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Agricultural Biotechnology Development and Policy in China

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This article provides an overview of China's agricultural biotechnology development policies. Research goals, strategies, priorities, commercialization, and China's organizational framework for agricultural biotechnology development are presented. Included is a description of the evolution of China's biosafety regulations as well as China's research capacity building and public investment—one of the largest public research efforts on agricultural biotechnology in the world.

Key words: biotechnology, policy, China, agriculture.

Introduction

In the past three years, the growth rate has slowed for acres planted with genetically modified (GM) crops globally, in contrast to its rapid increase in the late 1990s (James, 2002). This slowdown may be due to worldwide conflicting views on biotechnology that not only affect global investment in the biotechnology industry, but also impact farmers' adoption of this technology. Some, but not all, of these issues are present in China; however, China's development of its biotechnology industry has been unique, catalyzed by the active involvement of the public sector.

A survey of China's plant biotechnologists by the authors and their collaborators in 2000 shows that China is developing the largest plant biotechnology capacity outside of North America (Huang, Rozelle, Pray, & Wang, 2002). In 1997, when the National Genetically Modified Organisms (GMO) Biosafety Committee was established, this committee immediately approved 46 cases for field trials, environmental release, and commercialization, which covered 12 GM crops. Among them three cases of cotton, tomato, and petunia were approved for commercialization in certain locations (Huang, Wang, & Keeley, 2001).[1] A number of earlier studies concluded that China adopted a promotional policy to embrace the benefits of biotechnology (Chen, 2000; Huang, Wang, Zhang, & Zepeda, 2001; Paarlberg, 2000). China became one of the world's leading countries in biotechnology development. China also received criticism from biotechnology opponents for not paying enough attention to biosafety, the environment, consumer and food safety, and the potential impacts of biotechnology on China's future agricultural trade position.

However, the above perceptions regarding China's position on agricultural biotechnology lasted for only a few years. In May 2001, China's State Council decreed a new rule—Regulation on Safety Administration of Agricultural GMOs. And in early 2002, the Ministry of Agriculture (MOA) issued three detailed regulations on the biosafety management, trade and labeling of GM farm products.[2] After these events, China received more criticism than support from both proponents and critics of biotechnology. For example, biotech scientists and biotech industry representatives criticized China's new regulations as too restrictive to provide a favorable environment for the development of biotechnology. They called the period following 1999 as the "winter of biotechnology." Alternatively, Greenpeace and environmental agencies continuously warned China of the potential risks associated with GMOs.

International trade impacts occurred for both imports and exports. New regulations required importers of GM agricultural products to apply for official safety verification approval from China's Ministry of Agriculture. This led the US government to accuse Beijing of using these new rules to hinder imports and protect Chinese soybean farmers.[3] Pressure was also raised on the export side. China was frequently asked to certify that its agricultural exports to Japan and EU markets were free of GMOs. In addition, there has been growing criticism of China's financial and institutional ability to label its GM farm products.

1. *In 1998, GM sweet peppers were approved for commercialization.*

2. *Also see Marchant, Fang, and Song (2002), in this issue, for information on the evolution of China's agricultural biotechnology policies.*

3. *In 2001, China imported about 14 million metric tons of soybeans from the US, Argentina, and Brazil. Most of these imports were Roundup Ready soybeans. After two months of intensive negotiations between China and the US, an interim agreement was reached in early 2002. China in effect temporarily waived its import and export regulations of GMOs until December 2002, and this was further postponed to September 2003. Concurrently, China has agreed to recognize US assurances that its soybeans are safe for human consumption.*

Additionally, the media has claimed that China had reversed its former enthusiastic embrace of biotechnology by imposing extra restrictions on both domestic and imported varieties of genetically modified crops. These claims stated that China made a decisive shift away from its intentions to become the developing world's leader in biotechnology.[4] After 15 years of nationwide promotion of agricultural biotechnology in China, the current policy debate appears confusing to many observers. The industry wonders whether China will continue to advance its biotechnology, and some scientists question how to proceed in the near future.

Given the above background, the objectives of this article are to review the status of China's agricultural biotechnology research and commercialization, and to gain a better understanding of China's policies governing both agricultural biotechnology research and its applications (or commercialization).[5] In order to achieve these objectives, this article is organized as follows. The next section provides an overview of China's agricultural biotechnology development policies. We argue that despite the slight adjustment of GM strategies for commercialization policy in the short run, the overall goal of China's biotechnology development has not been altered. The growth of China's public investment in agricultural biotechnology has not slowed, but instead accelerated. These arguments are further discussed and supported by information provided in the third section of this article, focusing on agricultural biotechnology research capacity building and public investment. The fourth section examines specific cases in China's agricultural biotechnology development, research priorities, and commercialization. The final section provides concluding remarks.

An Overview of China's Agricultural Biotechnology Development Strategies and Policies

China's leaders have paid great attention to agricultural technology. Among various agricultural technologies, agricultural biotechnology is one of the priority areas that have received the greatest attention. For example, in response to *Science* Editor Ellis Rubenstein's question about concerns in the West regarding GMOs and criticisms of biotechnology, China's President Jiang Zemin stated, "We are also very much concerned about these.... I think it is important to uphold the principle of freedom of science. But advances in science must serve, not harm humankind. The Chinese government is now mulling over new rules and regulations to guide, promote, regulate, and guarantee a healthy development of science. I believe biotechnology—especially gene research —will bring good to humanity…"(Rubenstein, 2000).[6] This statement reflects China's position on biotechnology development: promoting the technology but showing appropriate precaution for biosafety, the environment, food safety, and the commercialization of biotechnology.

