of the "origin of country" for an approval process.

The Ministry of Health (MOH) issued in April 2002 *Management Regulation on GMO Food Hygiene* (Decree 28), which requires any foods or processed food using GMOs as materials to be approved by MOH before selling in the markets. MOH's regulation also requires GM foods be labeled. In 2004, the General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ) released *Measurement on Inspection and Quarantine Administration of Entry and Exit of GM Products* (Decree 62), which widened the scope of inspection on GM products to include cross-border trade. The State Council's 2001 regulation, along with MOA Decrees 8, 9, and 10, MOH Decree 28, and AQSIQ Decree 62, collectively form the current general regulation system that governs agri-biotech development in China.

Public Funds and Investments

Generally speaking, global biotech studies and applications began when American biology scientist Herbert Boyer founded the first biotech business, Genentech, in 1976. China's publicly supported agri-biotech-related studies began in 1982. Detailed programs and funding information have not been available. However, many believe that the former SDPC led the 1982 programs.¹⁰ Since then, China has become an important biotech player in the world. By now, China has about 30,000 scientists employed in roughly 200 publicly-funded labs in biotech. Life sciences and biotech account for about 20% of its total investment in research and development (R&D; Cao, 2012). Table 1 provides some general information about China's public investment in biotech-related R&D from its "863 Program," "973 Program," and the last three Five-Year Plans.

7. To review this regulation, see the *Food and Agriculture Organization of the United Nations* (1993).

8. China's Ministry of Environmental Protection (MEP) and MOST have been calling for a biotechnology law for a number of years since 1993, and a wave of this voice is related to the 2009 approved safety certificates for GM rice and corn. However, this is still far away from being realistic for now, based on interviews with Chinese officials.

9. To review this regulation, see Ministry of Agriculture of the People's Republic of China (2001).

10. For more information, see Huang and Wang (2002).

Table 1. China's public funds and investment in biotech.

863 Program (1980s)	973 Program (1990s)	10 th Five-Year Plan (2001-2005)	11 th Five-Year Plan (2006-2010)	12 th Five-Year Plan (2011-2015)
1.5 billion RMB	\$238 million US	\$795 million US	\$6.2 billion US	\$308.5 billion US

Notes: Compiled/estimated by the author based on a various sources

863 Program in the 1980s

Proposed by four prominent scientists (Daheng Wang, Ganchang Wang, Jiachi Yang, and Fangyun Chen), the late Chinese leader, Deng Xiaoping approved the National High-Tech R&D Program, namely the 863 Program, managed by MOST since 1986.¹¹ Implemented by three successive Five-Year Plans, the 863 Program awarded biotech the largest amount of the funds. Its priority areas included bioengineering, gene manipulation, bioinformatics, and bio-agriculture (Cao, 2012). According to the data, the 863 Program approved RMB 10 billion for 15 years to promote high-tech R&D in China. There was a total budget of roughly RMB 1.5 billion allocated to biotech as one of the seven priority areas from 1986 to 2000 (Huang & Wang, 2002). China's 863 Program promoted those high-tech R&D areas that had strong potential in yielding economic benefits. This program attracted thousands of scientists to adjust their research areas in order to receive the funds and helped stimulate China's technology capacity (including the biotech field) and became an effective driver of increased economic prosperity.

973 Program in the 1990s

In the 1980s, China sped up its domestic development to pursue global technology through its 863 Program, which encouraged scientists to conduct R&D to generate revenues. In the 1990s, China began to realize the importance of basic research in competition with global players. In this context, the State Science and Education Steering Group (SESG) in 1997 decided to formulate a National Plan on Key Basic Research and Development by implementing the National Program on Key Basic Research Projects.¹² As this program was initiated at the third meeting of the SESG in July 1997, it is also known

as the 973 Program. Life science and biotech in the 973 Program were again one of the key areas of focus. Along with other plans and programs, the government committed more than \$238 million to life sciences and biotech from 1996 to 2000 (Cao, 2012). With its rapid economic growth in the 1990s, China paid more attention to basic research in order to be a global player in R&D. In terms of its biotech R&D, the Chinese government budget and funds concentrated on both development and regulations. Taking 1997 as an example, China spent about \$120,000 on formulating policies and regulations to encourage and manage biotech development (Huang, Hu, Rozelle, & Pray, 2005).

It is worth mentioning that, during the 1990s, China set up many ministerial-level fund strategies to promote biotech development in addition to the national plans and programs. For example, starting from 1998, the former SDPC led a special program to promote applications and commercialization of high-technologies, including biotech. Supported by MOST and SDPC, a project on biotech (crop germplasm and quality improvement) was funded in 2000 with RMB 120 million. In 1999, MOST supported a five-year program to promote basic research and commercialization of transgenic plants. The total budget of this program in the first five years was RMB 500 million (Huang & Wang, 2002).

