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Biotechnology policy and regulation in China

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Summary

The argument refutes claims that China has in recent years fundamentally altered its stance on GMOs in response to trade, food safety and environmental biosafety concerns. On the contrary research investment has increased and policy-makers have continued to emphasise that biotechnology will pay a key role in China's agricultural future. The paper details China's achievements in biotechnology research and development, and explains what policies and institutional mechanisms have facilitated Chinese breakthroughs in the field of GMOs. The paper concludes that the recent increase in emphasis on biosafety as a research priority and corresponding elaboration of more sophisticated biosafety regulations suggest that China is committed to developing biotechnology in a balanced and responsible way.

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Preface

Biotechnology Policy Series

This IDS Working Paper series emerges from a series of three interlinked projects. They involve collaboration between IDS and the Foundation for International Environmental Law and Development (FIELD) in the UK and partners in China (Center for Chinese Agricultural Policy (CCAP)), India (Centre for the Study of Developing Societies, Delhi; Research and Information Systems for the Non-Aligned and Other Developing Countries (RIS), Delhi; National Law School, Bangalore), Kenya (African Centre for Technology Studies, Nairobi) and Zimbabwe.

Three key questions guide the research programme:

- What influences the dynamics of policy-making in different local and national contexts, and with what implications for the rural poor?
- What role can mechanisms of international governance play in supporting the national efforts of developing countries to address food security concerns?
- How can policy processes become more inclusive and responsive to poor people's perspectives? What methods, processes and procedures are required to "democratise" biotechnology?

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This paper is a product of the 'Biotechnology and the Policy Process in Developing Countries' project. Other papers in the Biotechnology Policy Series are listed inside the back cover.

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'Democratising Biotechnology: Genetically-Modified Crops in Developing Countries' Policy Briefing Series

Issues covered in the series include: food security and biotechnology, trade, IPRs, the role of the corporate sector, science and decision-making, biosafety regulation, biotech in Africa and China, Bt cotton, rights-based approaches to biotech, and the use of citizens juries to expand participation in biotechnology policymaking.

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1 Introduction

In the past three years, the growth rate has slowed for areas planted with genetically modified (GM) crops globally, in contrast to its rapid expansion in the late 1990s (James 2002). This slowdown may be due to conflicting views worldwide on biotechnology that not only impact on global investment in the biotechnology industry, but also on farmers' adoption of this technology. Some, but not all of these issues are present in China; as China's development of its biotechnology industry has been uniquely catalysed 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 and Wang 2002). In 1997, when the National Genetically Modified Organisms (GMO) Biosafety Committee was established, this Committee immediately approved a total of 46 cases for field trials, environmental release, and commercialisation, which covered 12 GM crops. Among them three cases of cotton, tomato, and petunia were approved for commercialisation in certain locations (Huang, Wang and Keeley 2001). In the following year, GM sweet peppers were also approved for commercialisation. A number of earlier studies also concluded that China had adopted a promotional policy to embrace the benefits of biotechnology (Chen 2000; Huang, Wang, Zhang and Zepeda 2001; Paarlberg 2000). Suddenly, China had become one of the world's leading countries in biotechnology development. At the same time, however, China 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 only lasted for a few years. In May 2001, China's State Council issued a new decree, the Regulation on Safety Administration of Agricultural GMOs. Following this in early 2002, the Ministry of Agriculture (MOA) issued three detailed regulations on biosafety management, trade and labeling of GM farm products. After these changes, 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 the "Winter of Biotechnology." At the same time, Greenpeace and other environmental organisations 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.[1] Pressure was also raised on the export side. China's

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1 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 recognise US assurances that its soybeans are safe for human consumption.

agricultural exporters to Japan and EU markets were frequently asked to certify that exports were free of GMOs. Japan refused to import China's soysauce made with soybeans imported from the US, which are principally GM soybeans. The Chinese government, especially the MOA, has been concerned that the commercialisation of Chinese GM rice will affect China's rice and rice-related food exports, so the National Biosafety Committee has hesitated to approve the commercialisation of GM rice. In addition to this, there has been growing criticism of China's financial and institutional ability to label its GM farm products.

Meanwhile, the media has claimed that China has 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.[2] 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 commercialisation, and to gain a better understanding of China's policies governing both agricultural biotechnology research and its applications (or commercialisation).[3] In order to achieve these objectives, this article is organised as follows. The next two sections provide overviews of China's policies and development in agricultural biotechnology. The fourth section focuses on biosafety management and regulations and the fifth section discusses research capacity building and investment. We argue that while there has been a slight adjustment of GM strategies for commercialisation 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. The final section provides concluding remarks.

