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Review on GM Rice Risk Assessment in China

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Abstract
Rice is the staple food for nearly half the world’s population. China is currently the largest rice producer and consumer in the world. China is the biggest rice biotechnology research spender in the world with an annual outlay of US$115 million. The commercialization of GM rice in China would have a major impact on the production of GM rice throughout the world. Experiences and knowledge from rice development and GM rice risk assessment in China should be valuable for the other governments around the world.

Key Words: GM Rice, Risk Assessment, China
1. Introduction

China is currently the largest rice producer and consumer in the world. Rice production accounts for about 40 per cent of total domestic grain production with one third of total grain acreage in China.\(^1\) To meet the challenges posed by increasing population, increasing consumption, reducing soil fertility, lack of new agriculture land and increasing shortages of water and energy, it is necessary for China to develop rice varieties with higher sustainable yields.

Biotechnology has been promoted as being able to help address the major challenges of food security and poverty alleviation in an environmentally friendly manner in developing countries. China, since the mid-1980s, has increasingly been exploring the potential of biotechnology to these challenges. Investments in public-sector biotechnology research have risen dramatically to $1.2 billion for 2001-2005, a 400 per cent increase over 1996-2000 levels, with about $120 million allocated for transgenic rice R&D.\(^2\) This makes China the biggest rice biotechnology research spender in the world.\(^3\) China has embraced biotechnology in other agricultural sectors with 6.4 million framers growing 3.3 million ha of GM cotton in 2005.\(^4\)

Promoted by the rapid advances in genomic studies, development of molecular marker technologies, identification, mapping and molecular cloning of a large number of agriculturally useful genes, China’s rice biotechnology research has generated a wide array of GM rice plants. Field testing of various genetically modified (GM) rice has been in progress since 1998.\(^5\) As of 2005 more than 100 varieties have been tested under restricted, or enlarged or productive-field testing in accordance with the relevant biosafety regulations. In 2003 53 ha of GM rice was planted for research and risk assessment purposes.\(^6\)
China is on the threshold of applying its research into GM rice on a commercial scale. Although Iran has already taken this step, the impacts of China following the same path will be of major significance for biotechnology internationally, especially in the developing world and will have a major impact on the acceptance of the technology in other agricultural sectors.

Rice is the most important food crop in the world, grown by 250 million farmers, and the principal food of the world’s 1.3 billion poorest people, mostly subsistence farmers. The commercialization of GM rice has enormous implications for the alleviation of poverty, hunger, and malnutrition. The development in China’s use of GM rice has already been the subject of international controversy. This international controversy is only likely to increase as China further develops its considerable investment in the technology.

Yet many of the facts about this research are not known to the international community due to language barriers and difficulties in accessing the information. This paper sets out to describe in an accurate, impartial and comprehensive manner what biotechnological research is currently being undertaken on rice in China and surveys the literature regarding GM rice development and risk assessment in terms of environment and food safety in China. The paper also highlights a number of areas in the risk assessment and management procedures that merit further attention.

2. GM Rice Research in China

There are two major rice varieties in China, *Indica* rice (*Hsien*) and *japonica* rice (*Keng*). Experimental lines of GM rice have been developed with traits such as increased yield, quality improvement, disease and insect resistance, herbicide resistance, salt and drought tolerant, and pharmaceutical usages. GM rice with disease and insect resistance are the most developed, accounting for about 80 per cent of all developed GM rice
varieties. In recent years, scientists are also looking forward to pyramiding of genes into rice varieties to reduce the likelihood of pest resistance. Approaches to prevent gene flow and to use the rice as bioreactor are also being explored. New techniques of genetic transformation in eliminating the antibiotic marker genes and promoter genes have also been developed and utilized in rice breeding.