10th Five-Year Plan (2001-2005)

China's economy continued its rapid growth at the beginning of the 21st century. In 2001, its GDP growth rate was 8.4% and reached a peak of 14.2% in 2007 (The World Bank, n.d.[d]). In this context, China implemented its 10th Five-Year Plan from 2001 to 2005, which directed significant public funds and investments to R&D, including in the biotech field. In the 10th Five-Year Plan, China's public funds for life science and biotech tripled from \$238 million to \$795 million between 1996-2000 and 2001-2005 (Cao, 2012).¹³ Rapid biotech development and commercialization globally during the late 1990s encouraged China to invest in this field. With respect to public expenditures on biotech R&D, China put its emphasis on agri-biotech crops, especially Bt cotton. By 1999, China annually spent an estimated RMB

11. As this plan was approved in March 1986, it is called the 863 Program. For more information, see MOST's 863 Program description at <http://www.most.gov.cn/eng/programmes1/index.htm> (retrieved March 22, 2013).

12. For more information about the 973 Program, see http://www.most.gov.cn/eng/programmes1/200610/t20061009_36223.htm (retrieved March 22, 2013).

0.6 million on agri-biotech. By 2002, this was increased to about RMB 7 million annually. In 2003, China invested RMB 14 million on biotech, including policies and regulations (Huang et al., 2005). During this period, China spent about \$3 million yearly on agri-biotech. This did not include the expenditures required to implement labelling and market inspections (Huang et al., 2005).

11th Five-Year Plan (2006-2010)

During the 11th Five-Year Plan, China became one of the top nations in biotech. Continuous public funds and investment went to four areas in biotech: GM seeds, biotech-based manufacturing, bio-energy, and biotech-based environmental protection. During the 11th Five-Year Plan period, the total investment was estimated to be RMB 50 billion (\$6.2 billion; *China Daily*, 2005). This increased investment actively promoted biotech R&D in China. In November 2009, China's MOA granted biosafety certificates to two Chinese-developed insect-resistant rice varieties and a high-phytase maize variety. This was the first time that the Chinese government granted biosafety certificates to major food and feed crops. The newly granted GM rice and maize had a significant impact on China's biotech development and commercialization towards staple agri-foods. It has also attracted both domestic and international attention, particularly from Asia and other developing nations.

12th Five-Year Plan (2011-2015)

With its 12th Five-Year Plan, China has clearly identified biotech as a key priority for development. The government restated four major priority areas, namely biopharmacy, bio-manufacturing, bio-agriculture, and bio-energy (State Council of the PRC, 2012). In order to promote these identified areas, China targets to invest during the 12th Five-Year Plan period about RMB 2 trillion (\$308.5 billion; *China Daily*, 2011).¹⁴ In terms of the biotech industrial output, China is well on its way to reach an annual growth rate of more than 22%. By 2011,

the total value of output was about RMB 2 trillion (State Council of the PRC, 2012). From 2011 to 2015, biotech is expected to create 1 million jobs, improve life expectancies by one year, reduce the infant mortality rate to 12%, and reduce carbon emissions of the most common pollutants by 10% (*China Daily*, 2011).

Policy Developments

China's agri-biotech policy started in the 1980s, expanded in the 1990s, and advanced after the 2000s. The country concentrated on developing regulations to encourage agri-biotech development during the 1980s and the 1990s. This section focuses on recent policy developments and changes. While reviewing China's agri-biotech policies from its 11th Five-Year Plan to the recently released biotech development plan, we can see that the country is building on its blueprint to be among the top agri-biotech players in the world. China is applying for agri-biotech applications, industrialization, and commercialization from non-staple crops to major staple foods.

Biotech Policies in the 11th Five-Year Plan

Starting from its 11th Five-Year Plan, China has built up a number of milestones for agri-biotech development. These include the State Council's policy guidelines, *The Medium and Long-term Plan (MLTP) for the Development of Science and Technology (2006-2020)*, released on February 9, 2006; the National Development and Reform Commission (NDRC)'s *11th Five-Year Plan on Biotech Industry*, released by the State Council on April 8, 2007; and *Several Policy Proposals for Promoting Biotech Industry and Development*, released by the State Council on June 2, 2009.

China's MLTP for Development of Science and Technology (2006-2020) sets up the country's objectives with a roadmap to become an innovation-oriented nation by 2020 and to be a world leader in science and technology (S&T) by 2050. This 50+-page document aims to put China among the major players in the world by enhancing its capacity of "indigenous innovation" (zizhu chuangxin; MOST, 2006).¹⁵ The document identifies eight areas as "frontier technologies," including biotech.¹⁶ China believes that, with these identified

13. According to the *China Daily*, during the 10th Five-Year Plan period (2001-2005), the central government quadrupled its investment in life sciences and biotech sectors to 13 billion RMB (\$1.6 billion US) from the previous five-year period. This was estimated by the National Biotech Development Center (see *China Daily*, 2005).

14. According to Cao, the government funding on biotech during the 12th Five-Year Plan period was 1.7 trillion RMB (see Cao, 2012).

15. In a number of documents, China uses this phrase addressing its innovation strategy for the 12th Five-Year Plan period. For example, in its *National Five-Year Plan*, China claims to build a so-called innovative country through indigenous innovation (zizhu chuangxin).

areas for development within 20 years, the country would make a great contribution to global science, technology, and innovation.

