COUNTRY REPORT: THE PEOPLE'S REPUBLIC OF CHINA
Grain Law (Exposure Draft) and China's Regulation on Genetically Modified Food Supplies

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Introduction

Genetically Modified Organisms (GMOs) are the results of modern biotechnology. GMOs impact on human society along a multidimensional scale and trigger health and safety concerns, economic consequences, and social and cultural concerns. GMOs have made contributions to agriculture, pharmaceuticals, energy and so on. However, on the other hand, they are claimed to represent significant risks to the environment, human and animal life and health, and food safety. Although there is no definitive scientific evidence that GMOs are harmful, there are widespread concerns that the transboundary movement of GMOs and their environmental release might have adverse effects on biological diversity, human health and the environment in the countries of import.[1]

China is a significant importer of soybean and maize, a large portion of which is GM products. According to the General Administration of Customs, the country imported 48,340,000 tons of soybeans[2] and 250,165 tons of maize[3] for the first ten months of 2012, respectively an increase of 16.6 per cent and 89.4 per cent over the counterpart figures in 2011. In order to meet the needs of more than 1.3 billion people, the Chinese Government has assigned a high priority to agriculture and crop biotechnology. It has made significant investment on the development of GM products. By the end of 2011, China has commercialized: Bt Coton, Bt Poplar, PRSV Papaya, VR Sweet Pepper, and DR, VR Tomato. In 2011, the total area under biotech crops increased by 11 per cent and reached 3.9 million hectares.[4]

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[1] *Cartagena Protocol on Biosafety*, Preamble.
[2] See http://www.customs.gov.cn/publish/portal0/tab400/module15677/info396980.htm.
[3] See http://www.customs.gov.cn/publish/portal0/tab400/module15677/info396979.htm.
[4] C. James, ISAAA Brief 43-2011, *Global Status of Commercialized Biotech/GM Crops: 2011* (2011, ISAAA), 93.

China's Regulation on Agricultural GMOs and GM Food Supplies

China has established a case-by-case domestic regulatory and administrative system for the regulation of GMOs.[5] In 1993, the Ministry of Science and Technology issued the first biosafety regulation in China: *Measures for Safety Administration of Genetic Engineering*. This regulation was replaced by the *Regulation on the Safety Administration of Agricultural GMOs* in 2001. According to its article 2, this Regulation applies to all activities relating to the research, experiment, production, process, operation, import, and export of agricultural GMOs in China. The 2001 Regulation contains general rules on biosafety and designated the Ministry of Agriculture (MOA) as the primary competent authority to oversee biosafety regulations on agricultural GMOs.

The Ministry of Agriculture has issued *Measures for the Administration of the Safety Assessment of Agricultural Genetically Modified Organisms* (2002), which require risk assessments to be undertaken for the research, experiment, production, process, operation, import, and export of agricultural GMOs. They set out the mechanism for the safety assessment of agricultural GMOs, including classification standards and assessment processes. The *Measures for the Administration of the Safe Import of Agricultural Genetically Modified Organisms* (2002) regulate the import administration of agricultural GMOs. The *Measures for the Administration of the Labelling of Agricultural Genetically Modified Organisms* (2002) implement a mandatory labelling scheme for agricultural and the *Measures for the Examination and Approval of the Processing of Agricultural GMOs* (2006) mandate that all domestic processing of agricultural GMOs requires a Processing Permit issued by MOA. In addition, the General Administration of Customs of the People's Republic of China promulgated the *Measures for the Administration of the Inspection and Quarantine of Genetically Modified Products Entering and Exiting the Territory* in 2006. The decree applies to the inspection and quarantine of GMOs in all forms of trade, exchange, donation, post, exhibition, and so on. It also establishes a system of permits for the movement of agricultural GMOs.[6]

[5] UNEP-GEF Biosafety Unit, *Guidance Towards Implementation of National Biosafety Frameworks: Lessons Learned from the UNEP Demonstration Projects* (April 2008), 6.
[6] *Measures for the Administration on the Inspection and Quarantine of the Genetically Modified Products Entering and Exiting the Territory*, article 5.

