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CHAPTER

3

# Current Regulations of the Genetically Engineered Crops in China

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## CONTENTS



## ABSTRACT

*During the past three decades, genetic engineering technology and its commercialization have been well developed in China, and the corresponding legal framework has simultaneously been formulated to regulate the biosafety and related issues. The legislation "Regulation on Administration of the Safety of Agricultural Transgenic Organisms", with support from other applicable laws and regulations, and several ad hoc administrative measures, laid a solid foundation for the administration of various activities involving genetically engineered (GE) crops and products, including inter alia safety assessment, safety measures, trade, import,*

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*labeling, inspection and quarantine. While China has established a legal framework for good governance of agricultural genetic engineering and its commercialization, problems and challenges continue for cultivating GE crops and their deregulation.*

***Key words*:** Genetic engineering, Genetically engineered crop, Biosafety, Golden rice, China

## 1. BRIEF HISTORY OF THE GE CROPS IN CHINA

As the largest developing country with a massive population but less arable land, the People's Republic of China ("China") has always been facing food shortage. Poverty alleviation remains a great challenge for the central government and consequently support to development of agricultural technology, including biotechnology, continues to remain a key element of strategies to enhance food production (Ma Youzhi *et al.,* 2012; Lu, 2013). During the past three decades, China has been making determined efforts to develop genetic engineering ("GE") technology and commercialize genetically engineered ("GE") crops. In 1978, when China had decided to adopt the Opening-Up and Reform policy, GE was included among the three branches of high science and technology (the other two were high-energy physics and laser technology) to be developed with priority. Ever since, biological sciences and biotechnology have been supported substantially as one of the main areas by state projects for basic sciences and high technologies, such as, among others, the *863 Programme, 973 Programme, Torch Project*, and *National Key Program of Development of Transgenic New Varieties*. Consequently, China became one of the earliest countries to conduct Research and Development (R&D) in agricultural biotechnology and has been playing a leading role in developing GE crops.

The *Bt* cotton story is a good example of the success achieved by China. In early 1990s cotton in China was seriously affected by bollworm, the most harmful pest that evolved resistance to a range of chemical pesticides. Cotton planting and its production declined sharply. As a result China was forced to import transgenic *Bt* Cotton seed from Monsanto, leading to patent application filing in China in 1988 by Monsanto which was granted in 1994 (CN 88102497.X). In view of the urgent demand, the Chinese scientists were determined to develop transgenic *Bt* cotton in house. With funding from the 863 Programme, widely grown cotton genotypes in China were modified in 1994 with a fused *Bt* gene encoding a smaller molecular weight protein albeit possessing high binding efficiency. These GE genotypes differed from those containing the Monsanto's patented gene and therefore patent infringement could be avoided. The Chinese Academy of Agricultural Sciences ("CAAS") filed a patent application for its own technological achievement and got a patent granted in 1998 (CN 95119563.8). Encouraged by the success achieved in developing *Bt* cotton, scientists in China have developed subsequently the second

and third generation *Bt* cotton with higher resistance to the bollworm and increased yield. These newly developed genotypes were patented in 2002 (CN 98102885.3) and 2009 (CN 200510109117.4) (Liu, 2012).

Meanwhile, China has achieved significant progress in increasing the area under commercial planting with *Bt* cotton. In 1997, China approved the commercial planting of the *Bt* cotton, developed by Monsanto and CAAS. In the year 2000, only 1% of the total cotton crop was GE cotton. In contrast, the area planted to GE cotton increased to 30% in 2003, and to 64% in 2006 (Huang, 2010). The comparative advantages between *Bt* cotton versions developed by Monsanto, CAAS and other domestic research organizations have changed. Monsanto *Bt* cotton led the markets during the years 1998 to 2000 with 81% share. However, since 2006, Monsanto's share declined to less than 18% and the locally produced *Bt* took the market share of 82%, and in 2010 it increased to 95% (Huang, 2010; Suo, 2011; Sun, 2009). Therefore it is abundantly clear that China could harness in house skills to develop GE cotton cultivars that are comparable to those introduced by Monsanto. Hopefully other developing countries would be encouraged by this achievement in China. In addition, the national scientists and institutes should strive to develop GE crops adapted to local conditions which in the long run are likely to outperform exotic GE cultivars (Liu, 2012).

During the past two decades, in addition to *Bt* cotton, the Chinese scientists have developed successfully various GE crops or organisms, that include, *inter alia*, GE tobacco, tomato, petunia, sweet pepper, papaya, rapeseed, soybean, wheat, *Bt* poplar, *Bt* rice, and phytase maize. The traits introduced into the GE crops include, among others, high keeping quality during storage, increased yield and quality, and resistance to biotic stresses that include insect pests, viruses and other pathogens and abiotic stresses (*e.g.*, cold, arid, and salt) thus exploiting fully the advantages offered by GE crops and products from them (Jiang, 2007; Jin, 2006). Due to the advantages of *Bt* cotton that include reduction in cost of production, labor, minimizing pesticide use and consequently greater safety to human beings and animals and above all increased production and quality, it was enthusiastically received by the farmers (Huang *et al.,* 2005). According to the ISAAA, in 2011 about seven million small farmers across China planted 3.9 million hectares with *Bt* cotton (James, 2011). To summarize, China became the leading developing country in the world for establishing world class research and development facilities and for large scale commercialization of especially *Bt* cotton.

## 2. CONSTRUCTION OF A LEGAL FRAMEWORK FOR GE CROPS IN CHINA

With the development of GE technologies, China during the past two decades has in parallel constructed a legal framework for the governance of GE crops, comprising the relevant laws, regulations, and rules that deal with the biosafety and other issues.