2 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 has 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

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2 See the recent report in the *Washington Post* ('China's new economy begins on the farm, growers bear burden of being first as trade brings opportunity, risk', by Peter Goodman, Page A01, 25 September 2002), the *New York Times* ('The science and politics of super rice', by Joseph Kahn, 22 October 2002), and a front page article in *China Daily* ('GM rules don't block imported products' by Xing Zhigang, 11 July 2002).

3 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 (forthcoming); and Pray, Huang and Rozelle (2002).

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).[4] This statement reflects China's government's position on biotechnology development: promoting the technology while being precautionary towards the environment and food safety, and the commercialisation of biotechnology.

2.1 Goals and strategies

Beginning in the early 1980s when China prepared to initiate its national biotechnology programme, its biotechnology developmental goals were multifaceted. The government defined its goals in terms of 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 programmes. 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 (MOST 1990 and 2000; SSTC 1990).

To meet these goals, the government's plan to modernise its agricultural biotechnology system has been composed of several key measures. These include measures to establish a comprehensive public financed research system, investment to enhance the innovative capacity (both human and physical) of the national biotechnology research programme, creation of institutions and regulations to ensure healthy development of the technology that contributes to human welfare, and stimulation of industrialisation (or commercialisation) of biotechnology by giving a high priority to support the R&D programme with the involvement of private sector (currently mainly domestic companies) in downstream commercialisation stages of the technological innovation process (MOST 2000; SDPC 2003).

2.2 National agricultural biotechnology research institutions

The first 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 2.1). The Outline defined research priorities (see later part of this section), development plans (e.g., '863' Plan), and measures to achieve targets or goals.

[4] In his opening speech at the International Rice Conference held in Beijing on 15 September 2002, President Jiang Zemin re-stated the importance of agricultural biotechnology in boosting agricultural productivity growth and food security.

Table 2.1 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 1599 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 Programme	A National Programme for Key Basic Research Projects, including biotechnology programme, initiated in the early 1980s.
High Technology Research and Development Plan (863)	Approved in March 1986 with 10 billion RMB for 15 years to promote high technology R&D in China. Biotechnology is one of 7 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 the agro-biotechnology.
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 the basic science and technology research. Life science is one of the key supporting areas.
Agricultural GMO Biosafety Committee	Ministry level Agricultural 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 Commercialisation	A 5-year programme launched in 1999 by MOST to promote the research and commercialisation of transgenic plants in China. The total budget of this programme in the first 5 years is 500 million RMB.
Key Science Engineering Programme	Started in the late 1990s under MOST and SDPC to promote basic research, including biotechnology programme. The first project on biotech (crop germplasm and quality improvement) was funded in 2000 with 120 million RMB.
Foundation for high-tech commercialisation	A special programme supported by the SDPC to promote the application and commercialisation 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	The 1996 MOA 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 20 March 2002.
Foreign investment in GMOs	In April 2002, the SDPC, State Economic and Trade Commission, and MOFTEC jointly issued a Guideline List of Foreign Investment, which puts GMO as a prohibited area for foreign investment

Under this Outline, a number of high profile technology programmes were launched after the mid-1980s. Some of the most significant programmes are the "863 High-tech Plan", the "973 Plan", the Initiative of National Key Laboratories on Biotechnology, the Special Foundation for Transgenic Plants Research and Commercialisation, the Key Science Engineering Programme, the Special Foundation for High-tech Industrialisation (or Commercialisation) and the Bridge Plan, among others (Table 2.1).

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 3 billion US$ based on the official exchange rate of 3.4 in 1985, or 1.2 billion US$ 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 per cent 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 (302 million US$ converted at 1997–2002 average exchange rate) in the period of 1997–2002, was another high-tech research plan and initiated in March 1997. This plan is complementary to "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 programmes 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 programmes indicates that China instead has accelerated its biotechnology development since the late 1990s. The view suggesting that progress in biotechnology research has slowed is not founded. For example, a new programme aimed at strengthening national research and industrialisation of China's agricultural biotechnology called the Special Foundation of Transgenic Plants Research and Commercialisation (SFTPRC), was initiated in 1999 by the Ministry of Science and Technology. This new programme is a unique Foundation promoting both research and commercialisation of transgenic plants. Only those projects that are jointly submitted by research institutes and companies are eligible to receive funding from SFTPRC. The Foundation also requires a significant financial commitment from companies to commercialise 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 60 million US$).