Goals and Strategies

Beginning in the early 1980s when China prepared to initiate its national biotechnology program, its biotechnology developmental goals were multifaceted. The government defined its goals of in terms improving the nation's food security, promoting sustainable agricultural development, increasing farmers' income, improving the environment and human health, and raising its competitive position in international agricultural markets along with other public agricultural development programs. And from the point of view of the technology itself, the most frequently stated goal was to create a modern, market-responsive, and internationally competitive biotechnology research and development system in China (Ministry of Science and Technology [MOST], 1990, 2000; State Science and Technology Commission [SSTC], 1990).

To meet these goals, the government's plan to modernize its agricultural biotechnology system was composed of several key measures. These included measures to establish a comprehensive public financed research system, investment to enhance the innovative capacity (both human and physical capacity) of the national biotechnology research program, and creation of institutions and regulations to ensure healthy devel-

4. *See the recent report in the* Washington Post *(Goodman, 2002), the* New York Times *(Kahn, 2002), and a front-page article in* China Daily *(Zhigang, 2002).*

5. *Issues related to impacts of biotechnology are not discussed in this paper. They can be found in a series of papers written by the authors with their collaborators, including Pray, Ma, Huang, and Qiao (2001); Huang, Rozelle, Pray, and Wang (2002); Huang, Hu, Rozelle, Qiao, and Pray (2002); Huang, Hu, Pray, Qiao, and Rozelle (in press); and Pray, Huang, and Rozelle (2002).*

6. *In his opening speech at the International Rice Conference held in Beijing on September 15, 2002, President Jiang Zemin restated the importance of agricultural biotechnology in boosting agricultural productivity growth and food security.*

Table 1. Major policy measures related to biotechnology in China since the early 1980s.

Key Breakthrough Science & Technology Projects	Started in 1982 by SDPC. Updated every five years. One of major components of these projects is biotechnology R&D.
Patent system	Patent law promulgated 1985. A total of 1,599 applications on genetic engineering for invention patents were filed between 1985 and 1999.
National Biotechnology Development Policy Outline	Prepared by scientists and officials led by MOST, SDPC, and others in 1985. Formally issued by the State Council in 1988. The Outline defined the research priorities, development plan and measures to achieve targets.
National Key Laboratories (NKLs) on Biotechnology	Started in 1985 under MOST. Thirty National Key Laboratories in biotechnology (15 on agriculture or agriculture related) have been established. NKLs are open laboratories, inviting both domestic and international visiting fellows.
The Climbing Program	A National Program for Key Basic Research Projects, including biotechnology program, initiated in the early 1980s.
High Technology Research and Development Plan (863 Plan)	Approved in March 1986 with 10 billion RMB for 15 years to promote high-technology R&D in China. Biotechnology is one of seven supporting areas, with a total budget of about 1.5 billion RMB from 1986-2000.
Natural Science Foundation of China	Established in 1986 to support basic science research. Life science and agronomy are two support areas related to agrobiotechnology.
Biosafety regulations	MOST issued the Biosafety Regulations on Genetic Engineering in July of 1993, which include the biosafety grading and safety assessment, application and approval procedure, safety control measures, and legal regulations.
Agricultural biosafety regulations	MOA issued the Safety Administration, Implementation, and Regulations on Agricultural Biological Genetic Engineering in July 1996.
973 Plan	Initiated in March 1997 to support basic science and technology research. Life science is one of the key supporting areas.
Agricultural GMO Biosafety Committee	Ministry-level Agri GMO Biosafety Committee was set up in MOA in 1997. The Committee was updated in 2002 to national level with its office in MOA.
Special Foundation for Transgenic Plant Research and Commercialization	A five-year program launched in 1999 by MOST to promote the research and commercialization of transgenic plants in China. The total budget of this program in the first five years is 500 million RMB.
Key Science Engineering Program	Started in the late 1990s under MOST and SDPC to promote basic research, including biotechnology program. The first project on biotech (crop germplasm and quality improvement) was funded in 2000 with 120 million RMB.
Foundation for high-tech commercialization	A special program supported by the SDPC to promote the application and commercialization of technologies, started from 1998.
Seed Regulation and Law	Regulation on the Protection of New Varieties of Plants was issued in 1999. The first Seed Law was issued in 2000.
Updated and amended agricultural biosafety regulations	1996 MOA's biosafety regulation was amended and issued by the State Council in May 2001. Three regulations on the biosafety management, trade, and labeling of GM farm products were issued by MOA to take effect after March 20, 2002.
Foreign investment in GMOs	In April 2002, the SDPC, State Economic and Trade Commission, and MOTEC jointly issued a Guideline List of Foreign Investment, which puts GMO as a prohibited area for foreign investment

opment of the technology that contributes to human welfare (MOST, 2000).

National Agricultural Biotechnology Research Institutions

The earliest plan to promote biotechnology research was initiated in the beginning of the "Seventh Five-year Plan" (1986-1990) when the first comprehensive National Biotechnology Development Policy Outline was issued (SSTC, 1990). This outline was prepared by more than 200 scientists and officials under the leadership of the Ministry of Science and Technology (MOST), the State Development and Planning Commission (SDPC), and the State Economic Commission in 1985 and further revised in 1986 (Table 1). The outline defined research priorities (see later part of this section), the development plan (e.g., the "863 Plan"), and measures to achieve targets or goals.

Under this outline, a number of high-profile technology programs were launched after the middle 1980s.

Some of the most significant programs included the "863 High-tech Plan," the "973 Plan," Natural Science Foundation of China, the Initiative of National Key Laboratories on Biotechnology, the Special Foundation for Transgenic Plants Research and Commercialization, the Key Science Engineering Program, the Special Foundation for High-tech Industrialization (or Commercialization), the Bridge Plan, and others (Table 1).

The 863 Plan, also called National High-Tech Research and Development Plan, was approved in March 1986. The 863 Plan supports a large number of applied as well as basic research projects with a 10 billion RMB yuan budget (equivalent to US$ 3 billion, based on the official exchange rate of 3.4 in 1985, or US$ 1.2 billion, based on the official exchange rate of 8.27 in 2000) over 15 years to promote high technology research and development (R&D) in China. Biotechnology is one of seven supporting areas, with a budget of 1.3 billion RMB yuan in 1986-2000, with 50% of this budget focused on agricultural biotechnology.