In 1993, the Measures for Administration of the Safety of Genetic Engineering was approved by the State Council and promulgated by the former State Commission of Science and Technology (now Ministry of Science and Technology, "MOST"). It covers experiments, pilot tests, industrial production, and environmental release of GE organisms, whether locally produced or imported. As the first administrative measure on GE issues, it initiated a framework for administration of GE crops including setting up of general standards for safety assessment, the corresponding control measures and procedures for notifications, and supplying with the civil, administrative and criminal liabilities for violations of the "Measures", such as recovering the damaged environment and paying damages (*Measures for Administration of the Safety of Genetic Engineering*, Articles 3, 4, 6, 9, 13-28). However, the provisions were rather conceptual with less enforceability, and also lacked measures to cover GE trade. As a result the "Measures" did not play a key role in the administration of GE issues.

Two additional Measures were promulgated: the *Measures for Implementation of the Safety of Genetic Engineering of Agricultural Organisms* promulgated in 1996 (revised in 1997 and abolished in 2002) by the Ministry of Agriculture ("MOA") to deal with the biosafety issues of agricultural GE organisms, and the *Measures for Administration of the Research and Its Application of Tobacco Genetic Engineering* promulgated in 1998 by the State Administration of Tobacco Monopoly to deal with the biosafety issues of GE tobacco and its products. While encouraging R&D and industrial applications of GE crops, the administrative measures covered largely the biosafety issues of the GE crops and products derived from them.

At the beginning of the 21st century, while *Bt* cotton planting was becoming popular, China had to import GE soybean from the USA and other countries, under the international free trade agreements. Just before China's access to WTO, the State Council promulgated on May 23, 2001 a set of rules under the *Regulation on Administration of the Safety of Agricultural Transgenic Organisms* ("Agricultural Transgenic Regulation", or the "Regulation"), and enforced them on the same day. The Regulation could be termed the first *ad hoc* regulation, and a milestone in China specifying conditions on governance of GE organisms in agriculture. It covered all kinds of GE activities, including R&D, testing, production, processing, and trade thereof. This Regulation was slightly modified in 2011. Under its purview a number of *ad hoc* administrative measures dealing with various aspects of GE crops were promulgated, as given below.

(1) *Measures for Administration of the Safety Assessment of Agricultural Transgenic Organisms*, promulgated by MOA on January 5, 2002, came into force on March 20, 2002, and revised on July 1, 2004;

(2) *Measures for Administration of the Safety of Imported Agricultural Transgenic Organisms*, promulgated by MOA on January 5, 2002, came into force on March 20, 2002, and revised on July 1, 2004 (*Decision of the Ministry*

*of Agriculture on Revising the Agricultural Administrative Regulations and Regulatory Documents*, Section 8, 2004);

(3) *Measures for Administration of the Labeling of Agricultural Transgenic Organisms*, promulgated by MOA on January 5, 2002, came into force on March 20, 2002, and revised on July 1, 2004 (*Decision of the Ministry of Agriculture on Revising the Agricultural Administrative Regulations and Regulatory Documents*, Section 9, 2004);

(4) *Measures for Administration of the Hygiene of Transgenic Food*, promulgated by the Ministry of Health ("MOH") on April 8, 2002, came into force on July 1, 2002, and abolished by the *Measures for Administration of the New Resources Food* (promulgated by MOH on July 2, 2007 and came into force on December 1, 2007);

(5) *Measures for Administration of the Inspection and Quarantine of Transgenic Products Entering and Exiting the Territory*, promulgated by the State General Administration of Quality Supervision, Inspection and Quarantine ("SAQSIQ") on May 24, 2004, and came into force on the same day;

(6) *Measures for Examination and Approval of the Processing of Agricultural Transgenic Organisms*, promulgated by MOA on January 27, 2006 and came into force on July 1, 2006;

(7) *Measures for Administration of the Examination and Approval of the Transgenic Activities on Forest Trees*, promulgated by the State Forestry Administration on May 11, 2006 and came into force on July 1, 2006.

Since the early 1990s, many relevant laws or regulations, including their revisions, have been promulgated in the fields of biosafety, food safety, agriculture and environmental protection which are applicable for the administration of GE crops, *e.g.*, the *Seed Law* (revised 2004), *Food Safety Law* (2009), and the forthcoming *Food-grain Law (draft)*. Additionally, there are *Regulation on Protection of New Plant Varieties* (1997) and *Patent Law* (revised 2008) regarding intellectual property issues of GE inventions. According to the *Seed Law*, for example, the selection, test, examination, and popularization of any GE plants should depend on adopting appropriate safety control measures, and any sale of seed of GE plants should be labeled with clear words and provide safety measures for use (*Seed Law*, Articles 14, 35). In addition, a number of international conventions and treaties China has acceded to may be applied for handling the GE issues, including the *Convention on Biological Diversity*, *Cartagena Protocol on Biosafety* ("Biosafety Protocol"), and the potential *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization*. The *Agricultural Transgenic Regulation*, together with the several *ad hoc* Measures specifying various aspects of GE plants and products, and other applicable laws or regulations, have constituted the basic framework for governance of the GE crops and their products.