Concurrently, the Ministry of Science and Technology and the State Development and Planning Commission jointly sponsored the Key Science Engineering Programme (KSEP), a national programme to promote the fundamental construction for research in the late 1990s. As an example, one large biotechnology project on crop germplasm and quality improvement through biotechnology received 140 million RMB yuan (17 million US$) from KSEP in 2000. Moreover, the State Council passed a new Agricultural Science and Technology (S&T) Development Compendium in 2001. The Compendium reemphasises 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).

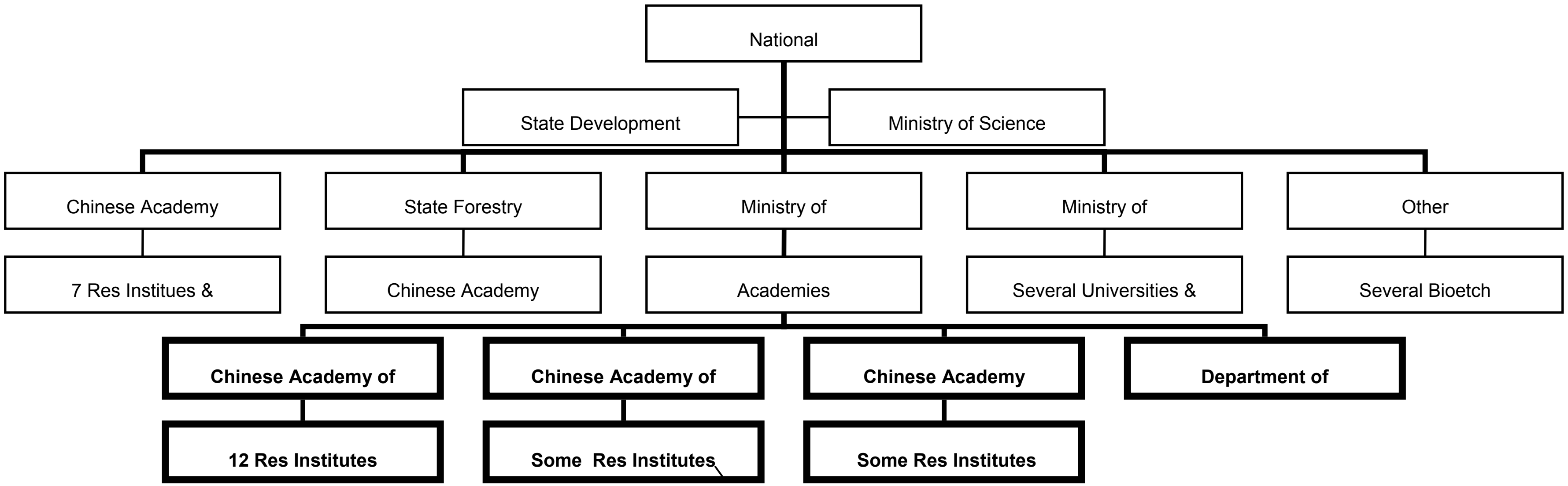
With the above efforts, by 2001 there were about 150 laboratories at national and local levels located in more than 50 research institutes and universities across China working on agricultural (plant and animal) biotechnology. Over the last two decades, China established 30 National Key Laboratories (NKL). Among these NKLs, 12 are exclusively working on, and 3 have major activities in agricultural biotechnology (Huang, Wang, Zhang, and Zepeda 2001). Besides NKLs, there are numerous Key Biotechnology Laboratories and programmes within Ministries and at provincial level.

At the national level, the Ministry of Agriculture, 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 2.1). Under the MOA, 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, 2 National Key Laboratories and 5 Key Ministerial Laboratories conducting biotechnology research programmes. The CAFi and the CATA also have several biotechnology laboratories or programmes, and each has one NKL for biotechnology.

Agricultural biotechnology research is also conducted by national institutes external to the Ministry of Agriculture's research system. For example, under the CAS there are at least seven research institutes and 4 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 Agricultural University) under the Ministry of Education (MOE) 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 agro-chemical (e.g. fertiliser) research by institutes in the State Petro-Chemical Industrial Bureau.