The National Basic Sciences Initiative, also called the 973 Plan, with a total budget of 2.5 billion yuan (US$ 302 million, converted at the1997-2002 average exchange rate) in the period of 1997-2002, was another high-tech research plan initiated in March 1997. This plan is complementary to the 863 and many other national initiatives on high-tech development, as it exclusively supports basic research. Life science, with biotechnology as a priority, constitutes one of the key programs under this plan.

In contrast to the perception that China's biotechnology development is shifting towards a "go slow" approach, our review of recent biotechnology research programs indicates that China instead has accelerated its biotechnology development since the late 1990s. The view suggesting that progress in biotechnology research has slowed is unfounded. For example, a new program aimed at strengthening the national research and industrialization of China's agricultural biotechnology, the Special Foundation of Transgenic Plants Research and Commercialization (SFTPRC), was initiated in 1999 by the Ministry of Science and Technology. This new program is a unique foundation to promote both research and commercialization of transgenic plants. Only those projects that are jointly submitted by research institutes and companies are eligible to receive funding from about half of the programs under SFTPRC. The foundation also requires a significant financial commitment from companies to commercialize technology generated by a project, a reflection of China's aim to accelerate the diffusion of biotechnology. The total budget of SFTPRC during its first five years (1999-2003) was 500 million RMB yuan (about US$ 60 million).

Concurrently, the Ministry of Science and Technology and the State Development and Planning Commission jointly sponsored the Key Science Engineering Program (KSEP), a national program to promote the fundamental construction for research in the late 1990s. As an example, one extremely large biotechnology project on crop germplasm and quality improvement through biotechnology received 140 million RMB yuan (US$ 17 million) from KSEP in 2000. Moreover, the State Council passed a new Agricultural Science and Technology (S&T) Development Compendium in 2001. The compendium reemphasizes the importance of agricultural biotechnology in improving the nation's agricultural productivity, food security, and farmers' income, and has led to a new decision to further increase the research budget for the development of biotechnology. The proposed biotechnology development budget for the Tenth Five-year Plan (2001-2005) is far more than all prior budgets over the past 15 years (see the next section for more detail).

With the above efforts, by 2001 there were about 150 laboratories at national and local levels located in more than 50 research institutes and universities across China working on agricultural (plant and animal) biotechnology. Over the last two decades, China established 30 National Key Laboratories (NKL). Among these NKLs, 12 are exclusively working on, and three have major activities in agricultural biotechnology (Huang, Wang, Zhang, & Zepeda, 2001). Besides NKLs, there are numerous Key Biotechnology Laboratories and programs within ministries and local provinces.

At the national level, the Ministry of Agriculture (MOA), the Chinese Academy of Sciences (CAS), the State Forestry Bureau (SFB), and the Ministry of Education (MOE) are the major authorities responsible for agricultural biotechnology research (Figure 1). Under the Ministry of Agriculture, there are three large academies—the Chinese Academy of Agricultural Sciences (CAAS, which employs about 8,000 research and support staff), the Chinese Academy of Tropical Agriculture (CATA), and the Chinese Academy of Fisheries (CAFi). Among the 37 institutes in CAAS, there are 12 institutes, two National Key Laboratories and five Key Ministerial Laboratories conducting biotechnology research programs. The CAFi and the CATA also have several biotechnology laboratories or programs, and each has one NKL for biotechnology.

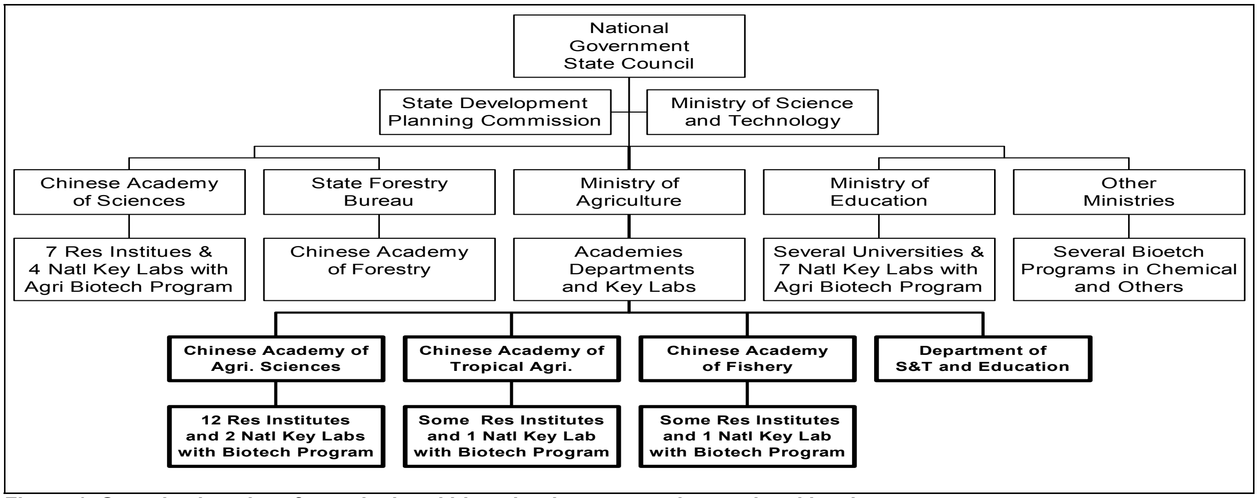

Figure 1. Organization chart for agricultural biotechnology research at national level.