The New Grain Law (Exposure Draft) and China's Most Recent Concerns on GMOs at the International Arena

China is a member state of the *Cartagena Protocol on Biosafety* governing the transboundary movement of GMOs. The Protocol entered into force on 11 September 2003, and has 164 member parties. From 1 to 5 October 2012, the sixth meeting of the Conference of the Parties (COP) to the *Convention on Biological Diversity* (CBD) serving as the Meeting of the Parties to the *Cartagena Protocol on Biosafety* (COP-MOP 6) was held in Hyderabad, India. COP-MOP 6 addressed substantive issues, including: risk assessment and risk management; socio-economic considerations; capacity building; handling, transport, packaging and identification of GMOs; notification requirements; unintentional transboundary movements and emergency measures; monitoring and reporting; the second assessment and review of the Protocol's effectiveness; the Biosafety Clearing-House; financial resources and mechanism; cooperation with other organizations, conventions and initiatives; and the status of the *Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress*.

Fifteen Chinese delegates participated from the Ministry of Environmental Protection, Ministry of Agriculture, State Council, State Forestry Administration, Chinese Academy of Inspection and Quarantine, China Academy of Science, Chinese Research Academy of Environmental Sciences, and Hong Kong Special Administration Region. The Chinese delegates were most concerned with risk assessment and risk management. The core of the *Cartagena Protocol* is the advance informed agreement procedure (the AIA procedure) that must precede the first intentional transboundary movement of GMOs intended for introduction into the environment. Under the AIA procedure, importing countries have the rights not to import GMOs intended for releasing into the environment without their prior consent; or to ban or restrict the import of GMOs based on a risk assessment which takes into account biodiversity and human health. The foundation of the AIA procedure is that importing countries should ensure that their informed decisions regarding GMOs intended for release into the environment are based on a risk assessment which is carried out in a scientifically sound manner. The Protocol sets out basic requirements on risk assessment and risk management in articles 15, 16 and Annex III. In addition, the parties to the Protocol are endeavouring to develop detailed guidance on risk assessment and risk management.

In COP-MOP 4, the parties to the Protocol established an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management, in order to develop further guidance

on specific aspects of risk assessment and risk management.[7] With the input from the Open-Ended Online Expert Forum, the fourth meeting of the AHTEG developed a revised version of the Guidance on Risk Assessment of Living Modified Organisms (the *Guidance*)[8] which was discussed by the parties during the COP-MOP 6 meeting. The Guidance was designed to assist Parties and other Governments in implementing relevant provisions on risk assessment.[9] Delegates in Working Group Two of the COP-MOP 6 considered risk assessment and risk management and the revised version of the *Guidance*.[10] Discussions focused on extending the mandate of the Ad hoc Technical Expert Group (AHTEG) on risk assessment and the open-ended online forum, and whether to endorse the *Guidance*. China, together with the EU, the African Group, CEE, Norway, and Colombia, supported the endorsement of the *Guidance* and continuation of the AHTEG and the open-ended online forum. Brazil, New Zealand, India, Ecuador, South Africa and the Philippines insisted that the *Guidance* ought not to be endorsed without further testing and refining. At the end of the meeting, the COP-MOP 6 decided not to endorse the *Guidance on Risk Assessment of LMOs*, but to 'commend' the progress made on developing the *Guidance*. The delegates recognized the *Guidance* as not imposing any obligations on parties. The parties decided that the *Guidance* will be tested nationally and regionally, the mandate of the open-ended online forum will be extended, and a new AHTEG will be established.[11]

At the domestic level, on 21 February 2012, the Legislative Affairs Office of the State Council published the *Grain Law (Exposure Draft*), and invited public comment on it before 31 March 2012. The drafting process of the *Grain Law* was led by the National Development and Reform Commission, executed by the State Administration of Grain, and supported by the Ministry of Agriculture and Ministry of Health. On 3 November 2012, officials from the Law Committee and the Agriculture and Rural Affairs Committee of the Standing Committee of National People's Congress visited the State Administration of Grain, to consult on the drafting of the *Grain Law*.[12] It is likely that the *Grain Law* will be included in the working plan on law reform of the National People's Congress in 2013. If adopted, the *Grain Law* will be the first Chinese legislation on food supplies and food safety endorsed by the National People's Congress in the format of law.

