Capacity Building Analysis Report on Promoting Synergistic Implementation of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity at National level

(Revised)

China is one of the countries with the richest biodiversity in the world. It also boasts rich genetic resources due to the long history of agriculture. Soybean, rice and other important crop species originated in China. Therefore, the country is quite careful in managing genetically modified organisms (GMOs), a complicated issue that influences environment, health, ethics, society and economic and technology development. China has set up a biosafety management office since the complexity of this issue requires the participation of multiple administrative departments. A safety management system comprising departments such as agriculture, forestry and quality inspection has been put in place.

I. National strategy on biosafety and biodiversity conservation

Chinese government issued an array of documents, including National Biosafety Framework, the Outline of The National Medium- and Long-Term Program for Science and Technology Development, the Outline on National Ecological Environmental Protection and the National Plan on Environmental Protection Technology Development, making biosafety management a long-term task for the country. China has also enhanced its regulation and research on GMO risks and control at different levels to become more capable in implementing national environmental conventions.

Reviewed and adopted by a State Council executive meeting, China National Biodiversity Conservation Strategy and Action Plan (2011-2030) was issued by the Ministry of Environmental Protection, in which advancing research on environmental release, risk assessment and environmental impact assessment of GMOs, improving related technical standards and regulations, and ensuring safe environmental release of GMOs were listed as national strategic tasks. The document also identified GMO management as one of the priority areas of work and proposed a plan to set up a system and platform for biosafety assessment, inspection and monitoring of GMOs. The document will guide China's effort to strengthen biosafety management.

Supported by China National Committee of Biodiversity Conservation (hereinafter referred to as the Committee), local governments of Shandong, Ningxia, Tianjin, Tibet, Fujian, Hubei, Hunan, Hainan, Heilongjiang, Jiangxi and Jiangsu issued their own local-context based biodiversity conservation strategy and action plans. Most of the Provinces in China have already included GMOs management into priority areas of work and priority actions. For example, Shandong Province has made carrying out GMO safety assessment and developing GMO inspection methods and monitoring techniques one of the priority actions and set up 4 priority projects. Tianjin has asked for strengthened monitoring and entry-exit inspection and quarantine of GMOs. Ningxia Hui Autonomous Region has decided to improve its GMOs management mechanism through enhancing detection procedure and establishing GMO safety assessment, inspection and monitoring system. Fujian Province said it would set up and improve a technical system for GMO inspection and monitoring. Hubei Province has planned to put in place an inspection system for the entry and exit of GMOs, and build up its capacity in early warning, emergency response and monitoring. Heilongjiang Province is determined to set up a system and platform for GMO safety assessment, inspection and monitoring techniques.

Hunan Province proposed a plan for setting up a strict GMO approval, filing and management system, and made the development of GMO safety emergency response plan of different levels of local governments one of the priority actions.

II. GMO Legislations in China

China is among the first countries in the world to formulate and implement regulations on GMOs. In order to regulate increasing GMO research and environmental release, and to protect the environment and human health, a series of regulations have been put in place since the guidance document on the safety management of GMOs made by the State Scientific and Technological Commission came out in 1993. The Ministry of Agriculture issued the Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering in 1996, asking for safety assessment and management on GMO research trials. In 2001, the State Council issued Regulations on Administration of Agricultural Genetically Modified Organisms Safety (hereinafter referred to as the Regulations), which specified requirements for safety assessment, labeling, production and marketing permits and import safety approval of GMOs. January 2002 witnessed the release of three supporting documents of the Regulations—the Application Requirements for Safety Assessment of Agricultural Genetically Modified Organisms, the Measures for the Administration of the Safe Import of Agricultural Transgenic Living Things and the Administrative Measures for Labeling Agricultural Genetically Modified Organisms. In January 2006, the Ministry of Agriculture carried out the Measures for the Examination and Approval of Agricultural Genetically Modified Organisms Processing. The coming out and the implementation of the Regulations and its supporting documents showed China's all-round management of GMOs in research, trial, production, processing, marketing, import and export processes.

In 2004, the General Administration of Quality Supervision, Inspection and

Quarantine of China (hereinafter referred to as GAQSIQ) issued the *Regulation on Inspection and Quarantine of Import and Export Genetically Modified Products* (hereinafter referred to as Regulation on IQIEGMP) that links to import and export safety management. It is clarified in the General Principles that this Regulation was formulated to enhance the administration on import and export GMPs, protect human health and the safety of animals, plants and microorganisms, and conserve the ecological environment, based on laws and regulations, e.g. *Import and Export Commodity Inspection Law of P.R.C.*, *Food Hygiene Law of P.R.C.*, *Import and Export Animals and Plants Quarantine Law of P.R.C.*, *Regulations on Administration of Agricultural Genetically Modified Organisms Safety*, etc. GAQSIQ is responsible for the management on import and export GMPs in whole country. And the inspection and quarantine institutions located in Province and cities are taking charge of inspection, quarantine and management on import and export GMPs within their jurisdiction areas. Most of these routine works are supported by national finance. The Regulation on IQIEGMP does not have the provisions related to public participation and awareness and has not yet been revised.