## 3. SAFETY ASSESSMENT AND MEASURES FOR GE CROPS

Safety assessment is a premise for R&D and commercialization of GE crops, and MOA is responsible for making appropriate rules for implementation. MOA had established the State Safety Committee for Agricultural Transgenic Organisms ("Agricultural Transgenic Committee"), with experts drawn from the fields of research, production, processing, inspection, quarantine, hygiene, and environmental protection of the GE crops and the related products. MOA also had established a Biosafety Office of Agricultural Transgenic Organisms for routine administration of issues related to GE crops (*Regulation on Administration of the Safety of Agricultural Transgenic Organisms*, Articles 6, 7, 9; *Measures for Administration of the Safety Assessment of Agricultural Transgenic Organisms*, Article 5). According to the *Measures for Administration of the Safety Assessment of Agricultural Transgenic Organisms*, the assessed risks shall include those incurred by agricultural transgenic organisms to human beings, animals, plants, microbes, and ecological environment. Assessment of the GE risks should be based on scientific evidences and on case-by-case decisions (*Measures for Administration of the Safety Assessment of Agricultural Transgenic Organisms*, Article 4). The risk assessment system established in China is considered to be the strictest in the world, being based on scientific data, and hence reliable (Yang, 2011).

Safety of GE crops and the products from them will be assessed at four different levels: Safety Level I with no risk; Safety Level II with low risk; Safety Level III with intermediate risk; and Safety Level IV with high risk. The factors to be assessed include: (1) the safety level of the recipients; (2) the type of impact of transgenic manipulations on safety level of the recipients; (3) the safety level of the transgenic organisms; (4) the impact of production and processing on the safety of the transgenic organisms; and (5) the safety level of the transgenic products (*Measures for Administration of the Safety Assessment of Agricultural Transgenic Organisms*, Articles 9, 10).

There are four safety levels for the recipients. Level I refers to those recipients meeting one of the following conditions: with no negative impact on human health and ecological environment; with low chances for the organism to become harmful; with very little possibility of survival in natural environment after completion of experiments due to their short life cycle. Level II refers to those recipients with possible low level risks to human health and ecological environment, but meanwhile the risks can be avoided completely by relevant safety measures. Level III refers to those with possible intermediate level risks, which can be essentially avoided by safety measures. Level IV refers to those with possible high level risks, and no appropriate measures can be taken to avoid risks outside the containment facilities. The recipients may include harmful organisms with abilities to exchange easily their genetic materials with other organisms; those that cannot be prevented from escaping and spreading by currently available techniques; and those that cannot

be prevented or eliminated before they can exert, presumably, deleterious effects on human health or ecological environment (*Measures for Administration of the Safety Assessment of Agricultural Transgenic Organisms*, Article 11).

Three types of transgenic manipulations are assessed for their impact upon the safety level of the recipient organisms. Type 1 refers to those manipulations to increase the safety of the recipient organisms, *e.g.*, deleting certain genes with known risks or inhibiting their expressions, such as certain pathogenic gene, fertility gene, or adaptability gene. Type 2 refers to those manipulations of genes (*e.g.*, certain marker gene or storage protein gene) having no effect on the safety of recipients, such as that changing the recipients' phenotype or genotype will not impact on human health or ecological environment. Type 3 refers to those reducing the safety of recipients, such as that changing the recipients' phenotype or genotype may have unfavorable or unpredicted impact on human health or ecological environment, *e.g.*, introducing into the recipient a toxin gene with potential health or ecological risks (*Measures for Administration of the Safety Assessment of Agricultural Transgenic Organisms*, Article 12).

Determination of the safety level of the GE organisms is based upon the nature of the recipients and the types of genetic manipulations (*Measures for Administration of the Safety Assessment of Agricultural Transgenic Organisms*, Article 12). In case the recipient is classified under Safety Level I, and the manipulation is of Type 1 or 2, the safety level of the resulting GE organism is of Safety Level I. In case the recipient is classified under Level I, and the manipulation is of Type 3: (1) if the safety reduction is minimal and there is no necessity to adopt any safety measures, the resulting GE organism is of Safety Level I; (2) in case the safety cannot be fully assessed, but nonetheless the potential risk can be avoided by adopting appropriate safety measures, the Safety Level should be II; (3) in case the organism is not safe, however, the potential risk can be avoided by strict safety measures, the Safety Level should be III; and, (4) if the organism is not safe and the potential risk cannot be completely avoided by any control measures, the Safety Level should be IV.

Through the various measures described the safety levels of the GE organisms or products thereof can be assessed. Technical elements for assessment of the safety levels of the GE crops and GE products, together with the corresponding control measures, have been described in details in the appendices to the *Measures for Administration of the Safety Assessment of Agricultural Transgenic Organisms* (Appendix I-V). According to the revision of the Measures (2004), MOA is responsible for arranging safety evaluation for GE organisms twice a year; and, for the new applicants, the Agricultural Transgenic Committee shall be responsible to conduct the safety assessment. MOA will take the final decision based on its own investigation.

Depending on the assessment of the safety level of the GE crops and their products, the safety measures can be extended from laboratory experiments to pilot tests, field tests, and commercialization or deregulation. However these steps were taken only after ensuring biosafety and adopting measures to avoid potential risks to human health and ecological environment. All institutes conducting research and tests on GE crops shall have the facilities and measures to guarantee the relevant biosafety, and shall establish a biosafety committee to be responsible for the biosafety issues, including examination and approval of lab experiments involving GE crops of Safety Level I and II. However the experiments involving GE crops of Safety Level III and IV shall be reported to MOA in advance (*Regulation on Administration of the Safety of Agricultural Transgenic Organisms*, Article 12). Before switching from lab experiments to pilot tests involving GE crops at four safety levels, the concerned institutes shall report to MOA with necessary information and materials such as the safety level and evidences, and the corresponding safety measures. When switching to environmental releases after pilot tests, or to production tests after environmental release, the concerned institute shall file applications to MOA, and can only continue the activities after getting the approvals. If an institute wants to conduct commercial production of GE crops, it can do so only after getting the biosafety certificate for commercial production (*Measures for Administration of the Safety Assessment of Agricultural Transgenic Organisms*, Articles 21-23).