The 11th Five-Year Plan on Biotech Industry and Development (2007) was prepared by NDRC and approved by the State Council. The document is based on the *11th Five-Year Plan for National Economic and Social Development* and the *MLTP for Development of Science and Technology*. This document posits that development of biotech will provide the country with more opportunities. Biotech and life sciences feature prominently among the knowledge economy development strategies. This national plan entails establishing specialized task forces and creating institutions responsible for coordinating government efforts to support and regulate the biotech industry. During the 11th Five-Year Plan period, China recouped significant profits from biotech. In 2010, the industry grew by 20% and became viewed as a low-risk, high-return investment during the global financial crisis (see *Wang China Times*, 2011).

*Several Policy Proposals for Promoting Biotech Industry and Development*¹⁷ released by the State Council in 2009 provides further guidelines on biotech industrial development in China. The document was guided by the *MLTP for the Development of Science and Technology* and the *11th Five-Year Plan on Biotech Industry and Development*. In this document, China reaffirms five major areas in biotech for development, including biomedicine, bio-agriculture, bio-manufacturing, bio-energy, and bio-environment. In the meantime, the document proposes a series of policy measures, such as technology training, tax preferences, financial support and strengthening governance and management of biotech development. It is worth mentioning that this document clearly targets bio-agriculture as one of the significant areas for development, pointing to the critical role agri-biotech plays in Chinese and global food security.

Biotech Policies in the 12th Five-Year Plan

Starting from its 12th Five-Year Plan in 2011, China entered a new stage of development, signified by the leadership transition in both the 18th Central Politburo

of the CPC in November 2012 and the State Council of the Central Government at the 12th National People's Congress in March 2013. Born in the 1950s with rural and agricultural experiences, Xi Jinping and Li Keqiang emerged as two top leaders of a new generation. With respect to agri-biotech development, three significant policy documents have been released since then. The *National MLTP for Cultivating Biotech Talents (2010-2020)* was released on November 26, 2011 by MOST, along with six other ministerial-level institutions, including the Ministry of Human Resources and Social Security (MOHRSS), Ministry of Education (MOE), Chinese Academy of Sciences (CAS), Chinese Academy of Engineering (CAE), National Natural Science Foundation of China (NSFC), and China Association for Science and Technology (CAST). *The 12th Five-Year Plan for Development of Biotechnologies*, released by MOST on November 14, 2011, and *The 12th Five-Year Plan for Agricultural Sciences and Technology Development*, released by MOA on December 30, 2012, complete the policy agenda.

- *National MLTP for Cultivating Biotech Talents (2010-2020)*: According to the Chinese Government, China will have 195 million college-educated graduates by 2020. In response to this challenge, the Chinese leadership launched its national talent development plan to attract and retain highly skilled individuals in six broad sectors: political leaders and officials, business entrepreneurs; technical professionals, highly-skilled talent in different industries, practical talent for rural areas and agriculture, and professional social workers. This new plan has far-reaching implications for China's efforts to build an innovation-driven economy and offers insights to the global business and policy communities (Wang, 2010).
- *The 12th Five-Year Plan for Development of Biotechnologies (MOST)*: In this document, China's policymakers stress the concept of "indigenous innovation." The document emphasizes the significance of biotech, particularly in implementing national food-security strategies. It also points out that agricultural industry will be developed by advancing agri-biotech, including new plant and/or animal varieties. According to the document, in the coming five years, MOST is intended to develop biotech by strengthening basic research, achieving a breakthrough in essential key technologies, researching

16. These identified eight areas include biotechnology, information, new materials, advanced manufacturing, advanced energy, ocean, laser, and aerospace and aeronautics.

17. This document can be viewed (in Chinese) at http://www.gov.cn/zwqk/2009-06/05/content_1332777.htm (retrieved on April 5, 2013).

featured products and technologies, and building an innovative capacity for the biotech sector (USDA FAS, 2012).¹⁸

- *The 12th Five-Year Plan for Agricultural Sciences and Technology Development* (MOA): MOA's plan serves as a guideline for agricultural development in 2011-2015 and specifies the essential targets and tasks. In terms of the development targets, the document emphasizes the transformation of scientific research into an industry capacity, agricultural management, and innovation. Regarding the major tasks, it emphasizes innovation and technology systems (e.g., a GMO New Variety Development Mega Project) and S&T in the seed industry. Based on this document, China plans to discover a series of genes to develop a batch of elite varieties with high yields, multiple-resistance, and wide adaptability (International Service for the Acquisition of Agri-Biotech Applications [ISAAA], 2012).

Recent Policies on Biotechnology

China's traditional concerns with food security in feeding its population are expressed in the Number One Document, which focuses on one or two aspects of the policy developments every year related to agriculture and agri-food sector. The new leadership is continuously developing its agricultural policy by setting up so-called small city-townships ("chengzhenhua", 城镇化) and agricultural farm strategies. With regard to agri-biotech, the first document under the new leadership was released on December 29, 2012, just one month after they took office. Entitled *Biological Industrial Development Plan*, this document was issued by the State Council and coordinated by NDRC (State Council of the PRC, 2012).¹⁹

