AGRICULTURAL BIOTECHNOLOGY POLICY PROCESSES IN CHINA

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BACKGROUND

Agricultural biotechnology, and particularly the field of genetically modified organisms (GMOs), has developed rapidly since the early 1990s. The global area of GM crops increased from 1.7 million hectares in 1996 to 39.9 million hectares in 1999, a 23-fold increase within 3 years, or an annual increase of 12.7 million hectares. However, GM crop area expansion significantly slowed down thereafter, increasing to 4.3 million hectares in 2000, only a 0.4 million hectare increase over the previous year (James, 2001). Most GM crops are planted in USA, accounting for about three-quarters of the global total in 2000 (James, 2001). In comparison, farmers demanding these technologies in many developing countries have limited access to them.

Institutional innovation has been much behind the development of this influential biotechnology (Paarlberg, 2001). Breakthrough technologies often require institutional innovations and new policies to ensure appropriate use, and to maximize potential benefits and minimize risks, if there are any, associated with their adoption. This is particularly relevant for GM crops, the centre of increasingly rancorous debate about the value of agricultural biotechnology. This debate has led to a large difference in biotechnology development strategies adopted by various countries, ranging from promotional, permissive, precautionary, to preventive policy postures (Paarlberg, 2001).

The different biotechnology development strategies adopted by various countries to a large extent reflect perceptions of policy makers of the role of biotechnology within society and the economy, of their effects

on environment and human health, and the balance of power between various stakeholders and actors in the policy process. The institutions and policy process surrounding new biotechnology development today involve a wide and growing range of actors, including scientists, government officials, international donors, transnational companies, food processing industries, traders, farmers organizations, consumers and NGOs, among others. The complexity of biotechnology means that the institutions and policies governing: research and investment, biotechnology commercialization, biosafety, food safety and consumer choice, intellectual property rights (IPRs), and trade also vary among countries (Paarlberg, 2001).

A particular national and local institutional and policy environment for the governance of biotechnology emerges from the interactions of different actors. Local contexts are especially important (NCB, 1999; Paarlberg, 2001). Too little work has been invested in trying to understand how the biotechnology policies are formulated and how national and local contexts influence policy processes. Clearly, no single agricultural strategy or regulatory framework is universally applicable, and so particular contexts matter. The challenge is what policy frameworks are realistic, given particular agricultural, environmental and livelihood priorities, scientific research capacities, regulatory frameworks and enforcement capacities, and broader economic and political contexts. Given the rapid pace of technological change and the fast-moving international regulatory environment, developing effective national policy process is a major contemporary challenge.

China has been selected as a case study country because it is a developing country with a large agricultural sector, and it may have implications for other developing countries in setting policies related to

biotechnology. The government in China sees agricultural biotechnology as a tool to help the nation improve its food security, raise agricultural productivity, increase farmer's incomes, foster sustainable agricultural development, and create competitive positions in international agricultural markets. China has initiated serious policy measures and ambitious biotechnology research programs since the middle 1980s (SSTC, 1990; NCBED, 2000; Huang, Wang, Zhang, and Falck-Zepeda, 2001). China is one of the first countries that commercialized the GM crops and now ranges as the fourth largest country in term of sown area of GM crops, after USA, Argentina, and Canada (James, 2001). A highly coordinated research effort to improve crops through biotechnology has been made for cotton, rice, maize, wheat, soybeans, tomato, tobacco and many other crops in China. Four GM crops have been approved for commercialization since 1997, including cotton, tomato, sweet pepper, and petunia (Cheng, 2000). GM crops such as rice, maize and others are also in the pipeline (OAGESA, 1999). Cotton varieties with the *Bacillus thuringiensis* (Bt) gene to control bollworm have spread widely. Huang et al have estimated that Bt cotton covered an area of 0.7 million hectares by 2000.

The recent increasingly diverging perceptions of GM crops worldwide, however, have impacted on policy makers when formulating biotechnology policies in both developed and developing countries, including China. While GM crops have continued to be generated in public research institutes, and while the number of imported GM crop varieties for field trial and environmental releases has been rising, the approval of GM crops, particular food crops, for commercialization has become more difficult since 1999. This reflects the influence of the global debate on GM crops, and particularly restrictions on imports to EU countries, on Chinese policymakers.

China, like many other developing countries, now faces a dilemma as to how to proceed on the further commercialization of GM crops. Some essential questions facing policymakers in China are as follows:

- *Should China allow the use of GM food crops?*
- *What will be the dominant global perspectives on GM crops in the future?*
- *What role can biotechnology play in agriculture, food security, trade, and environmental protection?*
- *How China can better formulate its policies on intellectual property rights, biosafety and food safety management to ensure that the nation benefits from this novel technology?*
- *Do existing institutions and policies guarantee the safe management and control of GM crops?*
- *What are the financial and human capacity requirements of establishing an internationally competitive biotechnology research program?*
- *What are the constraints that limit China in developing a strong biotechnology program consistent with its national objectives?*

Answers to these questions are critical to the government in fostering biotechnology development.

The goals of this paper are to have a better understanding of some of the questions raised above and the main features of policy and policy processes surrounding agricultural biotechnology, to trace the emergence of the current situation historically, and to identify potential issues for subsequent research.

The paper is organized as the follows. In the next section, the national context for biotechnology is presented. Our discussions focus on the

roles of agricultural technology in general and biotechnology in particular on China's food and agricultural economy, environment, and human health. Then an overview of national goals and policies on biotechnology are presented. In the third section, the development, research priorities and perspectives of agricultural biotechnology are followed. Policy processes are examined in the fourth section. In this section, biotechnology administration, policy formulation, implementation and challenges are discussed. The last section provides concluding remarks and lays out some preliminary ideas for the next phase of study.

1 THE NATIONAL CONTEXT FOR BIOTECHNOLOGY POLICY

Roles of Agricultural Biotechnology in China

During China's reform period, the rapid expansion of the real output of major food and agricultural products ranks as one of the nation's great achievements. This growth has mainly come from institutional changes, the mobilization of inputs, intensity of farming, and growth in productivity from technology changes (Huang, Lin and Rozelle, 2000). Increasing supply of agricultural products in the future in China may not be able to rely on increasing inputs as much as in the past. Other correlates of development, such as rising wage rates, environmental pollution, resource constraints, and China's joining WTO, mean that pressures will be on farmers to reduce input uses and lower production costs. When countries near input plateaus, further growth in output must begin to rely more on technological change. However, the declining growth rate of agricultural production, particular crop yields, suggests that China may encounter great challenges solely depending on conventional technology in increasing food production to meet growing domestic demand. Agricultural biotechnology that can speed up the path of technology innovation, has been considered as one of primary tools by both policy-makers and scientists to increase agricultural productivity, reduce production costs, improve the nation's food security, and raise China's agricultural competitive advantage in the future.

Food security, poverty and future demand for technology

The future demands on the agricultural research system in China will be sizable. The country has less than 10 percent of the world's arable land and 5 percent of world available water, but already feeds more than 20 percent of the world's population. To keep pace with

increased demands from projected population and income increases, food grain production in China will have to increase by close to 45 percent by 2020 (Huang et al., 2000; World Bank, 1999). Given the limitations on arable land and water, productivity increases will have to be the primary source of increases in output (World Bank, 1999).

Although tremendous progress was made in addressing China's poverty problem in 1980s due to general rural economic growth and government commitment to poverty alleviation, the progress has slowed down since the early 1990s. There were about 34 million rural people (3.7 percent of rural population) under the government poverty line in 1999. If applying the World Bank's poverty standard (1$ per day), the number of the poor raised to 106 million in 1999. The majority of today's poor live in marginal areas that are cut off from the economic mainstream. As argued by several studies from World Bank and ADB, the nexus between agricultural productivity growth, poverty reduction, and environmental sustainability is arguably strong in many developing countries. Without agricultural productivity growth in fragile environments and marginal areas, poverty incidence may worsen and environmental degradation will increase. Agricultural research will be the major source of productivity increases.

China traditionally has had a very strong agriculture research system that generated technologies adopted by millions of farmers to meet the increasing demand of food and agricultural products in the most populous country in the world. Research-led technological change has played an important role in crop productivity growth. In the 1950s, 1960s, and 1970s, China researchers developed a steady stream of productivity-increasing technology. China was the first nation to extend semi-dwarf rice varieties and drought and pest resistant wheat cultivars in the 1950s. Chinese scientists also developed hybrid rice in

the early 1970s and a number of successful varieties in the 1970s and 1980s. Several studies conducted by Chinese Academy of Agricultural Sciences (CAAS) show that technology contributed more than 40 percent of agricultural growth in the 1990s (Zhu and Shi, 1994; Zhu, 1997).

Recent studies on agricultural TFP further confirm that agricultural productivity growth has mainly come from technology, including both the expansion of HYVs and improvement in farming system (Hu et al, 2000; Huang, Rosegrant, and Rozelle, 1995; Fan and Pardey, 1997). Technology contributed half of the increase in rice yield between 1975-1992. More than 50 percent of the growth of grain production and nearly 40 percent of cash crop output between 1978 and 1992 can be attributed to agricultural research (Huang, Rosegrant, and Rozelle, 1995). The major outputs of agricultural research – improved varieties and hybrids – have come from national, provincial, and prefectural institutes as well as from agricultural universities (Huang, Hu, Zhang, and Rozelle, 2000).

There is concern, however, that overall growth of agricultural and food production has slowed down since the middle 1980s (Table 1). Annual growth of agricultural GDP fell from 7.1 percent in the early reform period (1979-84) to 3-4 percent thereafter. Among agricultural commodities, the growth of grain production declined most significantly. Annual growth of grain production fell from 4.7 percent in 1979-84 to 1.7 percent in 1985-95 and 0.4 percent in 1996-2000 (Table 1). There is growing concern as to whether innovation through conventional measures and traditional technologies will be able to meet the nation's central goal of food self-sufficient policy in the long term. China's future agricultural growth may have to rely more on progress in the speed of technology generation, particular before

reaching the nation's population peak in about 2030. Therefore, biotechnology is considered as one of the major tools to improve the national food security, reduce poverty, and increase farmers' income in China (MOST, 2000).

Pesticide uses, environment and human Health

China had ability of supplying enough food and fiber for its growing population from a limited land endowment in the past several decades mainly because of the Green Revolution combination of modern inputs, responsive varieties and increasing the intensity of farming system (Stone, 1988; Huang and Rozelle, 1996). One consequence of the rising intensity of farming is the sharply increasing frequency of pest occurrence over time in China's agriculture. Some estimated that the frequency of infestations have doubled over last 10 years (Huang et al. 1999). Increases in the intensity of crop production, longer periods of time when the crops are not monitored due to rising wages, and excessive pesticide use have led to higher pest populations and to higher resistance of pests to the pesticides that once effectively controlled them.

Because of the high incidence of pest infestations, various kinds of pesticides have been used on a large scale to protect crops from damage inflicted by insects and diseases in China since the 1950s (Stone, 1988). Especially during the past two decades, per hectare pesticide expenditures in crop productions has risen sharply for all crops (Table 2, rows 1 to 5). Moreover, the rate of increase of pesticides rose faster than other inputs, leading to a rise in its share of total costs (rows 6 to 10). Huang et al (2001a) estimated that by the late 1990s, China's farmers purchase and apply nearly US $5 billion of pesticides per year, making it one of the largest users of pesticides in the world.

Despite the high levels of pesticide spraying and significant gains in containing losses through pest control efforts, there is still large yield loss due to pest problem (i.e., 2-3 percent for grain and 5-15 percent for cotton, Table 3). For cotton production, the infestations from pests are more severe. Had farmers not sprayed, yields would have fallen nationally by 19 to 38 percent. The larger "gain" (or, more accurately, avoided loss) of cotton farmers when compared to grain farmers come from the fact that pests and pesticide use are both higher than that experienced by grain farmers. For example, pesticide use in cotton production was nearly 4 times as much as in rice (Table 2).

The rising pesticide use can have several drawbacks. In addition to the direct costs of the pesticides, highly concentrated application of pesticides not only contaminates the products of field crops, but also poses a serious danger to the agro-ecosystem (e.g., the surrounding soil and water quality) and human health (Rola and Pingali, 1995; Huang, Qiao and Rozelle, 2000). The increasing use of pesticides kills not only targets pests but also other organisms (beneficial and neutral) and may cause the resurgence of secondary pests. The breakout of brown and white-backed plant hoppers is a result from long-term excessive use of the pesticides with high toxicity and residues. On the other hand, increasing use of pesticides causes pollution of rivers and lakes through run off and seepage and become sources of ecological problems.

Huang, Qiao, and Rozelle (2000) claim that health costs and other external costs may be greater than the private cost of purchasing pesticides. Table 4 shows that people poisoned by pesticide ranged from about 53,300 to more than 123,000 each year in China in the past decade (the 1st column). Among poisoned people, average about

half of them relates to pesticide use in crop production.[1] Moreover, China had about, on average, 10,000 pesticide poisoning deaths every year (Table 4). The deaths due to improper and over use of pesticide in crop production are about 300-500 persons in normal years except for 1995 (741 persons) and 1996 (202 persons). The exceptional high level of deaths in 1995 was mainly caused by a substantial increase in pesticide use in cotton production in North China Plain where bollworm was a serious insect problem that year.

Alternatives to current agricultural chemical pesticide practices as a way of reducing pollution, lowering yield loss and improving human health is of critical importance in China. The government has been trying to extend integrated pest management (IPM) technology to control the increasing pest problems, but little progress has been made in the farm field. Small farm and very diversified farming system at individual household farms prevent the successful adoption of the IPM. Expanding host-plant resistance technology, particular biotechnology, has been showed to be the most effective way to reduce pesticide use without reducing crop yield (Pray et al., 2001 and Huang et al., 2001).

High production cost and the pressures from trade liberalization

Huang and Ma (2000) showed that the production costs of major crops in China are higher than the production costs in most exporting countries by a range of 10-40%. China will face great challenges after it joins WTO if the costs of crop production can not be reduced effectively. Among various inputs, labor inputs account for about 40-60% of total production costs, while this is only about 6-10% in USA and Canada. Pesticide use has been rising significantly. For example,

[1] The other half is due to purposive use of pesticides (e.g., suicide) or careless/mistakenly using pesticide.

in cotton production, the share of pesticide cost in the total material costs has been increasing and reached more than 20% by the late 1990s (Table 2).

Land consolidation is not expected to come with trade liberalization given the current institutional land arrangements and the social security system. Traditional mechanization mechanism in substituting labor may not be effective as the average farm size is only about 0.4 hectare. Technologies for substitution of fertilizer with other inputs so far are not available. Reduce fertilizer use to lower production costs is not feasible as crop yields have to keep rising with growing demand for agricultural products.

Avenues for lowering production costs have been limited to productivity increase and technological change. Alternatives allowing for reduction in pesticides and other inputs are available through progress in the modern biotechnology. Biotechnology techniques can allow breeders to make use of traits in wild and weedy relatives of cultivated plants and to introduce genes from other plants, from bacteria, or even from animals. Recent commercialization and rapid area expansion of Bt cotton in China have provided strong empirical evidence for government to promote the development of biotechnology in reducing costs of crop production. Several studies have shown that Bt cotton adoption will lower production costs by more than one fourth (Pray et al., 2001; Huang et al., 2001).

II BIOTECHNOLOGY DEVELOPMENT STRATEGY

China's leaders have paid great attention to agricultural technology. Technology is at the center of the "advancement of agriculture" (*kejiao xingnong*). The exhortation of Jiang Zemin, President of PRC, is widely quoted, "We are counting on breakthroughs in our agricultural research system. We need to begin *Re-inventing China's Green Revolution*" (Wei, 1998, pp. 1-2).[2]

Because of the important roles of agricultural biotechnology discussed above, of all agricultural technologies, biotechnology has been prioritised for increased public investment (Huang, Wang, Zhang, and Falck-Zepeda, 2001). In response to Science Editor Ellis Rubenstein's question about concerns in the West with GMOs and criticisms of biotechnology, President Jiang Zemin stated that "we are also very much concerned about these … The prevention of gene-based discrimination, …these are all issues of concern to us. 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…" (Science, 2000). This statement reflects China's position on biotechnology development: promoting the technology but showing precaution in relations to safety issues.

The goals of biotechnology development have been defined in several dimensions in China. From the point of view of users of biotechnology,

[2] Jiang Zemin's exact words were "*biran yao jinxing yici xinde nongye keji geming,"* which is literally translated as China needs to "should once again undertake a new agricultural technology revolution." To get to our translation, we use our translator's prerogative to interpret "should once again undertake a new" as "re-inventing" and "agricultural technology revolution" as "Green Revolution." Italics are ours.

the government defines the goals of biotechnology development as improving the nation's food security, promoting sustainable agricultural development, increasing farmer income, reducing pesticide use and improving the environment and human health, and raising its competitive positions in international agricultural markets along with other public agricultural development programs. From the point of view of the technology itself, the most frequent statement of the development goal of biotechnology in China is to create a modern, market responsive, and internationally competitive biotechnology research and development system (MOST, 1990 and 2000).

To meet the above goals, the government's plan to modernize the agricultural biotechnology system is composed of several main measures. These include measures that improve the innovative capacity (both human and physical capacity) of the national biotechnology program, that reform the current research system and provide better supporting institutions and incentive mechanisms, that promote development and commercialization of biotechnology, and increase investment in biotechnology research and development (MOST, 2000).

With the above goal and development strategy, despite a lack of universal acceptance of novel biotechnological products in policymaking circles worldwide, China is one of first few countries to commercialize GMO crops and distribute a biotechnological product - Bt cotton- on a large scale. While the policy on commercialization of biotechnology in the major grain commodities is not very clear now and more like a "wait-and-see-strategy", investment in biotechnology research has been rising substantially. The spread of Bt cotton has proceeded rapidly since the first year of this technology was commercialized in 1997. The benefits of Bt cotton to farmers in the

commercialized regions are obvious (Huang, Hu, Rozelle, Pray, 2001; Pray et al., 2000).

Institutional and Policy Measures

An ambitious scheme to promote biotechnology research was started in the beginning of "Seventh Five-year Plan" (1986-1990) when the first comprehensive National Biotechnology Development Policy Outline was issued. The Outline was prepared by more than 200 scientists and officials under the leadership of MOST, the State Development and Planning Commission (SDPC), and the State Economic Commission in 1985 and revised in 1986. Although the State Council issued this Outline 2 years later (in 1988), it has been used as policy guideline in developing modern biotechnology programs in China since 1986. A number of high profile technology programs have been launched thereafter (Table 5). Some of the most significant programs include "863High-tech Plan, "973 Plan, the Initiative of National Key Laboratories on Biotechnology, Special Foundation for Transgenic Plants, Key Science Engineering Program, Special Foundation for High-tech Industrialization, Bridge Plan, and so on (Table 5). A new "Agricultural S&T Development Compendium" that was announced recently in National Agricultural S&T Conference in January 2001 reemphasized the importance of biotechnology in improving the nation's agricultural productivity, food security, and farmers' income. The total investment in agricultural biotechnology for next 5 years (the period of 2001-2005) is targeted to be 4 times as total amount spent on biotechnology in the past 15 years (the period of 1985-2000).

Set up institutional framework for biotechnology program

Agricultural biotechnology research and development in China is overwhelmingly financed and undertaken by the public sector; private-commercial agricultural biotechnology research is minor. Policies

related to biotechnology in terms of development strategies, research priorities, and biosafety management are formulated by several ministries, including the Ministry of Sciences and Technology (MOST), State Development Planning Commission (SDPC), the Ministry of Agriculture (MOA), and the Ministry of Public Health (MPH) among others. Led by MOST and working closely with SPDC and MOA, these ministries are in charge of biotechnology research development strategy, research priority setting, and research program administration and management (see later sections for more details). After research institutes generate GMOs, field trials, environmental releases and commercialization are administered by the Agricultural Biotechnology Safety Committee (ABSC) under MOA. While MPH administrates the issues related to food safety of agricultural biotechnology.

Currently, there are about 150 laboratories at national and local level located in more than 50 research institutes and universities across the country working on agricultural (plant and animal) biotechnology (Figures 1 and 2). Over the last 2 decades, China established 30 National Key Laboratories (NKL). Among these NKLs, twelve NKLs are exclusively working on and 3 NKLs have major activities on agricultural biotechnology (Huang, Wang, and Zhang, 2001). Besides NKLs, there are ministerial and provincial biotechnology laboratories and programs.