### Table 1: GM Rice Development in China

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<th>Gene(s)</th>
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<td>IR72</td>
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<td>Herbicide</td>
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resistance

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<td>bar + gna</td>
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<tr>
<td>VHb+tzs+EPSPS</td>
<td>Xiushui-11, Qiufeng, Youfeng, Hanfeng</td>
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Salt tolerance

- the mouse calcineurin gene
- SsNHX1

Drought resistance

- MnSOD
- COX

Drought resistance and salt tolerance

- SNAC1

Biorector

- NDV F

Guanglinxiangjin (GLXJ)

Note: pepc: maize Phosphoenolpyruvate carboxylase gene; antisense Waxy (Wx) gene: starch granule-bound starch synthase gene; Xa21 (Xa gene family): confers resistance against the bacterial pathogen Xanthomonas oryzae (Xoo); Chitinase gene: chitinase gene from Phaseolus limensis; beta-1,3-glucanase gene: beta-1,3-glucanase gene from Nicotiana tabacum; cry2A*: a novel synthetic gene, the family of Cry genes from Bacillus thuringiensis (Bt) coding for the d-endotoxins; sck: modified CpTI gene, the CpTI gene encoding a cowpea trypsin inhibitor a cowpea trypsin inhibitor; PsnII: potato proteinase inhibitor gene; sbti: soybean trypsin inhibitor gene; bar: hygromycin phosphotransferase gene; VHb: Vitreoscilla hemoglobin gene; tzs: trans-zeatin secretion gene; EPSPS: the modified 5-enolpyruvylshikimate-3-phosphate synthase gene; ferritin gene: cloned from soybean (Phaseolus limensis); SsNHX1: the Suaeda salsa vacuolar Na+/H+ antiporter SsNHX1; MnSOD: manganese superoxide dismutase gene; COX: Arthrobacter pascens choline oxidase gene; SNAC1: stress responsive gene; NDV F: gene of Newcastle disease virus (NDV F).

2.1 Insect-resistant Transgenic Rice

Insect resistant rice has been produced expressing various Bt genes, as well as non-Bt genes such as the proteinase inhibitor genes (CpTi, SpTi), the mannose-specific lectin gene (gna).

Early in 1989, it was reported that Chinese scientist transformed Bt toxin gene, the insecticidal delta-endotoxin Bt gene (Cry toxin gene) from Bacillus thuringiensis, into japonica rice variety 209 by protoplast-fuse techniques.22 In 1991, Bt toxin gene was transferred into cultivated rice variety Zhonghua 11 by the pollen-tube pathway.23 Since 1993, transgenic rice plants with enhanced pest resistance have been reported in many experiments. Transgenic elite rice lines expressing a Bt fusion gene derived from Cry1Ab and Cry1Ac were developed in 2000.29 The lines used in the transformation were Indica CMS restorer line of Minghui 63 and its derived hybrid rice Shanyou 63. The Bt rice has shown resistance against several insect pests, such as the striped stem borer (Chilo suppressalis), yellow stem borer (Scirpophaga incertulas), leaffolder (Cnaphalocrocis medinalis), and has also shown
excellent agronomic performance.\textsuperscript{39, 51}

Other lines of insect-resistant GM rice varieties include, for example, a modified \textit{CpTi} gene (Cowpea Trypsin Inhibitor gene) named \textit{sck}, which was introduced into an elite \textit{Indica} rice lines used for three-line hybrid breeding in China.\textsuperscript{52} The homozygous transgenic restorer MH86 lines, and their combinations expressing both \textit{sck} and \textit{Cry1Ac} genes, marker-free rice lines with \textit{sck} gene or both \textit{sck} and \textit{bt} genes were also developed.\textsuperscript{34, 50} Bioassay and field test showed the transgenic insect resistant rice conferred high resistance to lepidopteran insects as rice stem borer.\textsuperscript{34}

\section*{2.2 Disease-resistant Transgenic Rice}

The \textit{Xa21} gene is useful for breeding bacterial blight resistant rice varieties because of its wide-spectrum resistance to \textit{Xoo} (\textit{Xanthomonas oryzae} pathovar \textit{oryzae}) blight.\textsuperscript{53} The cloned \textit{Xa21} gene has been transferred into several rice varieties through particle bombardment, or mediated by \textit{Agrobacterium tumefaciens}.\textsuperscript{14-17} The homozygous \textit{Xa21} transgenic Minhui63 restorer plants were crossed with Zhenshan97A to breed a BB resistant hybrid, Shanyou63 with the transgene \textit{Xa21}. The transgenic hybrid rice plants not only displayed high broad-spectrum resistance to \textit{Xoo} races but also maintained all the elite agronomic characters of the hybrid Shanyou63.\textsuperscript{19} The Minghui63-\textit{Xa21} and Shanyou63-\textit{Xa21} plants demonstrated resistance to \textit{Xoo} and maintained their normal elite traits under field conditions.\textsuperscript{54}