Agricultural biotechnology research is also conducted by national institutes external to the Ministry of Agriculture's research system. For example, under the Chinese Academy of Sciences there are at least seven research institutes and four NKLs that focus on agricultural biotechnology. Research institutes within the Chinese Academy of Forestry (CAFo) under the State Forest Bureau and numerous universities (i.e., Beijing University, Fudan University, Nanjing University, Central China Agricultural University, and China's Agricultural University) under the Ministry of Education are examples of other institutions conducting agricultural biotechnology research. There are seven NKLs located in seven leading universities conducting agricultural biotechnology or agriculturally related basic biotechnology research. Other public biotechnology research efforts on agriculturally related topics include agrochemical (e.g., fertilizer) research by institutes in the State Petro-Chemical Industrial Bureau.

Although the programs at the national level presented in Table 1 and Figure 1 and discussed above constitute China's mainstream agricultural biotechnology research, research at the provincial level also contributes to the development of China's agricultural biotechnology. They follow a similar institutional framework to that at the national level (Figure 1). Each province has its own provincial academy of agricultural sciences and at least one agricultural university. Each academy or university at the provincial level normally has one or two institutes or laboratories focused on agricultural biotechnology. Provincial biotechnology research is funded by both local governments (core funding and research projects) and the central government (research projects only).

Finally, it is worth noting that the numbers of both national and provincial biotechnology programs and institutes continue to increase. China is even considering establishing a new national agricultural biotechnology research center—a megaresearch center over the current 150 agricultural biotech laboratories. Based on these developments, if there were shifts in China's biotechnology developmental plan, it is towards probiotechnology research.

Biosafety Management Institutions and Regulations

Institutional Setting. Although the Ministry of Science and Technology is mainly responsible for biotechnology research, the Ministry of Agriculture is the primary institution in charge of the formulation and implementation of biosafety regulations on agricultural GMOs and their commercialization, particularly after 2000. In order to incorporate representation of stakeholders from different ministries, the State Council established an Allied Ministerial Meeting comprised of leaders from the MOA, the SDPC, the MOST, the Ministry of Public Health, the Ministry of Foreign Economy and Trade (MOFET), the Inspection and Quarantine Agency, and the State Environmental Protection Authority (SEPA). This Allied Ministerial Meeting coordinates key issues related to biosafety of agricultural GMOs, examines and approves the applications for GMO commercialization, determines the list of GMOs for labeling, and establishes import or export policies for agricultural GMOs and their products.

However, routine work and daily operations are handled by the Office of Agricultural Genetic Engineering

Biosafety Administration (OGEBA). The National Agricultural GMO Biosafety Committee (BC) is the major player in the process of biosafety management.[7] Currently, the Committee comprises of 56 members.[8] The committee meets twice each year to evaluate all biosafety assessment applications related to experimental research, field trials, environmental release, and commercialization of agricultural GMOs. It provides approval or disapproval of recommendations to OGEBA based on the results of its biosafety assessments. OGEBA is responsible for the final approval of decisions.

The Ministry of Public Health (MPH) is responsible for food safety management of biotechnology products. The Appraisal Committee, consisting of food health, nutrition, and toxicology experts nominated by MPH, is responsible for reviewing and assessing GM foods as they have been designated a Noval Food. The State Environmental Protection Authority participates in GMO biosafety management through the Allied Ministerial Meeting and through their members on the National Agricultural GMO Biosafety Committee. Although SEPA has taken the responsibility of international biosafety protocol, its focus on biotechnology in China is limited to biodiversity.

Concerning the institutional setting of agricultural GMO biosafety management, China has several unique elements compared to the US and the EU. The Ministry of Agriculture in China appears to have more power than its counterparts in the US and the EU. The leaders in the State Council of the previous government believed that the MOA is more familiar with, and has more expertise in agriculture and agricultural GMOs than any other ministry. Moreover, because the MOA is also in charge of pesticide use and its environmental assessment in agricultural production, national leaders consider the MOA a major player in China's agricultural biosafety management.

Critics (i.e., SEPA) of this system argue that this institutional setting might result in less attention paid to environmental risks of GMOs and may have a potential conflict of interest, as the MOA is primarily responsible for agricultural production, and many biotechnologies are developed under the MOA's own research system. The debate on whether SEPA or MOA is a more appropriate institution to take a lead role on biosafety has continued since the biosafety management system was set up in 1997. However, under the current national administrative system, it is unlikely for SEPA to take a significant role in biotechnology, unless there is significant reform of the government's structure by China's new leaders, who have been in office since early 2003.

The other unique aspect is that China's National Agricultural GMO Biosafety Committee plays a critical role in the biosafety decision-making process. As most of its 56 current members (29 for GM plants, nine for recombined microorganisms for plant, 12 for transgenic animals and recombined microorganisms for animals, and six for GM aquatic organisms) are experts from various research institutes within the public sector, its GMO biosafety assessment provides key information for decision makers on whether OGEBA should approve or disapprove GMO application cases. However, the weakness of this approach is the time constraint from BC members who often are leading scientists in various disciplines. Other concerns include the heavy service burden of a few key individual scientists and too many biotechnologists on the Biosafety Committee.

Biosafety Regulations. Before 2002, the principle governing China's agricultural GMO biosafety was to adopt a product-based GMO management system. However, China has attempted to impose labeling regulations on GMOs and GM products since March 2002. By imposing a compulsory labeling policy on GMOs, China's biosafety management partially shifts towards a process-based GMO management system. This adjustment has led to wide debate within China and between China and many other countries, as we described above in the introduction. Before we discuss this new labeling policy, it is worth reviewing briefly the evolution of China's agricultural GMO biosafety regulations and policies in the past.

Evolution of China's Biosafety Regulations. In response to the emerging progress in China's agricultural biotechnology, the first biosafety regulation, "Safety Administration and Regulation on Genetic Engineering," was issued by the Ministry of Science and Technology in 1993. This regulation consisted of gen-

7. The Biosafety Committee was established in 1997 under the Ministry of Agriculture; it was a ministry-level institution. Since June 2002, the Committee was upgraded to a national-level institution.