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[7] COP-MOP 4 Decision: BS-IV/11 Risk Assessment and Risk Management.
[8] COP-MOP6 Meeting Documents, Guidance on Risk Assessment of Living Modified Organisms, UNEP/CBD/BS/COP-MOP/6/13/Add.1 (available at: http://www.cbd.int/doc/meetings/bs/mop-06/official/mop-06-13-add1-en.pdf).
[9] Ibid, 8.
[10] UNEP/CBD/BS/COP-MOP/6/13/Rev.1 and 13/Add.1 (available at http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=4715).
[11] COP-MOP6 Decisions, BS-VI/12. Risk assessment and risk management (articles 15 and 16) (available at http://www.cbd.int/doc/meetings/bs/mop-06/official/mop-06-18-en.pdf).
[12] See http://www.gov.cn/gzdt/2012-11/13/content_2264178.htm.

Article 12(2) and article 15 of the draft *Grain Law* are relevant to the domestic regulation on agricultural GMOs. Article 12(2) of the draft *Grain Law* states that: “The research, experiment, production, sales, import and export of genetically modified grain seeds must comply with relevant national regulations. No organisations or individuals are allowed to utilize GM technology for the main commercially produced types of grain without authorization”. This provision, together with other provisions of the draft, has caused significant discussion, debates, and critics. Article 12(2) provides general guidelines and indicators which are vague. It does not provide the detailed regulation of agricultural GMOs that was expected by some commentators.

Article 12(2) simply requires relevant processes to be based on existing national regulations. It does not add any new elements to the regulation. It is likely that “relevant national regulations” refers only to earlier government decrees, including the 2001 *Regulation on the Safety Administration of Agricultural GMOs*, and the implementation regulations issued by the Ministry of Agriculture and the General Administration of Customs. In China, laws issued by the National People’s Congress, such as the proposed *Grain Law*, are superior to regulations decreed by the State Council, such as the 2001 Regulation. Laws take precedence over regulations when they conflict. The wording of article 12(2) seems to reaffirm the authority of existing regulations governing agricultural GMOs. The second sentence of article 12(2) has also attracted debate as the public are concerned with the potential risk caused by GMOs. This provision forbids unauthorized utilization of GM technology on the main commercial grain breeds, and seems to leave non-mainstream grain breeds unregulated. There exists the potential that GM technology in non-mainstream grain breeds may also cause damage to the environment or to human health and safety.

Article 15 of the *Grain Law (Exposure Draft)* states that: “the country encourages and supports research, innovation, protection, and utilisation of new production methods of grains, in order to increase the per unit area yield level and quality of grains”. There is no doubt that GM technology is a significant agricultural innovation which can contribute to the increase of per unit area yield level and quality of grains. The Chinese Government has made significant investments in the development of GM technology. Article 15 seems to indicate that China will continue its investment in biotechnology and agricultural GMOs to meet the needs of its population.

On 30 December 2011, the Ministry of Agriculture announced the *Twelfth Five-Year-Plan on the Development of Agricultural Technology*,[13] and decided to carry on developing GM technology, whilst implementing risk assessment and monitoring of GMOs, and revising and improving the laws on GMOs. On 1 February 2012, the Chinese Communist Party Central Committee and the State Council published its 'Number One Central Document', *Suggestions on Accelerating Agricultural Science and Technology Innovation to Continuously Improve and Ensure Adequate Supplies of Agricultural Products*. The document announced that the country will continue its efforts on developing technology in the fostering new species of GMOs.[14]

Conclusion

China has established a case-by-case domestic regulatory and administrative system for regulating GMOs. The Chinese Government regulates agricultural GMOs through government decrees. China is yet to develop a sophisticated biosafety regulation framework to balance economic development and environmental, human health, and food safety protection. A sophisticated 'Transgenic Biosafety Law' has been drafted but has not been adopted. The proposed *Grain Law* will serve to regulate agricultural GMOs. The exposure draft of the *Grain Law* seems to be too simple and vague. It does not provide detailed new requirements on the regulation of agricultural GMOs. It leaves the utilization of GM technology on non-mainstream grain breeds unregulated. However, the *Grain Law (Exposure Draft)* does reaffirm the authority of existing regulations. Together with other evidence, the proposed *Grain Law* indicates that China will continue its efforts to develop GM biotechnology and agricultural GMOs.

[13] Available at http://www.moa.gov.cn/zwllm/zcfg/nybgz/201112/t20111231_2449779.htm.
[14] *Suggestions on Accelerating Agricultural Science and Technology Innovation to Continuously Improve and Ensure Adequate Supplies of Agricultural Products*, paragraph 9 (available at http://www.gov.cn/jrzg/2012-02/01/content_2056357.htm).