At nation level, MOA, Chinese Academy of Sciences (CAS), State Forestry Bureau (SFB), and Ministry of Education (MOE) are the major authorities responsible for agricultural biotechnology research (Figure 1). Under MOA, there are 3 large academies, Chinese Academy of Agricultural Sciences (CAAS, about 8000 research and supporting staff), Chinese Academy of Tropical Agriculture (CATA), and Chinese Academy of Fisheries (CAFi). Among 37 institutes in CAAS, there are 12 institutes and 2 National Key Laboratories (NKL) and 5 ministerial

laboratories that conduct biotechnology research programs. CAFi and CATA also have several biotechnology laboratories or programs, and each has one NKL in biotechnology.

Agricultural biotechnology research is also undertaken by national institutes outside the MOA system. These include 7 research institutes and 4 NKLs under CAS, research institutes within the Chinese Academy of Forestry (CAFo) under the State Forest Bureau, and universities under the Ministry of Education (MOE). There are 7 NKLs located in 7 leading universities conducted agricultural biotechnology or agriculturally related basic biotechnology research. Other public biotechnology research efforts on agriculturally related topics include agro-chemical (e.g. fertilizer) research by institutes in the State Petro-Chemical Industrial Bureau.

Agricultural biotech research at provincial level follows 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 provincial level normally has 1-2 institutes or laboratories focused their works on agricultural biotechnology. Local biotechnology research is financed by both local government (core funding and research projects) and central government (research projects only).

While MOST is responsible for management of biosafety in general, MOA is in charge of the formulation and implementation of biosafety regulations on agricultural biotechnology in particular. Several divisions within MOA are involved in agricultural biosafety management. The Office of Agricultural Genetic Engineering Safety Administration (OAGESA) and the Biosafety Division of Agricultural Genetic Engineering (BDAGE) under the Center of Science and

Technology Development (CSTD) and the Planning Division under the Department of Science and Education are jointly responsible for the biosafety management. OAGESA and BDAGE focus mainly on biosafety assessment applications for GMOs and implementation of biosafety regulations. The Planning Division is responsible for the approval of GMOs release and making decisions on biosafety issues.

Strengthen research capacity for biotechnology

To create a modern and internationally competitive biotechnology research and development system, China has made great efforts to improve its innovation capacity of national biotechnology programs since the early 1980s. In contract to the stagnation or even declining trends of agricultural research expenditure and research staff in the late 1980s and the early 1990s (Huang and Hu, 1999), investment and research staff in biotechnology have increased significantly since the early 1980s. For example, based on a recent primary survey of 29 research institutes in the plant biotechnology conduced by Center for Chinese Agricultural Policy (CCAP) and International Service for National Agricultural Research (ISNAR), the number of researchers more than doubled in the past 15 years, and total investment in real terms nearly doubled every five years (Huang, Wang, Zhang, and Falck-Zepeda, 2001).

China's public agricultural research system, the largest in terms of research numbers in the world, employs more than 130,000 staff (Huang and Hu, 2001). China's agricultural biotechnology research system probably is also one of the largest in the world. Table 6 shows the number and composition of plant biotechnology research staff in a recent study conducted by the authors. The total researchers in 29 plant biotechnology research institutes reached 1657 in 1999 (Table 6). For China as a whole, we estimate that the number of researchers

in plant biotechnology could be over 2000.

Similar to other agricultural research programs in China, plant biotechnology research primarily is built around the research institutes (Table 6). Among 29 institutes surveyed, the number of plant biotechnology researchers in the universities is 166, accounting for only 10 percent of the total research staff.[3] Among the total researchers, nearly 60 percent are professional and the share of the professional staff has been rising over time (Table 6), again indicating rising human capacity in biotechnology research.

A more remarkable improvement has occurred in terms of human capacity to conduct biotechnology research. In 1986, there were only 5 researchers with Ph.D. degrees. The number of researchers with Ph.D. reached 141 in 1999 for 22 institutes and 203 for 29 institutes (Table 7). Among professional staff, the share of researchers with Ph.D. degrees raised from 2 percent only in 1986 to about 20 percent in 1999. This share is expected to keep rising in the future as the capacity to run Ph.D. programs in biotechnology has been strengthened. The percentage of professional researchers with Ph.Ds. in universities is much higher than that in research institutes. Among 124 professional staff in the universities, fifty-two had Ph.D. degrees in 1999, accounting for 47 percent. In the research institutes, the researchers with Ph.D. degrees among the total professional staff were 17 percent only in 1999, and this varied largely among the institutes. The large number of biotechnology research institutes and wide variety of levels of human capacity will be a challenge for China when consolidating its national biotechnology research programs for any given amount of research budget in the future.

While the share of researchers with Ph.D. degree in biotechnology 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 the national agricultural research system, the researchers holding Ph.D. degrees account for only 1.1 percent of the total professional staff in 1999 (Huang and Hu, 2001).

Remarkable growth has been observed in biotechnology research investment (Table 8). Biotechnology research investment was trivial in the early 1980s in China (MOST, 1990). For 22 institutes interviewed by the authors, the total investment in plant biotechnology research reached 16 million yuan in 1986 when China formally started its "863 Plan". By 1990, the investment grew to 27.7 million yuan, increased by 73 percent over 1986 or about 20 percent annual growth rate. The strong growth in this period was mainly due to increases research project budget (which nearly tripled) and equipment expenses (which nearly doubled). While the growth rate of biotechnology research investment slowed down to 4 percent in 1990-95 (this is expected as the large investment in biotechnology physical equipment was nearly completed in the early 1990s), the annual growth rate in the research project budget remained as high as 10 percent in 1990-95.

The second bold move of biotechnology programs was started in 1997. Several large biotechnology programs or programs with biotechnology components have been promoted since the middle 1990s. These include "the 973 Plan, the Special Foundation for Transgenic Plants, and the Key Science Engineering Program, the Bridge Plan, among others (Table 5). With the implementation of these programs, the biotechnology research investment increased dramatically from 32.7 million yuan in 1995 to 92.8 million yuan (8.27 yuan/US$) in 1999 for

[3] In terms of the overall agricultural research system in China, researchers in universities account for about 8 percent

the 22 institutes studied. This increase represented an annual growth rate of about 30 percent. Based on our best estimates, the total investment in plant biotechnology research alone could have reached 150 million in 1999 for the country as a whole.

The investment in biotechnology in China is mainly from government sources. Donors contribute only 6 percent of the total plant biotechnology budget for the 29 institutes studied in 1999 (Table 8). Budgets from competitive grants for research projects accounts for two thirds of the total budget and the share has shown an increase over time, reflecting the development moving from capacity building stage to research stage.

III DEVELOPMENT, PRIORITIES AND PERSPECTIVES ON AGRICULTURAL BIOTECHNOLOGY

Overview of Biotechnology Development

While the application of biotechnology in China has a long history, modern biotechnology developed only recently. It covers agriculture, medicine, chemistry, environment, and food processing. Several research institutes in CAAS and CAS as well as in universities initiated their first agricultural biotechnology research programs in the early 1970s (Huang, Wang, Zhang, and Falck-Zepeda, 2001). The research focus of biotechnology in the 1970s was on cell engineering, such as tissue culture, anther culture, and cell fusion etc. This research covered many crops, including rice, wheat, maize, cotton, vegetables and others (KLCMC, 1996). The most significant progress in biotechnology was made only with the development of transgenic techniques after 1983, particularly after China started its bold national

of the nation's total agricultural researchers.

biotechnology programs in 1986. Since then biotechnology laboratories have been established in almost every major academy and university. By the late 1990s, for example, there were over one hundred laboratories in China involved in research on transgenic plants (Chen, 2000). Bt cotton is one of the most often cited examples on the progress of agricultural biotechnology. Seven transgenic and 1 hybrid transgenic cotton varieties with high resistance to bollworm, have been registered and approved for commercialization in China (BRI, 2001). In addition, a number of other transgenic plants with high resistance to insect, disease, herbicide or quality improvement have been approved for environmental release, and are ready for commercialization. These include transgenic cotton resistant to fungal disease, transgenic rice resistant to insects or herbicide, transgenic wheat resistant to BYDV (Cheng, He and Chen, 1997), transgenic maize resistant to insects or with better quality (Zhang, et al., 1999).

The progress in plant biotechnology has also been made in recombined microorganisms such as recombined soybean nodule bacteria, genetically engineered nitrogen-fixing bacteria for rice and corn, and genetic engineered phytase for feed additives have been approved for commercialization since 2000 among others. In the transgenic animal sector, transgenic carp has been developed since 1997 (NCBED, 2000).

In medical science, ten National Key Laboratories (NKL) were founded in the 1980 and 1990s (Huang, Wang, Zhang, and Falck-Zepeda, 2001). In additional to NKLs, numerous laboratories in medical academies (both national and provincial), universities, and CAS have been established since 1985. The significant progresses were made in new genes cloning such as human primary diseases (i.e., hereditary diseases of the nervous system and blood diseases) and functional

genes of major tissues and organs. China also participated in global collaborative program in the sequencing of human genomics. Other progresses include genetic treatment of malignant brain tumors, cardiovascular disease, nervous system disease, and genetic modified vaccine such as hepatitis B vaccine, virus disease vaccine, genetic modified pharmaceuticals, and genetic engineering of antibodies and proteins among others. In the animal breast bioreactor area, human protein gene was expressed in goat breasts and interferon was produced from cow's breasts. In environmental biotechnology, the research has been conducted on recombined microorganisms, such as bacteria isolation for wastewater treatment (NCBED, 2000).

Agricultural Biotechnology Development

After the Office of Agricultural Genetic Engineering Safety Administration (OAGESA) of MOA was established in 1996, China approved 46 cases of GMOs from 57 applications for field trial, environmental release, and commercialization in 1997 (Table 9). Among the approved cases, four commercial licenses were granted in 1997: two for Bt cotton (one from CAAS and the other from Monsanto), one for extended shelf-life tomatoes and one for flower-color-altered petunias (Table 10). By July 2000, the total number of approved cases reached 251 (Table 9). Among these, thirty cases were for commercialization of plant crops, including Bt and Bt + CpTI cotton, tomato, petunia and sweet pepper and four cases for commercialization of microorganisms (OAGESA, 1999; Peng, 2000). For field trials and environmental release, China approved 17 recombined microorganisms, 2 transgenic fish, and 18 transgenic plants in 1997-1999, the later covers almost all major crops in China (Table 11).

Applied basic research on plant biotechnology

Isolation and cloning of new plant disease and insect resistant genes, including the genes resistant to cotton bollworm (Bt and CPTI), rice stem borer (Bt), rice bacterial blight (Xa22 and Xa24), rice plant-hopper, wheat powder mildew (Pm20), wheat yellow mosaic virus, and potato bacterial wilt (cecropin polypeptide) were completed (MOA, 1999; NCBED, 2000). These technologies have been applied to plant genetic engineering since the late 1990s.

After initiation of plant functional genomics research in 1997, progressive achievements have been made in this area for rice and arabidopsis. Significant progress has also been made in plant bioreactors, especially in utilizing transgenic plants to produce hepititics oral vaccines (BRI, 2000).

Transgenic plants resistant to insect

There are over 50 different plant species and more than 120 functional genes that have been used in plant genetic engineering in China since the middle 1980s (Author's survey), or over 95 organism species and more than 200 genes that have been involved in genetic engineering. Prioritized crops are cotton, rice, wheat, maize, soybean, potato and rapeseed. The traits introduced to these crops include insect resistance, disease resistance, herbicide resistance, stress tolerance and quality improvements (Table 11).

Transgenic plant resistant to disease

Transgenic plant resistant to disease also has made significantly progress in major crops, particular in cotton, rice and potato. The breakthrough on transgenic cotton resistant to fungal disease was made recently by the Biotechnology Research Institute (BRI), CAAS.

Disease resistant genes were introduced into major cotton varieties. Transgenic cotton lines with enhanced resistance to fungal disease were approved for environmental release in 1999 (BRI, 2000). Transgenic rice resistant to bacteria blight or rice blast was developed by the Institute of Genetics of CAS and China Central Agricultural University. These transgenic rice plants have been approved for environmental release since 1997 (Zai and Zhu, 1997; NCBED, 2000). For potatoes, synthesized cecropin polypeptide genes and transgenic potato lines resistant to bacteria wilt were developed by BRI in the middle 1990s. These transgenic potato lines were approved for environmental release in Beijing and Sichuan province in 1998 (Jia and Tang, 1998).

Other plant biotechnologies and recombined microorganisms

The most significant progress in transgenic plants with drought and salinity tolerance has been made in rice. This transgenic rice has been undergoing field trials since 1998. Besides plant genetic engineering, tissue culture techniques have also often been applied in horticulture, production of virus free potatoes and propagation of strawberries. Several adopted rice and sugar-beet varieties were developed by anther culture (Authors' survey). Progress has also been made in molecular marker assisted selection. For example, new high-yielding soybean lines with resistance to cyst nematode disease were generated in 1998. In agricultural microorganism research, genetic recombined nitrogen-fixing bacteria for rice or corn, and phytase for feed additives, were approved for commercialization in 2000.

Priorities of Agricultural Biotechnology Research

Since 1985, MOST has developed a Biotechnology Development Outline every five years. The Outline defines the goals and objectives of biotechnology development in agriculture, medicine, chemistry,

environment, and food processing. The Outline also provides policy measures and research priorities in each field of agriculture, medicine, chemistry, environment, and food processing. After the 5-year development outline is formulated, it is implemented through several programs in biotechnology or biotechnology related fields such as "the 863 Plan", "the 973 Plan", SFTP, KSEP, NSFC, and others (Table 5). Based on the Outline, each biotechnology program develops its own guideline that specifies the research priorities within its program for a certain period (usually 5 years), and also annually. In each program there is an expert committee with members from CAAS, CAS, leading universities and several other government organizations that formulate program guidelines. Therefore in the whole policy making procedure for biotechnology research, the scientists play a very important role in setting priorities.

Table 12 summarizes the research priorities of plant biotechnology identified in the Biotechnology Development Outline in various periods over the past 15 years in China. In the selection of major crops to be included in the biotechnology programs, cotton, rice, wheat, maize, soybean, potato, and oilseed crops have been consistently listed as the top prioritized crops for research funding from the national biotechnology programs since the middle 1980s. The total sown area of these crops was over 100 million hectares, accounted for more than two-third of the total crop area in 1990s (SSB, 1999).

Cotton is selected as the first prioritized crop not only because of its importance in the sown area, textile industry and trade, but also because of the serious insect problems associated with cotton production and rapid increase in pesticide application to control insects (i.e., bollworm and aphids). Per hectare pesticide expenditures in cotton productions increased considerably in recent decades, reaching

RMB 834 ($100) in 1995- - much higher than grain crops but lower than horticultural production (Huang, Qiao, Hu, Pray, and Rozelle, 2001). Cotton production alone consumed about US $500 million annually in recent years.

Rice, wheat and maize are three most important crops in China: each accounts for about 20 percent of the total cropping area. The production and market stability of these three crops are a primary concern of the Central Government. National food (grain) security has been a central goal of China's agricultural and food policy and has been incorporated into biotechnology research priority setting. These crops are prioritized crops not only for biotechnology programs, but also for non-biotechnology research programs (Huang and Hu, 2001), irrigation investment and other government support programs in agriculture (Huang and Ma, 2001).

Prioritized traits that can be genetically transferred into targeted crops include traits related to insect and disease resistance, stress tolerance, and quality improvement (Table 13). Among them pest resistant traits are the top priorities. As a recent study has shown various kinds of pesticides have been used on a large scale to protect crops from damage inflicted by insects and diseases in China since 1950s, particular after the 1980s (Huang, Hu, Rozelle, Qiao, and Pray, 2001). This study estimated that currently Chinese farmers might spend as much as 36 billion yuan (US$ 4.34 billion) annually on chemical pesticides.

The first generation of GM crops focus mainly on input traits, such as insect or disease resistance. Output traits, such as quality improvement traits, have only been included as prioritized traits recently in response to market demand for quality foods, particularly

rice and wheat, reflecting consumer income increases. Quality improvements are also associated with the recent government agricultural structural adjustment policy that emphasizes the production of better quality food. On the other hand stress tolerance traits, particular drought resistant traits, are gaining attention as there is a growing concern with water shortage in north China: a key wheat, maize and soybean production region. This would have serious implications for China's future food security and trade.

Role of the private sector: the Chinese private sector and multinational corporations

The vast majority of research into agricultural biotechnology is conducted in the public sector, as we have seen. However, there are examples of research collaborations between public sector institutes and particularly multinational corporations geared towards production for Chinese markets. Examples include: Biotechnology Research Institute collaborated with Pioneer in GM maize (Author's survey); Ricetech with Hunan Hybrid Rice Research Centre conducting research into GM rice (Pray, 1999); Delta and Pineland with CAAS in Bt-cotton biosafety management research; Monsanto in maize, cotton and rice; and Syngenta in GM rice.

In relation to commercialization and marketing of particular crops, the private sector is assuming a role of growing importance. Three developments are worth noting. The seed business in China has been undergoing gradual liberalization following the seed market reform in the late 1990s. A process of consolidation appears to be underway with mergers taking place between prefectural and provincial seed companies. Some of the gap between research and marketing is narrowing, as agricultural research institutes develop new collaborations with seed companies, or as seed companies develop

research capacity. Further to this new Chinese actors are entering seed markets, acquiring seed companies and making substantial investments. These include conglomerates with no previous experience in the sector. According to some informants there is anticipation that some of these companies might in the future develop to become major players in regional or even global seed markets. The potential profits anticipated from new GM technologies seem to be one factor in attracting this type of new investment.

The second area as we have seen is that links between research and commercialization and marketing may be changing. Some institutes or even individual scientists are setting up companies to market research products. While technical ownership of these companies often remains in the public sector, they are run on a market basis, in some cases even listed on domestic stock exchanges. Patterns of ownership and finance are clearly becoming more complicated in the agricultural biotechnology sector.

Thirdly, multinational corporations are expanding their activities in this area. The most prominent example has been Monsanto, which is the only multinational commercializing one of its GM products in China (*Bollgard*, Bt cotton). Monsanto together with Delta and Pineland began operating in Hebei in 1997, forming a joint venture with Hebei Provincial Seed Company, known as Jidai. A similar joint venture has been formed with the Anhui provincial seed company, but significantly not in the other key cotton producing province, Shandong, and as such the Monsanto market share remains significantly smaller in that province than in the other two. Were commercialization of GM food crops to go ahead, MNCs would be likely to enter those markets, particularly for maize where Monsanto and Pioneer have varieties that have passed environmental release stages of the biosafety process.

Some argue that it is in maize that MNCs expect the best returns on their investments. For rice the picture is less clear, with Monsanto significantly recently announcing that it would not be continuing development of GM rice. Syngenta, however, continues to operate in this area.

Perspectives on the role of Agricultural Biotechnology

Biotechnology will play a critical role in China's future: in agriculture, food security, supporting farmer incomes, environmental protection, human health, and in pursuing the comparative advantage of Chinese agriculture in international markets. There is little doubt that China's current development strategy of promoting biotechnology will continue in the future. However, the impacts of recent worldwide debates on GMOs and on the pace of commercialization and diffusion of this novel technology should not be underestimated. Indeed, after 24 cases from 4 crops approved for commercialization by 1999, China as with many other countries with strong biotechnology programs now faces a dilemma when making decisions over further commercialization of GM crops. Although biosafety and food safety concerns have assumed growing importance recently, the key constraint limiting Chinese promotion of biotechnology development might not come from domestic factors, but from the impacts of worldwide debates on the place of GMOs in agricultural trade. So far consumers have not created many problems for the development of GMOs in China.