\section*{3. Biosafety Regulation and Policies on GMOs Risk Assessment}

Environmental release and marketing of GMOs has attracted wide spread concerns about the environmental and health risks in China. In response to the emergence of these concerns, Chinese Ministry of Science and Technology (MOST) issued the first biosafety regulation in
1993, named as *Safety Administration Regulation on Genetic Engineering*. The *Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering* issued by the Ministry of Agriculture (MOA) in 1996 covered agricultural use of biotechnology in more detail. These regulations were updated by the State Council of China in 2001 when they issued the *Regulation on Safety of Agricultural Genetically Modified Organisms* for the purpose of strengthening the safety evaluation administration of agricultural genetically modified organisms; safeguarding the health of humans and the safety of animals, plants, and microorganisms; and protecting the environment. To implement this Regulation, the MOA issued three implementation regulations including *Implementation Regulations on Safety Assessment of Agricultural Genetically Modified Organisms*, which provided the legal basis and technical guidelines in GM crops risk assessment in China (The English version of these regulations can be found in the Biosafety Clearing-House of the *Convention on Biological Diversity*).

The 2001 Regulations endorses the authority of the MOA over national agricultural GMOs. To implement the Regulations, the MOA established the Office for Biosafety Administration of Agricultural GMOs (OBA). A national biosafety committee (NBC) has been established under the administration of the OBA, and in charge of safety assessment of agricultural GMOs. Members of the NBC come from different administrative departments, academic institutions, etc. who are experts in biological research, production, processing, inspection and quarantine, public health and environmental protection with respect to agricultural GMOs. All 31 provinces in China have established provincial biosafety management offices under the provincial agricultural bureaux. They are responsible for the supervision and administration of the safety of agricultural GMOs in their respective administrative areas. In the case of biosafety assessment of GM crop, for example, the field-testing of a specific GM
crop should be supervised by the provincial biosafety office where the GM crop is planted. Whether the GM crop is permitted to plant in that province for field–testing or whether go to next biosafety assessment stage should be approved by the NBC.

Agricultural GMOs in accordance with the 2001 Regulations are divided into four safety levels from level I (No danger for the time being) to IV (High degree of danger), according to their potential risk to the human, animals, plants and microorganisms. Safety assessment shall be conducted for plants, animals, and microorganisms on the basis of science, using case by case examinations; and under varying degrees of controls depending on the different stages. Safety assessment of GM plants is divided into five stages: 1) “laboratory research” means any work of genetic manipulation or GMO research in a laboratory and contained system; 2) “restricted field-testing” means any small-scale test of GMOs in a contained system or under confined conditions; 3) “enlarged field testing” means any moderate-scale test in natural conditions with appropriate safety control measures; 4) “productive testing” means any large-scale test prior to commercial production and use of GMOs; 5) Application for the safety certificate. The application for the safety certificate should be after productive testing.

The 2001 Regulations meet the generally accepted risk assessment procedures outlined in the relevant international instruments, such as Annex III of the Cartagena Protocol on Biosafety to the Convention of Biological Diversity, the Codex Alimentarius Commission Principles for the Evaluation of Food Derived from Modern Biotechnology (FAO/WHO, 2003), and Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants (FAO/WHO, 2003). Generally the practice in China is to use a comparative risk assessment approach, in which the transgenic crop is compared with the corresponding non-transgenic crop in ecological risk assessment and hazard identification in transgenic
Although there are no official guidelines in China for risk assessment on food derived from transgenic crops, the assessments carried out so far on nutrition, toxicity and allergenicity generally followed the relevant Codex principles and guidelines.

In China, GM rice, along with many other types of agricultural GMOs, also need to satisfy the procedures governing the release of new seed varieties. These procedures are governed by the Seed Law in China. Only agricultural GMOs that have previously obtained a biosafety certificate are eligible to be classified as a new seed variety in accordance with the Seed Law and relevant regulations. After the GMO has passed seed variety testing and received the permission for production, it is eligible to enter into the chain of production, and marketing.