8. Biosafety Committee members work part-time for the BC and are scientists from different disciplines including agronomy, biotechnology, plant protection, animal science, microbiology, environmental protection, and toxicology. A few members are also agricultural administrations. All BC members are nominated by the Ministry of Agriculture.

Table 2. The number of cases in agricultural (plant, microorganism, and animal) biotechnology submitted and approved for field trials, environmental release, and commercialization in 1997-2000.

	1997	1998	1999	2000	Total
Submitted					
Field trial	14	41	28		
Environmental release	37	18	63		
Commercialization	6	9	35		
Total	57	68	126	182	433
Approved					
Field trial	12	40	22	115	189
Environmental release	30	10	34	19	93
Commercialization	4	2	27	7	40
Total	46	52	83	141	322

eral principles, safety categories, risk evaluation, application and approval, safety control measures, and legal responsibilities. After the above regulation was decreed, MOST required relevant ministries to draft and issue corresponding biosafety regulations on biological engineering (i.e., the Ministry of Agriculture for agriculture and the Ministry of Public Health for food safety). Following MOST's guidelines, the MOA issued the Implementation Regulations on Agricultural Biological Engineering in 1996. This regulation is similar in many aspects to the US GMO biosafety regulations. Labeling was not part of this regulation, nor was any restriction imposed on imports or exports of GMO products. The regulation also did not regulate processed food products that use GMOs as inputs.

Under the 1996 GMO biosafety regulation policy, OGEBA received 433 applications for field trials, environmental release, or commercialization in 1997-2000 (Table 2). Among them, 322 cases had been approved, covering more than 60 crops and several animals, as well as numerous microorganisms. It is interesting to note that both the number of cases applied or submitted and cases approved increased persistently over time. Imposing more GMO restrictions did not reduce the number of applications. However, if we decompose this data into different stages of GMO development and by crop, they do show that the numbers of cases approved for commercialization declined in 2000 and that no new GMO crops have been approved since 1999, excluding cotton, tomatoes, sweet peppers, and petunias.

China's Stance on Biotechnology Development—For or Against? Using solely the above approval case numbers may lead to erroneous conclusions regarding China's stance on GMO development. Indeed, the small number of approvals for commercialization of GM crops in 2000 (seven cases, Table 2) was due to many factors. First, in the prior year, 1999, a large number of cases were approved for commercialization (27 cases, Table 2), almost all for Bt cotton. As expected, there were fewer applications for Bt cotton commercialization in 2000, as most of the Bt cotton varieties (nearly 20 varieties from both CAAS and Monsanto) had been earlier approved for commercialization. Second, as argued by OGEBA and the Biosafety Committee, the existing food-related GM crops were not ready for commercialization due to unclear issues over their food safety. For example, food safety testing managed by Ministry of Public Health has not come to a conclusion on whether the current GM rice is not substantially different from non-GM rice. Research on GM rice's food safety is still ongoing. Third, the testing on environmental safety and biodiversity has been limited to a very small scale and in few locations. Lastly, Bt cotton had been tested and adopted widely in other countries before China approved its commercialization, and given that cotton is a nonfood crop, the context surrounding GM rice differs than that for cotton. Rice is the most important food crop in both China and the rest of Asia. Additionally, GM rice has never been commercialized anywhere in the world.

More recently, our communication with OGEBA's officials and members of the Biosafety Committee reveal that China is badly in need of institutional and capacity building for GMO biosafety management. During the 7th International Symposium on the Biosafety of Genetically Modified organisms held in Beijing in October 2002, an official from OGEBA concluded his speech with five major challenges that OGEBA currently faces: "an appropriate regulatory approach *(to improve current practices),*[9] a science-based safety assessment, capacity building, transparency, communication and information exchange (Cheng & Peng, 2002).

Given the above discussion, it is no surprise that OGEBA declined three applications for GM rice commercialization in 1999-2000. We believe that China's current adjustment in biosafety management is just one effort to establish a more comprehensive GMO biosafety management system that provides a firm base for

9. *Because biosafety management is a new activity for OGEBA, it is understandable that they are seeking a more appropriate approach even after years of commercialization of nonfood crops* (*Bt cotton*).

future sustainability. Current adjustment is also partly in response to the growing worldwide debate on GMOs and their potential risks, as well as China's agricultural trade.[10]

Chinese policymakers are concerned about environmental and food safety in response to the debate on the potential risks of GMOs recently raised by the Chinese media. The debate in China has involved scientists, government officials, and newspaper reporters; responses and reactions vary among stakeholders and change over time as more information becomes available on biotechnology (Huang, Wang, & Keeley, 2001). A consensus seems to be growing in China that the most important task a scientist or biotechnologist can do is to reduce the potential negative effects and demonstrate the safety of GMOs.

As a consequence of this consensus, research budgets allocated to biosafety management and the study of biosafety have increased. Since 1999-2000, nearly all biotechnology research programs have expanded their scope into biosafety issues, particularly for the following programs: 863, 973, and the Special Foundation for Transgenic Plants Research and Commercialization. A number of national institutes under the Ministry of Agriculture, the Ministry of Public Health and the State Environmental Protection Agency have launched various biosafety programs, including capacity building for biosafety management and risk assessment, research studies on environmental safety and food safety, detection technology for GMOs and GMO products, and monitoring of international practices.

However, arguing for a more comprehensive and science-based safety assessment as reasons for the recent adjustment of China's GMO commercialization does not imply that there is no concern over the impacts of GMO development on agricultural trade. Issues such as labeling of GM products and possible trade barriers resulting from biotechnology concerns in countries that follow precautionary and preventive policies do have impacts on the current (short run) pace of GMO commercialization in China. Agricultural trade had been an important contributor to the aggregate Chinese economy and trade.