Concerns with food and agricultural trade

Issues such as labeling of GM products and possible trade barriers resulting from concerns about biotechnology in those countries that follow precautionary and preventive policies could have impacts on the future commercialization of agricultural biotechnology in China. Agricultural trade had been an important contributor to the Chinese

economy, and to Chinese foreign trade. Despite a decline in the share of agricultural trade in China's total trade, the annual agricultural trade value increased from US$9,112.8 million in 1980-84 to US$25,772 billion in 1995-97, with an annual growth rate of 6.0% (SSB). During the same period, the annual growth rate of agricultural exports was 8.0%. China's agricultural trade balance has been in a surplus position since 1983. The annual agriculture trade surplus reached about US$ 4-6 billion in 1990s. While trade liberalization will increase imports of land-intensive bulk commodities, such as grains and oilseeds, exports of higher-valued, more labor-intensive products, such as horticultural and animal products are expected to rise (Huang and Rozelle, 2001).

It appears that trade concerns -articulated by MOFTEC- may have been the dominant factor in recent agricultural biotechnology policy processes. It is possible that several GM food crops would have been commercialized by now, were it not for uncertainties about potential impacts on export markets. The critical event here appears to have been the EU decision to ban Chinese soy sauce imports produced with GM soybeans imported from the US. The recent decision made by Thailand, the worlds leading rice exporter, to halt further development of GM rice may also have been significant. It is unclear whether public attitudes to GMs in Europe are now softening, or whether policies may change soon, hence, a 'wait and see' approach in China.

Concerns on biosafety and food safety

Concerns about biosafety and food safety were raised in the media in China when the criticisms of biotechnology were growing in the rest of world a year ago. Although in China the champions of biotechnology, most are the biologists, seem to have won the debate over the critics at this point how much public concern over GMOs there will be in the future is still unclear. The debate in China has involved scientists,

government officials and newspaper reporters: responses and reactions vary between different stakeholders and change over time, as more information becomes available on biotechnology.

Most biologists and government officials are very clear about the essence of the debate. However scientists in plant protection and human health tend to pay more attention to what are perceived as the scientific aspects of biosafety management, such as risk assessment, field management, field monitoring and monitoring techniques. What they are really concerned about is the potential risk of GMOs to humans and the environment, and with measures that can minimize the risk if there is any. Among scientists, the perspectives on biotechnology also differ to some extent. Some have a more environmentalist perspective and are concerned with the effect of GMOs on biodiversity, and they think that the development of GMOs will reduce the biodiversity of the ecosystem. The fear is that the commercialization of GM crops will produced a mono-cultural agricultural environment. They advocate a precautionary policy towards the research and development of transgenic plants. Biotechnologists take an optimistic view of GMOs and believe that any new product or technology is potentially risky, including both biotechnological and non-biotechnological products (Jia, 1999). They have argued that the main reason for this biosafety debate was economic conflict rather than scientific issues.

A consensus seems to be being reached in China that the most important thing a scientist or a biotechnologist can do is to reduce the negative effects and demonstrate the safety of GMOs. As a consequence of this consensus, research budgets allocated to biosafety management and study of biosafety have been raised. Several biotechnology research programs have expanded their scope into

biosafety issues since 1999, such as the Special Foundation for High-tech Industrialization and the Special Foundation for Transgenic Plants. A number of national institutes under the Ministry of Agriculture, the Ministry of Public Health and the State Environmental Protection Bureau have launched various biosafety studies, include capacity building for biosafety management and risk assessment, research studies on environmental safety and food safety, and monitoring of international practice and experience.

IV Administration and Policy Process of Biotechnology

Biotechnology research and administrative system

Several supra ministries and agencies are involved in the design of research strategies and priorities and in approving/allocating budgets. These include MOST, SDPC, MOA and MOE among others (Figure 1). A similar organizational structure is followed at the provincial level where Provincial Science and Technology Commissions (PSTC) are the key agency administering biotechnology programs (Figure 1). PSTC receives advice and guidelines from MOST in designing research strategy and priorities, and is allocated research fund for local level biotechnology activities.

At the national level, the senior science and technology entity, MOST, establishes overall agricultural biotechnology research and development (R&D) plans with MOA through its five-year and long-term plans. It proposes R&D legislation, and implements legislated policies. MOST also supervises, coordinates, and evaluates biotechnology R&D plans, projects and budgets – including some competitive grants which it administers. Four departments and centers under MOST administer its biotechnology programs (Figure 2). They are the National Center for Biological Engineering Development (in charge of High-Tech R&D, including biotechnology), the Department

of Rural & Social Development (especially the Biotechnology Division under this department, in charge of research program development), the Department of Infrastructure (especially Base Construction Division in charge of physical capacity building), and China's Center for Rural Development (in charge of commercialization of agricultural high-tech program).

Four giant high-tech and biotechnology programs, are run by MOST and SDPC. They are the "863 Plan, the "973 Plan, the Special Foundation for Transgenic Plants, and the Key Science Engineering Program (Figure 3 and Table 5). The "863" Plan, also called the High-Tech Plan, was initiated in March 1986 on the recommendation of 4 leading scientists (academicians) in China. The Plan supports a large number of applied as well as basic research projects to promote high technology R&D in China. Biotechnology is one of 7 supporting areas.

Key Science Engineering Program (KSRP) is another huge program started in the late 1990s under MOST and SDPC to promote infrastructure construction and physical capacity building for high-technology, including the biotechnology program. The first project on agricultural biotechnology (crop germplasm and quality improvement) was funded in 2000.

Similar to the "863 Plan", the "973 Plan" was initiated in March 1997 and launched in April 1998 to supports the basic S&T research. Life science with biotechnology as a priority is one of the key supporting areas. The Special Foundation for Transgenic Plants is a new and unique Foundation as its name spells out. It is a 5-year-program with 500 million yuan launched in 1999 by the MOST to promote research and development of transgenic plants (major crops) in China.

SDPC makes annual, five-year and long-term plans and ultimately determines national level financial budgets for all ministries. SDPC authorizes the Ministry of Finance (MOF) to transmit such funds to MOST for onward transmission to the various ministries (and their research institutes) and the Chinese Academy of Science (CAS). The principle institution under SDPC in charge of biotechnology is the Department of High Technology (DHI, Figure 2). Under DHT, there are several divisions responsible for different aspects of advanced technologies. The Agricultural Division specializes in agricultural biotechnology and together MOST co-manages one of the major agricultural biotechnology programs in China, namely the Key Scientific Engineering Program (KSEP). The other division (Industrialization Division) was established recently to promoting the commercialization and extension of biotechnology in both agricultural and non-agricultural areas through a large and unique program, called the High-tech Industrialization Program (HTIP, Figures 2 and 3, and Table 5).

MOA contains a Science, Technology and Education Department that coordinates national level biotechnology research within the Ministry's research system and attempts to coordinate R&D between national and sub-national levels and provide some guidance to lower jurisdiction institutes, but local institutions have considerable autonomy. Activities of research institutes that lie outside the domain of MOA are largely uncoordinated with MOA R&D. Coordination between institutes at local levels is generally weak – which contributes to unnecessary and inefficient duplication of efforts.

MOA contributes to agricultural biotechnology research programs mainly through its involvement in formulation of overall agricultural biotechnology research and development plans (i.e., five-year and

long-term plans; R&D legislation) and implementation of legislation and policies. This activity is coordinated by MOST. Only one Foundation was set in the late 1990s and run by the MOA, this is the China Agricultural Sciences and Education Foundation (CASEF). The budget of this Foundation is nothing, however, when compared with the biotechnology programs administered by MOST and SDPC. Moreover, biotechnology is only a small component of CASEF. The debate on which ministry is the appropriate institution to manage agricultural research programs in general, and agricultural biotechnology in particular, has been going for while. This debate has generally been resolved in favour of MOST. This may be explained by the fact that agricultural research institutes directly under MOA account for only 8 percent of total agricultural research staff and 12 percent of the total agricultural research budget in 1999 (Huang and Hu, 2001). Most of research is conducted at provincial (39 percent of the budget) and prefectural (35 percent of the budget) research institutes. Some agricultural research is also conducted at universities (8 percent of budget) and at CAS and other ministries (8 percent of budget in 1999) (Huang and Hu, 1999).

Based on the national guidelines provided by SDPC, MOST, MOA, provincial development plans, and consultations with other bureaux, the local Science and Technology Commission (CST) establishes an overall biotechnology research and development strategy through its annual, five-year and long-term plans, and ultimately determines provincial level financial budgets for all bureaux including funds for "key" programs, and for capital construction in the local province. CST also supervises, coordinates, and evaluates biotechnology R&D plans, projects and budgets. Compared to the research at national level, research budget allocation is less competitive at local levels.

Research coordination among NKLs is relative stronger than elsewhere due to the similar funding sources from national biotechnology programs. Each of these funding programs has a special committee composed of experts from different academies and universities. These set research priorities and evaluate research progress. While the institutional framework of agricultural research is comprehensive in the way it is laid out at national and provincial levels, lack of coordination among various players among local institutions has led to a large degree of overlap in agricultural biotechnology research. Weak coordination between institutes at local levels contributes to unnecessary and inefficient duplication of effort.

Biosafety Management, Regulations and the Policy Process

Principles of biosafety management

The theoretical principles that have been set by Chinese government in biosafety management are summarized as follows:

1. Equal attention should be paid to both biotechnology R&D and to safety management. The government actively supports and encourages biotechnology R&D through preferential policy measures, at the same time it pays great attention to biosafety issues. Promotion of biotechnology and its related industries must guarantee human health and environmental safety.

2. In safety issues prevention should be the priority. Based on the particular biotechnology product, negative ecological and environmental effects and potential dangers to human health in the period of experimental research, field trials, environmental release, commercialization and processing, storage, utilization and waste treatment etc should be prevented.

3. There should be cooperative management between related ministries. Biotechnology products are associated with many fields,

such as agriculture, forestry, pharmaceuticals and health, and food processing etc. Biosafety management involves not only human health and ecological and environmental protection, but also export and import management and international trade activities. Therefore, the cooperation among related ministries and agencies is necessary.

4. Management should be based on fair and scientific principles. Biosafety assessment must be based on science, the related manipulation techniques, monitoring processes, monitoring methods and results must be up to scientific standards. According to regulations, all released biotechnology products should be monitored regularly and corresponding safety measures should be adopted regarding monitoring data and results. A system of national biosafety assessment standards and monitoring of technology should be established.

5. Public participation. Consumers have the right to know the facts about the products of biotechnology. The public should be aware of similarities and differences between biotechnological and traditional products. The consumers have choice as to whether to use new genetically modified products or not.

6. Assessment should be on a case by case basis. Genetic information exchange during processes of genetic manipulation is complex, so specific analysis and assessment must be taken for every particular product. Based on requited information, appropriate safety measures should be taken according to the progress of genetic engineering. On the other hand, these scientific measures will be gradually improved and perfected with the development of technology, accumulation of experience, public opinion and acceptance (Liu and Zhu, 2001)

Biosafety management system

In general, biosafety management is implemented at 3 levels:

national, ministries and research institutes. The Ministry of Science and Technology (MOST) represents the national level and is responsible for the general management of biosafety. Recently, a new division for biosafety management has been set up within the National Center of Biological Engineering Development (NCBED, Figure 2). It is responsible for the administration of new regulations, for promoting academic exchange on biosafety, and coordinating different ministries involved with biosafety issues (Author's survey).

At the ministry level, the Ministry of Agriculture (MOA) is in charge of the formulation and implementation of biosafety regulations for agricultural biotechnology. Within the MOA, the Office of Agricultural Genetic Engineering Safety Administration (OAGESA) under the Department of Science and Education is responsible for the implementation of regulations (Figure 4 and Table 14). The Biosafety Committee on Agricultural Biological Engineering (BCABE) composed of officials from MOA and scientists from different disciplines including agronomy, biotechnology, plant protection, animal science, microbiology, environmental protection and toxicology, nominated by the MOA, is responsible for the biosafety assessment of experimental research, field trials, environmental release and commercialization of GMOs. The Ministry of Public Health is responsible for the 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 food since it has been designated as a New Resource Food. The State Environmental Protection Agency and MOA assume responsibility for environmental safety.

Within every biotechnology or research institute, there is usually a biosafety management group led by the director of the particular

research institute. The group is in charge of the reviewing application documents and biosafety related consulting services. The Biosafety Division of Agricultural Genetic Engineering (BDAGE) under the Center of Science and Technology Development, MOA, takes responsibility for accepting and pre-reviewing applications for biosafety assessment.

Biosafety regulations

The first biosafety regulation in China, "Safety Administration Regulation on Genetic Engineering" was issued by MOST in 1993, aiming at promoting the R&D of biotechnology in China (Appendix A). This regulation is a general guideline for implementing regulations of related ministries. The regulation consists of general principles, safety classes and evaluation, application and approval, safety control measures, and legal responsibilities. MOST required the related ministries to draft and issue corresponding biosafety regulations on biological engineering, but only MOA has issued the Implementation Regulations on Agricultural Biological Engineering in 1996 (Appendix B-1 and B-2).

According to this general regulation of MOST, MOA has organized an Expert Panel of 10 eminent professors and experts to draft the Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering (hereinafter referred to as the Regulation) during the period of June 1994 to October 1995. The Regulation was reviewed and approved at the Conference of the Standing Committee of MOA, and issued by the Minister of Agriculture as an order of MOA in July 1996.

In May 2001, the State Council issued new biosafety guidelines: 'Agricultural GMO Safety Regulations' (State Council, 2001; see

Appendix C). Although detail regulations corresponding to this general Guidelines that will be issued by the concerned ministries have not been announced, there are several important changes to existing procedures included in these guidelines, and also details of regulatory responsibilities after commercialization. These include the addition of an extra production trial stage prior to commercial approval; new processing regulations for GM products; labeling requirements for marketing; new export and import regulations of GMO products; and local and provincial level monitoring guidelines. Further detailed elaboration of these regulations is currently being drafted. A more detailed biosafety process may also strengthen China's hand were it to invoke the Cartegena Biosafety Protocol to deal with future trade issues on certain GMOs. It also may be possible to avoid WTO trade disputes where it can be shown that an adequate transparent and non-discriminatory national biosafety process has happened.

The National Environmental Protection Agency also recently published a biosafety framework, funded by UNEP (NEPA, 2000). This document has not however been followed by any change in institutional mandates: biosafety assessment continues to be managed by the MOA where institutional capacity resides. This is clearly felt to be the most realistic option in the Chinese context given resource constraints and the complexity of the issues.

Regarding food safety policy, “The Food Health Law of the People’s Republic of China” was issued by the Ministry of Public Health (MPH) in 1982, and amended in 1995. This is a general law for food health monitoring and management, and a major legal basis for other food health related regulations and standards. Transgenic food has been included in the wider category of “novel foods” in China, so the management of GM food has been added to the existing “Management

Regulation of Novel Foods", which was issued in 1990 by MPH. According to this regulation, any trial production or commercial production of a new food must be approved by MPH.

Other regulations related to biotechnology and safety issue are "Quality control guideline of recombined DNA products for humans" issued by MPH in 1990 and "Administrative measures for biological veterinary products" issued by MOA in 1996.

Biosafety policy process

Any application for field trials, environmental release and commercialization of GMOs, developed either by domestic institutions/companies or foreign institutions/companies, within the territory of China must follow the process specified in the Regulation (Appendixes B-1, B-2 and D). In addition of the required application documents, foreign institutions or companies must submit the related certificate of biosafety approvals from the original country to OAGESA.

Any experimental research, field trial, environmental release and commercialization of GMOs can only be conducted after biosafety assessment and approval applied on a step by step basis. Biosafety assessment applications for foreign companies or institutions should start from the field trial stage. Experimental research for GMOs in safety classes I and II can be approved by the Biosafety Committee at research institute level. Experimental research of GMOs of safety class III must apply for approval from related administrative agencies of the State Council after the pre-approval of the Institutional Biosafety Committee and the Director of the relevant institute. Field trials, environmental release and commercialization of GMOs of safety classes I, II and III must apply for approval of MOA. Any experimental research, field trial, environmental release and commercialization of

safety class IV GMOs must be submitted for the approval from the State Genetic Engineering Safety Commission after the investigation of MOA. For the commercialization application, food safety documents (certificate and report of toxicity experiment) should be submitted, in addition to pilot experiment and environmental release documents.

Only after approval for commercialization can a genetically modified new crop variety, veterinary medicine, pesticide, fertilizer and feed apply for registration. GMOs are still monitored and controlled by the Biosafety Committee even after commercialization, applicants should report the basic information (extension area, location and existing problems and so on) to OAGESA. Any GMO can not be used as germplasm for hybridization experiments without approval for environmental release.

In total, MOA received 446 applications for biosafety assessment in the period of 1997- 2000. 322 cases have been approved. The majority of the applications were for transgenic plants (Table 10).

Although the biosafety regulation and implementation system have been established in China, several problems have emerged during practice, for example, the monitoring system and consulting service at local and farm levels is relatively weak, and collaboration and coordination between ministries needs to be further strengthened.

Intellectual property rights

There are several agencies responsible for IPR management in China. These include the State Patent Office, The Trademark Office (the State Administration for Industry and Commerce), and the National Copyright Administration. China Patent Law was issued in 1984, amended in September 1992 and in 2000, and the new amended

Patent Law was become effective on July 1, 2001. The Regulations for implementation of the newly amended Patent Law were issued in 2001 too. With the development of biotechnology in China, a biotechnology division was set up under the State Patent Office, to promote and manage applications for and granting of biotechnology patents. In addition, An IPR Affair Center under the Ministry of Science and Technology was set up, this is a government consulting agency for IPR processing in China (SIPO, 1999).

From April 1, 1985 to the end of 2000, about 1265,974 applications for invention patents were filed with the State Patent Office, and 687,541 cases have been granted. Genetic engineering is ranked among the top 20 groups. But the amount of patent on genetic engineering accounted for only 1.1% of total patents granted in the 1990s (SIPO, 2000). Among the applications for genetic engineering patents, 75% of applications were made by foreign companies and research institutes. Applications submitted by Chinese scientists only accounted for 25%. Chinese scientists are facing great challenges from biotechnology companies and institutes of developed countries.

Regarding New Plant Variety Protection, the Regulations of PRC on the Protection of New Varieties of Plants were issued in 1997 and became effective on 23 April 1999 when China became the 39th member country of UPOV. Detailed regulations on the implementation of PVP have been put in effective thereafter. The use of new plant variety for propagating purposes by farmers on their own holdings is protected by the PVP policy (SIPO, 1997). The Plant New Variety Protection Office under MOA and SFA (State Forest Agency) has been established since 1999 and is responsible for granting PVP. The Seed Law was issued in 2000; the IPR of a new transgenic plant variety can now be doubly protected by PVP and the Seed Law.

In addition to protecting intellectual property and plant breeder's rights, policymakers are also concerned to protect farmer's rights. Balancing the IPR and farmers' rights is a challenging issue that the policy makers will face in the future, particularly after China's accession to WTO.

Capacity building in relation to IPRs is the other emerging challenge for China. This challenge may include several dimensions. Increase incentive mechanism and awareness of IPR within the Chinese scientific community are frequently mentioned issues by Chinese scientists and research administrators. A particular concern of IPAC in MOST is how to encourage Chinese scientists to identify more opportunities to seek patents on products and processes they develop. Scientists in the public sector have not traditionally seen patents as an important as peer recognition. The on-going policy allows the research institutes or the patent holders to have up to 35% shares in the profit generated from the technology. However, so far most research institutes have neither human capacity nor financial ability to manage the issues related to IPR.

Another area is the process of inspecting patent applications. This has become substantially more complicated following advances in biotechnology science, particularly functional genomics. The volume and complexity of patent applications is particularly demanding. International linkages contribute to building capacity in this area, including for example, links to WIPO where the former DG of the State Patent Office holds a key position.

Finally, China has been also increasing interest in looking for new ways

of using patented technologies from private sector in national biotech research program. The focus of capacity building efforts is on evaluating the costs and benefits of different models of collaboration and technology transfer, including licensing, MTAs and collaborative agreements.

V Concluding Remarks

The biotechnology development policies adopted by China largely reflect perceptions of policy makers of the role of biotechnology in its economy (production, consumption and trade) and of its effects on environment and human health. China decidedly considers agricultural biotechnology as a primary measure to improve its national food security, raise agricultural productivity, and create its competitive position in international agricultural markets. China also intends to develop itself in biotechnology as one of the leading countries in the world and to reduce any risks in the minds of policy makers associated with dependency of national food security on imported technologies. Investment in plant biotechnology and research capacity has increased remarkably since the middle 1980s. Agricultural biotechnology research programs and the institutions for supporting biosafety management are comprehensive. China is one of the first countries to commercialize GM crops, and was the fourth largest country by GM crop area in 2000. Furthermore, there are about 20 genetic modified plants that are in the pipeline for commercialization. Examination of research focuses reveals that food security objectives and current farmers' demands have been appropriately incorporated into priority setting.