Institutes carrying out lab experiments, pilot tests, production tests, and commercial production of GE crops shall, depending on the safety levels, formulate safety control measures, including those physical, chemical, biological, environmental, and implement/scale suitable safety measures (*Measures for Administration of the Safety Assessment of Agricultural Transgenic Organisms*, Article 35, Appendix IV). Physical measures refer to those physical means adopted to restrict survival and spread of GE crops outside the experimental or test areas, such as installation of fences. Chemical or biological measures refer to those chemical or biological means adopted to restrict survival and spread of GE crops (including residue) in field tests or outside of confinement, or transfer of genetic materials from GE crops to other organisms, *e.g.*, disinfecting biological materials, tools and facilities, removing species near the test areas which may cross contaminate (hybridize) with the GE crops, preventing flowering of the GE crops, removing the reproductive materials of the GE crops, or differentiating flowering time of the GE crops. Environmental measures refer to those making use of environmental conditions to restrict survival, reproduction, spread or residue of the GE crops outside the areas, *e.g.*, controlling temperature, moisture, or photoperiod. Scale control measures refer to those reducing the number of GE crops or the experimental area to lessen the possibility of spread of the GE crops, and completely eliminating the GE crops in the case of unexpected events (*Measures for Administration of the Safety Assessment of Agricultural Transgenic Organisms*, Article 44).

Regarding pilot tests, environmental releases, and production tests for GE crops, safety measures should be adopted. These measures should be tailored to suit the nature of the materials under test. For Safety Level I, the measures to ensure biological isolation should be adopted. The isolation distance or alternative conditions for some GE crops are, at least: (1) maize, *Zea mays* L., 300 metres, or an interval of 25 days or more between flowering; (2) wheat, *Triticum aestivum*, 100 metres, or an interval of 20 days or more between flowering; (3) barley, *Hordeum vulgare*, 100 metres, or an interval of 20 days or more between flowering; (4) cotton, *Gossypium L*., 150 metres, or an interval of 20 days or more between flowering; (5) brassica, *Brassica* L., 1000 metres; (6) rice, *Oryza sativa* L., 100 metres; (7) soybean, *Glycine max* (L.) *Merrill*, 100 metres; (8) tomato, *Lycopersicum esculentum Mill*, 100 metres; (9) tobacco, *Nicotiana tabacum*, 400 metres; (10) sorghum, *Sorghum vulgare Pers*., 500 metres; (11) potato, *Solanum tuberosum* L., 100 metres; (12) pumpkin, *Cucurbita pepo*, 700 metres; (13) clover, *Trifolium repens*, 300 metres; (14) ryegrass, *Lolium perenne*, 300 metres; and, (15) capsicum, *Capsicum annuum*, 100 metres (*Measures for Administration of the Safety Assessment of Agricultural Transgenic Organisms*, Appendix IV, Section 2.1, Table 1).

For Safety Level II, the safety measures shall include, among others: (1) appropriate isolation measures to control entry and exit of people and animals, such as setting up net houses or cages built with wire net to prevent entry of insects, while for aquatic organisms, they should be controlled within an artificial water trench area to prevent escape from dams and boards, while it is essential to ensure that GE Organisms will be prevented from entering natural water reservoirs for at least 10 years; (2) disinfection of the used tools and facilities; (3) certain biological isolation measures, *e.g.*, selection of an experimental plot within an area where GE crops cannot hybridize with local ones; (4) the corresponding physical, chemical, biological, environmental and scale control measures; and, (5) after completion of the tests, the residual plants other than the harvested parts should be destroyed collectively to prevent survival of the GE crops and residues that originated from them(*Measures for Administration of the Safety Assessment of Agricultural Transgenic Organisms*, Appendix IV, Section 2.2).

For Safety Level III, the safety measures shall include, *inter alia*: (1) appropriate isolation measures, such as prohibition of entry and exit of unauthorized personnel, artificially controlled industrialized husbandry facilities, specialized containers and related facilities for eliminating GE crops in accordance with the objectives of the experiment; (2) disinfection of the tools and facilities to prevent carry over of GE crops away from experimental areas, and eliminating the unrelated organisms by herbicides, pesticides, fungicides and rodenticides; (3) the most effective biological isolation measures to prevent other organisms from hybridization, transduction, transformation, conjugation, parasitism and heteroecism with the GE crops; (4) strict environmental measures, *e.g.*, humidity, moisture, temperature, or radiation measures, to restrict survival and propagation of the GE crops outside the

experimental areas, or encourage the testing in a desert or alpine frigid region where the escaped GE crops cannot survive or spread; (5) scaling strict control of the experiment, so that if necessary the GE crops can be eliminated at any time; and, (6) after completion of the tests, the residual plants other than the harvested parts should be destroyed collectively to prevent its survival. All these measures should be reported to the Agricultural Transgenic Committee for approval, and strictly followed accordingly (*Measures for Administration of the Safety Assessment of Agricultural Transgenic Organisms*, Appendix IV, Section 2.3). For Safety Level IV, in addition to these measures, the test conditions, facilities, and treatment of the test materials shall be more strictly implemented (*Measures for Administration of the Safety Assessment of Agricultural Transgenic Organisms*, Appendix IV, Section 2.4).

