Current Development of Field Tests of GMOs and Guidelines in China

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Abstract

Since 1986, significant achievements have been made in China in the field of genetic engineering of plants, animals and microorganisms related to agriculture. Rough estimation indicates that 15 transgenic plants, including tobacco, cotton, tomato, potato, sweet pepper, cabbage, alfalfa, soybean, rice, wheat, corn, poplar, papaya with characteristics of insect and disease resistance or improved quality have been developed and tested in fields. Modified microorganisms for nitrogen fixation, biopesticides for control of diseases, as well as the transgenic pig, sheep and fish have been developed and tested on a small scale. Therefore, it is urgently needed to develop a national safety regulation system to conduct risk assessment on the field tests and environmental release of genetically modified organisms (GMOs). In December 1993, the State Science and Technology Commission issued an order named "Safety Administration Regulation on Genetic Engineering" to regulate the laboratory work, medium-size scale-up tests and environmental release of GMOs in medical, agricultural and industrial fields, etc. Correspondingly, since August 1994, the Ministry of Agriculture has set up a leading group and an expert group, with expertise in different disciplines to draft guidelines for biosafety regulation of GMOs relevant to agriculture. The principles for drafting the guidelines are as follows: (1) For a developing country like China, it is important to facilitate rather than limit or hamper the development of biotechnology, while ensuring human health and environmental protection. (2) As the GMOs are, in principle, the same as the products produced by conventional technology, we adopt a science- or product-based regulation system rather than a technology- or process-based system. (3) Fully considering the experiences and scientific data accumulated to-date in the world scientific community, the risk assessment will be carefully conducted according to the rule of "case by case" study. (4) Along with the experience and data gathered by ourselves and worldwide, the guidelines and implementation procedures shall be amended and improved "step by step". The guidelines are now under examination for government approval. Classification of potential risk levels of the recipient organisms, genetic manipulation and end-products is described.

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Introduction

Modern biotechnology based on recombinant DNA technology and cell culture has opened a new era for genetic modification of living organisms. Since the cloned gene(s) can be transferred among plants, animals and microorganisms, the natural crossing barrier between species has been removed. Therefore, the products developed by modern biotechnology are new and could not have been generated by traditional techniques. Consequently, potential risk assessment to human health and environment is needed. On the other hand, conventional breeding has a long history that created thousands of new varieties. The data and experiences gained in traditional breeding indicate that through careful handling practice there is no adverse effect on human health and environment. In addition, since 1986, more than 1,500 field tests of genetically modified organisms (GMOs) have been conducted worldwide and a large number of scientific data as well as a great deal of experience have been accumulated (MacKenzie and Henry, 1990; Casper and Landsmann, 1992; Jones, 1994; Deshayes, 1994), including the evaluation of GMOs for toxicity and allergenicity, natural competence, pollen dispersion and gene flow to related wild species, effect on target and non-target organisms, etc. According to the data reported by the APHIS, in 99% of the field tests, transgenic plants were found to be safe for human health and the environment if certain performance standards were adopted. In only less than 1% of field trials were transgenic plants reported to induce abnormal phenomena (Prott and Reding, 1995). To date, 11 commodities derived from transgenic plants with different genes inserted have already been approved for commercial production (Dale, 1995). It is obvious that we now better understand the biosafety issues of GMOs than before and we are more confident on a promising future. Regulations tend to be relaxed and simplified.

Current field tests of GMOs in China

With the largest population in the world, China has paid a great deal of attention to the development of agriculture to meet the increasing demand for food and other agricultural products. Among the R&D in different disciplines of science and technology, modern biotechnology has continuously been a top priority in recent years in China. In the National High-Tech Program (so-called 863 program) starting from March 1986, priority has been given to both agricultural and medical biotechnology. In addition, the State Science and Technology Commission has promoted research and development on biotechnology in each five-year plan. Financial support can also be obtained from the Ministry of Agriculture and provincial sources. Therefore, during the past decade, significant achievements were made in China in the field of genetic engineering of plants, animals and microorganisms relevant to agriculture. Rough estimation indicates that 15 kinds of transgenic plants, including tobacco, cotton, tomato, potato, sweet pepper, cabbage, alfalfa, soybean, rice, wheat, corn, poplar and papaya with characteristics of insect and disease resistance, or improved quality have been developed and