Differing from many developed and other developing countries, the institutions and policy process related to this novel biotechnology involve only a narrow range of actors, mainly government officials,

scientists and traders. Although biosafety and food safety concerns have assumed growing importance recently, so far consumers have not created many problems for the development of GMOs in China. The key constraint limiting Chinese promotion of biotechnology development is not expected to come from domestic factors, but from the impacts of worldwide debates on the place of GMOs in agricultural trade. The trade concerns is a dominant factor in recent agricultural biotechnology policy processes and will continue to be an important factor affecting the speed of commercialization of GM food crops. The events of the EU decision to ban Chinese soy sauce imports produced with GM soybeans imported from the US and concerns of exporting agricultural commodities to Far Eastern Asian countries are closely associated with the recent State Council decree of new biosafety guidelines for agricultural GMOs. While there is little doubt that China's current development strategy of promoting biotechnology will continue to some extent in the future, the impacts of worldwide debates of GMOS and China's new biosafety guidelines for agricultural GMOs on the pace of commercialization and diffusion of this novel technology should not be underestimated.

In China, the majority of research into agricultural biotechnology has been conducted in the public sector. Recently, the private sector is assuming a role of growing importance in relation to commercialization and marketing of particular crops. Multinational corporations in the live sciences are expanding their activities in China. On the other hand, there seems a great room for improving the public and private coordination. The development of a strong IPR system for agricultural sector with hundreds of millions farmers is one of biggest challenges that China will face in the future.

Our review of the current institutional arrangements also shows that

the coordination among institutions, consolidation of agricultural biotechnology programs, and capacity building in biosafety management, particular biosafety management in local and farm levels, will be very necessary for China to create an even stronger and more effective biotechnology program in the future.

Regarding issues for future study in the policy-making processes, we propose that our Phase Two Case Study research work may focus on:

1. Stakeholder perceptions of the challenges associated with the new biosafety guidelines;
2. Investigation of the biosafety policy process for Bt cotton, including monitoring of biosafety post-commercialisation; and
3. Public/private comparison of biotechnology R & D and IPR.

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Table 1. The annual growth rates (%) of China's economy, 1970-2000.

	Pre-reform	Reform period		
	1970-78	1979-84	1985-95	1996-00
Gross domestic products	4.9	8.5	9.7	8.0
Agriculture	2.7	7.1	4.0	3.0
Industry	6.8	8.2	12.8	9.5
Service	na	11.6	9.7	8.0
Grain production	2.8	4.7	1.7	0.4
Oil crops	2.1	14.9	4.4	3.5
Population	1.80	1.40	1.37	0.97
Per capita GDP	3.1	7.1	8.3	7.0

Note: Figure for GDP in 1970-78 is the growth rate of national income in real term. Growth rates are computed using regression method. Growth rates of individual and groups of commodities are based on production data; sectoral growth rates refer to value added in real terms.

Source: SSB, Statistical Yearbook of China, various issues; MOA, Agricultural Yearbook of China, various issues.

Table 2. Pesticide uses in major crop productions in China, 1980-98.

Year	Rice	Wheat	Maize	Cotton	Tomato	Cucumber
	Per hectare pesticide cost (yuan at 1995 prices)					
1980	87	25	11	257	na	na
1985	118	23	12	292	na	na
1990	129	38	20	381	371	466
1995	207	64	59	834	868	803
1998	210	75	61	724	1122	1064
	Share (%) of pesticide cost in total material costs of crop production					
1980	5.8	1.9	1.0	13.1	na	na
1985	6.0	1.4	0.8	11.5	na	na
1990	7.5	2.7	1.6	18.1	4.8	6.3
1995	7.0	2.8	2.7	21.7	7.9	9.2
1998	8.0	3.0	2.9	19.9	7.8	7.3
	Million US$ converted at official exchange rate					
1980	655	164	51	280		
1985	434	78	23	172		
1990	713	198	72	356		
1995	762	220	161	542		
1998	849	290	200	418		

Note: Rural retail price index of pesticides is used to deflate the current value.
Source: State Economic Planning Commission and State Statistical Bureau.

Table 3. Official estimate of pest-related losses and losses abated from the existing pest control effort in China in 1990s.

	Proportion (%) of losses abated from pest control effort to crop production		Proportion (%) of actual losses occurred in the field to crop production	
Year	Grain	Cotton	Grain	Cotton
1990	7.6	19.0	3.2	5.3
1992	6.8	31.1	2.0	14.0
1994	7.2	38.1	2.0	11.8
1996	7.9	26.6	2.1	6.2
1997	9.3	29.1	2.4	6.3

Note: Actual crop production loss is due to inability of pest control effort by farmers. Crop production loss abated from the pest is the avoided loss after the existing pest control effort in the farm field.

Source: Computed by authors based on the data from MOA, Agricultural Yearbook of China.

Table 4. Number of pesticide related incidences in China, 1987-96.

Year	Poisoned			Deaths		
	Total	Farm production related	Others	Total	Farm production related	Others
1987	91466	32029	59437	16019	358	15661
1988	93524	32414	61110	13153	475	12678
1989	88879	25877	63002	11609	420	11189
1990	114404	45744	68660	13786	383	13403
1991	112881	49534	63347	13139	578	12561
1992	123150	69290	53860	10673	506	10167
1993	86987	44378	42609	8747	497	8250
1994	108196	71166	37030	6740	499	6241
1995	85437	58392	27045	4908	741	4167
1996	53304	26967	26337	3951	202	3749

Source: Agricultural Technology Extension Center, the Ministry of Agriculture.

Table 5. Major science and technology policy measures related to biotechnology in China since the early 1980s

Policy measures	Description
Technological transformation	Providing criteria of royalty and advanced payment to the scientists and the institutions for the technology transformation. The "Temporary regulation of technology transfer" was issued in 1985. The Technology Contract Law (draft) was issued in 1987, amended and completed in 1998. It was implemented by the State Economic Commission and includes both domestic and imported technologies.
Key Breakthrough S&T Program	Since 1982 the State Planning Commission (SPC, the later SDPC) has formulated the Program and updated every five years and approved. The projects are increasingly open to tenders from competing research institutions. One of major components of these projects is on biotechnology.
Patent system	Patent law promulgated 1985. Introduced as a complement to S&T awards in order to provide incentives for the discovery and dissemination of new technology. A total of 1599 applications on genetic engineering for invention patents were filed in past 14 years (1985 to 1999).
National Biotechnology Development Policy Outline	Prepared by more than 200 scientists and officials under the leadership of MOST, SDPC, and the State Economic Commission in 1985 and revised in 1986. Formally issued by State Council in 1988. The Outline defined the research priorities, development plan and measures to achieve the targets.
National Key Laboratories (NKLs) on Bioetchnolgy	Key laboratories equipped with advanced instruments have been established in agricultural biotechnology fields by the SDPC and the MOA since 1985, the laboratories should receive both domestic and foreign guest researchers and call for open projects. A total number of 30 NKLs in biotechnology have been established, and 15 NKLs are focused on plant, animal, and agriculturally related biotechnology. The MOST is responsible for NKLs establishment and assessment.
S&T Firms	Promotion of new research, development and production ventures. These may be established jointly by research or production and entrepreneurial units or may be independently

	operated by research or entrepreneurial units.
National Program for Key S&T Projects	Started in 1982 to promote the modernization of traditional industries and to enhance the nation's S&T capacity.
The Climbing Program	A National Program for Key Basic Research Projects.
Natural Science Foundation of China (NSFC)	Established in 1986 to support basic science research complementary with "863 plan" according to criteria of academic excellence. Life science and Agronomy are two support areas related to the agro-biotechnology.

Table 5 (Continued…). Major science and technology policy measures related to biotechnology in China since the early 1980s

Policy measure	Description
High Technology Plan (863)	Established in 1986 to support a large number of applied research projects 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 0.7 billion RMB.
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, legal regulations, et al.
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 S&T research. Life science is one of the key supporting areas.
Safety Committee	Bioetech Safety Committee was set up in MOA in 1997. The committee is in charge the implementation of agricultural biosafety regulations
Special Foundation for Transgenic Plants	A 5-year-program launched in 1999 by the Ministry of Science and Technology to promote the research and development of transgenic plants in China. The total budget of this program in the first 5 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 genoplasm and quality improvement) was funded in 2000 with 120 million RMB.
Special Foundation for Hightech Industrialization	A program supported by the SDPC to promote the application and commercialization of technologies, started from 1998
Bridge Plan	In 1999, MOA initiated the Bridge Plan, focused on diffusion of new technology that is about ready for diffusion.
New varieties protection	Regulation on the Protection of New Varieties of Plants was issued in 1999

Seed law	A first Seed Law was issued in December 2000. The Law indicates that the selection/breeding, GM plant varieties, experiment/testing, certification/approval, and extension must follow the safety evaluation procedures according to the regulation issued by the State Council. The sale of GM plant variety seeds should be labeled clearly and remind the safety control measures when applying the seeds.

Table 6. Numbers and composition of plant biotechnology research staff in the sampled institutes, 1986-99.

Year	Professional staff			Support staff			Total staff
	Mgt	Research	Sub-total	Technical	Other	Sub-total	
Staff number							
1986	82	203	285	80	276	356	641
1990	114	295	409	98	301	399	808
1995	164	371	535	111	322	433	968
1999	207	484	691	133	381	514	1205
1999a	264	705	969	233	455	688	1657
Composition (%)							
1986	13	32	44	12	43	56	100
1990	14	37	51	12	37	49	100
1995	17	38	55	11	33	45	100
1999	17	40	57	11	32	43	100
1999a	16	43	58	14	27	42	100
Staff number by institute and university in 1999a							
University	52	72	124	15	27	42	166
Research institute	212	633	845	218	428	646	1491

Note: All data are from 22 biotechnology research institutes except for those with 1999a that includes 29 institutes in 1999. These 29 institutes account for about 80% of research staff, about 85% of research expenditure, and more than 90% of research output in China’s plant biotechnology.

Source: Huang, Wang, Zhang and Falck-Zepeta, 2001.

Table 7. Professional research and management staff of plant biotechnology by education in the sampled institutes, 1986-99.

Year	Professional staff by education				Total
	Ph.D.	MS	BS	Others	
Staff number					
1986	5	39	172	69	285
1990	31	90	197	91	409
1995	72	112	238	113	535
1999	141	159	269	122	691
1999a	203	279	343	144	969
Composition (%)					
1986	2	14	60	24	100
1990	8	22	48	22	100
1995	13	21	44	21	100
1999	20	23	39	18	100
1999a	21	29	35	15	100
Staff number by institute and university in 1999a					
University	58	35	27	4	124
Research institute	145	244	316	140	845

Note: All data are from 22 biotechnology research institutes except for those with 1999a that includes 29 institutes in 1999. These 29 institutes account for about 80% of research staff, about 85% of research expenditure, and more than 90% of research output in China's plant biotechnology.

Source: Huang, Wang, Zhang and Falck-Zepeta, 2001.

Table 8. Plant biotechnology research budget in the sampled institutes, 1986-99

Year	By source								Total
	Core	Project	Equipment	Commerce	Consultant	Contract	Donors	Others	
Million yuan in 1999 price									
1986	4.2	5.4	4.9	0.0	0.0	0.0	1.5	0.0	16.0
1990	4.1	13.3	8.1	0.0	0.0	0.0	2.1	0.0	27.7
1995	4.8	20.3	3.3	0.1	0.0	0.0	2.6	1.5	32.7
1999	14.4	60.0	8.1	0.3	1.0	0.1	6.9	2.0	92.8
1999a	19.4	86.9	10.9	0.3	1.3	1.1	7.6	3.3	130.8
Composition (%)									
1986	26	34	31	0	0	0	9	0	100
1990	15	48	29	0	0	0	8	0	100
1995	15	62	10	0.3	0	0	8	5	100
1999	16	65	9	0.3	1.1	0.1	7	2	100
1999a	15	66	8	0.3	1.0	0.8	6	3	100
Research budget by institute and university in 1999a									
University	2.4	29.4	2.6	0.2	0.0	0.0	0.8	1.3	36.7
Research institute	17.0	57.5	8.2	0.2	1.2	1.1	6.9	2.0	94.1

Note: All data are from 22 biotechnology research institutes except for those with 1999a that includes 29 institutes in 1999. These 29 institutes account for about 80% of research staff, about 85% of research expenditure, and more than 90% of research output in China's plant biotechnology.. Exchange rate was 8.27 RMB/US$.

Source: Huang, Wang, Zhang and Falck-Zepeta, 2001.

Table 9. The number of cases in agricultural biotechnology submitted and approved for field trials, environmental release, and commercialization in 1997- July.2000.

	1997	1998	1999	July.2000	Total
Plant					
Field trial					
-- Submitted	**7**	21	14	na	
-- Approved	5	20	27(18+9)*	na	52
Environmental release					
-- Submitted	**35**	16	53	na	
-- Approved	29	8	28	na	65
Commercialization					
-- Submitted	**6**	9	30	na	
-- Approved	4	2	24	**1**	31
Microorganism					
Field trial					
-- Submitted	5	20	14	na	39
-- Approved	5	20	13	na	38
Environmental release					
-- Submitted	**2**	2	10	na	
-- Approved	1	2	6	na	9
Commercialization					
-- Submitted	0	0	4	na	4
-- Approved	0	0	3	**1**	4
Animal					
Field trial					
-- Submitted	2	0	0	na	2
-- Approved	2	0	0	na	2
Environmental release					
-- Submitted	0	0	0	na	0
-- Approved	0	0	0	na	0
Commercialization					
-- Submitted	0	0	1	na	1
-- Approved	0	0	0	**0**	0
Total					
-- Submitted	**57**	**68**	**126**	**102**	**353**
-- Approved	**46**	**52**	**101**	**52**	**251**

Source: MOA

*Applying for environmental release ,but approved for field trails only.

Tables 10. The cases of plant biotechnology approved for field trials, environmental releases, and commercialization.

	1997	1998	1999 (July)	Total
Field trials	5	19	20	44
Rice	1	7	13	21
Wheat	1	0	0	1
Maize	1	1	0	2
Cotton	0	1	4	5
Tomato	0	2	1	3
Tobacco	0	1	0	2
Papaya	1	0	0	1
Peanut	0	1	0	1
Melon	0	1	0	1
Cabbage	0	1	0	1
Guanghuoxiang	1	0	0	1
Environmental releases	29	8	14	51
Rice	0	1	1	
Maize	1	0	3	4
Soybean	1	0	0	
Cotton	6	2	6	
Potato	6	1	1	8
Tomato	3	1	1	5
Tobacco	4	1	0	5
Sweet pepper	2	0	0	2
Poplar tree	1	0	1	2
Commercialization	4	2	20	26
Cotton	2	0	14	16
Tomato	1	1	3	5
Sweet pepper	0	1	3	4
Petunia	1	0	0	1

Table 11. The available GM plant in China by 1999.

Crop	Introduced trait	Field Trial	Environmental release	Commer-cialized
1.Cotton	Insect resistance			
	Bollworm (Bt)	Yes	Yes	Yes
	Bollworm (Bt+CpTI)	Yes	Yes	Yes
	Bollworm (CpTI)	Yes	Yes	No
	Bollworm (API)	Yes	No	No
	Disease resistance			
	Verticillium & *fusarium* (Chi)	Yes	Yes	No
	Verticillium & *fusarium* (Glu)	Yes	Yes	No
	Verticillium & *fusarium* (Glu+Chi)	Yes	Yes	No
2.Rice	Insect resistance			
	Stem borer (Bt)	Yes	Yes	No
	Stem borer (CpTI)	Yes	Yes	No
	Rice planthopper	Yes	Yes	No
	Disease resistance			
	Bacteria blight (Xa21)	Yes	Yes	No
	Fungal disease	Yes	Yes	No
	Rice dwarf virus	Yes	Yes	No
	Herbicide resistance	Yes	Yes	No
	Salt tolerance (BADH)	Yes	No	No
	Ac/Ds (rice mutant)	Yes	No	No
3.Wheat	BYDV resis. & quality improv.	Yes	No	No
4.Maize	Insect resis. (Bt) & quality improv.	Yes	Yes	No
	Herbicide resistance	Yes	Yes	No
5.Soybean				
6.Potato	Disease resistance			
	Bacteria wilt	Yes	Yes	No
	PVY resistance	Yes	Yes	No
	Viroid resistance	Yes	Yes	No
	Disease resis. & quality improv.	Yes	Yes	No
7.Oil rape	Disease resistance	Yes	Yes	No

8.Tobacco	Insect resistance (Bt or CpTI)	Yes	Yes	Yes->No*
	TMV resistance	Yes	Yes	No
9.Peanut	Stripe virus resistance	Yes	No	No

Table 11 (Continued…) The available GM plant in China by 1999.

Crop	Introduced trait	Field Trial	Environmental release	Commer-cialized
10.Chinese cabbage	Turnip mosaic virus resistance	Yes	No	No
11.Tomato	CMV resistance	Yes	Yes	Yes
	TMV & CMV resistance	Yes	No	No
	Thelf-time altered	Yes	Yes	Yes
	Cold tolerance (afp)	Yes	Yes	No
12.Melon	CMV resistance	Yes	No	No
13.sweet pepper	CMV resistance	Yes	Yes	Yes
14.Chilli	CMV/TMV resistance	Yes	Yes	No
15.Papaya	PRSV resistance	Yes	Yes	No
16.Poplar tree	Insect resistance	Yes	Yes	No
17.Pertunia	Flower-color altered	Yes	Yes	Yes
18.pogostemun	Bacteria wilt resistance	Yes	No	No

*: Commercialized in 1992 but stopped in the middle 1990s due to trade issues.

Table 12. Research focus of plant biotechnology.