Along with the previous documents, such as the 12th Five-Year Plan for Development of Biotechnologies, this plan highlights the biotech industry by outlining its general approach and principles. It focuses on four areas: bio-medicine, bio-agriculture, bio-manufacturing, and

bio-information.²⁰ The document formulates two significant objectives: by 2015, China's biotech industry is targeted to make increased contributions to the country's economic and social development, as well as occupy a leading position in a global context; and, by 2020, the Chinese biotech industry is expected to become a pillar in the national economy. The plan targeted to maintain sectoral growth in 2013 and 2014 at above 20 so that by 2015 its share of GDP would be more than double that of 2010. In terms of bio-agriculture, the document reaffirms the significance of biotech to enhance competitiveness by applying S&T to the sector. As indicated, China is highly concerned with food security, ecological improvement, farmer income, and technologically advanced agriculture. The document emphasizes:

- taking advantage of agricultural biological resources,
- promoting resource innovation into industry,
- strengthening biological breeding and agricultural R&D for bio-products,
- accelerating new varieties research and industrialization,
- encouraging applications and commercialization,
- improving a quality- and safety-management system, and
- developing a high quality of agricultural standardization for bio-breeding industry and biological products.

According to the document, China is promoting a number of new technologies and GM products. By 2015, agri-biotech industry's annual output value in China was targeted to reach RMB 300 billion. The government is cultivating a group of agri-biological enterprises with an annual output value of RMB 10 billion.²¹

Agri-Biotech Governance System

Growing food demands to feed the population drives China's aspiration to develop its agri-biotech industry. In order to be a leading player in global S&T, China targets to "enter a high rank among innovative countries by 2020" and to be a global scientific power by this mid-

18. Compared with the 11th Five-Year Plan for Biological Industry Development (2006-2010), the 12th Five-Year Plan reveals that the Chinese government places emphasis on the development of the whole sector, not just the technology, and particularly pays attention to raw materials and consumption.

19. This document can be viewed (in Chinese) at http://www.gov.cn/zwgk/2013-01/06/content_2305639.htm (retrieved April 8, 2013).

20. For the major tasks or focused areas, there are some differences from various documents. However, agri-biotech is always a focus without changes.

21. For more information about the agricultural sector (in Chinese), please see http://www.gov.cn/zwgk/2013-01/06/content_2305639.htm.

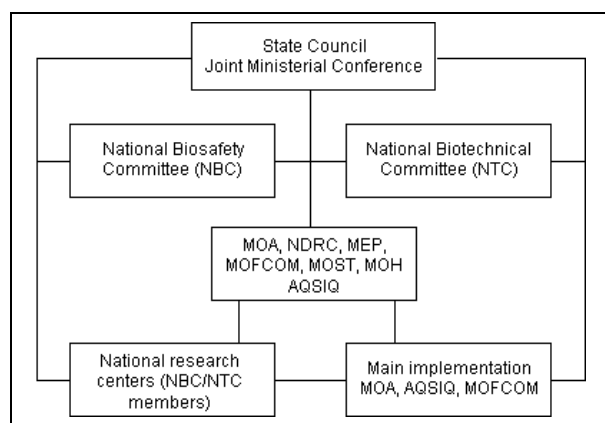


Figure 3. Overview of key institutions involved in China's agri-biotech decision-making process.

Source: Authors compiled based on the available information from Chinese publications, 2013. Notes: MOA=Ministry of Agriculture; NDRC=National Development and Reform Commission; MEP=Ministry of Environment Protection; MOFCOM=Ministry of Commerce; MOST=Ministry of Science and Technology; MOH=Ministry of Health; AQSIQ=General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China.

century (Jintao, 2010). This objective underlines the government's national innovation framework. As one of the strategic priorities for scientific and technological development identified in its 12th Five-Year Plan, promoting biotech applications provides a clear illustration of the dominant role of the government (Cao, 2012). This section briefly examines China's agri-biotech governance system, including its central institutions and major players (Figure 3).

Centralized Governance

Since the late 1980s, China has established a unitary governance system controlled by the central government, one of few such systems in the world. In China, all the organs of the state are under the direction of the State Council. With this system, the rural economy and agriculture (including agri-biotech) are governed by the Central Rural Work Leading Group (CRWLG) under the Communist Party of China (CPC). The top leader of this Group is Wang Yang, the former leader of Guangdong Province. The leader for the Office of CRWLG is Chen Xiwen.²² In terms of agri-biotech policy, China has established a Joint Ministerial Conference (JMC), which consists of several government agencies under the State Council, including the MOA, the NDRC, the Ministry of Environmental Protection (MEP), MOST, AQSIQ, the Ministry of Commerce (MOFCOM), and the

National Health and Family Planning Commission (MOH).²³

JMC acts as a forum under the State Council to discuss the major issues in bio-safety management of agricultural products in biotech. The major role of JMC includes high-level discussions of biosafety and examination and approval of biotech applications. It also discusses topics concerning the commercialization of GM plant varieties, such as the identification of the GM plants and commodities subjected to labeling, as well as the establishment of import and export policies for GM plant varieties (USDA FAS, 2012).