While the programmes at the national level presented in Table 2.1 and Figure 2.1 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 2.1). 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 1–2 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).

Figure 2.1 Organisation chart for agricultural biotechnology research at national level



Finally, it is worth noting that the number of both national and provincial biotechnology programmes and institutes continue to increase. China is even considering establishing a new national agricultural biotechnology research centre, a mega research centre over the current 150 agricultural biotech laboratories. Based on these developments, if there were shifts in China's biotechnology developmental plan, they were favourable towards biotechnology research.

3 Agricultural biotechnology development

3.1 An overview

The focus of biotechnology development in the early stages was on cell engineering, tissue culture, and cell fusion and emphasised crops such as rice, wheat, maize, cotton, and vegetables (KLCMCB 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 "863 Plan" in 1986 (Table 2.1).

Bt cotton is the most successful agricultural biotechnology story in China. Cotton is ranked as the most important economic crop. 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 gene isolated from the bacteria, *Bacillus thuringiensis* (*Bt*), China's scientists transferred this modified *Bt* gene into major cotton cutivars by the so-called pollen-tube pathway transformation method. 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 programme.

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 commercialisation. 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, and Chen 1997), maize resistant to insects and with improved quality (Zhang *et al.* 1999), poplar trees resistant to Gypsy moth, soybeans resistant to herbicides, transgenic potato resistant to bacterial disease or Colorado beetle, among others (MOA 1999; 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). Genetic modified nitrogen-fixing bacteria and phytase have been commercialised since 1999. In terms of animals, transgenic pigs and carp have been produced since 1997 (NCBED 2000). Recently, Chinese researchers also announced the successful sequencing of the rice genome in 2002 (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 MOA in 1996, Chinese scientists have tried to use more than 190 genes transferred to over 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 been expanded after 1996 (Cheng and Peng 2002). By 2001, there were over 60 plants under research and 121 genes used for transformation (Peng 2002). The list of GM crops in trials is also impressive and differs from those being worked on in other countries.

3.2 Research priorities and products in the research continuum

In preparing research priorities, the officials from MOST and MOA provide general guidelines that consider the goals of China's biotechnology development for those who prepare the drafts of the research priorities. During the process of priority setting agricultural scientists play a very important role. They participate in all drafting stages for key documents. Some serve as members of the expert consultant committee for the formulation of priorities and directly participate in drafting the policy documents. Others participate in the consultation meeting before the final draft was presented to the decision makers at the national level. While individual interests might have impacts on the way to set research priorities, a large number of scientists across various disciplines participate in this policy formulation process, and this serves to minimise bias towards special individual interests. According to these outlines and the actual budget spent on agricultural biotechnology in the past 15 years, rice, cotton, wheat, maize, soybean, potato, and rapeseed receive much more attention than other crops (Table 3.1), which is consistent with the relative importance of the crops and farmers' demand for biotechnologies (i.e., *Bt* cotton).

Table 3.1 The number of cases in agricultural (plant, microorganism, and animal) biotechnology submitted and approved for field trials, environmental release, and commercialisation in 1997–2000

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

Rice is the most important food crop in China's agricultural economy. During the last three decades rice sown area has been about 27–29 per cent of total grain sown area or about 20 per cent of the total crop area in the country, with rice production accounting for 41–45 per cent of total grain production (NSBC 2001). While cotton is the number one cash crop with an annual sown area of about 5–6 million hectares (size of area is often associated with the seriousness of bollworm attacks in previous years), or nearly 4 per cent of total crop area. Insect pests, particularly the cotton bollworm (*Helicoverpa armigera*), have been a major problem for cotton production in northern China. China's farmers have learned to combat these pests using pesticides. However, China's bollworms developed further resistance to pesticides in the mid 1990s. With rising pest pressure and increasingly ineffective pesticides, the use of pesticides by cotton farmers in China has risen sharply. Farmers use more pesticide per hectare on cotton than on any other field crop (Huang, Hu, Rozelle, Qiao and Pray 2002). Per hectare pesticide cost reached US$ 101 in 1995 for cotton, much higher than that for rice, wheat or maize, and many times more than the level applied by most other farmers in the world. Cotton production consumes nearly US$ 500 million in pesticides annually (Huang, Hu, Rozelle, Qiao and Pray 2002).