Emergency measures should be prepared to prevent unexpected accidents, *e.g.*, accidental spread of GE crops, in which an institute or the persons are required to close the site immediately, make a thorough investigation, adopt effective measures to prevent continuous spread of the GE crops, and report to the concerned administration (*Measures for Administration of the Safety Assessment of Agricultural Transgenic Organisms*, Appendix IV, Section 3.1). For appropriate disposal of GE crops, adequate and dependable measures should be adopted to destroy, inactivate or kill the GE crops grouped under the Safety Level II, III and IV for prevention of their dispersal and avoid deleterious negative effects on environment. In the case of an unexpected escape, the concerned institute or persons shall adopt effective measures immediately to control and eliminate the GE crop and report to the local agricultural administration (*Measures for Administration of the Safety Assessment of Agricultural Transgenic Organisms*, Article 36). If a GE crop is found to be harmful to human beings, animals, plants, or ecological environment, MOA is authorized to prohibit its production, processing, sale and import, and even cancel the safety certificate, and may additionally order the GE crop to be destroyed (*Measures for Administration of the Safety Assessment of Agricultural Transgenic Organisms*, Articles 37, 38).

If the procedures and measures have not been followed strictly, the relevant parties and persons are legally liable for the violations and damages. For the unauthorized environmental releases, production tests, production, manufacturing, or processing, or those activities beyond the authorized scope, or those not following strictly the approved standards or conditions, the parties will be held liable and be punished by MOA or an agricultural administration at provincial level (*Regulation on Administration of the Safety of Agricultural Transgenic Organisms*, Articles 44-48). Traders not entitled for the production or sale, or those who violate the rules for GE labeling, are liable and will be punished by an agricultural administration at county level or above, including administrative fines or confiscation of the illegal earnings or products. Unauthorized imports of GE crops could be stopped by MOA and importers would be obliged to pay administrative

fine, and the imported products and the illegal earnings will be confiscated. For any damages caused by research, test, production, process, transportation, sale, import or export of GE crops or products, the parties are liable to pay the damages according to the applicable laws (*Regulation on Administration of the Safety of Agricultural Transgenic Organisms*, Articles 50, 52, 54).

## 4. REGULATION OF TRADE, IMPORT, INSPECTION AND LABELING OF GE CROPS

Domestic trade activities of GE crops and products, *e.g.*, production, processing, transporting, stocking, and sale thereof, should first secure a certificate from MOA. For manufacturers of commercial products derived from GE crops to apply for such a certificate, they should obtain a certificate certifying the safety of GE crops, plant the GE crops in the designated places, and adopt the necessary safety measures (*Regulation on Administration of the Safety of Agricultural Transgenic Organisms*, Article 19). They should maintain files to record the places, the transferred genes and their origin, the transgenic methods, and the flow of reproductive materials of the GE crops. Additionally they should report regularly information related to production, processing, safety management, and product flow to the local agricultural administration. In case of accidents, the manufacturers and processors should adopt immediately emergency measures and report to the local administration. The agents who are transporting and stocking GE crops should adopt the appropriate safety measures as well (*Regulation on Administration of the Safety of Agricultural Transgenic Organisms*, Articles 20, 23-25). Commercial seed companies should maintain specific files for managing personnel and quantities sold, with information about origin of the GE seed, the stocks remaining, transporting, and flow of the goods, and the safety measures adopted. They also should check labels of the GE products and re-label them in case the original package was opened (*Regulation on Administration of the Safety of Agricultural Transgenic Organisms*, Articles 26-28). For processing GE crops into commercial products, the manufacturers should first get a certificate from the agricultural administration at provincial level. For doing so, they should have ad hoc production lines and secure stocking facilities, and have knowledge of management of all the procedures of purchasing, transportation, stocking, processing, and sale, and planned measures for emergency situations. All the certificates granted, by the agricultural administration at provincial level, should be reported to MOA. The duration of certificate lasts for three years and can be reapplied for additional terms (*Measures for Examination and Approval of the Processing of Agricultural Transgenic Organisms*, Articles 3-7).

Importing of GE crops and products has been an important aspect for GE trade. The imported GE crops may be used as materials for R&D, manufacturing, processing, or commercial products. MOA is responsible for assessment and administration of the safety issues. Different procedures are applied for applications

involving different kinds of GE crops, and those used directly for commercial production should be treated in the same way as those used for processing. In case a GE crop has already been authorized for research and evaluated in a foreign country and appropriate safety measures have been adopted, the application will be approved. A foreign company can apply, for exporting to China, GE crops to test them and their products, if they can prove that they are safe to human beings, animals and ecological environment. Additionally the exporting country should show that they are safe for marketing. In such situations, the application will be approved. Subsequently if the material is proven to be safe, a safety certificate will be issued by MOA (*Regulation on Administration of the Safety of Agricultural Transgenic Organisms*, Articles 31, 32). The application for importing GE crop products for processing should fulfill the same conditions as those for GE crops (*Regulation on Administration of the Safety of Agricultural Transgenic Organisms*, Article 33). With a safety certificate and the relevant documents, the importers can apply for inspection of the imported GE crops and products by the quarantine administration. The maximum time allotted for MOA or the quarantine administration, in order to give a decision, is 270 days since the date of receipt of the application, as stipulated in the Biosafety Protocol (*Regulation on Administration of the Safety of Agricultural Transgenic Organisms*, Article 36; *Biosafety Protocol*, Article 10.3).