At the central government level, along with the JMC, two councils oversee agri-biotech development. The National Biosafety Council (NBC) is concerned with biosafety issues, while the National Technical Council (NTC) focuses on the standardization of biosafety management. Both consist of experts and administrative officials with multidisciplinary backgrounds (USDA FAS, 2012). The current NBC is comprised of experts from 22 institutions, including ministries, research institutes, and universities. It is divided into different expert groups responsible for biotech plants, animals and micro-organisms, food, and feed. It was announced that the NBC had increased the number of its annual meetings since 2008 in order to effectively evaluate applications for safety certificates of biotech prod-

22. *Understanding this centralized governance system is important in terms of doing business with China or conducting relevant studies. Under this system, decisions from the ministries or provinces have to be reported to the central body for approval. In other systems, departments or provinces/states might have autonomy or be able to veto policies or regulations from one another. For example, in India, the Department of Environment in 2010 vetoed the decision from the Department of Biotechnology regarding the commercialization of biotech eggplants. In terms of the Chinese top leadership for rural agriculture, while it is confidentially restricted to the CPC, some documents revealed that Ma Kai, the previous leader of the National Development and Reform Commission (NDRC) and/or Wang Yang, the previous leader of the Guangdong Province, would be responsible for agri-biotech development. Either Wang Yang or Ma Kai is viewed as the school of the reformism in China. Along with the leadership for the Office of CRWLG, many analysts believe that Chen Xiwen would be quite active for agri-biotech development in the near future. For more information, please see Chen's talk about this on March 7, 2013 at <http://lianghui.people.com.cn/2013cppcc/n/2013/0307/c357952-20707196.html>.*
23. *In the 2013 reform, the Ministry of Health was integrated into the National Health and Family Planning Commission (NHFPC, see <http://www.who.gov.cn>).*

ucts in different uses as submitted by domestic and foreign seed developers. The NTC for standardization of biosafety management of agri-biotech appears to be a 'closed-door' agency. It is difficult to find relevant information regarding the NTC. According to a USDA report, the NTC consists of experts and administrative officials similar to the NBC (USDA FAS, 2009).

Major Players in Agri-Biotech

As China has a centralized governance system, the ministries might not be able to reject any policy or regulations from the central government. However, any ministry or local government has its own interest groups. Therefore, understanding the major ministries involved in agri-biotech is important for analyzing this sector and getting access to the market. China's central government has assigned MOA to coordinate the agri-biotech sector.²⁴ Along with MOA, MEP and AQSIQ are major players in agri-biotech development.

Agri-Biotech with MOA. As discussed, China has established panels of experts and government officials to support the regulatory system of its agri-biotech. While there are a number of central government departments involved in overseeing agri-biotech practices, along with AQSIQ, MOA is mainly responsible for approval of biotech applications, including import and domestic products. As a component of the State Council, MOA is in charge of agriculture and rural economic development. In its mandate statement, MOA works out development strategies and mid- and long-term plans for agriculture and rural development. In terms of agri-biotech-related S&T, MOA formulates development plans and relevant policies regarding scientific research, education, technology extension, and implementation of the strategies for revitalizing agriculture through science and technology. Within MOA, its Department of S&T is responsible for agri-biotech development, including:

- drawing up development strategies, policies and measures, programs and plans for agricultural S&T, ecology and environment, and rural renewable energy;

- engaging selection, implementation, supervision, and management of major S&T extension and importation of major technologies, as well as S&T industrialization;
- administering the safety of agri-biotech products by putting forward policy recommendations;
- organizing the verification, appraisal, and review of major performances of agricultural S&T and supervising new varieties' protection of agricultural plants, as well as agricultural intellectual property rights.

In addition to being responsible for the approval of biotech crops for import and domestic production, MOA manages distribution of government funds to institutes and universities for R&D in biotech crops and other innovations.²⁵

Agri-Biotech with AQSIQ. The General Administration of Quality Supervision, Inspection, and Quarantine of the People's Republic of China (AQSIQ),²⁶ along with its local offices, is responsible for the nationwide management of inspection and quarantine at the border for biotech products. With Ministerial Decree 62 on agri-biotech management,²⁷ AQSIQ governs the procedures undertaken at customs for imports and exports.

AQSIQ is a ministerial administrative organ under the State Council. It is in charge of national quality, metrology, entry-exit commodity inspection, entry-exit health quarantine, animal and plant quarantine, import-

24. This is different from other countries. For example, in Canada, agri-biotech governance is coordinated by the Department of Health. In India, it is coordinated by the Department of Science and Technology, while other departments, such as the Department of Environment, have authority to veto the decision from the Department of Science and Technology.

25. For more information, see two MOA documents: *Main Functions of the Ministry of Agriculture* (<http://english.agri.gov.cn/aboutmoa/mandates>) and *Main Functions of Department of Science, Technology and Education* (http://english.agri.gov.cn/aboutmoa/departments/201301/t20130115_9511.htm; Accessed April 10, 2013).

26. AQSIQ comprises the following major departments and bureaus: Department of Policy and Regulations; Quality Management; Metrology; Inspection and Quarantine Clearance; Supervision on Health Quarantine; Supervision on Animal and Plant Quarantine; Supervision on Inspection; Bureau of Import and Export Food Safety; Special Equipment Safety Supervision; Department of Supervision on Product Quality; Supervision on Food Production; Law Enforcement and Supervision (AQSIQ Office of Fight against Counterfeits); International Cooperation (WTO Affairs Office); and Science and Technology. For more information, see <http://english.aqsiq.gov.cn/>.