Crops/traits	Prioritized areas
Crops	Cotton, rice, wheat, maize, soybean, potato, rapeseed
Traits	
Insect resistance	Cotton bollworm and aphids
	Rice stem borer
	Maize stem borer
	Soybean moth
	Potato beetle
Disease resistance	Rice bacteria blight and blast
	Wheat yellow dwarf and rust
	Soybean cyst nematode
	Potato bacteria wilt
	Rapeseed sclerotio
Stress tolerance	Drought, salinity, cold
Quality improvement	Cotton fiber quality
	Rice cooking quality
	Wheat quality
	Maize high lysine content
Herbicide resistance	
Functional genomics	Rice, rapeseed and arabidopsis

Table 13. Authorities for approval of agricultural biological genetic engineering organisms

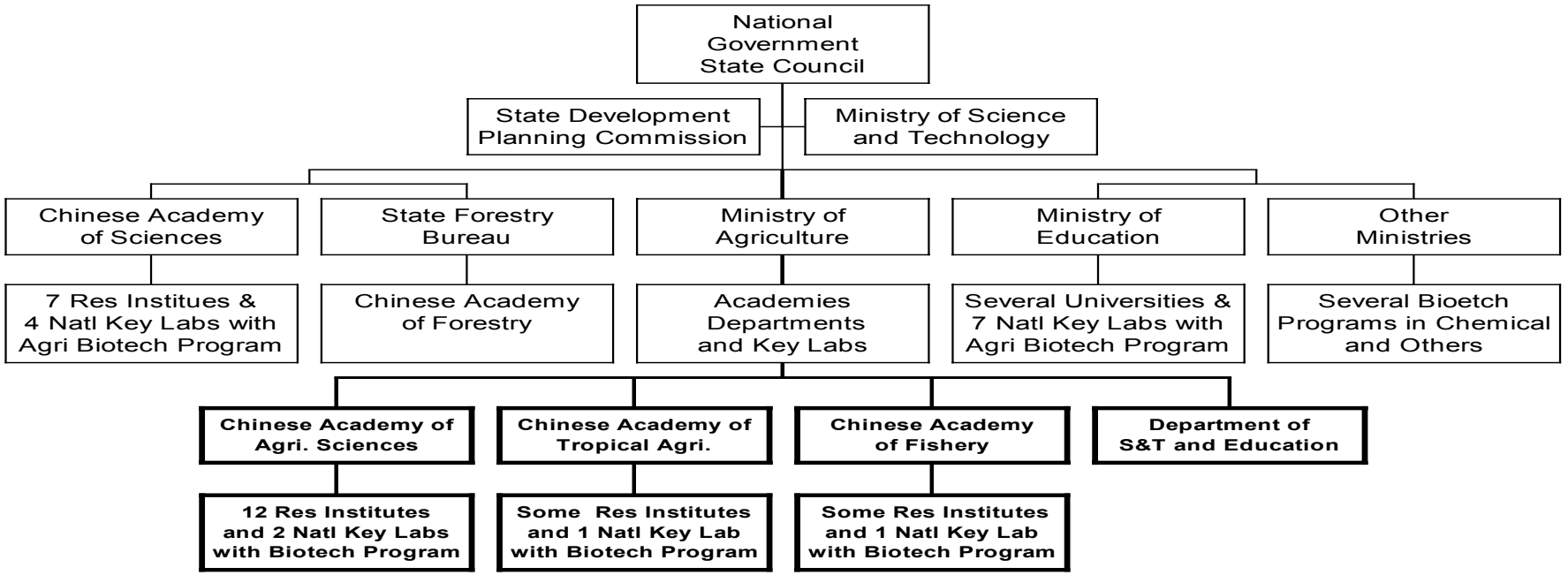
	Laboratory	Field trial	Environmental Release	Commercia-lization
Safety Category I	The chief administrators of the institutes	The chief administrators of the institutes and submitted to MOA for record	MOA	MOA
Safety Category II	The chief administrators of the institutes	Approved by MOA and submitted to the NGESC for record	MOA	MOA
Safety Category III	Examined by the chief administrators of the institutes and submitted to MOA for approval	Approved by MOA and submitted to NGESC for record	MOA	MOA
Safety Category IV	Examined by MOA and approved by the NGESC for approval	Examined by MOA and approved by NGESC	Examined by MOA and approved by NGESC	Examined by MOA, approved by NGESC

NGESC: National Genetic Engineering Safety Committee

Table 14. Authorized Testing Agency for Biosafety Assessment

Items	Authorized Agencies
Toxicity	National or Provincial Epidemic Prevention Stations; Or National or Provincial Preventive Medical Academies/Stations
Allergy	National or Provincial Epidemic Prevention Stations; Or National or Provincial Preventive Medical Academies/Stations
Disease or insect Resistance	Institute of Plant Protection, CAAS; Or National or Provincial Plant Protection Agencies
Environmental safety	Applicants
Soil microorganism	Institute of Plant Protection, CAAS; Or National or Provincial Designated Agencies

Figure 1: Organization chart for agricultural biotechnology research
A: At national level



B: At local level

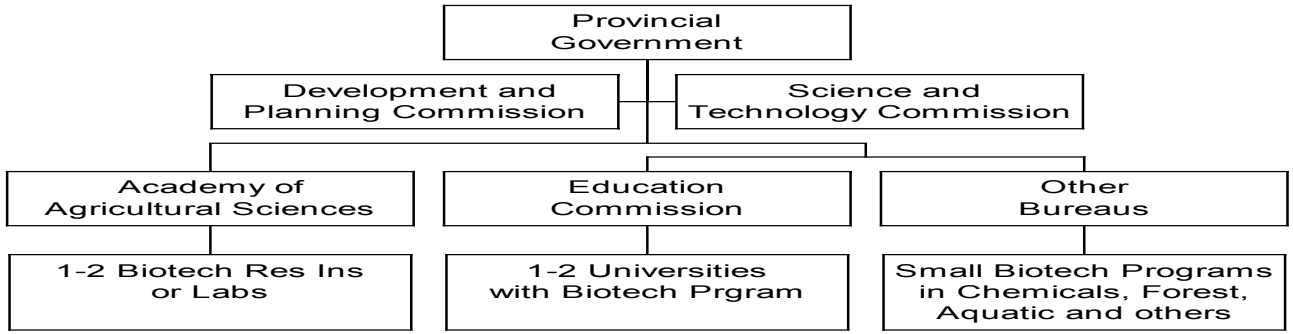


Figure 2. Administrative chart of biotechnology programs

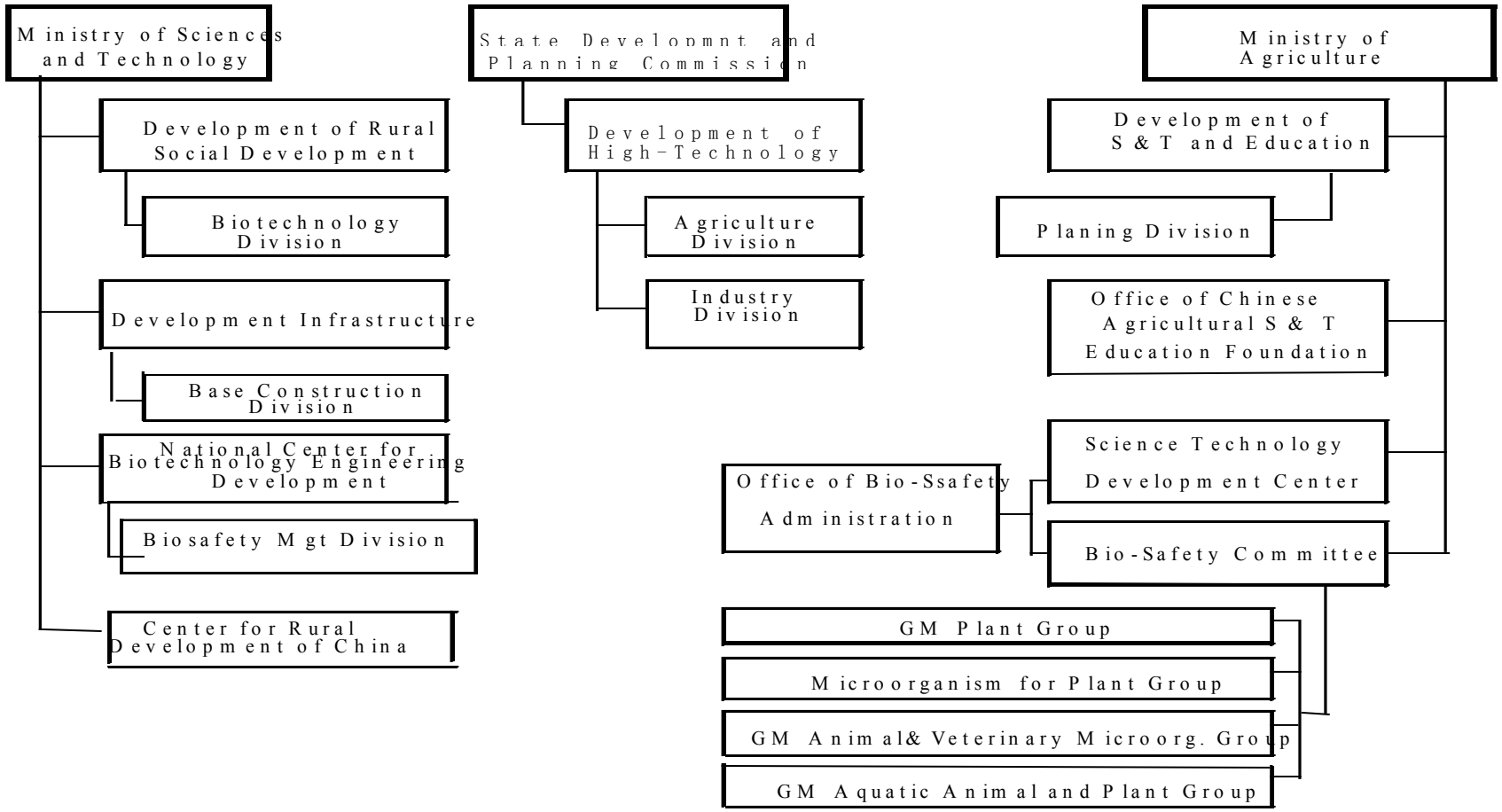
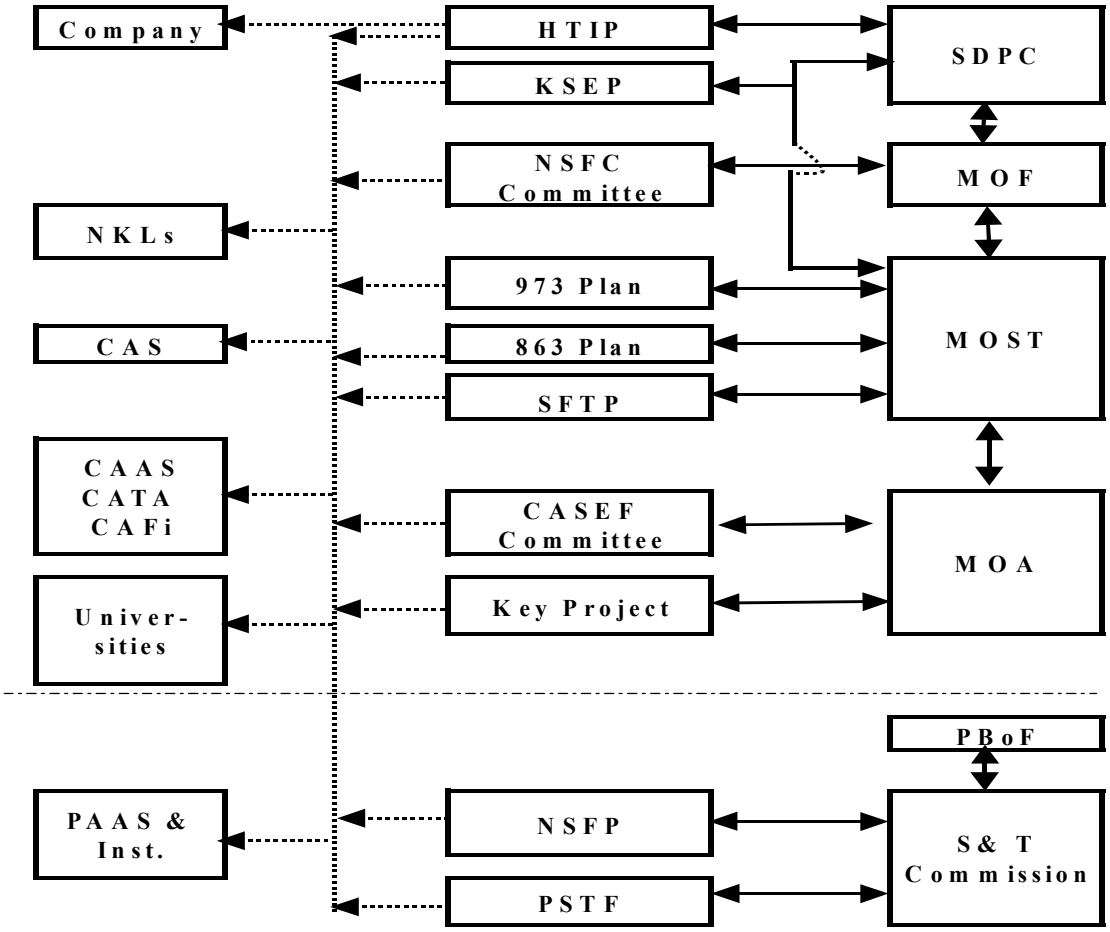


Figure 3. Flow chart of agricultural biotechnology R&D funds



⟷	Request for R&D funding and return flow of funds
→	Flow of funds
CASEF	China Agricultural Sciences and Education Foundation
HTIP	High-tech Industrilization Program
KSEP	Key Scientific Engineering Program
NSFC:	Natural Science Fundation of China
NSFP:	Sciences and Technology Foundation of Province
PAAS:	Provincial Academy of Agricultural Sciences
PBoF:	Provincial Bureanu of Financial
SFTP	Special Foundation of Transgenic Plants
Key Project:	Stopped in 1998

Figure 4. Authority System of Biosafety Administration on Agricultural Biological Genetic Engineering

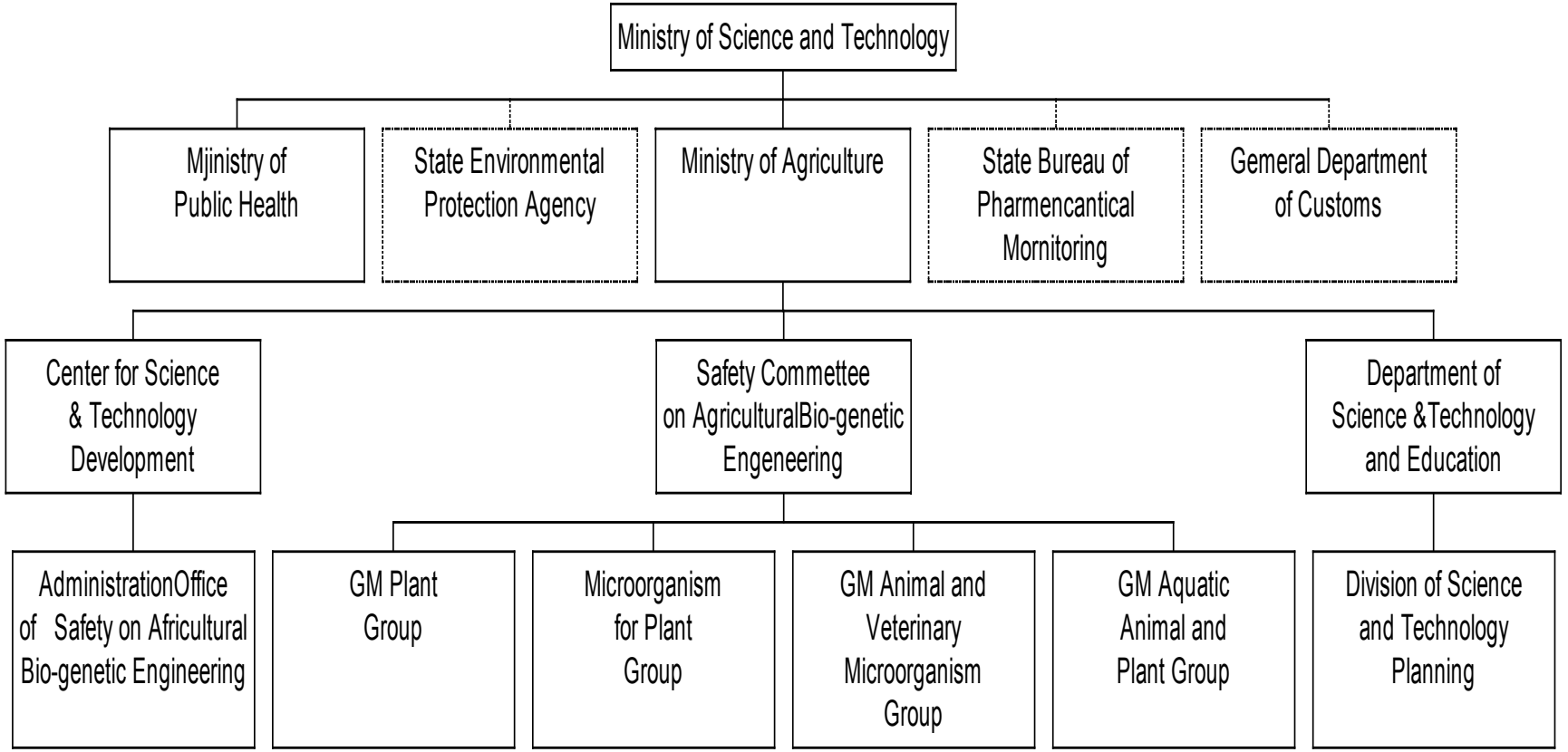
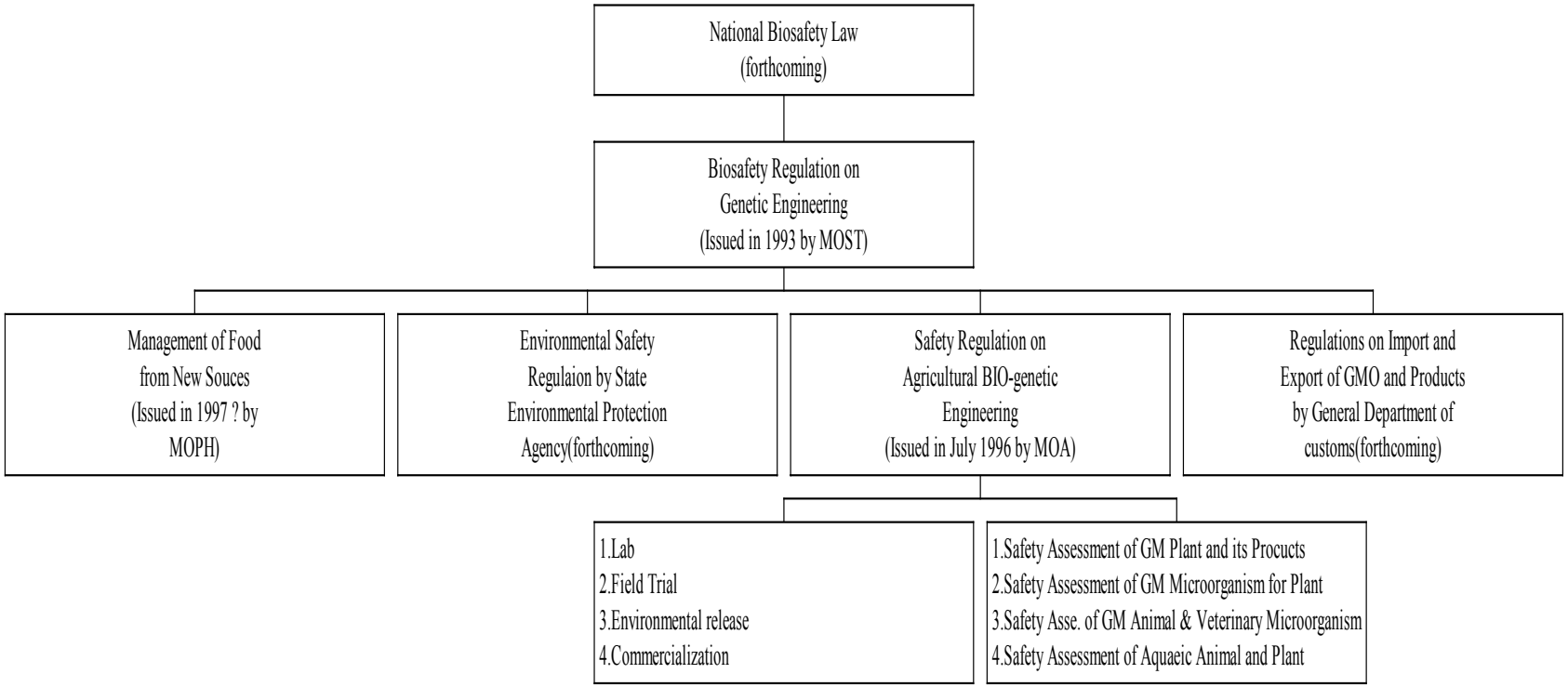


Figure 5. Legal and regulation framework of safety administration



Appendix A:
Safety Administration Regulation on Genetic Engineering

(Order No.17, the State Sciences and Technology Commission, People's Republic of China, 24 December 1993)

Chapter One: General Principles

1. This regulation is aimed at promoting research and development of biotechnology in China, tightening safety control of genetic engineering work, guaranteeing public health of common citizens and genetic engineering workers, preventing environmental pollution, and maintaining ecological balance.

2. The genetic engineering items covered in this regulation include recombinant DNA technology using the vector system, and direct introduction of heterologous DNA into organisms by using physical or chemical means. The following genetic manipulations are not included.
   (1) Cell fusion technology and protoplast fusion technology.
   (2) Traditional hybridization and propagation technology.
   (3) Variation induction technology, in vitro fertilization technology. Cell or embryo culture technology.

3. The regulation is applicable to all genetic engineering work underway in the territory of the people's Republic of China, including experiments, pilot tests, industrial production, release of genetic engineered organisms and utilization of finished genetic engineering products.

   The genetic engineered organisms imported from outside China when being adopted in genetic engineering work in China, should abide by this regulation.

4. The state Science and Technology Commission is responsible for the nationwide genetic engineering safety work. A national genetic engineering safety committee has been set up to handle safety supervision and coordination.