tested in the field. Meanwhile, modified microorganisms for nitrogen fixation, biopesticides for control of diseases, as well as the transgenic pig, sheep and fish have been developed and tested on a small scale (Table 1). These field tests were conducted by scientists according to the rules and safety measures adopted by their colleagues in developed countries. However, the performance of these field tests was not officially approved by the government. Therefore, it is urgently needed to develop a national biosafety regulation system to conduct risk assessment of the field tests and environmental release of GMOs.

Table 1 GMOs currently under field testing in China

Species	Gene(s) coding for	Characteristics
Tobacco	CP-TMV, CMV	Virus resistance
Tomato	CP- CMV	Virus resistance
	PG	Fresh fruit keeping
Sweet pepper	CP-CMV	Virus resistance
Wheat	CP-BYDV	Virus resistance
Rice	CP-RDV, Ribozyme	Virus resistance
Papaya	CP-PRSV	Virus resistance
Cotton	*B.t.*, Proteinase inhibitor	Insect resistance
Cabbage	*B.t.*	Insect resistance
Soybean	*B.t.*	Insect resistance
Corn	*B.t.*	Insect resistance
Poplar	*B.t.*	Insect resistance
Potato	Polypeptides	Bacterial resistance
	Zein	Nutritional improvement
Alfalfa	Sulfur-rich protein	Nutritional improvement
Alcaligenes faecalis	Tn5::*nifA*^{c}	Rice-associated nitrogen fixation
Rhizobium japonicum	Hup, etc.	Soybean nitrogen fixation
Pseudomonas fluorescens	Tn5 mutagenesis	Control of wheat Take-all disease
Pig	Pig growth hormone	Lean meat
Sheep	GH, Insulin	Model of bioreactor
Carp	Fish growth hormone	Fast growing

Development of guidelines

In December 1993, the State Science and Technology Commission issued an order named "Safety Administration Regulation on Genetic Engineering" to regulate the laboratory work, medium-size scale-up tests and environmental release and commercialization of GMOs and products in medical, agricultural and industrial fields, etc. A national leading body, called "the National Biosafety Committee for Genetic Engineering" was then established under the State Science and Technology

Commission. Representatives from different departments, such as the Ministry of Public Health, the Ministry of Agriculture, the Ministry of Light Industry, responsible for biosafety regulation of medical, agricultural or industrial products, are represented in this leading body.

In addition since August 1994, the Ministry of Agriculture has set up a leading group and an expert group, with expertise in different disciplines, to draft guidelines for biosafety regulation of GMOs related to agriculture. The principles we considered for drafting the guidelines are as follows:

1. Agriculture and food supply has been and will be continuously a major issue for the development of our economy. We believe that biotechnology will contribute significantly to this objective in the future. Therefore, for a developing country like China, it is important to facilitate rather than limit or hamper the development of biotechnology while ensuring human health and environmental protection.

2. As the GMOs are, in principle, the same as the products developed by conventional technology, the GMO-derived products should be regulated according to the same criteria as any other products. We therefore adopt a science - or product-based regulation system rather than a technology- or process-based system.

3. Fully considering the experience and scientific data accumulated to-date in the world scientific community, the risk assessment will be carefully conducted according to the rule of "case by case" study.

4. Along with the experience and data gathered by ourselves and worldwide, the guidelines and implementation procedures shall be amended and improved "step-by- step".

"The Guidelines for Safety Regulation of Genetically Modified Organisms Related to Agriculture" are now under examination for government approval.

Classification of biosafety levels

The draft of the guidelines contains 6 chapters and 7 appendices. According to the draft, the level of potential risk of GMOs depends on the risk assessment of recipient organisms and genetic manipulation. The potential risk is classified into four levels. In Level I the risk to human health and environment is unlikely. In Levels II, III and IV there is a low, intermediate, and high level of potential risk to human health and environment, respectively.

For maximum security for insurance of human health and environment protection, all the studies at level IV should be authorized by the National Biosafety Committee for Genetic Engineering.