Furthermore, there is a summary procedure for reapplication of safety certificate. After getting an approval from MOA, if the same company applies for a safety certificate for re-entry of the same GE products to China, it can file an application utilizing a short procedure by providing the registration, a copy of the original safety certificate and safety measures, and can be granted with an identical safety certificate if qualifies for the requirements (*Measures for Administration of the Safety of Imported Agricultural Transgenic Organisms*, Article 14). In case that live GE crops are used as processing materials, records should be maintained on their origin, stocking and transportation. Simultaneously appropriate safety measures should be adopted to ensure that they will not be released into environment (*Regulation on Administration of the Safety of Agricultural Transgenic Organisms*, Article 16). If without a safety certificate or relevant documents, or if the GE crops do not comply with the safety certificate or relevant documents, those GE crops will be destroyed or prevented from exporting. However, if the GE crops are only mis-labeled, they can be correctly re-labeled and permitted to enter in to the country.

Those GE crops or products imported from abroad in to China for various purposes, *e.g.*, trade, processing, research, aid, donation, exchange or exhibition, should go through procedures of inspection and quarantine to ensure biosafety. SAQSIQ, together with its regional branches across the country, is responsible for such procedures (*Measures for Administration of the Inspection and Quarantine of Transgenic Products Entering and Exiting the Territory*, Articles 2-4). Any agency importing GE products should notify the administration in customs all the

relevant information and provide the safety certificate for the GE product issued by MOA, the document of approval for the GE label, and other relevant documents. For certified GE crops and products from them, *e.g.*, transgenic soybean, rapeseed, maize or their product, the administration will inspect and test for compliance, and for those not claimed to have been derived from GE crops, the administration will inspect the products randomly (*Measures for Administration of the Inspection and Quarantine of Transgenic Products Entering and Exiting the Territory*, Articles 6, 7, 9). In case the transgenic components of the claimed GE products do not comply with the approval document, or those not claimed to be GE products but having transgenic components, the administration will notify the parties or their agents that the goods will be rejected or destroyed. For those products used in exhibitions, they will be destroyed or returned to the exporting country after that event; in some cases for specific reasons they may be used for other purposes by following inspection and subjecting to appropriate quarantine measures (*Measures for Administration of the Inspection and Quarantine of Transgenic Products Entering and Exiting the Territory*, Articles 10, 11). In case an agency wishes to export certain products to a foreign country, it may request the administration to test for transgenic components and issue a document to prove that the products are non-transgenic (*Regulation on Administration of the Safety of Agricultural Transgenic Organisms*, Article 37).

For GE products which are carried as personal belongings from abroad to China, the person shall provide to the administration of inspection and quarantine at customs the safety certificate for the GE products and the certificate of quarantine issued by an authority in the exporting country, and the GE products should be labeled correctly if the products were derived from GE crops (see *infra*). For those who are unable to provide the required documents, or if the products are suspicious, the imported GE products may be rejected or destroyed (*Measures for Administration of the Quarantine of the Belongings Carried by Persons Entering or Exiting Borders*, Articles 18, 30).

The *Agricultural Transgenic Regulation*, together with the *Measures for Administration of the Labeling of Agricultural Transgenic Organisms*, creates a partially compulsory labeling system for selective GE organisms and products, which are listed in the Catalogue of Agricultural Transgenic Organisms. The first Catalogue, promulgated by MOA in consultation with other ministries (*Measures for Administration of the Labeling of Agricultural Transgenic Organisms*, Articles 2, 3), was attached to the above Measures and published in 2002. It includes five varieties of GE crops and seventeen kinds of GE products: (1) soybean, including soybean seed, soybean, soybean powder, soybean oil, and soybean meal; (2) maize, including maize and its seed, oil, and powder; (3) canola, including canola seed, rapeseed, rapeseed oil, and rapeseed meal; (4) cotton, including cotton seed; (5) tomato, including tomato seed, fresh tomato, and tomato sauce (*Measures for Administration of the Labeling of Agricultural Transgenic Organisms*, Annex).

The GE crops and products listed in the catalogue should be labeled compulsorily, whether imported or locally manufactured, while those not on the list can be labeled voluntarily.

Traders of manufacturing or retailing of GE crops or products are responsible for correct labeling and for re-labeling if the original packages are opened or repackaged. Labeling should be in one of the following forms: (1) GE crops or products, including GE plants, plant seeds, or products with components of GE crops or products, should be labeled directly "transgenic XX"; (2) products processed directly from agricultural GE products should be labeled "transgenic XX processed product (manufacture)" or "of which raw materials are GE XX"; (3) for those products processed from agricultural GE organisms or having their components, if the final products do not have any components of GE organisms or the components could no longer be detected, the products can be labeled "this product is processed from transgenic XX, but the product does not have transgenic components any more", or, "this product is processed from the raw materials having the transgenic XX, but this product does not contain transgenic components any more"(*Measures for Administration of the Labeling of Agricultural Transgenic Organisms*, Articles 5, 6). The labels should be marked clearly and apparently in standard Chinese language, affixed to the products and their packages, or indicated by a plate, on price tags or by other means. The labels should be approved in advance by agricultural administration at county level or above, and should be reported to MOA by agricultural administration at provincial level; and the labels for imported GE products should be approved in advance by MOA (*Measures for Administration of the Labeling of Agricultural Transgenic Organisms*, Articles 7-10). Negative labels, *e.g.*, "GE free product" or "organic product without GE components", have neither been encouraged nor prohibited. For violations of the GE labeling, agricultural administration at county level or above may order them *ex officio* to correct the labels, to seize the illegal products and earnings, and to order the parties to pay an administrative fine of 10 to 50 thousand RMB (*Regulation on Administration of the Safety of Agricultural Transgenic Organisms*, Article 52).