   Relevant administrative departments under China's State Council carry out safety administration of genetic engineering work according to the related regulations within their own responsibility scopes.

5. Safety administration of genetic engineering work is carried out on the basis of safety class control and classification approval, which means that different categories of genetic engineering work should be approved by relevant administrative departments.

Chapter Two: Safety Classes and Safety Evaluation

6. According to potential risk levels, genetic engineering work is divided into four safety classes:

   Safety class I: genetic engineering work of this class has no threat to human health and ecological environment.

   Safety class II: genetic engineering work of this class has low-level risk to human health and ecological environment.

   Safety class III: genetic engineering work of this class has intermediate-level risk to human health and ecological environment.

   Safety IV: genetic engineering work of this class has high-level risk to human health and ecological environment.

7. The technical and environmental standards of different safety classes for different categories of genetic engineering work are formulated by relevant administrative departments of the State Council of China, and then submitted to the national genetic engineering safety committee for record.

8. Institutions carrying out genetic engineering work should conduct safety evaluation to assess potential risk, determine safety class and work out corresponding safety control methods and measures.

9. Institutions carrying out genetic experimental research should conduct evaluation on DNA donors, vectors, hosts and genetic engineered organisms. The evaluation should be focused on the pathogenicity, carcinogenicity, chemical resistance, transfer possibility, and effects on environment of target genes, vectors, hosts and genetic engineered organisms, and on determining biological control and physical control classes.

10. Institutions carrying out genetic engineering pilot experiments or industrial production should conduct safety evaluation on the physical barriers of the equipment and facilities of the culture, fermentation, separation and purification processes according to genetic engineered organisms safety class, to determine the safety class of pilot experiments or industrial production.

11. Institutions carrying out the release of genetic engineered organisms should conduct evaluation on the safety of genetic engineered organisms, the purpose of the release, ecological environment conditions of the release site, releasing methods, monitoring means and control measures, to determine the safety class of the release.

12. Using finished genetic engineering products should conduct biological tests for safety evaluation, which will determine the possible impact of genetic engineering products on the public health and ecological environment.

Chapter Three: Application and Approval

13. Institutions carrying out genetic engineering work should submit applications to relevant administrative departments at different levels according to genetic engineering products' utilization scope and safety class before being approved to kick off.

14. Institutions carrying out safety class I and safety class II genetic engineering experiment research should get approval from the heads of their institution's administration. The work of safety class III should be examined by chief administrators of the institutions and then be submitted to relevant departments under the State Council for approval. The work of safety class IV should be examined by relevant State Council departments and then be submitted to the national genetic engineering safety committee for approval.

15. Genetic engineering pilot experiments of safety class I should get approval from chief administrators at the institutional level. The work of safety class II should be approved by responsible State Council departments. The work in safety class III should be approved by relevant State Council departments and be submitted to the national genetic engineering safety committee for record. The work in safety class IV should be examined by relevant State Council departments and submitted to the national genetic engineering safety committee for approval.

16. Genetic engineering industrial production, release of genetic engineered organisms and utilization of genetic engineering products, if in safety class I to III scope, should be approved by relevant administrative departments under the State Council and submitted to the national genetic engineering safety committee for record. The work in safety class IV should be examined by relevant administrative departments of the State Council and submitted to the national genetic engineering safety committee for approval.

17. Institutions carrying out genetic engineering work should go through the following application procedures:

    (1) The chief of the planned genetic engineering project should evaluate the safety of the project and fill in the application form.

    (2) The academic committee of the institution should conduct technical evaluation on the application.

(3) Application should be submitted along with technical documents.

18. All genetic engineering work meeting the following requirements should be given approval and certificates issued at the same time.

(1) No doubt has been found on the safety evaluation of the project applied.

(2) No threat to the public health and ecological environment has been found if the genetic engineering project applied has adopted safety control measures, which are up to modern scientific and technological standards, according to the requirement of its safety class.

(3) The project chief and staff members are qualified for conducting genetic engineering work and have acquired necessary professional knowledge and safety operation knowledge. They have no hesitation in carrying out the obligations specified in this regulation.

(4) The project accords with relevant state regulations and laws.

Chapter Four: Safety Control Measures

19. Institutions carrying out genetic engineering work should formulate safety control measures and work out safety operation regulations in accordance with safety class.

20. Institutions carrying out genetic engineering work should work out relevant safety measures to handle waste materials according to the safety class. The remaining genetic engineered organisms should be killed before discharge to prevent spread and environment pollution.

21. Institutions carrying out genetic engineering work should formulate measures to prevent emergency accidents. The measures should be listed as part of safety operation regulations.

22. Genetic engineered organisms should be stored in specific containers. The storage site should have its physical control fit in with their safety class.
The storage of genetic engineered organisms of safety class VI should be supervised by specific person.
Institutions carrying out genetic engineering work should compile a list of storage catalogues for inspection.

23. Transporting or transferring genetic engineered organisms should guarantee that specific containers used fit the safety class of the organisms. It should also be guaranteed that transportation or

transfer strictly abide by relevant sate laws and regulations on transporting or mailing of biological materials.

24. Institutions or individuals carrying out genetic engineering work should write down a detailed safety control record and keep the record for a period of no less than 10 years for inspection.

25. Institutions if causing harm to the public health or causing environment pollution due to carrying out genetic engineering work must take immediate measures to prevent the harm of the pollution from spreading and report to relevant administrative departments.

Chapter Five: Legal Responsibilities

26. In any of the following cases, relevant administrative departments will issue warnings, stop operation, suspend financial support, confiscate illegal profits according to actual conditions of violation.

    (1) The genetic engineering project begins operation without approval.

    (2) Equipment, apparatus, laboratories that do not fit in with regulations have been used.

    (3) Violation of safety operation regulations of genetic engineering work.

    (4) Violation of other rules under these regulations.

27. The approval office staffs who have direct responsibility for neglecting duties, receiving briberies or practicing irregularities will be punished with administrative disciplinary measures by the higher authorities.

28. The responsible unit of those violating this regulation and causing one of the following results must immediately stop the violation and take measures to handle the pollution and compensate for losses. In case a crime is caused, those who are directly responsible for will take criminal responsibilities according to laws.

    (1) Causing serious environment pollution.

    (2) Causing damage or harm to the public health.

    (3) Causing severe damage to ecological resources and ecological balance.

29. The staffs in the approval office and specialists who are involved in the approval process are responsible for keeping the technical secrets for applicants.

Chapter Six: Supplementary Articles

30. The meaning of the special terms in this regulation

(1) DNA, short for deoxyribonucleic acid, is the genetic material for storing genetic information of living things.

(2) Gene is a functional and structural unit of genetic information, which controls characteristic of living thing. It is the DNA section with genetic information.

(3) Target gene is the heterologous DNA fragment for the modification of genetic constitution of host cells, and for the expression of genetic information of host cells.

(4) Vectors are the DNA molecules capable of transferring heterologous DNA into host cells and capable of self-duplication.

(5) Host cells or receptor cells are those cells into which recombinant DNA molecules have been introduced.

(6) Recombinant DNA molecules are hybrid molecules, which consist of heterologous DNA and vector DNA.

(7) Organisms refer to the living cells or living things, which can propagate or can transfer genetic materials.

(8) Recombinants refer to the organisms into which the heterologous DNA has been introduced with natural factors or artificial means to change their genetic constitution.

(9) Variants refer to the organisms whose genetic materials are changed by natural factors or artificial factors.

(10) Recombinant DNA technology refers to the technology, which artificially modifies the genetic constitution of the organisms with vector systems. e. g. the recombination of heterologous DNA and vector DNA with enzymes and the recombinant DNA molecules is transferred into host cells to multiply heterologous DNA and express its function.

(11) Genetic engineered organisms refer to the organisms coming from the genetic manipulation of genetic engineering, including genetic engineered animals, plants and microorganisms.

The following variants and recombinants do not belong to genetic engineered organisms.

The living organisms coming from cell fusion and protoplast fusion.

The animals and plants coming from traditional hybridization technology.

The living things whose genetic constitution has been changed by physical and chemical inducing technology, and the living things which have teratogeny in their chromosome structure

and number.

(12) Genetic engineering products are products with genetic engineered organisms, its components or products coming from the expression of target gene in genetic engineered organisms.

(13) Genetic engineering experimental research refers to laboratory scale research work on genetic engineering conducted within a control system.

(14) Genetic engineering pilot experiments refer experiments or pilot production in a control system aimed at testification, supplementation of relevant data, determination and perfection of technical rules (product specifications and operation processing) to test the key technology for large scale production, before the application of genetic engineering experiment research results into industrial production (falling into production pattern and appraisal).

(15) Genetic engineering industrial production refers to commercial production of drugs, agricultural chemicals, veterinary chemicals, fodders, fertilizers, food, additives, raw material of the chemical industry in the control system by using genetic engineered organisms. It also includes utilizing genetic engineering in the technical processes of metallurgy, oil exploration and the recycling of waste materials.

(16) Release of genetic engineered organisms refers to research, production and application of genetic engineered organisms in an open system, including releasing genetic engineered organisms into natural ecological environments, such as cropland, grazing land, forests, mineral deposits and water areas. etc.

(17) Utilization of genetic engineering products refers to putting genetic engineering products into market for sales or for utilization by human being.

(18) Control system refers to the operation system established through physical and biological controls.

Physical control refers to airtight sealing of the equipment, special installation design and safety operation which aim at reducing the spreading of potentially dangerous DNA donors, vectors and host cells or genetic engineered organisms to the environment to the lowest level.

Biological control means using genetic modification to reduce to the lowest level the abilities of vectors and host cells with potential risks to survive, propagate and transfer outside the control system.

Any operation system not fitting in with the above-mentioned control conditions is called an open system.

31. Relevant administrative departments of China’s State Council should formulate their own detailed implementation measures according this regulation within the scope of their responsibilities.

32. This regulation is explained by the State Science and Technology Commission of China.

33. This regulation is enforced from the date of publication.

Appendix B:
Safety Administration, Implementation, and Regulation On Agricultural Biological Genetic Engineering
(Order No.7, the Ministry of agriculture, People's Republic of China, 10 July 1996)

Chapter One: General Principles

1. This implementation regulation (hereinafter referred to as the "Implementation Regulation") is aimed at promoting research and development in the area of agricultural biological genetic engineering in China, strengthening safety administration, preventing possible hazards caused by genetic engineered organism and its product to human health, environment on which human beings rely for existence and agricultural ecological equilibrium in accordance with the Safety Administration Regulation on Genetic Engineering (hereinafter referred to as the "Regulation") published by the State Science and Technology Commission.

2. This genetic engineering items covered in the "Implementation Regulation" include recombinant DNA technology by using the vector system, and introduction of recombinant DNA into organism by using physical, chemical and biological means.

3. The "Implementation Regulation" is applicable to agricultural organisms whose genome constitution has been changed by using genetic engineering technologies. The scope of agricultural organism includes plants and animals related to agricultural production, plant-related microorganisms, veterinary microorganisms, aquatic animals and plants. The following organisms are not included:

I. Plants obtained by using the following methods:

(1) Plants obtained via spontaneous generation, and by using artificial selection and hybridization technologies;

(2) Plants obtained from mutagensis via chemical or physical means; and

(3) Plants obtained by using organ culture, tissue culture and cell culture as well as protoplast fusion technology and chromosome ploidy manipulation.

II. Animals obtained via spontaneous generation and by using artificial se lection, artificial insemination (excluding recombinant DNA), super ovulation, embryo chimera, embryo partition, and nucleus transfer or ploidy manipulation technology.

III. Genetically modified microorganisms obtained by using the

following methods (excluding virus and subvirus):

(1) Chemical and physical mutagensis; and

(2) Transfer of non-recombinant DNA via transduction, transformation, and conjugation processes.

4. The "Implementation Regulation" is applicable to all agricultural biological genetic engineering work underway in the territory of the people's republic of China, including experimental research, pilot experiments, environmental release or industrial production of genetic engineered organisms.
   When agricultural biological genetic engineered organism and its products imported from outside China are planned to be used in pilot experiment, environment release and industrial production in the territory of the people's Republic of China, the applicant must first hold the certificate of conducting similar working the country of origin, and must submit application in accordance with the procedures stipulated in the "Implementation Regulation". Otherwise, no application will be accepted and processed.

5. The ministry of Agriculture will establish a Safety administration Office for Agricultural Biological Genetic Engineering to be in charge of the implementation of the "Implementation Regulation". A Safety Committee for Agricultural Biological Genetic Engineering will be set up to handle the safety evaluation of pilot experiments, environment release of industrial production of agricultural biological genetic engineered organism and its final products throughout the country.
   The production and business administration of agricultural chemicals, veterinary drugs and other biologicals, as well as agriculture-related plant seeds and seedlings will be implemented in accordance with relevant regulations of the State.

Chapter Two: Safety Classes and Safety Evaluation

6. According to potential risk levels, genetic engineering work is divided into four safety classes:

   Safety class I: genetic engineering work of this class has no threat to human health and ecological environment.

   Safety class II: genetic engineering work of this class has low-level risk to human health and ecological environment.

   Safety class III: genetic engineering work of this class has intermediate-level risk to human health and ecological environment.

   Safety class IV: genetic engineering work of this class has high-level risk to human health and ecological environment.

7. The following procedures should be followed in safety evaluation and safety class determination of genetic engineered organisms.

I. Safety class determination of recipient organism:

(I) Recipient organism which accords with one or more than one conditions listed below will be classified as Safety Class I:

(1) Recipient organism, which has never occurred unfavorable impact on human health and ecological environment;

(2) Recipient organism, which has little possibility of evolving into harmful organism;

(3) Due to the short life cycle, the specifically investigated recipient organism which has extremely little possibility of survival in natural environment after the completion of the experiment.

(II) Recipient organisms of Safety Class II refer to those which produce low-kevel risk to human health and ecological environment, but their risk can be completely avoided by adopting safety control measures.

(III) Recipient organisms of Safety Class III refer to those which produce intermediate-level risk to human health and ecological environment, but their risk can be fundamentally avoided by adopting safety control measures.

(IV) Recipient organisms of Safety Class IV refer to those that produce high-level risk to human health and ecological environment, and there is no appropriate safety measure to avoid the occurrence of such risk outside confined facilities. For example:

(1) Harmful organism that may exchange their genetic material with other organisms with high frequency;

(2) There is no effective technique to prevent the escape and spread of the harmful organism or its product;

(3) There is no effective technique to guarantee that the harmful organism, after its escape, can be captured or eliminated before it produces unfavorable impact on human health and ecological environment.

II. Determination of the impact of genetic manipulation on safety class

The major basis for the evaluation of the impact of genetic manipulation on safety class: The direct and indirect impact of genetic engineered organism and its products on human health and ecological environment, as well as its impact produced via the occurrence of genetic information exchange with other organisms.
People involved in genetic engineering work must make precise

evaluation on genetic manipulation, including gene transfer methods, characteristics of vectors, and the source, function, expression and stability of genes, etc.
The impact of genetic manipulation on the safety of recipient organism is divided into three types, i.e., improving the safety of recipient organism, having no impact on the safety of resilient organism, and reducing the safety of recipient organism.

Type 1 Genetic manipulation which improve the safety of recipient organism, include:

Deleting certain (some) gene (s) or inhibiting the expression of these genes, such as pathogenic genes, fertility genes, adaptability genes, etc.

Type 2 Genetic manipulations which have no effect on the safety of recipient organisms, include:

(1) Genetic manipulation in which the changes of the recipient organism's phenotype or genotype have no impact on human health and ecological environment, such as certain marker genes with no risks;

(2) Genetic manipulation in which the changes of the genetic trait of the known or expectable recipient organism have no unfavorable effect on human health and ecological environment, such as the storage protein gene for improving nutrition values.

Type 3 Genetic manipulations which reduce the safety of recipient organisms, include:

(1) Genetic manipulations which cause the occurrence of known or expectable genetic changes of recipient organisms and produce additional unfavorable impact on human health and ecological environment. Such as gene introduction which can produce harmful toxins;

(2) Genetic manipulations which affect gene expression, have inadequate knowledge of its outcomes, and have uncertainty of whether or not the risk of the final genetic engineered organism is greater than that of the recipient organism.

III. Determination of the safety class of genetic engineered organisms

The safety class of genetic engineered organisms is determined on the basis of the safety class of the recipient organism as well as the impact type and impact level of the genetic manipulation on the recipient organisms.

(I) Genetic engineered organism from recipient organism of safety class I

(1) The genetic engineered organism obtained fro, recipient organism

of Safety Class I via Type 1or 2 genetic manipulations still belong to Safety class I.

(2) The genetic engineered organism obtained from recipient organism of Safety Class I via Type 3 genetic manipulation still belongs to Safety Class I only if the safety reduction is very small and there is no need to adopt any safety control measures. If the safety has certain degree of reduction but its potential risk can be avoided through appropriate safety control measures, the safety class should be determined as Safety Class should be determined as Safety Class II. If the safety has been seriously reduced but its potential risk can be avoided through strict safety control measures, the safety class should be determined as Safety Class III. If the safety has been seriously reduced and its potential risk cannot be completely avoided through safety control measures, the safety class should be determined as Safety Class IV.

(II) Genetic engineered organism from recipient organism of Safety Class II

(1) The genetic engineered organism obtained from recipient organism of Safety Class II via Type 1 genetic manipulations belongs to Safety Class I, if the safety has increased to the extent that it no longer has any unfavorable impact on human health and ecological environment. If the safety level has been increased but it still has low-level risk on human health and ecological environment, the genetic engineered organism obtained from recipient organism of Safety Class II via type 1 genetic manipulation belongs to Safety Class II.

(2) The genetic engineered organism obtained from recipient organism of Safety Class II via Type 2 genetic manipulations belongs to Safety Class II.

(3) The genetic engineered organism obtained fro, recipient organism of Safety Class II via Type 3 genetic manipulations belongs to Safety Classes II, III or IV on the basis of the extent of safety decrease, with the same classification standard as that of the recipient organisms.

(III) Genetic engineered organism from recipient organism of Safety Class III

(1) The genetic engineered organism obtained from recipient organism of Safety Class III via Type 1 genetic manipulations belongs to Safety Classes I, II and III on the basis of the extent of safety increase, with the same classification standard as that of the recipient organisms.

(2) The genetic engineered organism obtained from recipient organism of Safety Class III via Type 2 genetic manipulations belongs to

Safety Class III.

(3) The genetic engineered organism obtained from recipient organism of Safety Class III via Type 3 genetic manipulations belongs to Safety Classes III or IV on the basis or the extent of safety decrease, with the same classification standard as that of the recipient organisms.

(IV) Genetic engineered organism from recipient organism of Safety Class IV

(1) The genetic engineered organism obtained from recipient organism of Safety Class IV via Type 1 genetic manipulations belongs to Safety Classes I, II, III or IV on the basis of the extent of safety increase, with the same classification standard as that of the recipient organisms.

(2) The genetic engineered organism obtained from recipient organism of Safety Class IV via types 2 or 3 genetic manipulations belongs to Safety Class IV.

Please refer to appendixes I, II, III, IV and V for more information on the safety evaluation of the genetic engineered organisms, including plants, animals, plant-related microorganisms, veterinary microorganisms and aquatic animals and plants, and their products.

8. Before conducting relevant experimental researches, pilot experiment, environment release and industrial production, institutions carrying out genetic engineering work should determine the safety class and work out corresponding safety control measures on the basis of the safety evaluation of the genetic engineered organism and its products.

Chapter Three: Application and Approval

9. Institutions carrying out genetic engineering work should submit applications to relevant administrative departments at different levels according to the safety class of the genetic engineering work before approved to kick off.

10. Institutions carrying out safety Class I and Safety Class II genetic engineering experimental research should get approval from the heads of their institution’s administration. The work of Safety Class III should be examined by the chief administrators of the institutions and then be submitted to relevant departments under the State Council for approval. The work of Safety Class Iv should be examined by the Ministry of Agriculture and then be submitted to the National genetic engineering Safety Committee for approval.

11. Genetic engineering pilot experiments of Safety Class I should get approval from the chief administrators at the institutional level and

be submitted to the ministry of Agriculture for record. The work of Safety Classes II and III should be approved by the Ministry of Agriculture and be submitted to the National Genetic Engineering Safety Committee for record. The work of Safety Class IV should be examined by the Ministry of Agriculture and be submitted to the National Genetic Engineering Safety Committee for approval.