It appears that international trade concerns may have been one of the important factors, but not the dominant factor, in recent agricultural biotechnology policy processes. The critical event here appears to have been the EU's decision to ban Chinese soy sauce imports produced with GM soybeans imported from the United States. Additionally, the recent decision by Thailand (the world's leading rice exporter) to halt further development of GM rice may also have been significant. It is unclear whether public attitudes toward GMOs in Europe are now softening or whether policies may soon change; hence, a short-run "wait and see" tactic is probable in China.

New Biosafety Regulations. In response to the above concerns, in May 2001 the State Council decreed a new and general rule of Regulation on Safety Administration of Agricultural GMOs to replace an early regulation issued by the Ministry of Sciences and Technologies in 1993 (Safety Administration Regulation on Genetic Engineering, Table 1). The Ministry of Agriculture then announced three new implementation regulations on biosafety management, trade, and labeling of GM farm products that were planned to take effect after March 20, 2002.[11] There were several important changes to existing procedures included in these guidelines, as well as details of regulatory responsibilities after commercialization. These included the addition of an extra preproduction trial stage prior to commercial approval, new processing regulations for GM products, labeling requirements for marketing, new export and import regulations for GMOs and GMO products, and local- and provincial-level GMO monitoring guidelines. In the meantime, the Ministry of Public Health also promulgated its first regulation on GMO food hygiene in April 2002, to take effect after July 2002.

By late 2002, the system of biosafety regulation in China had clearly become progressively more elaborate and sophisticated. Many provinces have established provincial biosafety management offices under provincial agricultural bureaus. These biosafety management offices collect local statistics on and monitor the performance of research and commercialization of agricultural biotechnology in their provinces and assess and approve (or disapprove) all applications of GM related research, field trials, and commercialization in their provinces. Only those cases that are approved by provincial biosafety management offices are submitted to the National Biosafety Committee for further assessment. However,

10. So far, Chinese consumers have not created many problems for GMO development in China.

11. These three new regulations replaced the Safety Administration, Implementation, and Regulation on Agricultural Biological Genetic Engineering issued by the Ministry of Agriculture in July 1996.

Table 3. Estimated number of research staff and expenditures on plant biotechnology research in China, 1986-2000.

Year	Number of staff	Research expenditure: Million RMB at current price	Million RMB at 2000 price	Million US$
1986	740	14	38	4.2
1990	1067	40	68	8.3
1995	1447	88	87	10.5
2000	2128	322	322	38.9

Note. Expenditures include both project grants and costs related to equipment and buildings. Both staff and research expenditures are estimated by the authors based on our earlier studies (Huang, Wang, Zhang, & Zepeda, 2001) and recent interviews in China. The results from our recent interviews show that the data in Table 2 are higher than our earlier estimates. Official exchange rate in the corresponding year is used to convert the domestic currency to US dollars.

China still has a long way to go before all decreed regulations could be fully implemented. Our three years of Bt cotton farm surveys across five provinces during 1999-2001 found that about half of Bt cotton varieties had been adopted by farmers, but they did not apply to the National Biosafety Committee for commercialization. Seeds are distributed to farmers mainly by local seed companies, the extension system, research institutes, and small traders. The institutions, human capacity, and financial support for implementation of GMO regulations are far away from the necessary requirements. In addition to this, collaboration and coordination between ministries on research, commercialization, and biosafety management needs to be further strengthened.

Agricultural Biotechnology Capacity Building and Public Investment

Creation of a modern and internationally competitive biotechnology research and development system requires substantial investments in human and financial capacities. Since the early 1980s, China's public investment in, and the number of research staff working on biotechnology has increased significantly, in contrast to stagnating trends for general agricultural research expenditures in the late 1980s and early 1990s (Huang, Hu, & Rozelle, 2002). For example, based on our 2000 survey of 29 research institutes in plant biotechnology[12] and on extensive interviews with ministries and research institutes in 2002, we estimate that the number of plant biotechnology researchers tripled in the past 15 years (Table 3). More than 2,100 researchers are now working on plant biotechnology alone. If we include biotechnology from the animal sector, the number of agricultural biotechnology researchers may reach 3,000, and may be one of the largest biotechnology research efforts in the world.

Similar to other agricultural research programs in China, agricultural biotechnology research is primarily built upon research institutes. Among the 29 institutes surveyed, the number of agricultural biotechnology researchers in universities accounted for only 10% of total research staff.[13] Among total researchers, nearly 60% are professionals, and the share of the professional staff has been increasing over time (Huang, Wang, Zhang, & Zepeda, 2001), again indicating growing human capacity in biotechnology research.

The quality of human capacity to conduct biotechnology research has improved over time. Among professional staff, the share of researchers with Ph.D. degrees increased from only 2% in 1986 to more than 20% in 2000. This share is expected to continue to increase in the future. Although the share of researchers with biotechnology Ph.D. degrees is still low by international standards, it is interesting to note that this share is much higher than those in the general agricultural research system. In China's national agricultural research system, Ph.D. researchers accounted for only 1.1% of the total professional staff in 1999 (Huang, Hu, & Rozelle, 2001).

Even more dramatic growth has occurred in China's biotechnology research investment (Table 3). China's biotechnology research investment was trivial in the early 1980s (MOST, 1990). Although there are no statistics available from official sources, our estimates show that biotechnology investment has grown substantially. For example, the estimated investment in plant biotechnology research was only US$ 4.2 million in 1986 when China formally started its 863 Plan (Table 3). By 1990, China's investment grew to US$ 8.3 million. During this period, the research project budget nearly tripled, and equipment expenses nearly doubled (Huang, Wang, Zhang, & Zepeda, 2001). Although the growth rate of biotechnology research investment slowed between

12. *The survey was conduced by the Center for Chinese Agricultural Policy and the International Service for National Agricultural Research; detailed results are reported in Huang, Wang, Zhang, and Zepeda (2001).*
13. *In terms of the overall agricultural research system in China, researchers in universities account for about 8% of the nation's total agricultural researchers.*

1990 and 1995 (this is expected as the large investment in biotechnology equipment was nearly complete in the early 1990s), the annual growth rate in the research project budget in real terms remained as high as 10% during this period.