27. See the document (in Chinese) at http://www.aqsiq.gov.cn/zwgk/jlgg/zjl/zjl20032004/200610/t20061027_12236.htm (Accessed April 10, 2013).

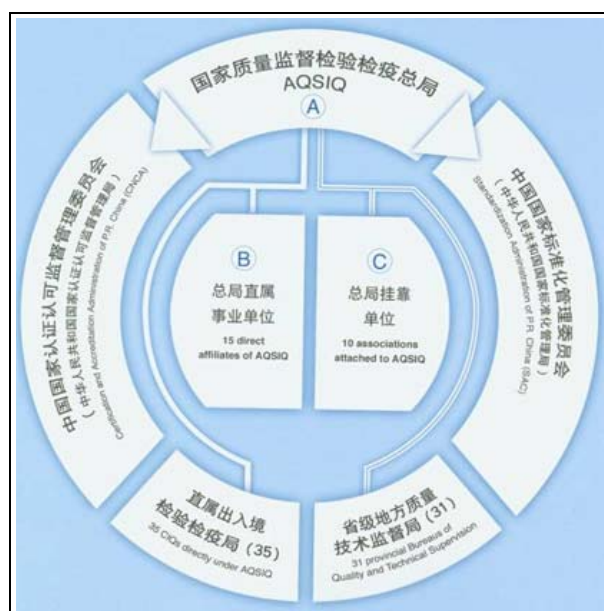


Figure 4. AQSIIQ's structure.

Source: AQSIIQ

export food safety, certification and accreditation, standardization, as well as administrative law-enforcement. Along with its mandate, AQSIIQ coordinates the Standardization Administration of China (SAC) and Certification and Accreditation Administration of China (CNCA). It includes 31 China Entry-Exit Inspection and Quarantine Bureaus (CIQs), 31 provincial bureaus for quality and technical supervisions, 15 direct affiliates, and 10 associations (Figure 4).

With regard to agri-biotech, AQSIIQ takes the responsibility of drafting and implementing the policies and regulations of quality supervision, inspection, and quarantine. It also administers and supervises the work of technical policies, regulations, and law enforcement. The Bureau of Import and Export Food Safety in AQSIIQ is specifically in charge of formulating and implementing the provisions and regulations on the safety of imported and exported foods, including agri-biotech products. It conducts implementation of risk assessment and evaluation over imports and exports, as well as emergency preventive measures. AQSIIQ also administers the investigation and punishment of major safety and quality lapses of imports and exports and the disposal of food-borne pollution sources.²⁸

Agri-Biotech with MEP. As China's agri-biotech is mainly governed by MOA, MEP does not have decisive power to veto any biosafety certificates granted by MOA. However, MEP is still important as it implements

a number of policies, regulations, and measures related to agri-biotech development and monitors a number of biosafety procedures. Moreover, MEP proposes policies, regulations, or even laws to address environmental concerns with biotech development. For example, since MOA granted the biosafety certificates to GM rice and corn in 2009, MEP, along with other institutions, has driven discussions about establishing a Biotech Law (J. Huang, personal communication, 2011). From this perspective, it is important to look at MEP's mandate related to agri-biotech development.

MEP (formerly the State Administration of Environmental Protection) is a leading agency for negotiation and implementation of the Biosafety Protocol, which China ratified in 2005. This ministry develops measures and standards related to the agri-biotech sector in order to implement laws and regulations such as the Environmental Protection Law and the Regulations on Wild Plants Protection. MEP collects genetic resources, strengthens protection of genetic resources, and facilitates research and utilization of genetic resources. It also specifies the procedures, technical specifications, and notices for collection of genetic resources of wild biological resources within the country.

Take the implementation of the Convention on Biological Diversity as an example: MEP developed standards and measures including a) standardizing the sharing of benefits resulting from utilization and exchange of genetic resources; b) protecting the rights and interests of owners and users of genetic resources; and c) facilitating the protection, reservation, utilization, and foreign exchange of biological genetic resources in the country. All the standards and measures specify the principles, procedures, methods, and requirements for evaluating economic value of genetic resources. The ministry evaluates economic value of genetic resources within the country.²⁹

28. In terms of agri-biotech products, AQSIIQ manages low-level presence (LLP) issues with imports and exports. China is currently implementing a zero-tolerance policy related to any agri-biotech products that are not approved to import or export. For more information related to this issue, see Huang and Yang (2011).

29. For more information about MEP's policies, regulations, standards, and measures related to agri-biotech or genetic resources, see http://english.mep.gov.cn/standards_reports/standards/Eco_Environment.

Other Important Players

As discussed, China's agri-biotech governance is centralized with MOA as a major player for research, application, and commercialization. Implemented by MOA, China's nationwide agri-biotech operations, particularly for GM crops, are also involved with a number of other important departments and organizations, including NDRC and DRC for overall policy analysis, MOFCOM for GM-related trade, and MOST for R&D-related policy developments.