Wheat and maize are the second and third largest crops in China by sown area. Each accounted for 15–16 percent of the total crop area in recent years. Production and market stability of these crops (including rice) are a primary concern of the Chinese government as they are central to China's food security.

Priority traits include those related to insect and disease resistance, stress tolerance, and quality improvement (Table 3.1). Pest resistance traits have top priority over all traits. Recently, quality improvement traits have been included as priority traits in response to increased market demand for quality foods. In response to growing concern over water shortages in northern China, stress tolerance traits – particularly resistance to drought – are gaining attention. Although no stress tolerant GM crop have been commercialised, the budget allocated to stress tolerance has been increasing and recently reached as much as the budget allocated to insect or disease traits (personal communications with MOST's officials). Stress tolerance has a more complicated mechanism that involves many metabolic pathways between the plant and its environment.

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 utilising transgenic plants to produce oral vaccines (BRI 2000).

By the end of 2001, genetically modified plants from 13 plant species and more than 50 genes had been approved for field trial, environmental release, and commercialisation. Thirty-six recombined microorganism's species and 51 strains have been involved in research with 89 genes for insect and disease resistance or nitrogen fixation.

3.3 Commercialisation of agricultural biotechnology

By the 2002, 18 transgenic cotton varieties generated by Chinese institutions and five varieties from Monsanto with resistance to bollworm have been approved for commercialisation in China. While several GM varieties of tomato, sweet pepper, chili pepper and petunia have also been approved for commercialisation since 1997, the area planted with these four crops remains small. Personal communications with several member of agricultural BC show that the economic benefits of adopting the current three MG crops are minimal or not at all, and so it has not been possible to attract any private company to invest in their commercialisation.

Table 3.2 presents our most updated estimates of *Bt* cotton areas sown in China in 1997–2001. *Bt* cotton varieties were approved for commercialisation in 1997, and the total area planted using *Bt* cotton had increased to 0.65 million hectares by 1999. In 2001, the area reached more than 2 million hectares and accounted for 45 per cent of China's cotton area. China's GM crop area follows that of the US, Argentina, and Canada in size. Although less than 4 per cent 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.

Table 3.2 Estimated number of research staff and expenditures on plant biotechnology research in China, 1986–2000

		Research expenditure		
Year	Number of Staff	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 and Zepeda 2001) and recent interviews in China. The results from our recent interviews show that the data in Table 3.1 are higher than our earlier estimates. Official exchange rate in the corresponding year is used to convert the domestic currency to US dollars.
4 Biosafety management and regulations

4 Biosafety management and regulations

4.1 Institutional setting

While 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 biotechnology applications and their commercialisation, 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 commercialisation, determines the list of GMOs for labeling and import or export policies for agricultural GMOs.

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.[5] Currently, the Committee is comprised of 56 members.[6] They meet twice each year to evaluate all biosafety assessment applications related to experimental research, field trials, environmental release and commercialisation of agricultural GMOs. They provide approval or disapproval of recommendations to OGEBA based on the results of their 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 Novel Food. The State Environmental Protection Authority (SEPA) participates in GMO biosafety management through the Allied Ministerial Meeting and through their members on the National Agricultural GMO Biosafety Committee. While SEPA has taken the responsibility of international Biosafety Protocol and most of international activities, particular the activities implemented by UNEP, SEPA's focus on biotechnology in China is limited to biodiversity.

Comparing China to the US and the EU, China has several unique elements with regard to the institutional setting of agricultural GMO biosafety management. The Ministry of Agriculture in China appears to have more power than its counterparts in the US and the European Union. The leaders in the State Council of the previous government believe that the MOA is more familiar with, and has more expertise in agriculture and agricultural GMOs than any other ministry. Moreover, because MOA in China is also in charge of pesticide use and its environmental assessment in agricultural production, the national leaders such consider MOA as 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 being paid to the environmental risks of GMOs, or even involve a potential conflict of interests as the MOA is primarily responsible for agricultural production, with many biotechnologies developed under MOA's own research system. The debates on whether SEPA or MOA is a more appropriate institution to take a leading role on biosafety have continued since the biosafety management system was set up in 1997. But under the current national administrative system, it is unlikely that SEPA will take a significant role in biotechnology unless there is a large reform of government structures by the new national leadership.

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5 The 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.

6 Biosafety Committee (BC) 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 administrators. All BC members are nominated by the Ministry of Agriculture.