Since 1997, many types of transgenic rice varieties have undergone various biosafety assessment trials. In 2002, 199 GMOs were approved in different stages of biosafety testing in China, 158 were GM crops, among which GM rice accounted for about 24 per cent. In 2003, 235 GMOs were approved in different stages of biosafety testing in China. 67.7 per cent of approved GMOs were GM crops, 12 per cent of these were rice, which amounted to 19 organisms - mostly were insect-resistant transgenic rice lines. Four GM rice varieties including transgenic rice with the Xa21 gene and the Bt rice varieties are at the stage of application for biosafety certificate, the final regulatory check before commercialization.

4. Research on GM Rice Risk Assessment

Since 1997, the MOST has invested more than $25 million in the biosafety research. GMO detection methodologies, technical standards for GMO biosafety assessment, covering basic biosafety issues to specific questions relevant to a targeted GMO product, monitoring of long-term effects and questions to be urgently answered are some of the major areas of
research.\textsuperscript{59} Most of the risk evaluation on transgenic crops has been on cotton, rice, wheat and maize. Among the published papers on risk assessment of environment and food safety reviewed for this paper, insect-resistant transgenic rice lines accounted for about 80 per cent of materials used in risk assessment including 60 per cent of transgenic rice based on \textit{B. thuringiensis} (Bt) endotoxin, 20 per cent of other modifications for insect resistance such as proteinase inhibitors (SCK) and 13 per cent of risk assessments were herbicide-tolerant transgenic rice lines.

4.1 Environmental Risk Assessment

The possible environmental risks that have been considered in the risk assessments examined for the purposes of this paper include (1) non-target and biodiversity risks, which include non-target pests, natural enemies, and etc., and effects to ecosystem; (2) risks associated with gene flow and recombination; and (3) risks associated with the evolution of resistance in the target organisms.\textsuperscript{60}

4.1.1 Effects on Non-target Pests

The non-target effect studies are mostly focused on \textit{bt} and \textit{CpTi} genes in rice. The Bt protein is known to be toxic to only a narrow spectrum of Lepidopteran species. Consequently, the effect of these transformations on non-target species is difficult to measure and will if there is any effect only be indirect. The effects on non-target pests, the brown plant hopper (BPH) \textit{(Nilaparvata lugens)} and the white-back plant hopper (WBPH) \textit{(Sogatella furcifera)} have been investigated using Bt transgenic \textit{Indica} rice (B1 and B6) carrying the \textit{Cry1Ab} gene, the transgenic restore line of hybrid rice (MSA and MSB) carrying the \textit{sck} gene or both \textit{CpTi} and \textit{bt} genes, the Bt rice lines (TT9-3, TT9-4) as experimental materials.\textsuperscript{61-63} The studies found that under selection conditions of host plants, transgenic \textit{Indica} rice B1, B6 and transgenic
restored line of hybrid rice (MSA), the loading percentage, oviposition preference and number of eggs on the transgenic plants of the two insects were not significantly different from those on the control, whereas the total number of probing wound caused by the BPH was higher in the transgenic plants than in the control.\textsuperscript{61} The studies found that transgenic rice lines MSA containing both \textit{CpTi} and \textit{bt} genes showed no significant effect on the biological parameter of the BPH compared with the parent line. MSB rice with \textit{CpTi} and \textit{bt} genes did not significantly influence most of the biological indices of the two species of plant-hoppers.\textsuperscript{62} The studies found that there were no significant differences between the densities of adult \textit{S. furcifera} and \textit{N. cincticeps} in the plots of the two Bt rice lines (TT9-3, TT9-4) and their parental control (IR72) during the whole growing season of rice.\textsuperscript{63} The studies concluded that the ecological risk of transgenic rice causing the outbreak of rice plan-hoppers seemed small compared with the non-GM controls.

\textit{4.1.2 Effects on Natural Enemies}

Although the effects of Bt plants have been investigated in China for a limited number of predator and parasitoid species under confined conditions, these investigations have found no evidence of direct effects of Bt plants on natural enemies.\textsuperscript{64} Laboratory and field studies with Bt rice provide a similarly positive results. Under laboratory condition, predation by 2 spiders (\textit{Pirata subpiraticus} and \textit{Oedothorax insecticeps} (\textit{Ummeliata insecticeps}) fed on planthoppers \textit{N. lugens} reared on the transgenic rice cultivars (KMD1, RBS and II-32/RBS) were not significantly affected compared to planthoppers reared on non-transgenic rice.\textsuperscript{65} Bt toxin expressed in transgenic Cry1Ab rice pollen had no evident negative impacts on the fitness of \textit{Propylea japonica} (Thunberf), an important predator of rice insect pests when the pollen was used as a food by this beetle.\textsuperscript{66}
The impacts of transgenic Bt rice (TT9-3 and TT9-4) on the field population dynamics of the dominant spider species, *Tetragnatha maxillosa*, *Dyschiriognatha quadrimaculata*, *Ummeliata insecticeps*, *Pardosa Pseudonannulata* and *P. subpiraticus* were similar to those in control field, where the population of most of spiders showed no significant difference. The results indicate that the two Bt rice lines have no adverse effects on the dominant spider species in rice paddies.