Transgenic food, or GE food, includes those products from GE crops and those processed directly or indirectly from GE crops (*Measures for Administration of the Hygiene of Transgenic Food*, Article 2). GE food must be safe, should not cause acute, chronic or other latent harmful effects to human health, and should have nutrient value not less than its non GE counterparts (*Measures for Administration of the Hygiene of Transgenic Food*, Articles 3-5). MOH (since March 2013, "the National Committee of Health and Family Planning") is responsible for administration of GE food, including assessment of its safety and nutrient value. However, due to the inconsistencies between this Measures and the *Agricultural Transgenic Regulation*, enforcement of these Measures met with difficulties. While the *Regulation* requests only those GE organisms or products on the selective list being compulsorily labeled "transgenic organism" as such, this Measures prescribes

that all transgenic food (including raw materials and the processed food) containing GE organisms or the derived GE products should be labeled "transgenic food" as such (*Regulation on Administration of the Safety of Agricultural Transgenic Organisms*, Article 8; *Measures for Administration of the Hygiene of Transgenic Food*, Article 16). This conflict arose due to the existence of different branches of administration and their counterparts, creating confusion among the traders and consumers. In reality, the *Measures for Administration of the Hygiene of Transgenic Food* was not enforced, and was substituted by the *Measures for Administration of the New Resources Food* and promulgated by MOH on December 1, 2007, prescribing that GE food or food additives should be evaluated in accordance with the applicable laws and regulations (*Measures for Administration of the New Resources Food*, Articles 8, 26-28).

## 5. CURRENT SITUATION AND SOCIAL AND ECONOMIC ASPECTS OF GE CROPS IN CHINA

Since 1997, China began to grant certificates for commercial cultivar of several GE crops. However, only the *Bt* cotton has been planted on a large scale, making China one of the leading countries in the commercialization of GE crops. According to the Agricultural Transgenic Office, between 1997 to 2010, about 1795 safety certificates have been granted by MOA to agricultural GE organisms, majority of which were *Bt* cottons, and some other GE crops and some GE microorganisms or their products used in vaccines and medicines (Agricultural Transgenic Office of MOA, 2011a). Other approved GE crops have all been cultivated on a small scale, including the variegated petunia (getting approval in 1997), tomatoes with virus-resistance and delayed fruit ripening (getting approvals in 1998 and 2000), virus-resistant sweet pepper (getting approval in 1998), *Bt* poplar (getting approval in 2005), and virus-resistant papaya (getting approval in 2006, about 10,000 hectares) (Lu, 2013). Though biosafety certificates for planting of two species of *Bt* rice, *Huahui #1* and *BT Shanyou #63*, were granted by MOA in 2009 in Hubei Province, the relevant certificates for crop variety release have not yet been approved, and therefore the *Bt* rice has not been deregulated for commercial planting (Ma *et al.,* 2012). One GE phytase maize approved in 2009 has a similar status.

Since the commercialization of *Bt* cotton in 1997, the area under its cultivation in 2004 was 3.7 million hectares, reaching a plateau during the next six years (3.9 million hectares in 2010). Correspondingly, China lagged behind the world leading countries in the cultivation of GE crops, attaining a global position from No. 4 in 2000-2002 to No. 6 since 2006, preceded by Brazil and India (James, 2011). Arguably this decline in the commercialization of various GE crops that include *Bt* cotton and others can be attributed to the anti-GE movement by activists compounded by lack of enthusiasm in the administration (see *infra*). Consequently, China became one of the largest importers of especially GE soya bean, from USA, Brazil and Argentina, reaching 51 million tons in the year 2010. This represents more than 70% of the soybean consumed in China (Ma Youzhi *et al.,* 2012).

For importing GE products or crops used in the food processing (*e.g.*, for cooking oil), from 2004 to 2010, MOA granted a total of 69 certificates, involving products from GE soya bean, maize, rapeseed, and cotton, imported mainly by multinational companies such as Monsanto (30 certificates), Bayer (25 certificates), Syngenta (8 certificates), and Du Pont/Dow Agrosciences (6 certificates) (Agricultural Transgenic Office of MOA, 2011b). Presumably, since 2010, the anti-GE movement had contributed to prevention of approvals by MOA to import GE products. In June 2013, coinciding with the visits by agricultural ministers from the Latin American and Caribbean countries, MOA had given approvals for importation of several consignments of GE soya bean and corn. The producers of the newly approved GE products included Monsanto (Intacta RR2 and another one), BASF (CV127), and Bayer (Liberty Link), and the exporting countries were Argentina and Brazil (Reuters, 2013; Li, 2013). These events may mark a rekindling of commercialization of the imported GE crops for utilization in food processing.

For promotion of the seed industry in China, including R&D and commercialization of GE crops or products, on April 10, 2011, the State Council issued *Opinion on Enhancing Promotion of Development of Modern Agricultural Crop Seed Industry* (*GuoFa [2011] No.8*). It recognized the seed industry as one of the state's strategic and fundamental industries, and need for fundamental research on crop varieties, including enforcement of the *National Key Program of Development of Transgenic New Varieties* and commercialization of the seed industry. From the economic and social perspectives, commercialization of GE crops with novel traits can, not only reduce insecticide and fertilizer application, but also improve the quantity and quality of the agricultural products, and consequently increase farmers' income. It is appropriate to mention that *Bt* cotton cultivation alone had accumulatively increased the farmers' income to more than 30 billion RMB (about 5 billion USD) during the past decade (Ma Youzhi *et al.,* 2012).