China's biotechnology research investment increased considerably from US$ 10.5 million in 1995 to US$ 38.9 million in 2000, representing an annual growth rate of about 30%. This investment in China's biotechnology is mainly due to government sources. According to our survey of 29 biotech research institutes, public investment accounted for 94% of the total plant biotechnology budget in 1999, and this share has been increasing over our study period, from 1986 to 1999 (Huang, Wang, Zhang, & Zepeda, 2001). Budgets from competitive grants for research projects accounted for two thirds of the total budget and this share also has shown an increase over time, reflecting China's biotechnology development moving from a capacity-building stage to a research stage.

Our recent interviews with officials and research administrators from the Ministry of Science and Technology confirm that the Ministry is accelerating its investment in national biotechnology program: the Tenth Five-year Plan (2001-2005) for biotechnology development. Under this plan, the total investment in agricultural biotechnology is targeted to be four times as much as the total amount spent on agricultural biotechnology in the past 15 years (1985-2000). If this goal is realized, China will account for more than one fourth of the world's current public spending on agricultural biotechnology.

Agricultural Biotechnology Development, Research Priorities and Commercialization

An Overview

The focus of China's biotechnology development in its early stages (in the early 1970s) was on cell engineering, tissue culture, and cell fusion and emphasized crops such as rice, wheat, maize, cotton, and vegetables (Key Laboratory of Crop Molecular and Cell Biology, 1996). However, the most significant progress in agricultural biotechnology was made following the development of transgenic techniques after 1983. The pace of biotechnology research accelerated significantly after China initiated the 863 Plan in 1986 (Table 1).

Bt cotton is a most successful story of agricultural biotechnology in China. In response to rising pesticide use and the emergence of a pesticide resistant bollworm population in the late 1980s, China's scientists began research on GM cotton. Starting with a synthesized gene originally from the bacterium *Bacillus thuringiensis* (Bt), China's scientists transferred this modified Bt gene into major cotton cultivars by the so-called pollen tube pathway transformation. Greenhouse testing began in the early 1990s. The first commercial use of GM cotton was approved in 1997. During the same year, Bt cotton varieties from publicly funded research institutes and from a joint venture with Monsanto became available to farmers. The release of Bt cotton began China's first large-scale commercial experience with a product of the nation's biotechnology research program.

In addition, other transgenic plants with resistance to insects, disease or herbicides, stress tolerance, or plants with improved quality have been approved for field release, and some are nearly ready for commercialization. These include transgenic cotton lines resistant to fungal disease, rice resistant to rice stem borer or bacteria blight, diseases, herbicide, and salt tolerance, wheat resistant to barley yellow dwarf virus (Cheng, He, & Chen, 1997), maize resistant to insects and with improved quality (Zhang, Liu, & Zhao, 1999), poplar trees resistant to gypsy moths, soybeans resistant to herbicides, transgenic potato resistant to bacterial disease or Colorado beetles, among others (Ministry of Agriculture [MOA], 1999; National Center of Biological Engineering Development [NCBED], 2000; Li, 2000).

Progress in plant biotechnology has also been made in recombinant microorganisms such as soybean nodule bacteria (nitrogen-fixing bacteria for rice and corn) and phytase from recombinant yeasts for feed additives (Huang, 2002). Genetically modified nitrogen-fixing bacteria and phytase have been commercialized since 1999. In animals, transgenic pigs and carp have been produced since 1997 (NCBED, 2000). Recently, Chinese researchers also announced the successful sequencing of the rice genome (Yu et al., 2002). They have produced a draft sequence of the rice genome for the most widely cultivated subspecies in China, *Oryza sativa L.* ssp. *indica*, by whole-genome shotgun sequencing.

According to a nationwide survey conducted by the MOA in 1996, Chinese scientists have tried to use more than 190 genes transferring to more than 100 organisms (103 genes used in 47 plants, 32 genes used in 22 animals, 56 genes used in 31 species of microorganisms). These figures have been further expanded after 1996 (Cheng & Peng, 2002). By 2001, there were more than 60 plants under research and 121 genes used for transformation (Peng, 2002). The list of GM crops in trials is

Table 4. Research focus of plant biotechnology programs in China.

	Prioritized areas
Crops	Cotton, rice, wheat, maize, soybean, potato, rapeseed, cabbage, tomato
Traits:	
Insect resistance	Cotton bollworm, boll weevil, and aphids Rice stem borer Wheat aphids Maize stem borer Soybean moth Potato beetle Poplar gypsy moth
Disease resistance	Rice bacteria blight and blast Cotton fungal disease Cotton yellow dwarf Wheat yellow dwarf and rust Soybean cyst nematode Potato bacteria wilt Rapeseed sclerosis CMV and TMV
Stress tolerance	Drought, salinity, cold
Quality improvement	Cotton fiber quality Rice cooking quality Wheat quality Maize quality Corn with phytase or high lysine
Herbicide resistance	Rice, soybean
Functional genomics	Rice, rapeseed, and arabidopsis

also impressive and differs from those being worked on in other countries.

Research Priorities and Products in the Research Continuum

Huang, Wang, Zhang, and Zepeda (2001) summarized research priorities for plant biotechnology identified in various Biotechnology Development Outlines over the past 15 years in China (Table 4). Since the mid-1980s, cotton, rice, wheat, maize, soybean, potato, and rapeseed have been consistently listed as priority crops for biotechnology research funding. Functional genomics for major plants and animals, crop genetic breeding through the application of gene transformation, chromosome hybridization and marker assisted selection, cultivation of crops with improved resistance or quality and genetic breeding of animals, use of animal and plant cells as bioreactors in producing secondary products, special proteins and vaccines, recombined microorganisms to produce biofertilizers and biopesticides, and others have been identified as priority technologies for public funding.