### 4.1.3 Effects on Soil Microorganisms

Soil microbiological and biochemical properties have often been proposed to be an early and sensitive indicator of anthropogenic effects on soil ecology both in natural and agroecosystems. Studies showed the residue of Cry1Ab protein in Bt transgenic rice (KMD) rhizosphere soil was undetectable, the half-lives of the Cry1Ab protein in the soils amended with transgenic rice straw were no more than 35d depending on soils under laboratory studied. Under laboratory conditions, Cry1Ab toxin in straws of Bt-transgenic rice (KMD) appears to be toxic to the cultural microrganisms in upland soil, and a change in some important biological properties was reported but was not toxic to a variety of culturable microorganisms in the studied flooded paddy soil.

### 4.1.4 Gene Flow

Gene flow is referred as the movement of genes from one organism to another. Gene flow is possible through pollen from open-pollinated varieties crossing with local crops or wild relatives. The likelihood that a transgene will spread in the environment depends on its potential fitness impact. Rice is a self pollinating plant, and there are no known insect pollinators. It was reported that gene flow between traditional variety (Huangkenuo) and hybrid rice Shanyou 63 showed an average frequency of 0.04 per cent in Huangkenuo and
0.18 in Shanyou 63. It was also reported that gene flow from a rice cultivar (Minghui-63) with high pollen production to wild \textit{O. rufipogon} had a maximum frequency of less than 3 per cent.\textsuperscript{71}

Gene flow from Bt/CpTI rice lines to their non–GM control cultivated with different mixed planting patterns in the field was detected at a low frequency (0.046-0.833 per cent) even if the GM rice is planted at close spacing with non-GM rice. High densities of GM rice cultivated in the neighborhood of non-GM rice will increase the probability of outcrossing with the non-GM rice.\textsuperscript{72} While, the \textit{bar} gene in a transgenic herbicide resistant rice moved from GM to non-GM rice through pollen- mediated gene flow at a low frequency within a 3m distance.\textsuperscript{73}

Gene flow study of transgenic rice (Y003 and 99t) carrying \textit{bar} gene to wild rice (\textit{O. officinalis} Wall) and barnyard grass (\textit{Echinochloa crusgalli} var. \textit{mitis}) concluded that it was not possible for the bar gene to move from the GM rice to these wild species. The germination rate of pollen grains of transgenic rice on the stigma of \textit{O. officinalis} was lower than that of self-pollination.\textsuperscript{74} Pollen grains of transgenic rice on the stigmas of barnyard grass could neither germinate or grow normally after crossing, nor penetrate the stigmas of barnyard grass.\textsuperscript{75} Emasculated barnyard grass pollinated with the rice pollen grains under mentor pollen inducement conditions did not produce seeds.\textsuperscript{76} It indicated the low gene flow maybe due to the strong reproductive barriers between rice and the wild species.

\textbf{4.1.5 Resistance Risk and Management}

Insect adaptation to conventional insecticides and crop cultivars has been a pervasive and costly problem in pest management.\textsuperscript{77} Studies showed that expression of Bt toxic protein
differs with the growth stage, and segment of Bt rice.\textsuperscript{78-79} Geographic variation in susceptibility of \textit{C. suppressalis} to Bt toxins was observed in China.\textsuperscript{80} However, none of the Bt crops used so far has suffered a resistance failure despite widespread use.\textsuperscript{81} Whether this is because of effective resistance management such as plant refuges or other factors is not generally known.\textsuperscript{82} Refuges may be of the same crop or another crop that the insect pest feeds on. Since most farmers in China are small scale householders, it is difficult to design and implementation of resistance management strategies for Bt rice. Assumptions of intercropping between rice and Water Bamboo or \textit{Eleocharis dulcis}, and other farming systems to manage resistance risk have been raised as a possible approach.\textsuperscript{83} Recently, Bt rice cultivars with two or more toxin genes for producing a high dose of toxin protein have been proposed to defer the development of resistance.\textsuperscript{84} For examples, a transgenic elite rice lines expressing a Bt fusion gene derived from \textit{Cry1Ab} and \textit{Cry1Ac} were developed in China.\textsuperscript{29} Combining \textit{CpTi} with \textit{bt} gene also improved rice resistance against insect pests and delayed the mergence of resistance.\textsuperscript{34, 50}