- *The NDRC and the State Council's Development Research Center (DRC)* are the top two policy think tanks in China. While DRC is mostly engaged in policy analysis, NDRC does more policy development. Both serve top Chinese leaders. NDRC has more than 30 divisions to handle national economic policies and programs. Mr. Ma Kai, previous leader for NDRC, was just promoted to be one of the State Council members in the 18th CPC congress. Mr. Du Ying, as the Deputy Director in NDRC, has served in agricultural development for many years. According to its mandate, in terms of the agricultural sector, NDRC is responsible for analyzing the development of agriculture and rural economy, making policy recommendations on rural development strategies and reforms of rural economic system, and coordinating major issues concerning agriculture and rural economic and social development.³⁰ DRC is a comprehensive policy institution for research and consulting directly under the State Council. Established in 1981, as a leading policy body, DRC attracted prominent economists, experts, and researchers in the fields of macroeconomics, development strategy, regional policy, industrial economy, rural economy, technical economy, as well as international economics. In terms of its main functions related to agri-biotech and rural development, it undertakes studies on rural reform and development issues, rural-urban development, S&T application, institutional reform of the rural economy, and economic restructuring in rural and agricultural areas.³¹

- *The Ministry of Commerce (MOFCOM)*, formerly known as the Ministry of Foreign Trade and Economic Co-operation (MOFTEC), is the executive agency of the State Council responsible for formulating policy on foreign trade, export and import regulations, foreign direct investments, consumer protection, and market competition and for negotiating bilateral and multilateral trade agreements. The current minister is Chen Deming. This ministry conducts research on development trends in the global economy, regional economic cooperation, and the market system. It also does research on opening-up to the rest of the world and reforms of domestic and international trade systems. In terms of trade policy, MOFCOM formulates policies on reform plans for foreign trade development strategies for imports and exports. It develops foreign trade policies by coordinating relevant departments. Related to agricultural and agri-biotech trade, the ministry participates in the management of import and export of endangered plants and animals and develops the policies of trading by working with international stakeholders.³²
- *The Ministry of Science and Technology (MOST)* takes the lead in drawing up S&T development plans, policies, relevant laws, and regulations for guaranteeing their implementation. MOST coordinates basic research, frontier technology, research on social development, as well as key and popular technology. It is responsible for drafting the National Basic Research Program, National High-tech R&D Program, and S&T Enabling Program. The ministry also organizes the formulation of S&T development and annual plans, suggests fund allocation for national S&T programs, and coordinates the implementation of the programs. It works with relevant agencies in building national S&T platforms and major innovation bases, stimulates regional S&T advancement, and serves in the administration of S&T special projects. With respect to agri-biotech related R&D, MOST is responsible for drafting plans and policies to enhance agricultural and rural development through S&T, for organizing the implementation of hi-tech R&D plans, the S&T supporting plan and policy-guiding S&T plans in related

30. For more information about the NDRC and its policies and programs on agriculture, see <http://en.ndrc.gov.cn/>.

31. For more information about the DRC and its policy studies on agriculture, see <http://en.drc.gov.cn/>.

32. For more information about MOFCOM and its policy involvements on agriculture, see <http://english.mofcom.gov.cn>.

fields, and for and promoting rural and agricultural S&T development.³³

In addition, China has a number of other institutions involved in agri-biotech development, including the State Food and Drug Administration (SFDA), which manages GM foods and medicines; the State and Forestry Administration (SFA), which manages GM trees; and the State Intellectual Property Office (SIPO), responsible for intellectual property and patent-related issues. It is worth mentioning that the Chinese Academy of Sciences (CAS) and Chinese Academy of Agricultural Sciences (CAAS) are also involved in agri-biotech R&D projects with the National Natural Science Foundation (NNSF).

Institutional and Policy Challenges

Agri-biotech is a fast growing industry globally. In terms of GM crops, about 30 countries worldwide are actively involved. Since the 1980s, China has paid significant attention to this technology. The Chinese authority is facing a huge demand for food due to a large, growing, and prospering population. However, its arable land is decreasing due to urbanization and environmental degradation. Increasing yields is becoming a challenge for the Chinese. In an effort to solve the issue of food security, China needs to develop its agri-biotech related policy, regulations, and institutions (Jones, 2012). This section briefly looks at the challenges for developing the agri-biotech sector in China from an international policy and institutional perspective.

Concerns with Policy and Regulation

Many policy researchers, analysts, and practitioners have identified the problems related to the agri-biotech policies and regulations, in particular, policy implementation in China.³⁴ In terms of international biotech development, one of the major concerns is that China is currently implementing a “zero-tolerance” policy for unapproved varieties. The lack of an effective low-level presence (LLP) policy is constraining trade in biotech. In China, any imported product is rejected if events not yet authorized are detected. China’s existing policy of “zero tolerance” is leading to trade disruptions resulting

from LLP of GM events in either imports from or exports to other countries (Huang & Yang, 2011).

Another major issue identified is its asynchronous approval process. China’s current regulations require that biotech events be fully approved from an exporting country before MOA accepts an application for a biosafety certificate. Obtaining a biosafety certificate is required before the product can be exported to China. Generally, the approval process takes two or three years to get through a number of testing procedures and risk assessments. Along with its asynchronous approvals, this process creates unnecessary delays in trading new biotech products that are already approved in exporting countries.