Among crops, cotton is listed as a priority crop not only because of its importance by sown area and its contributions to the textile industry and trade, but also because of the serious problems with the associated rapid increase in pesticide applications to control insects (i.e., bollworm and aphids). Per-hectare pesticide expenditures for cotton production in China increased considerably over recent decades, reaching 834 RMB yuan (approximately US$ 100) in 1995. This amount is much higher than comparable expenditures for grain crop production but lower than horticultural production. Cotton production alone consumed about US$ 500 million annually in pesticides in recent years.

Rice, wheat, and maize are the three most important crops in China. Each accounts for about 20% of the total area planted. Production and market stability of these three crops are a primary concern of the Chinese government, as they are central to China's food security. National food security, particularly related to grains, has been a central goal of China's agricultural and food policy and has been incorporated into biotechnology research priority setting.

Among all traits, pest resistance traits have top priority (Table 4). Recently, quality improvement traits have been included as priority traits in response to increased market demand for quality foods. Quality improvements have been targeted particularly for rice and wheat, as consumer income rises in China. In addition, stress tolerance traits—particularly resistance to drought—are gaining attention, particularly with the growing concern over water shortages in Northern China. In addition, Northern China is a major wheat and soybean production region with significant implications for China's future food security and trade.

Newer research focuses on the isolation and cloning of new disease and insect resistance genes, including the new genes conferring resistance to cotton bollworm (Bt, CpTI and others), rice stem borer (Bt), rice bacterial blight (Xa22 and Xa24), rice plant hopper, wheat powdery mildew (Pm20), wheat yellow mosaic virus, and potato bacterial wilt (cecropin B) (MOA, 1999; NCBED, 2000). These genes have been applied in plant genetic engineering since the late 1990s. Significant progress has also been made in the functional genomics of arabidopsis and in plant bioreactors, especially in utilizing transgenic plants to produce oral vaccines (Biotechnology Research Institute, 2000).

By the end of 2001, GM plants from 13 plant species and more than 50 genes were approved for field trial, environmental release, and commercialization. Thirty-six recombined microorganism species and 51 strains

Table 5. Bt cotton adoption in China, 1997-2001.

Year	Cotton area (000 hectare) Total	Bt cotton	Bt cotton share (%)
1997	4491	34	1
1998	4459	261	6
1999	3726	654	18
2000	4041	1216	30
2001	4810	2174	45

have been involved in research with 89 genes for insect and disease resistance or nitrogen fixation.

Commercialization of Agricultural Biotechnology

By 2002, 18 transgenic cotton varieties generated by Chinese institutions and five varieties from Monsanto with resistance to bollworm have been approved for commercialization in China. Although several GM varieties of tomato, sweet pepper, chili pepper, and petunia have also been approved for commercialization since 1997, the area planted with these four crops remains small. Personal communications with several member of the agricultural Biosafety Committee show that the economic benefits of adopting the current three GM crops are minimal or nonexistent; no private companies have been attracted to invest in their commercialization.

Table 5 presents our most updated estimates of Bt cotton areas sown in China in 1997-2001. After the Bt cotton variety was approved for commercialization in 1997, the total area planted using Bt cotton increased to 0.65 million hectares in 1999. In 2001, the area reached more than 2 million hectares and accounted for 45% of China's cotton area. China's GM crop area follows that of the US, Argentina, and Canada. Although less than 4% of the total global area of GM crops was grown in China in 2001, we estimate that nearly 5 million Chinese farmers planted Bt cotton, as the average farm size is only about 0.5 hectares and includes several crops.

Concluding Remarks

Chinese policymakers consider agricultural biotechnology as a strategically significant tool for improving national food security, raising agricultural productivity, and creating a competitive position in international agricultural markets. Consistent with these aims, China also intends to be one of world leaders in biotechnology research and major domestic supplier of biotechnologies. This objective is closely linked to the perception by Chinese policymakers that there are risks associated with reliance on imported technologies to guarantee national food security. Despite the growing debate worldwide on GM crops, China has developed agricultural biotechnology decisively since the mid-1980s. By 2001, China had the fourth largest sown area of GM crops in the world. Research and development has continued apace, and China now has several genetically modified plants that are in the pipeline for commercialization.

The institutional framework for supporting agricultural biotechnology research program is complex both at national and local levels. The growth of government investment in agricultural biotechnology research has been remarkable. However, coordination among institutions and consolidation of agricultural biotechnology programs will be essential for China to create an even stronger and more effective biotechnology research program in the future.

Examination of the research foci of agricultural biotechnology research reveals that food security objectives and farmers' current demands for specific traits and crops have been incorporated into priority setting. Moreover, the current priority setting for investments in agricultural biotechnology research has been directed at commodities for which China does not have a relative comparative advantage in international markets (such as grain, cotton, and oil crops). This implies that China is targeting its GMO products at the domestic market. The emphasis on developing drought-resistant and other stress-tolerant GM crops also suggests that biotechnological products are not only being geared to high-potential areas, as critics argue, but also at the needs of poorer farmers.

Many competing factors are exerting pressure on Chinese policymakers to continue with research and commercialization of transgenic crops. The demand of producers (for productivity-enhancing technology) and consumers (for cost savings), the current size and rate of increase of research investments, and past success in developing technologies suggest that products from China's plant biotechnology industry are likely to become widespread in China in the near future. Although China is still struggling with issues of environmental and consumer safety, and the system of biosafety regulation has become progressively more elaborate and sophisticated, the system might not work well and might eventually hurt its national biotechnology application in the future if biosafety management capacity is not improved as much as research capacity. Investment in China's biotechnology R&D is essential for the nation to promote its biotechnology industry;

investment in biosafety management capacity and policy implementation are also critical factors for health and sustainable development of this industry.

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