4.2 Food Safety Assessment

In China the food safety of trangenic rice has been largely studied based on the principle of substantial equivalence. There were no significant differences in major nutritional components between the transgenic rice (KMD) and the wild-type (Xiushui 11), or between the transgenic rice (Huachi B6) and the parent Jiazao 935.\textsuperscript{85} Although a small amount of \textit{Cry1Ab} protein was detected in raw rice, no transgenic protein was detected in the cooked rice due to the denaturation of Bt toxin protein after cooking.\textsuperscript{86} Toxicological evaluation has also been investigated on Bt transgenic rice on the development of silkworm (\textit{Bombyx mori}) larvae and rats. The silkworms had a slight loss of body weight, but no lethality was recorded.\textsuperscript{87} The submicrostructure of the midgut of silkworm larvae in the Bt trangenic rice
raw flour treatment changed. However, results demonstrated that Bt rice flour at a dosage of 64g Kg-1 BW, Bt toxin and NPTII and HPT proteins have no toxic effects on rats at 90 day feeding test. Transgenic rice line with sck gene was another example. There was no difference in the nutritional indices between rats fed with transgenic rice and non transgenic rice for 90 day test. No significant difference was detected between minipigs fed in GM rice and non-GM rice for 62 days in all measured variables. Toxicity evaluation on transgenic rice lines containing mtlD/gutD gene, or cod gene on rats in a 30 day feeding test indicated no significant differences on the physiological metabolism between the treatment and control.

5. Gaps in the Risk Assessment Procedures

This review of the various risk assessment procedures and assessments in China illustrates a number of areas that merit further attention.

5.1 Field Testing.

More than 70 per cent of studies were conducted under laboratory condition. Laboratory studies have limited predictive ability regarding large-scale, long-term effects in the imperfect conditions of the real world. For example, human activities and agricultural practices have not been adequately incorporated into the risk assessment process. One example of this gap is that although there has been a considerable amount of research on natural pollen dispersal in China, under some conditions human-mediated seed dispersal may have a stronger influence on the risks associated with gene flow. A landmark study in risk assessment was the ‘Farm-Scale Evaluations’ study in the UK. The studied gene flow from oilseed rape (Brassica napus) to bargeman’s cabbage (Brassica rapa) on a national scale in the UK involved remote sensing, field ecology, plant molecular biology and mathematical
modeling.\textsuperscript{94} The data had great statistical power and direct relevance for the decision-making process of the UK regulators. The study highlights the need for this type of multidisciplinary field testing to be undertaken in China.

\subsection*{5.2 Compliance and Risk Management}

Rice is still largely a small scale endeavour in China where the average farm size is one acre. Millions of farms pose compliance problems for any coordinated management effort. Indeed, even in the early testing phase of GM rice compliance issues have arisen. For example, \textit{The Implementation Regulations on Risk Assessment of Agricultural Modified Organisms} of the MOA requires that risk management measures should be adopted during risk assessment of Agricultural GMOs. However, for one assessment of productivity and health effects of two insect-resistant transgenic rice varieties, farmers cultivated GM rice without the assistance of technician, contrary to the Regulations.\textsuperscript{95} Conducting biosafety trails without technicians’ support raised serious issues about whether the safeguards to prevent GM contamination were properly followed.\textsuperscript{96}