In addition, China’s policies and regulations related to agri-biotech include some duplicate registration rules. Currently, MOA biosafety certificates are valid for three years in food crops and five years for non-food crops. During this period, practitioners are required to get seed samples for registration and for the renewal of biosafety certificates, even for varieties no longer marketed. Its variety-based biotech registration applies to both exports and domestically produced products. Because of these complicated registrations, some biosafety certificates might expire before the varieties can be produced for trade and commercialization. China granted biotech rice and corn biosafety certificates in 2009. Because of complicated registrations and pre-production testing, these biotech crops are still far from commercialization,³⁵ and the biosafety certificates expired last December, which lead to re-application or de-registrations.

We find that many Chinese policies and regulations are vague or opaque. During policy implementation, we also find that many policies and regulations are explained as embodying certain flexibility; precise conceptions are not carefully considered. From an international perspective, translations and interpretations from Mandarin to English or other languages also have created problems for understanding and communications.

Institutional Challenges

China has a centralized governance system, which creates highly centralized power. But, China is also a huge country with a complicated institutional framework. From top-level authority to the very bottom, the policy decision process and results in many cases do not reflect

33. For more information about MOST and its policy involvements on agriculture, see <http://www.most.gov.cn/eng/index.htm>.

34. For more information about this, please see Huang and Yang (2011), Cao (2012), and USDA FAS (2012).

35. Other elements have also caused delay for these GM products’ commercialization. For example, consumers display resistance, and the policy process is not transparent.

reality (Sauvant, 2011). In terms of agri-biotech development, China needs to handle a number of institutional challenges.

- *Systematic Concern:* China is a one-party system with the State Council under the CPC leadership, which is not transparent. While this system can serve to integrate power in some situations, such as in war time, it generally lacks effective supervision. According to Marxist theory, all matters involve positive and negative perspectives. However, the CPC lacks a balance to its monopoly power, and this can be dangerous. In terms of agri-biotech development, public expenditures are under a one-party political process, which leads to a large amount of overlaps and duplications without effective auditing mechanisms. At the policy level, China's objective of being a global leader in biotech will face difficulties without careful handling of the trade-offs inherent in the technology.
- *Institutional Deterioration:* China's national institutions are deteriorating because the bureaucracy is not fully accountable. Within this institutional framework, bureaucrats advance their own interests, exploit their inside networks, and exploit the system. In the last decade, the government-sponsored S&T institutions and programs have come under fire from officials, technocrats, and especially from the S&T community for undermining effort in strengthening China's innovation capacity (Cao, 2012). At the operational level, China's goal to become a global player in biotech will be hindered without innovating or reforming its institutions.
- *Utilitarian Implementation:* Along with its bureaucratic institutions under the one-party system, agri-biotech research and applications are mostly under technocratic control. During the implementation of the government policy and programs, technocrats mostly advance "utilitarianism" options.³⁶ This implementation is a utilitarian approach without a long-term plan, which often hurts the research and development, particularly with the intellectual property rights (IPRs). In China, researchers often ignore

or misunderstand IPRs. This utilitarian approach also discourages capacity building. Under this mechanism, it is hard for the government to attract private investment for development. In order to be a global player, China needs to correct its utilitarian approach for implementation.

Concluding Remarks

This study suggests that China is a significant player in the global agri-biotech sector, both as a developer and market for imports of biotech products. It might also become an important exporter of biotech goods in the medium to long term. China's central government is actively fostering the agri-biotech industry as an emerging strategic sector. Since 2011, the Chinese government issued many policies promoting agri-biotech development, including its 12th Five-Year Plan, which focused on developing key industries and sectors related to agri-biotech industrialization and commercialization; the 12th Five-Year Plan on National Economic and Social Development; the 12th Five-Year Plan for National Agriculture and Rural Economic Development; the 12th Five-Year Plan for Development of Biotechnologies; the 12th Five-Year Plan on Agricultural Science and Technology Development; and, most recently, the State Council's *Biotech Industrial Development Plan*, released in December 2012.

China's regulatory infrastructure is still under development, including some agri-biotech regulations that impede market access. The barriers involve asynchronous approval, inadequate protection for IPRs, and a restrictive zero-tolerance LLP threshold. Moreover, Chinese biotech policies and regulations as well as its application procedures for new products lack transparency and accountability. The Chinese government believes that the greater challenge might not be alleviating consumer fears but finding more support within the scientific community. However, one of the recent surveys by the Asian Food Information Center stated that general Chinese consumer knowledge of biotech products was low (USDA FAS, 2012). Approximately 45% of the population knew that GM products could be found in the grocery store. There was a lack of knowledge without factual support, which is a challenge for promoting and marketing biotech products to influence consumer beliefs. Many Chinese and overseas researchers question long-term effects of the technology, such as an environmental concern. From a global perspective, greater efforts from the Chinese government to provide accessible and clear public information on the advan-

36. The author interviewed a number of technocrats from China about this with a sense that Chinese researchers are motivated by "money-seeking" without understanding academia's or technology's long-term benefits.

tages and safety of biotech may be needed to gain support for its biotechnology policy. All of these concerns could make China's aspiration to lead the world in agri-biotech more challenging.

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