In recent years, R&D on GE crops in China had made significant achievements, with the successful development of numerous new species of GE crops with technological and commercial advantages. Among others, the main target crops include cotton, rice, maize, and wheat; and the general traits introduced or modified include resistance to viruses, fungal diseases, insects, and herbicides. Additionally resistance to such abiotic stresses as drought, salinity and alkalinity, is being pursued. For example, 66 new species of GE cottons resistant to insects were developed and cultivated on about 11 million hectares; a *Bt* cotton with increased seeding efficiency of 40%, with lower cost of production was developed (Qi *et al.,* 2012). Other GE crops with novel traits include, *inter alia*, (a) high yields, (b) high quality, (c) high recovery of nutrients, such as nitrogen and phosphorus, and, (d) insensitivity to photoperiod. A GE rice transformed with human serum albumin gene, a GE soya bean with high-yield of α-linolenic acid (transferred with Δ6-fatty acid dehydrogenase gene), a GE maize with high lysine; a GE wheat being marker-free and resistant to the yellow mosaic virus, and several other GE wheat species

resistant to gibberellic disease, banded sclerotial blight, and aphids, among others, have been reported. These GE crops were in the various stages of R&D, under safety assessment, pilot tests, and eventually were expected to be deregulated. (Qi *et al.,* 2012; Ma Youzhi *et al.,* 2012; Lu, 2013). The R&D aimed at producing GE crops with enhanced yield, quality and safety for human beings and animals will bring about a bright future for China's modern agriculture.

It should however be pointed out, as with many other countries, China has been experiencing immense pressure from activists involved in anti-GE movement, which will only result in impeding the progress in the field of agriculture. An illustrative example was the case related to introduction of Golden Rice. The GE Rice was developed by scientists in both universities and biotech industry, and has been shown to be efficient in supplying β-carotene, the precursor of vitamin A, and thus will be useful in overcoming the serious vitamin A deficiency prevailing in especially Asian developing countries where rice is the staple food (Potrykus, 2001). Numerous tests required to ensure biosafety of GE crops were conducted successfully on the Golden Rice for more than two decades, that included laboratory, glass house and field tests. As a result the Golden Rice should be deregulated and ready for commercial planting creating a hope for millions of poor people (especially children) who suffer from vitamin A deficiency. Correspondingly, many children in Hunan Province of China were selected as participants in a trial conducted in 2008 jointly by Chinese scientists and a team of US scientists from Tufts University, Boston, to assess the vitamin A value of β-carotene in Golden Rice (Tang *et al.,* 2012).

Unfortunately, there may have been shortcomings within the procedures adopted to seek consent from the parents of the kids who participated in the experiments (Feng, 2012a). Greenpeace, a prominent opponent to GE technologies, collected the information in 2012 on the deficiencies that occurred during the experiments conducted by Tuft University. Arguably, they exploited this deficiency to the extent of jeopardizing the efforts by Chinese government to commercialize the Golden Rice and other GE crops. This also led to apathy from public towards GE technologies in general and resentment to the efforts by the US scientists in particular (Miller, 2012). Additionally these events have led to suspicion among the concerned administrators in China to extend support for research on GE technologies, and could wrongly prevent the introduction of the GE rice into China that will have come as a boon to thousands of people that suffer from vitamin A deficiency. This can be regarded as a typical example of misrepresentation of valuable scientific data. To allay the public wrath, the concerned authorities issued orders to punish heavily the investigators in China and paid each child, fed with a meal of 60 grams of Golden Rice, a compensation of 80,000 RMB (about 13,000 US dollars) (Feng, 2012b). Obviously, this decision was not based on the scientific evidence. It is reasonable to predict that the administration in China will provide the much needed support to GE technologies that will go a long way in providing nutritious food to millions of families in China and abroad. The event that occurred in

deregulating Golden Rice in China should come as a wakeup call for governments in developing countries. Any efforts to impede the progress will only lead to compounding the problems that arise from deficiency diseases, especially for those under poverty line. China once had been a beacon of light in promoting GE technologies and one could be optimistic that the same situation would return to China and an environment will prevail that will lead to commercialization of numerous GE crops in the pipe line (Ma Aiping, 2013).

## 6. CONCLUDING REMARKS

Substantial progress has been made in China in the commercialization of GE crops. This paper deals at length the regulations formalized by the Chinese government for the correspondingly, many of GE crops and products derived from them. They include various legislations including, the *Agricultural Transgenic Regulations*, together with several administrative Measures. Principles underlying them, rationale, and procedures for safety assessment and management for undertaking research and commercialization of GE crops were given. They are to some extent influenced by the lessons learned in the USA and European Union. The rules and practices do reflect commitment by China to adopt GE technology for increasing agricultural production and alleviate poverty. During the past decade, this legal framework has been modified and improved, thus laying solid foundation for R&D, commercialization, consumption and administration of GE crops.

A brief account of the deregulated GE crops was given including the remarkable impact made by *Bt* cotton. Regarding the current situation, the social aspects and economic impact of the GE crops, the hype that existed in the late 1990s and early 2000s was no longer visible. Many issues that include international trade, politics and even ideology as well, are influencing especially the deregulation of GE crops. Unfortunately the activists are influencing the political decisions thus creating stumbling blocks. A good example is that, despite the scientific merits and need for the vitamin A enriched rice, activists played a significant role in preventing the deregulation of the Golden Rice. Science and social welfare, together with rigorous tests to ascertain their safety and impact on health and welfare of farmers and consumers, among others, should be the driving factors for commercialization of GE crops.

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