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, 9 for recombined microorganisms for plant, 12 for transgenic animals and recombined microorganisms for animals, and 6 for GM aquatic organisms) are experts from various research institutes within the public sector. Their 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. There has been concern about the problem of heavy burdens on a few key individual scientists and also that there are too many biotechnologists on the Biosafety Committee.

4.2 Biosafety regulations

Before 2002, the principle governing China's agricultural GMO biosafety has been to adopt a product-based GMO management system. However, China has attempted to impose labeling regulations on GMOs and their 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 briefly reviewing the evolution of China's agricultural GMO biosafety regulations and policies in the past.

Following progress in China's agricultural biotechnology research, 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 general 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 in many aspects is similar to the US's 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 either field trials, environmental release or commercialisation in 1997–2000 (Table 4.1). Among them, 322 cases were 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. But if we decompose this data into different stages of GMO development and by crop, they do show that the numbers of cases approved for commercialisation declined in 2000 and no new GMO crops have been approved since 1999, excluding cotton, tomatoes, sweet peppers and petunias.

Table 4.1 Research focus of plant biotechnology programmes in China

Crops/traits	Prioritised 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 Arabidopsis

Source: Authors' survey.

Using the above approval case numbers alone may lead to erroneous conclusions regarding China's stance on GM development. Indeed, the small number of approvals for commercialisation of GM crops in 2000 (seven cases, Table 4.1) was due to many factors. First, in the prior year, 1999, a large number of cases were approved for commercialisation (27 cases, Table 4.1), almost all for *Bt* cotton. As expected there were fewer applications for *Bt* cotton commercialisation in 2000 as most of the *Bt* cotton varieties (nearly 20 varieties from both CAAS and Monsanto) had been earlier approved for commercialisation. Second, as argued by OGEBA and the BC committee, the existing food related GM crops were not ready for commercialisation due to lack of clarity about their food safety. For example, the food safety testing managed by MPH has not reached a conclusion as to whether the GM rice varieties submitted for commercialisation approval are substantially different from non-GM rice. Research on GM rice's food safety is still on-going. Third, testing for environmental safety and biodiversity impact has been limited in both scale and number of locations. Lastly, unlike *Bt* cotton that had been tested and adopted widely in other countries before approval in China, and is a non-food crop, rice is the most important food crop in China and in Asia and no GM rice has ever been commercialised anywhere in the world.

More recently, our communication with OGEBA's officials and BC's members 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 OGESA currently faces: "an appropriate regulatory approach *(to improve current practices),*[7] science-based safety assessment, capacity building, transparency, communication and information exchange (Cheng and Peng 2002).

Given the above discussion, it is no surprise that OGEBA declined three applications for GM rice commercialisation 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 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.[8]

Chinese policy-makers 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 and 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 programmes have expanded their scope into biosafety issues particularly for the following programmes: "863", "973" and the Special Foundation for Transgenic Plants Research and Commercialisation. A number of national institutes under the Ministry of Agriculture, the Ministry of Public Health and the State Environmental Protection Authority have launched various biosafety programmes, 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.

The development of more comprehensive and science-based safety assessment are reasons for the recent adjustment of China's GMO's commercialisation. Concern over the impacts of GMO development on agricultural trade is another important factor. 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 commercialisation in China as agricultural trade is 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

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7 Since biosafety management is a new activity for OGEBA, it is understandable that they are seeking a more appropriate approach even after years of commercialisation of non-food crops *(Bt* cotton).

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

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 towards GMOs in Europe are now softening, or whether policies may soon change, hence, a "wait and see" tactic in the short run in China is probable.

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 2.1). And then, the Ministry of Agriculture announced new implementation regulations on biosafety management, trade and labeling of GM farm products which took effect from March 20, 2002.[9] There were several important changes to existing procedures included in these guidelines, and also details of regulatory responsibilities after commercialisation. These included the addition of an extra pre-production trial stage prior to commercial approval, new processing regulations for GM products, labeling requirements for products marketed in both domestic and international markets, new export and import regulations for GMOs and GMO products, and local and provincial level GMO monitoring guidelines. Meantime, the MPH also promulgated its first regulation on GMO food hygiene in April 2002 and take effect after July 2002.