12. Genetic engineering industrial production, environment release of genetic engineered organisms, if in Safety Class I to II scope, should be approved by the Ministry of Agriculture. The work in Safety Class IV should be examined by the ministry of Agriculture and be submitted to the National Genetic Engineering Safety Committee for approval.

13. Institutions carrying out genetic engineering work should have their legal representatives to be in charge of the setting up of a genetic engineering safety administration group, and organize the examination of the application materials submitted by the institutions themselves and give safety instruction on relevant work.

14. Twenty copies of application forms along with relevant technical documents should be submitted to the relevant administrative departments. The Ministry of Agriculture accepts application approval twice a year, the receptive deadlines for application are March 31 and September 30 every year. Application materials which fail to meet the requirements (for example, incomplete documents) will be disqualified for approval.

15. Institutions carrying out genetic engineering work should work should go through the following application procedures:

(1) The chief of the planned genetic engineering project (applicant) should evaluate the safety of the project and fill in the application (refer to Appendix for the format.)

(2) The Genetic Engineering Safety Administration Group of the institution should conduct technical documents of the application.

(3) Application should be submitted along with related technical documents.

16. Application should include the following major technical documents:

(1) Application form;

(2) The biological characteristics of the recipient, gene, vector and genetic engineered organism, as well as the basis for the determination of the safety class;

(3) The impact of the genetic engineered organism and its product on human health;

(4) The favorable and unfavorable factors of the ecological environment of the release site on the survival, Propagation, spread and transmission of the genetic engineered organism, especially the possibility of acquiring target gene from the genetic engineered organism by other organisms in the environment;

(5) The monitoring method of the genetic engineered organism; and

(6) The proposed safety control measures and emergency measures to prevent the happening of accidents.

17. Application of the industrial production and large-scale application of genetic engineered products should be submitted along with technical documents of pilot experiment and environment release of the genetic engineered organism, and should accord with the stipulations of relevant regulations and laws.

18. All experimental researches, pilot experiments, environment releases or industrial production of agricultural biological genetic engineered organisms meeting the following requirements should be given approval and certificates issued at the same time:

(1) No doubt has been found on the safety evaluation of the project applied;

(2) No threat to public health and ecological environment has been found if the genetic engineering project applied has adopted safety control measures which are up to modern scientific and technological standards, according to the requirement of its safety class.

(3) The project chief and staff members are qualified for conducting genetic engineering work and have acquired necessary professional knowledge and safety operation knowledge. They have no hesitation in carrying out the obligations specified in the “Implementation Regulation”.

(4) The project accords with relevant state regulations and laws.

19. Institutions which accept the application of agricultural biological genetic engineering work should sign and issue approval or disapproval documents to applicants within 3 months starting from the deadline of each acceptance.

20. The staffs in the approval office and specialists who are involved in the approval process are responsible for keeping the technical secrets for applicants. Avoidance should be exercised for applications of personal involvement.

Chapter Four: Safety Control Measures

21. Institutions carrying out genetic engineering work should formulate safety control measures and emergency measures to prevent the occurrence of accidents in accordance with the safety class of the genetic engineering experimental research, pilot experiment, environment release and industrial production of the genetic engineered organism as well as the ecological environment of the release site.

22. Safety control measures include physical control, chemical control, biological control, environment control, scale control, etc.

23. Experimental research, pilot experiment, environment release and industrial production of genetic engineered organism of Safety Classes I, II, III and IV should adopt corresponding safety control measures. Please refer to Appendix VI for the details of the safety control measures and emergency measures.

24. Institutions carrying out genetic engineering work should work out relevant safety measures to handle waste materials according to the safety class. The remaining genetic engineered organisms of Safety Classes II, III and IV should be killed before discharge to prevent spread and environment pollution.

25. In the case of pilot experiment of the genetic engineered organisms of Safety Classes II, III and IV, monitoring should be conducted to the experimental area and its surrounding environment according to the approved monitoring duration after the completion of the pilot experiment. In the case of finding the spread and residue of any genetic engineered organism, effective measures must be taken to eliminate it.

26. Genetic engineered organisms should be stored in specific containers. The storage site should have its physical control fit in with their safety class.

    The storage of genetic engineered organisms should be supervised by specific person.
    Institutions carrying out genetic engineering work should compile a list of storage catalogues for inspection.

27. Transporting or transferring genetic engineered organisms should guarantee that specific containers used fit the safety class of the organisms. It should also be guaranteed that transportation or transfer strictly abide by relevant state laws and regulations on transporting or mailing of biological materials.

28. Institutions or individuals carrying out genetic engineering work should write down a detailed safety control record and keep the record for a period of no less than 10 year for inspection.

29. During the implementation period of proved pilot experiment and environment release of genetic engineered organisms of Safety Classes III and IV, safety inspection must be conducted by the project institutions themselves and the results of such inspection should be submitted to the relevant approval departments for inspection.

30. Institutions if causing harm to human health or causing environment pollution due to carrying out genetic engineering work must take immediate measures to prevent the harm of the pollution from spreading and report to relevant administrative departments.

Chapter Five: Legal Responsibilities

31. In any of the following cases, relevant administrative departments will issue warnings, stop operation according to actual conditions of violation.

    (1) The genetic engineering project begins operation without approval;

    (2) Equipment, apparatus, laboratories that do not fit in with regulations have been used;

    (3) The safety control measures adopted fail to meet the requirements stipulated in the approval documents;

    (4) Violation of safety operation regulations of genetic engineering work; and

    (5) Violation of other rules under the Regulation and this "implementation Regulation".

32. The responsible unit of those violating the Regulation and the "Implementation Regulation", and causing one of the following results must immediately stop the violation and take measures to handle the pollution and compensate for losses. In case a crime is caused, those who are directly responsible for will take criminal responsibilities according to laws:

    (1) Causing serious environment pollution;

    (2) Causing damage or harm to public health;

    (3) Causing severe damage to ecological resources and ecological balance; and

    (4) Causing great economic losses.

33. The approval office staff who has direct responsibility for neglecting duties, receiving briberies or practicing irregularities will be punished with administrative disciplinary measures by the higher authorities.

Chapter Six: Supplementary Provisions

34. The meaning of the special terms in this "Implementation Regulation":

(1) DNA, short for deoxyribonucleic acid, is the genetic material for genetic information of living things.

(2) Gene is a functional and structural unit of genetic information that controls characteristic of living things. It is the DNA fragment with genetic information.

(3) Target gene in the gene for the modification of genetic constitution of recipient cells, and for the expression of genetic information of recipient cells.

(4) Vectors are the DNA molecules capable of transferring heterologous DNA into recipient cells and capable of self-replication.

(5) Recipient organisms are those organisms into which recombinant DNA molecules will be introduced.

(6) Genome refers to the sum total of the chromosomes and all extra chromosomal genetic materials of a specific organism.

(7) Recombinant DNA technology refers to the technology, which artificially modifies the genetic constitution of the organisms with vector systems. i. e., the technology of recombining heterologous DNA and vector DNA with enzymes in vitro and introducing the recombinant DNA molecules into recipient cells with the objective to multiply heterologous DNA and realize its functional expression.

(8) Genetic engineered organisms refer to organisms coming from the genetic manipulation, including genetic engineered animals, plants, microorganisms, etc.

(9) Genetic engineering products are products of the genetic engineered organisms, its components or products coming from the expression of target gene in genetic engineered organisms.

(10) Genetic engineering work refers to genetic engineering experimental research, pilot experiment, and environment release of genetic engineered organisms or genetic engineering industrial production.

(11) Genetic engineering experimental research refers to

laboratory-scale research work on genetic manipulation conducted within a control system.

(12) Genetic engineering pilot experiment refers to experiment or pilot production in a control system aimed at verification and supplement of relevant data, determination and perfection of technical rules (product specifications and operation processing rules) , to test the key technology for large scale production, before the application of genetic engineering experimental research results into industrial production (falling into production pattern and appraisal).

(13) Environment release of genetic engineered organisms refer to research, production and application of genetic engineered of organisms in an open system, including releasing genetic engineered organisms into natural ecological environments, such as cropland, grazing land, forests, mineral deposits and water areas, etc.

(14) Genetic engineering industrial production refers to commercial production of drugs, agricultural chemicals, veterinary chemicals, feed, fertilizers, food, additives, raw materials of the chemical industry in the control system by using genetic engineered organisms. It also includes the technological processes of utilizing genetic engineering in metallurgy, oil exploration and waste treatment.

(15) Control system refers to the confinement or semi-confinement operation system established through physical and biological controls. Any operation system not fitting in with the above-mentioned control conditions is called an open system.

(16) Physical control measures refer to physical means adopted to restrict the survival and spread of genetic engineered organism and its products outside the experimental areas, e.g., the installation of fences to prevent the escape of genetic engineered organisms from the experimental areas or being carried away by human beings or animals to areas outside the experimental areas.

(17) Chemical control measures refer to chemical means adopted to restrict the survival, spread or residual of genetic engineered organism and its products outside the experimental areas, e.g., the disinfections of biological materials, tools and facilities.

(18) Biological control measures refer to biological means adopted to restrict the survival, spread and residual of genetic engineered organism and its products outside the experimental area, and to restrict the transfer of genetic materials from the genetic engineered organism to other organisms, e.g., setting up effective isolated areas as well as monitoring areas, clearing away species near the experimental areas which might

hybridize with the genetic engineered organisms, preventing the flowering of the genetic engineered organisms, or removing reproductive organs, etc. with the objective of preventing the transfer of the target genes of the genetic engineered organisms to relevant organisms.

(19) Environment control measures refer to methods which make use of environment conditions to restrict the reproduction of genetic engineered organisms and their products outside the experimental areas, e.g., controlling temperature, moisture, photo-period, etc.

(20) Scale control measures refer to methods that reduce the number of genetic engineered organisms and their products or reduce the area of experimental areas at the best way, with the objective of reducing the possibilities of a rapid and broad spread of the genetic engineered organisms and their products. And a fairly thorough elimination of the genetic engineered organisms and their products can be conducted when unexpected outcomes do take place.

35. The Ministry of Agriculture is responsible for the interpretation of the "Implementation Regulation".

36. The "Implementation Regulation" enters into effect on the date of its issuance.

Appendix B-1:

Safety Assessment of Plant Genetic Engineered Organism and Its Products

1 Safety Assessment of Recipient Plant

1.1 Historical background of the recipient plant.

1.1.1 The recipient plant is a wild species or a cultivar (indicate the scientific name and its uses).

1.1.2 Place of origin and date of introduction of the recipient plant

1.1.3 Historically, the possibility of the recipient plant evolving into harmful plant (e.g., weed, etc.).

1.2 Biological characteristics of the recipient plant

1.2.1 The recipient plant is an annual or a perennial.

1.2.2 Is the recipient plant toxic to human beings and other organisms? If it is toxic, indicate the location of the toxin in the recipient plant and the nature of the toxicity.

1.2.3 Reproductive modes of recipient plant: sexual or asexual. If in the case of sexual reproductive modes, is it self-pollination or allogamy or normal allogamy? Then is it insect pollination or wind pollination?

1.2.4 The cross-fertilization rate of the recipient plant with plants of the same species and close species in nature.

1.2.5 The recipient plant is fertile or sterile, and the level of fertility. If is it sterile, what type of sterility does the recipient plant belong to.

1.2.6 The survival and reproductive competitive capability of the recipient plant in nature, such as the winter hardiness, summer hardiness, stress tolerance, etc.

1.3 The geographical distribution of the recipient plant in China, the ecological environment conditions required for its growth and development, as well as its ecological relation with relevant species.

1.4 On the basis of the above-mentioned evaluations, determine the safety class of the recipient plant by referencing related standards stipulated in Item I of article 7 of this "Implementation regulation".

2 Safety Assessment of Genetic Manipulation

2.1 What donor organism does the target gene come from? What method is used to acquire the gene? (e.g., artificial synthesis, PCR [poly-merase chain reaction] amplification or molecular cloning) Is it a structural gene or regulator gene?

2.2 The uses of the target gene and the function of its gene product.

2.3 The nucleotide sequence of the target gene and the deduced amino acid sequence.

2.4 The map of the constructs (the target gene and the vector), the name and source of the vector. Is the vector pathogenic or whether it can evolve to be pathogenic?

2.5 What type of promoter and terminator is used? Sources?

2.6 The name of the marker gene and reporter gene as well as their sources.

2.7 Transformation method.

2.8 What selection system is used to screen the genetic engineered organism? The technical data on the integration of target gene onto the plant genome should be provided.

2.9 On the basis of the above-mentioned evaluation, determine the safety class of the genetic manipulation by referencing related standards stipulated in Item II of Article 7 of this "Implementation Regulation".

3 Safety assessment of Genetic Engineered Organism and Its Product

3.1 Is the expression of the target gene developmental specific or tissue specific?

3.2 Is the modified genetic characters stable?

3.3 In comparison with recipient plant, have the following characteristics of the genetic engineered organism and its product been changed?

A. Adaptability
B. Pathogenicity
C. Toxicity
D. Fertility
E. Dormancy duration
G. Possibility of transforming to weeds, etc.

3.4 On the basis of the above-mentioned evaluations, determine the safety class of the genetic engineered organism and its product by referencing related standards stipulated in Item III of Article 7 of this "Implementation Regulation"

4 Release Site

4.1 Please provide the topographic and meteorological data of the release site, describe, in general, the environment of the release site, and indicate the location of the experimental plot.

4.2 The surroundings of the experimental plot belong to natural ecological type or agricultural ecological type. In the case of natural

ecological type, Please state the distance from the region of the agricultural ecological type.

4.3 List the names of related cultivars and wild species in the surroundings of the experimental plot.

4.4 Favorable and unfavorable factors of the ecological environment of the release site for the survival, propagation, spread and transmission of the genetic engineered organism, especially the possibility of acquiring target gene form the genetic engineered organism by other organisms in the environment.

5 Experiment Program

5.1 Starting date and terminating date of the field experiment.

5.2 Area of the experimental plot (excluding the area occupied by isolation materials).

5.3 Isolation measures.

5.3.1 Isolation distance.

5.3.2 Types of isolation plants and the composition modes.

5.3.3 Methods adopted to prevent the spread of pollen outside the experimental plot.

5.4 Plantation of genetic engineered organism

5.4.1 Dosage of genetic engineered organism

5.4.2 Methods for packaging the genetic engineered organism and method for transporting the genetic engineered organism to the experimental plot.

5.4.3 Mechanical method or artificial method has been used for the plantation of the genetic engineered organism.

5.4.4 Measures to prevent the spread of the genetic engineered organisms.

5.5 Time, category and dosage of using agricultural chemicals.

5.6 Harvest of genetic engineered organism and its products.

5.6.1 Does the genetic engineered organism set seeds?

5.6.2 Mechanic harvesting or artificial harvesting? How to avoid losses?

5.6.3 What method has been used to treat the residual part after harvest?

5.6.4 What method has been used to preserve the genetic engineered organism and its products after harvest?

5.7 Post-harvest monitoring of the experimental plot?

5.7.1 Responsible person for the monitoring of the experimental plot.

5.7.2 Is there any border marker remained on the experimental

plot?

5.7.3 Monitoring measures and monitoring duration after the completion of the experiment.

5.8 Emergency measures in case of unexpected accidents during the experiment process.

Appendix B-2: List of Safety Assessment for Other Agricultural Biotechnologies

1. Safety Assessment of Animal Genetic Engineered Organism and Its Products
2. Safety Assessment of Plant-Related Microorganism's Genetic Engineered Organism and Its Products
3. Safety Assessment of Veterinary Microorganism's Genetic Engineered Organism and Its products
4. Safety Assessment of Genetic Engineered Organism and Its products Acquired from Aquatic Animal and Plant

Regulation on the Safety Administration of Agricultural GMOs
(The State Council, People's Republic of China, May 2001)

Chapter 1. General

Article 1. This regulation is promulgated to strengthen the administration of Agricultural Genetic Modified Organisms (hereafter referred to as Ag GMOs), to safeguard the health of humans and the safety of animals, plants and microorganisms, to protect the ecological environment, and to promote research on Ag GMO technology.

Article 2. Activities of Ag GMO research, testing, production, processing, marketing and imports/exports are subject to the requirements of this regulation.

Article 3. "Ag GMOs" in this regulation refer to animals, plants, microorganisms and their products whose genetic structures have been modified by genetic engineering technology for the use of agricultural production or processing. Ag GMOs mainly include:
1) Genetically modified animals, plants (including planting seeds, breeding livestock, poultry and fish fry) and microorganisms.
2) Genetically modified animal products, plant products and microorganism products.
3) Products directly processed from genetically modified agricultural products.
4) Planting seeds, breeding livestock, poultry, fish fry, pesticides, veterinary medicines, fertilizer and additives with genetically modified animal, plant or microbe ingredients.

"Ag GMO safety" in this regulation refers to protecting humans, animals, plants and microorganisms and the ecological environment from the danger or potential risk caused by Ag GMOs.

Article 4. The Agricultural Administrative Department of the State Council is responsible for nationwide Ag GMO safety supervision and administration. The agricultural administrative departments of local people's governments at and above the level of county are responsible for Ag GMO safety supervision and administration within their jurisdictions. The health administrative departments of local people's governments at and above the level of county are, in accordance with relevant regulations of the Law of the People's Republic of China on Foods and Health, responsible for supervision and administration of GM foods safety within their jurisdictions.

Article 5. The State Council has established an Ag GMOs Joint-Ministry Conference System, consisting of responsible officials from Ministries of Agriculture, Science and Technology, Environmental Protection, Health, MOFTEC and AQSIQ to research and coordinate the

major problems regarding Ag GMOs.

Article 6. Ag GMO safety is subject to the Classified Administration and Evaluation System of the state. Ag GMOs are classified into Class I, II, III and IV by the nature of their potential danger to humans, animals, plants, microorganisms and the ecological environment. Detailed standards of classification have been stipulated by the Agricultural Administrative Department of the State Council.
Article 7. Ag GMOs are subject to the Safety Evaluation System of the state, detailed standards and technical rules of which have been stipulated by the Agricultural Administrative Department of the State Council.

Article 8. Ag GMOs are subject to the Labeling System of the state. The detailed rules for the Ag GMO categories are to be stipulated, adjusted and announced by the Agricultural Administrative Department after consulting with other relevant departments of the State Council.

Chapter 2. Research and Testing

Article 9. The Agricultural Administrative Department of the State Council should strengthen the safety evaluation of Ag GMOs research and testing and set up the Ag GMO Safety Committee to be in charge of safety evaluations for Ag GMOs. The GMO Safety Committee consists of experts in biological research, production, processing, inspection, quarantine, health and environmental protection.

Article 10. If needed, the Agricultural Administrative Department of the State Council can entrust technical testing institutes, which have appropriate staff and facilities, to test Ag GMOs.

Article 11. Organizations that are engaged in Ag GMO research and testing should have safety facilities and measures appropriate to the safety class, ensure the safety of Ag GMO research and testing, and establish an Ag GMO safety group to be in charge of the safety of their respective Ag GMO research and testing.

Article 12. Organizations that are engaged in the research of class III and IV Ag GMOs should report to the Agricultural Administrative Department of the State Council before starting the research.

Article 13. Ag GMO testing normally includes three stages: medium testing, environmental release and productive testing. Medium testing refers to small-scale tests conducted within controlled system or under controlled conditions. Environmental release refers to middle-scale tests conducted by taking relevant safety measures under natural conditions. Production testing refers to large-scale tests conducted prior to production and application.

Article 14. After finishing the Ag GMO research in the laboratory, if the testing organization needs to proceed to medium testing, the testing organization shall report to the Agricultural Administrative Department of the State Council.

Article 15. If they need to proceed to the next stage of Ag GMO testing, the testing organization shall apply to the Agricultural Administrative Department of the State Council. Only after passing the safety evaluation of the Ag GMO Safety Committee will the Agricultural Administrative Department of the State Council approve movement to the next stage.
When making the above mentioned application, testing organizations shall provide:
1) The safety classes of the Ag GMOs and the basis on which the classes are determined.
2) The inspection report issued by the technical inspection institute of Ag GMOs.
3) The relevant measures on safety control and prevention.
4) The testing report from the previous stage of testing.