More importantly, questions have been raised about the extent that farmers are using GM rice illegally. This has proven to be a major problem with other GM crops in other countries – effectively forcing Brazil and India to legalise the use of GM crops. The recent banning of US rice exports by the EU, Japan and Korea demonstrate the significant international consequences of not properly ensuring compliance with risk management procedures. Greenpeace International has also reported in 2005 that GM rice had entered into Hubei (where a GM rice variety was being field tested) and Guangdong (near to Hubei) markets.\textsuperscript{97} In March 2006, Greenpeace alleged that insect-resistant Bt transgenic rice has been found in Heinz’ nutritious rice flour in China.\textsuperscript{98} In response to these arguments, the MOA instructed
the Hubei Provincial Agricultural Bureau to conduct an investigation. The Hubei Provincial Agricultural Bureau confirmed three companies had illegally enlarged their plantings of GM rice, but advised all illegal GM rice had been eradicated. The Hubei Provincial Agricultural Bureau denied that rice sampled in Hubei and Guangzhou market contained GM rice.99 On 31 March, 2006, the MOA based on results provided by entrusted GMO detecting institutes clarified that Heinz' nutritious rice flour sampled does not contain GM rice.100 Even so, the MOA issued the Guidelines of Biosafety Investigation on Field-Testing of GM Crops on 12 May, 2006 to safeguard the field-testing of GM crops.101 Illegal use and contamination are likely to be ongoing problems that will require a high degree of vigilance by MOA if they are to avoid farmers taking matter into their own hands. Clearly greater awareness about the requirements of the Regulations amongst farmers using GM crops would be helpful. Greater vigilance by MOA is also needed. If compliance problems persist then stronger sanctions will need to be considered. But as a first step a more independent investigation of compliance and illegal use is called for in China.

5.3 Science Uncertainty

In practice, relationships linking environmental effects to GMOs, even when they exist, are difficult to discern due to compounding factors, various sources of uncertainty and scientific limitations. In food safety assessment, although the array of analytical and epidemiological techniques available has increased, there remain sizeable gaps in the ability of scientists to identify compositional changes that result from genetic modification of organisms intended for food; to determine the biological relevance of such changes to human health; and to devise appropriate scientific methods to predict and assess unintended adverse effects on human health.102 These shortcomings are as evident in China risk assessment procedures as elsewhere.
5.4 Socio-economic Consideration

Socio-economic considerations refer to a broad spectrum of concerns about the actual and potential consequences of GM rice, such as impacts on farmers’ incomes and welfare, cultural practices, community well-being, traditional crops and varieties, rural employment, trade and competition, ethics and religion, consumer benefits, and ideas about agriculture, technology and society.\textsuperscript{103} Taking such considerations into account during the risk assessment process is not legally required in China. Nevertheless they are considered important factors in China and there have been a number of empirical economic studies on GM cotton that tend to reveal income gains for farmers who plant GM seeds.\textsuperscript{10} Much more attention needs to be given to this issue if GM rice is to be commercialized in a sustainable way.

5.5 Studies on Pest Resistance to GM Rice

The development of resistance by insect and pathogen to GM rice is a potential risk. No studies on pathogen resistance to GM rice in China have been reported. For Bt rice grown extensively in China, as mentioned at the part of resistance risk and management, there is a risk for the development of insect resistance. Prudence suggests that some exploration of the issue should be undertaken before commercialization of GM rice.

6. Conclusion

Rice has been cultivated for more than 10,000 years, grown around the world and is the staple food for nearly half the world’s population. Due to the need to increase rice yields, China has invested heavily in biotechnology and varieties of GM rice. Although commercial release of GM rice has not so far happened in China, field testing of various types are in their final stages. Moreover, in 2005 Iran used GM rice at a semi-commercial level. The
commercialization of GM rice in China would have a major impact on the use of GM crops around the world.

This review shows that the development of GM rice in China has been monitored by detailed risk assessments. Risk assessment procedures are improving and evolving in China as more experience is gained in the technology and the procedures. Even so more attention needs to be paid to some critical areas such as field testing, more sophisticated risk management procedures, and the need for long term studies and socio-economic considerations, to ensure that these risk assessment procedures are adequate.

GM rice risk assessment also is being conducted in several countries, like the U.S., Japan, India, and etc.\textsuperscript{105-106} In each of the world’s major rice-growing countries, information about the geographic distribution, population ecology, and reproductive biology of sympatric wild relatives of the crop could be useful for evaluating the ecological effects of new transgenic traits. Much could be gained if more systematic cooperation was established between the relevant authorities in these countries about the various risk assessments that have been undertaken and the various techniques that have been developed.
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