By the late 2002, the system of biosafety regulation in China has 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 commercialisation of agricultural biotechnology in their provinces, and assess and approve (or refuse) all applications of GM related research, field trials and commercialisation in their provinces. Only those cases that have been approved by the provincial biosafety management offices can be submitted to the National Biosafety Committee for further assessment. However, China still has a long way to go before all decreed regulations can be fully executed. Our three years of *Bt* cotton farm surveys across five provinces in 1999–2001 found that about half of *Bt* cotton varieties that had been adopted by farmers had not been approved by the National Biosafety Committee for commercialisation. These seeds are distributed to farmers mainly by local seed companies, local extension workers, research institutes, and small traders. The institutions, human capacity and financial supports for the implementation of GMO regulations fall far short of the necessary requirements. In addition to this, collaboration and coordination between ministries on research, commercialisation and biosafety management needs to be further strengthened.

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

5 Research capacity building and 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 and Rozelle 2002). For example, based on our 2000 survey of 29 research institutes in plant biotechnology[10] 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 5.1). 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.

Table 5.1 *Bt* cotton adoption in China, 1997–2001

	Cotton area (000hectare)		***Bt* cotton**
Year	**Total**	***Bt* cotton**	**share (%)**
1997	4491	34	1
1998	4459	261	6
1999	3726	654	18
2000	4041	1216	30
2001	4810	2091	43

Source: Authors' survey.

Similar to other agricultural research programmes in China, agricultural biotechnology research is primarily built upon research institutes. Among the 29 institutes surveyed, the number of agricultural biotechnology researchers in universities accounts for only 10 per cent of total research staff.[11] Among total researchers, nearly 60 per cent are professionals and the share of the professional staff has been increasing over time (Huang, Wang, Zhang, and 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 PhD degrees increased from only 2 per cent in 1986 to more than 20 per cent in 2000. This share is expected to continue to increase in the future. While the share of researchers with biotechnology PhD degrees is still low by international standards, it is interesting

[10] The survey was conduced by Center for Chinese Agricultural Policy (CCAP) and International Service for National Agricultural Research (ISNAR), detailed results are reported in Huang, Wang, Zhang and Zepeda (2001).

[11] In terms of the overall agricultural research system in China, researchers in universities account for about 8 per cent of the nation's total agricultural researchers.

to note that this share is much higher than those in the general agricultural research system. In China's national agricultural research system, PhD researchers accounted for only 1.1 per cent of the total professional staff in 1999 (Huang, Hu, and Rozelle 2002).

Even more dramatic growth has occurred in China's biotechnology research investment (Table 5.1). China's biotechnology research investment was trivial in the early 1980s (MOST 1990). While 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 4.2 million US$ in 1986 when China formally started its "863 Plan" (Table 5.1). By 1990, China's investment grew to 8.3 million US$. During this period, the research project budget nearly tripled and equipment expenses nearly doubled (Huang, Wang, Zhang and Zepeda 2001). While the growth rate of biotechnology research investment slowed between 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 per cent during this period.

China's biotechnology research investment increased considerably from 10.5 million US$ in 1995 to 38.9 million US$ in 2000, representing an annual growth rate of about 30 percent. 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 per cent 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 and 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 programme: the 10th Five-year Plan for biotechnology development. Under this plan, the total investment in agricultural biotechnology for the 10th Five-year Plan (2001–2005) is targeted to be 4 times the total amount spent on agricultural biotechnology in the past 15 years (1985–2000). If this goal is realised, China will account for more than one-fourth of the world's current public spending on agricultural biotechnology.

6 Concluding remarks

Agricultural biotechnology is considered by Chinese policy-makers 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 a world leader in biotechnology research and a major domestic supplier of biotechnologies. This objective is closely linked to the perception by Chinese policy-makers 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 commercialisation.

The institutional framework for supporting agricultural biotechnology research programme 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 programmes will be essential for China to create an even stronger and more effective biotechnology research programme 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 at high-potential areas, as critics argue but also at the needs of poorer farmers.

Many competing factors are exerting pressure on policy-makers to continue with research and commercialisation 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 within China in the near future. However, an equally important aspect of biotechnology development is the investment in biosafety management. Although China has been struggling with issues of environmental and consumer safety and its biosafety regulation system 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 in the local level does not improve to match research capacity. The results of the authors' recent survey of a large number of unapproved *Bt* cotton varieties adopted by farmers should provide a warning message to policy makers on the importance of effective enforcement of biosafety policy implementation at the local level. Investment in biotechnology R&D is essential for the nation to promote its biotechnology industry, investment in biosafety management capacity and policy implementation is also a critical factor for a health and sustainable development of this industry.

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