Implementation procedures

1. The Ministry of Agriculture is a national leading agency for the implementation of biosafety regulation of GMOs relevant to agriculture. Since regulatory bodies for controlling veterinary vaccines and biological agents, fertilizers, pesticides, feeds and quarantine of plants and animals are already operating at the Ministry of Agriculture, we do not need to establish a specific body for the regulation of GMOs. For coordinating the implementation of the regulatory system, a Biosafety Office has been set up under the Bureau of Science and Technology, Ministry of Agriculture. All applications relevant to agriculture should be submitted to this office for evaluation .

2. The National Agricultural Biosafety Committee is controlled by the Ministry of Agriculture, in which experts from different disciplines are included. The function of this committee is to conduct risk assessment of GMOs nationally and provide suggestions to the authorities concerned of the Ministry of Agriculture for decision making. Local biosafety committees are also required to operate in different institutions.

3. All applications, either by Chinese or foreign agencies, should be approved by the Ministry of Agriculture. The applications involving foreign agencies to carry out field tests or for commercialization of GMOs and products within China, should be approved by the authorities concerned in their native country. For the experiments conducted before the guidelines were issued, applications for authorization should be submitted . At the beginning of the implementation of the regulation, a notification system was not adopted. This procedure will be amended and added in the regulatory system while enough data and experience are accumulated.

4. Applications will be accepted twice annually. The deadline for submission is March 31 and September 30. The authorities concerned will answer in writing to the applicants within 120 days after the deadline, indicating whether the application is approved, rejected or if additional information should be provided for further evaluation.

5. The biosafety assessment consists of three categories: laboratory work, field tests and commercialization of GMOs. For laboratory work, the evaluation is conducted by the authorities concerned of the respective government department to which the applicant's organization belongs . For example, the applications from an institution affiliated to the Chinese Academy of Science (CAS) will be evaluated by the CAS. However, all applications on the field tests of GMOs relevant to agriculture should be submitted to and evaluated by the Ministry of Agriculture. Field tests of GMOs at Level I will be evaluated by the local biosafety committee, but detailed information and results should be notified to the Ministry of Agriculture for re-evaluation necessary. For the commercial release of GMOs, all the applications at Levels I, II and III should be approved by the Ministry of Agri-

culture. The detailed approved results obtained from field tests should be included at the time of application. The studies conducted at Level IV in all three categories should be approved by the National Biosafety Committee for Genetic Engineering.

6. In order to carry out the risk assessment on GMOs correctly, the applicants should provide the following information:

A. General information: such as a map indicating the location of field test(s) or commercial release, the climatic conditions and ecosystem(s) under which the experiment will be conducted, the distance of the experimental site from a residential community, the duration of the experiment, etc.

B. Information on recipient organism: such as the name (as well as Latin name), the center of origin, and the biological characteristics of the recipient organism, including the mode of pollination and reproduction, the ability of colonization in nature, possible detrimental effects on human health and environment historically, etc. The biosafety level of the recipient organism should be defined.

C. Information on genetic manipulation: such as characteristics of gene from donor organism, marker gene, the vector, method of transformation, etc. The impact of genetic manipulation on biosafety should be defined indicating whether it increases or decreases biosafety or does not have any effect.

D. Information on GMO and its product: whether it is toxic, allergic, pest or weed, the inheritance and stability of transgene, etc. In conclusion, what is the level of potential risk of the GMO and its product.

E. Biosafety control measures: including physical, chemical and biological measures, the methodology to be used for the detection of GMO, and the method of control in case of accident.

Conclusion

When the situation of the regulatory issues in different countries is considered, it seems that there are two extremes. In one case there are no regulations and GMOs' field tests and commercial release are not controlled. In the past decade in China, in the case of commercial-scale production, extensive requirements for environmental assessment were not needed. On the other hand, some countries have undertaken process-based regulations which require that a large number of precautions be taken and which may be obsolete and unscientific. The resulting bureaucracy, cost and delay impose an unnecessary burden to academic researchers and industry (Miller *et al.*, 1995). Therefore, for a developing country, the above international lessons should be learned for the design and implementation of own regulatory system in a realistic way.

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