Article 16. After finishing the productive testing, Ag GMO testing organizations can apply to the Agricultural Administrative Department of the State Council for the Ag GMO Safety Certificate.
When making the above mentioned application, testing organizations shall provide:
1) The safety classes of Ag GMOs and the basis on which the classes are determined.
2) The inspection report issued by the technical inspection institute of Ag GMOs.
3) The summary report of the productive testing.
4) Other materials required by the Agricultural Administrative Department of the State Council.

After receiving the application, the Agricultural Administrative Department of the State Council shall arrange for the Ag GMO Safety Committee to conduct a safety evaluation. Only when passing the safety evaluation can the Ag GMO Safety Certificate be issued.

Article 17. Before such normal formalities as examination, registration, evaluation and approval are gone through, the Ag GMO Safety Certificate shall be obtained for GM planting seeds, breeding livestock, poultry and fish fry; and pesticides, veterinary medicines, fertilizers and additives containing GM ingredients, as stipulated in Article 16 of this regulation.

Article 18. Joint-venture or solely foreign-owned organizations that are engaged in Ag GMO research and testing within the territory of the People’s Republic of China should get approval from the Agricultural

Administrative Department of the State Council.

Chapter 3. Production and Processing

Article 19. Any organization that is engaged in production of GM planting seeds, breeding livestock, poultry or fish fry must get a Production Licence from the Agricultural Administrative Department of the State Council. Persons or organizations that apply for the Production Licence of GM planting seeds, breeding livestock, poultry or fish fry should meet not only relevant laws and administrative regulations, but also the following requirements:
1) They must get an Ag GMO Safety Certificate and pass the variety examination.
2) They must engage in production within a designated area.
3) They must undertake appropriate safety administration and prevention measures.
4) They must meet other conditions of the Agricultural Administrative Department of the State Council.

Article 20. Persons or organizations that are engaged in production of GM planting seeds, breeding livestock, poultry or fish fry should keep production records which indicate the place of production, gene, genetic source and method of genetic modification, as well as the whereabouts of the GM planting seeds, breeding livestock, poultry or fish fry.

Article 21. Persons or organizations that are engaged in GMO production and processing must get approval from the Agricultural Administrative Departments of the State Council or local agricultural administrative department at the level of province, autonomous region or municipality. Details will be stipulated by the Agricultural Administrative Departments of the State Council.

Article 22. In the case of farmers growing GM plants or feeding GM animals, sellers of seeds, breeding livestock, poultry or fish fry should, in accordance with the requirement in Article 21 of this regulation, go through the procedure of approval on behalf of farmers. Approval departments and sellers shall not charge farmers for such approval and procedure handling.

Article 23. Persons or organizations that are engaged in GMO production and processing should arrange their production and processing in accordance with approved varieties, scope, safety control requirements and relevant technical standards. They should regularly report their production, processing, safety control and products' whereabouts to their local agricultural administrative department.

Article 24. If any genetic safety accident happens during the

production and processing of GMOs, the producer and processor shall immediately take remedial safety measures and report the situation to the local agricultural administrative department of the same county in which the producer is located.

Article 25. Persons or organizations that are engaged in transportation and storage of Ag GMOs should take safety control measures appropriate to the safety class so as to ensure the safety of transportation and storage of Ag GMOs.

Chapter 4. Marketing

Article 26. Persons or organizations who market Ag GMO planting seeds, breeding livestock, poultry and fish fry must obtain a Marketing Licence from the Agricultural Administrative Department of the State Council.
Persons or organizations that apply for the Marketing Licence of GM planting seeds, breeding livestock, poultry or fish fry should meet not only relevant laws and administrative regulations, but also the following requirements:
1) They must have special managerial personnel and marketing records.
2) They must undertake appropriate safety administration and prevention measures.
3) They must meet other conditions of the Agricultural Administrative Department of the State Council.

Article 27. Persons or organizations that are engaged in the marketing of GM planting seeds, breeding livestock, poultry or fish fry should keep marketing records which indicate the place of production, genetic source, storage and transportation as well as the whereabouts of the GM planting seeds, breeding livestock, poultry or fish fry.
Article 28. Ag GMOs that are listed in the Ag GMO category must be clearly labeled when sold within the territory of the People's Republic of China. Ag GMOs that are listed in the Ag GMO category shall be labeled by producers, packers and individuals. Unlabeled products shall not be sold. When procuring such products, marketing organizations and persons should check the goods and their labels. Marketing organizations and persons should re-label the goods for sale if they open the original packing.

Article 29. The label should indicate the name of the GM materials. It should also indicate the area in which product will be sold if there are special restrictions on the area of sale. The product must be sold within that designated area.

Article 30. The publishing, broadcasting, setting and posting of advertisements for Ag GMOs are subject to examination and approval

by the Agricultural Administrative Department of the State Council.

Chapter 5. Imports and Exports

Article 31. Those who introduce Ag GMOs from outside the People's Republic of China for research and testing must apply to the Agricultural Administrative Department of the State Council and meet the following requirements:
1) They must be a qualified applicant that meets all the regulations promulgated by the agricultural
administrative department of the State Council.
2) The Ag GMOs being introduced must have undergone the relevant research and testing abroad.
3) They must have established appropriate safety administration and prevention measures.

Article 32. Any foreign company that exports to the People's Republic of China GM planting seeds, breeding livestock, poultry, fish fry, and pesticides, veterinary medicines, fertilizers and additives containing GM ingredients must apply to the Agricultural Administrative Department of the State Council. Those who meet the following requirements will be permitted by the Agricultural Administrative Department of the State Council to bring along their testing materials and undergo the medium test, environmental release and productive test under this regulations:
1) The exporting nations or regions must allow usage of those products for the same relevant purpose, and sell them in their domestic markets;
2) Exporting nations or regions must have verified the products' safety for humans, animals, microorganisms, and the environment through scientific testing;
3) Exporting nations or regions must have established appropriate safety administration and measures to prevent problems.

After finishing the productive testing and receiving the Safety Certificate, traders can go through normal importing formalities such as examination, registration, evaluation and approval.

Article 33. Exports of Ag GMOs to the People's Republic of China as raw materials for processing should apply to the Agricultural Administrative Department of the State Council. If meeting the following requirements and passing the safety evaluation, exporters can obtain a Safety Certificate issued by the Agricultural Administrative
Department of the State Council:
1) The exporting nations or regions must allow usage of those products for the same relevant purpose, and sell them in their domestic markets;

2) Exporting nations or regions must have verified the products' safety for humans, animals, microorganisms and the environment through scientific tests;
3) Ag GMO technology examination and testing organizations should confirm that the products indeed will not harm humans, animals, microorganisms or the environment after examination and testing.
4) They must have established appropriate safety administration and prevention measures.

Article 34. With regard to introduction of Ag GMOs from outside the People's Republic of China or exportation of Ag GMOs to the People's Republic of China, the introducers or foreign companies must submit the Safety Certificate from the Agricultural Administrative Department of the State Council and relevant approval documents to the Entry-Exit Inspection and Quarantine Department at the border. Upon passing inspection, they can go through normal procedures at Customs.

Article 35. Ag GMO products transiting China must apply in advance to Entry-exit Inspection and Quarantine Department of the State. Upon getting approval, such transition can be carried out in accordance with relevant laws and administrative regulations of the People's Republic of China.

Article 36. The Agricultural Administrative Department of the State Council and the State Entry-exit Inspection and Quarantine Departments should make their decision of approval or disapproval within 270 days from the date of receiving the application and inform the applicant.

Article 37. With regard to export of agricultural products to foreign countries, if importers require non-GMO certification, the State Entry-Exit Inspection and Quarantine Departments should examine and test the products and issue such certification according to the information given by the Agricultural Administrative Department of the State Council.

Article 38. With regard to importation of GMO products: if goods arrive without the Safety Certificate issued by the Agricultural Administrative Department of the State Council and the relevant approval documents, or if the goods do not match the Safety Certificate and approval documents, the goods will be rejected or destroyed. If the label is not in accordance with the labeling requirements, the goods can not enter China until they are relabeled.

Chapter 6. Supervision and Inspection

Article 39. When the agricultural administrative departments implement supervision and inspection, they have the right to:

1) Question the researchers, testers, producers, processors, marketers, importers, exporters and concerned persons or organizations whose products are being inspected, and require them to provide supporting materials or other materials relating to Ag GMO safety;
2) Consult or copy records, accounts and materials relating to the Ag GMOs research, testing, production, processing, marketing, import and export;
3) Require the concerned persons or organizations to explain the questions about Ag GMO safety;
4) Charge the persons or organizations who violate Ag GMO safety regulations to stop their illegal activities;
5) If urgent, they may seal or detain the Ag GMOs involved in illegal research, testing, production, processing, marketing, import and export.

Article 40. Enforcers of the agricultural administrative departments should present their credentials when implementing supervision and inspection.

Article 41. Concerned persons or organizations should support and cooperate with enforcers and should not refuse or hamper them when they implement supervision and inspection.

Article 42. If it is found that Ag GMOs are dangerous for humans, animals, plants or the ecological environment, the Agricultural Administrative Department of the State Council has the right to prohibit production, processing, marketing and importation of concerned Ag GMOs, to revoke the Ag GMO Safety Certificate and to destroy the dangerous GMOs.

Chapter 7. Enforcement

Article 43. Those who conduct the research and medium testing of class III and IV Ag GMOs without reporting to the Agricultural Administrative Department of the State Council shall be charged by the Department to stop their research or medium test and correct their behaviors within a specific period.

Article 44. Those who conduct environmental release and productive test without being permitted or who get permit but fail to take measures of safety control and prevention or conduct testing beyond the permitted scope shall be charged by the Agricultural Administrative Department of the State Council or the agricultural administrative department of the province, autonomous region or municipality, to stop the test and pay a fine of RMB 10,000 to 50,000.

Article 45. Those who put Ag GMOs into production and application

without getting an Ag GMO Safety Certificate after finishing production test shall be charged by the Agricultural Administrative Department of the State Council to stop production and application and pay a fine of RMB20,000 to 100,000.

Article 46. Those who violate the requirement of Article 18 of this regulation by conducting the research and test of Ag GMOs without being permitted by the Agricultural Administrative Department of the State Council shall be charged by the Department to stop their research and testing until the approval formalities are completed.

Article 47. Those who produce and process Ag GMOs without being permitted or whose production and processing are not in accordance with permitted varieties, scope, safety control requirement and technical standard shall be charged by the Agricultural Administrative Department of the State Council or the agricultural administrative department of the province, autonomous region or municipality to stop production or processing. In this case, their products illegally produced or processed and their illegal earnings shall be confiscated. If their illegal earnings exceed RMB100,000, they will be charged to pay a fine 1 to 5 times their illegal earnings. If there are no illegal earnings or illegal earnings are less than RMB100,000, the violator shall be charged to pay a
fine of RMB100,000 to 200,000.

Article 48. Persons and organization who are engaged in production and marketing of GM planting seeds, breeding animals, poultry and fish fry, if failing to keep the records on production and marketing as required, shall be charged by the people's government's agricultural administrative department at or above the county level to correct their error and pay a fine of RMB1,000 to 10,000.

Article 49. Sellers of GM planting seeds, breeding animals, poultry and fish fry, if failing to perform their obligation of handling approval formalities on behalf of farmers or charging farmers for such handling, shall be charged by the Agricultural Administrative Department of the State Council to correct their error and pay a fine of less than RMB20,000.

Article 50. Those who import Ag GMOs without being permitted by the Agricultural Administrative Department of the State Council shall be charged to stop importation. In this case, the imported products and illegal earnings will be confiscated. If the illegal earnings exceed RMB100,000, the violator shall be charged to pay a fine 1 to 5 times the illegal earnings. If there are no illegal earnings or illegal earnings are less than RMB100,000, the violator shall pay a fine of RMB100,000 to 200,000.

Article 51. Those who import, carry or mail Ag GMOs without declaring them to the port Entry-Exit Inspection and Quarantine Department, or whose Ag GMOs transit China without a permit from the Entry-Exit Inspection and Quarantine Department of the State shall be fined by the port Entry-Exit Inspection and Quarantine Department or the Entry-Exit Inspection and Quarantine Department of the State by reference to the relevant regulations in the Law and the regulations for Entry and Exit Inspection and Quarantine of Animals and Plants.

Article 52. Those who violate the Ag GMO labeling requirement of this regulation shall be charged by the people's government's agricultural administrative department above the county level to revise the label within specified period. In this case, the products illegally sold and the illegal earnings may be confiscated, and the violator may be fined RMB10,000 to 50,000.

Article 53. If any persons or organizations forge, falsify, transfer, and sell or buy any supporting certificates of Ag GMOs, the certificates shall be confiscated by the people's government's agricultural administrative department at or above the county level and a fine of RMB20,000 to 100,000 shall be imposed. If such behavior constitutes a crime, the concerned party will be held under criminal responsibility.

Article 54. Those whose failure to abide by this regulation causes any genetic safety accident in the course of Ag GMO research, test, production, processing, storage, transportation, sales, import and export shall bear responsibility of compensating for damage caused thereby.

Article 55. If the Agricultural Administrative Department of the State Council or the agricultural administrative department of a province, autonomous region or municipality issues a permit, an Ag GMO Safety Certificate or other approval document not according to this regulation, or fails to perform its duty of supervision and administration after issuing a permit, Ag GMO Safety Certificate or other approval document, the persons directly responsible shall be punished with administrative disciplinary action. If their behavior constitutes criminal activity, they shall bear criminal responsibility as stipulated by law.

Chapter 8. Appendix

This regulation goes into effect from the issuance date.

Appendix D:

Safety Control Measures of Agricultural Biological Genetic Engineered Organism and Its Products

In order to avoid potential unfavorable impact of agricultural organism's genetic engineering on human health and ecological environment, it is essential to formulate corresponding safety control measures for different classes of genetic engineering work.

1 Laboratory Safety Control Measures

1.1 Control measures for Safety class I

Laboratory and its operation should accord with the requirements of common biological laboratory.

1.2 Control measures for Safety Class II

1.2.1 Laboratory requirements:

In addition to the same laboratory requirements of Safety Class I, it is required that the laboratory must be equipped with ultra-aseptic working table, disinfecting facilities and autoclave sterilizing equipment for waste disposal.

1.2.2 Operation requirements:

In addition to the same operational requirements of Safety Class I, it is essential to meet the following requirements:

1.2.2.1 Try all means to avoid the production of aerosol during the operation process.

1.2.2.2 Operate (handle) the experiments within the designated area of the laboratory.

1.2.2.3 Wastes should be kept in seepage-proof and non-fragile containers and conducted inactivation treatment.

1.2.2.4 Laboratory workers should wear work clothes during genetic manipulation, and leave the work clothes in the laboratory before leaving the laboratory.

1.2.2.5 It is essential to prevent all unrelated organisms, such as insects and rodents, from entering the laboratory. In the case of an accident, in which harmful target gene, vector, genetic engineered organism do escape and spread, emergency measures must be taken immediately.

1.2.2.6 The safety control measures for veterinary microorganism's genetic engineered organism should also accord with the relevant regulations for veterinary

biologicals.

1.3 Control measures for Safety Class III

1.3.1 Laboratory requirements:

In addition to the same laboratory requirements of Safety Class II, it is essential to meet the following requirements:

1.3.1.1 Laboratory should be located within the isolated area and have striking warning signs. Before entering the operation room, laboratory workers should pass through a special locker room (changing room) that is equipped with shower facilities. In addition, automatic door and air shower should be equipped at the doorway of the operation room.

1.3.1.2 The wall, floor and ceiling inside the laboratory should be smooth, waterproof, leak-proof and corrosion-protected.

1.3.1.3 Windows should be airtight.

1.3.1.4 Laboratory should be equipped with autoclave sterilizing facilities.

1.3.1.5 Operation room should be equipped with negative-pressure circulatory purification facilities and wastewater treatment equipment.

1.3.2 Operation requirements:

In addition to the same operation requirements of Safety Class II, it is essential to meet the following requirements:

1.3.2.1 The entry of a person into the laboratory must be approved by the project leader.

1.3.2.2 Everyone must change work clothes and wear gloves and other protection tools in the locker room before entering the laboratory and must take a shower before leaving the laboratory. It is forbidden to wear work cloth outside the laboratory and work clothes must be autoclave sterilized before washing.

1.3.2.3 Working table must be cleaned and disinfected immediately after use.

1.3.2.4 Laboratory containers used for transferring materials must be double-layered, non-fragile and airtight.

1.3.2.5 Used containers and all laboratory utensils must be sterilized before leaving the laboratory.

1.3.2.6 All organisms and active materials used in genetic manipulation must be taken care of by special personnel, and stored in specific containers or facilities.

1.4 Control measures for Safety Class IV

Laboratory and its operation should accord with relevant requirements stipulated in the "Implementation Regulation".

2 Control Measures for Pilot Experiment and Environment Release of Genetic Engineered Organism

2.1 Control measures for Safety Class I

It is required to adopt common biological isolation methods to put experiment under necessary range of control.

2.2 Control measures for Safety Class II

2.2.1 It is essential to adopt appropriate isolation measures to control the entry and exit of both animals and people. It is necessary to set up a solarium to prevent the entry of insects, set up dams and boards to prevent the escape of aquatic organisms. Aquatic organisms should be controlled within a small-scale artificial water areas so as to guarantee that the experimental organisms will never enter the natural water areas despite of disastrous climates within 10 years.

2.2.2 It is essential to conduct timely disinfection treatment for tools and related facilities.

2.2.3 Certain biological isolation measures should be adopted, such as the selection of experimental plot within the geographical area where genetic engineered organism can not hybridize with related organisms.

2.2.4 Adopt corresponding environmental and scale control measures.

2.2.5 It is also essential to disinfect and treat fish ponds, livestock barn and soil after the completion of the experiment, so as to prevent the escape and survival of the genetic engineered organism.

2.3 Control measures for Safety Class III

2.3.1 It is essential to adopt appropriate isolation measures, and prohibit the entry and exit of unauthorized personnel, animals, poultry and vehicles. It is also essential to equip the laboratory with solarium, artificially controlled industrialized husbandry facilities, containers for collecting and eliminating genetic engineered organism and related facilities in accordance with the objectives of the experiment.

2.3.2 It is essential to undertake timely disinfecting treatment of tools and related facilities, prevent the take-away of genetic engineered organism from the experimental areas eliminate plants, insects, microorganisms and rodents which are not related to the experiment by using herbicide, insecticide, fungicide and rodent poison bait.

2.3.3 It is essential to adopt the most effective biological isolation measures to prevent related organisms from hybridization, transduction, transformation, conjugation, parasitism and heteroecism with the genetic engineered organism within the experimental areas.

2.3.4 It is essential to adopt strict environmental control measures, such as the utilization of environment (humidity, moisture, temperature, etc.) to restrict the survival and propagation of the genetic engineered organism and its product outside the experimental areas, or set up the experimental areas in desert, alpine frigid regions where the genetic engineered organism can not survive once it gets escaped or spread.

2.3.5 It is essential to strictly control the experiment scale. When necessary, genetic engineered organism can be eliminated at any time..

2.3.6 It is also essential to disinfect and treat fish ponds, livestock barn and soil after the completion of the experiment, with objective of preventing the escape and survival of the genetic engineered organism.

2.4 Control measures for Safety Class IV

The control measures should be reported to the National Genetic Engineering Safety Committee and implementation should be conducted in accordance with relevant requirements.

2.5 The control measures of the pilot experiment and environment and environment release of veterinary microorganism's genetic engineered organism and its product should also accord with relevant regulations of veterinary biologicals.

3 Emergency Measures

3.1 when accidental spread of genetic engineered organism occurred, it is imperative to close the accident site as soon ad possible, make a thorough investigation of the accident immediately, adopt effective measures to prevent continuous spread of the genetic engineered organism, and submit report to the relevant administrative departments.

3.2 If genetic engineered organism has already been spread, it is essential to adopt effective measures immediately according to its safety class.

3.3 In the case of a spreading area of genetic engineered organism which has already produced unfavorable effect, it is imperative to isolate personnel within the area for the time being and put them under medical monitoring.

3.4 It is essential to undertake trailing monitoring over spreading

areas until no more risk exists.