In December 2013, the State Forestry Administration issued the *Regulation on Biosafety Monitoring of Genetically Modified Forest Trees* (hereinafter referred to as Regulation on BMGMFTs). This regulation took into force on 1st February 2014 and valid until 31st January 2019. The Genetically Modified Forest Trees (hereinafter referred to as GMFTs) are the forest plants in which the genome composition was changed by genetic engineering techniques, and for the purposes of forestry production and processing. The Biosafety Monitoring shall be mandatory, standardized and scientific, and carried out on GMFTs refers to the investigation, inspection and analysis related to human health and environmental safety. This regulation applies within the territory of P.R.C. for the GMFTs in pilot experiment stage, environmental

release stage, production test stage and commercialization stage. Once a new GMFT is approved for pilot experiment and therefore become the object of Biosafety Monitoring. The Contents of Biosafety Monitoring include non-target effects of trait variation of exogenous gene imposed on recipient plant, gene flow and their ecological consequences, genetic stability of GMFTs, impacts on human and animal health, not-target effects, impacts on ecological process and biological diversity, and risk of resistance of target organisms. The period of Biosafety Monitoring lasts 2-3 years. The Biosafety Monitoring activities are organized by the State Forestry Administration and appointed to eligible institutions. The Regulation on IQIEGMP does not have the provisions related to public participation and awareness and not linked to climate change.

In April 2015, the amended Food Safety Law of the People's Republic of China was adopted by Standing Committee of the National People's Congress. The law, which came into force on October 1, 2015, stipulates that GMO foods should be labeled in production and marketing, if not, punishments, including fines will be imposed. Moreover, Chinese government has also released a series of national and industrial standards on GMO labeling, environmental safety assessment and GM component testing.

III. Biosafety Management System in China

Established in June 2011, the National Committee for Biodiversity Conservation (hereinafter referred to as NCBC) is the highest body to coordinate biosafety management in China. It is composed by 25 ministries and institutions, listed as below: the Propaganda Department of the Central Committee of the Communist Party of China, the Ministry of Foreign Affairs, the State Development and Reform Commission, the Ministry of Education, the Ministry of Science and Technology, the Ministry of Public Security, the Ministry of Finance, the Ministry of Land Resources, the Ministry of Environmental Protection, the Ministry of Housing and Urban-Rural

Development, the Ministry of Water Resources, the Ministry of Agriculture, the Ministry of Commerce, State Administration of Custom, State Administration for Industry and Commerce, the General Administration of Quality Supervision, Inspection and Quarantine, the State Administration of Press, Publication, Radio, Film and Television, State Forestry Administration, State Intellectual Property Office, the Xinhua News Agency, the Chinese Academy of Sciences, State Oceanic Administration, State Administration of Traditional Chinese Medicine, People's Daily, GUANGMING Daily. Its responsibility includes coordinating biodiversity conservation actions at national level, organizing relevant departments to compile biodiversity conservation plans and carry out conservation and management work, implementing the Convention on Biological Diversity and other relevant conventions and implementing China National Biodiversity Conservation Strategy and Action Plan (2011-2030). The Vice Premier of the State Council serves as the chairman of the committee (the first chairman of the committee was then Vice Premier Li Keqiang and the current chairman is the present Vice Premier Zhang Gaoli). The highest decision-making mechanism for NCBC is the National Committee plenary, which was held irregularly and considered the important issues of national biodiversity conservation. The plenary was hosted by the Vice Premier. All documents considered in plenary was provided by the secretariat of NCBC and checked then by the General Office of the State Council. The First Meeting of NCBC was held in June of 2012, the documents of Ten-year Action Plan in China of Biological Diversity Conservation under UN and inter-sectors division cooperation plan were approved in this meeting. The Second Meeting of NCBC was held in December of 2014, the documents of the Proposal for accession to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity, National Action Plan for Strengthening the Management of Biological Genetic Resources (2014-2020), and the Implementation Plan for Major Programme

of Biological Diversity Conservation(2014-2020) were approved in the meeting. The Proposal for accession to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety was submitted to the Secretariat and waiting for the Third meeting of NCBC.

The State Council has established a mechanism of joint conference of relevant ministries and departments including agriculture, technology, environmental protection, health, quality inspection and food and drug, which is responsible for studying and coordinating major policy and legal issues concerning biosafety management of agricultural GMOs. The Ministry of Agriculture set up an office for day-to-day management of agricultural GMOs. Agricultural administrative departments above county level are responsible for GMO safety management within its own administrative region. Based on globally accepted assessment rules, the common practice of Europe and the US and its domestic context, China has established a system of laws and regulations comprising 1 State Council regulation and 5 department-level regulations, covering risk assessment, production licensing, business licensing, product labeling and import/export approval processes. China has also set up a Biosafety Committee of Agricultural GMOs composed of 64 academicians and experts, a Standardization Technical Committee on Agricultural GMOs composed of 47 experts, as well as 42 third-party detection and testing organizations, for GMO safety assessment, standard setting, detection and testing.

The Ministry of Environmental Protection manages and coordinates the environmental safety issues of GMOs through mechanisms such as China Coordinating Group on Implementation of the Convention on Biological Diversity (herein after referred to as the Coordinating Group) and the Inter-ministerial Joint Conference on Conservation of Biological Resources. It leads the efforts in China to implement the Convention on Biological Diversity and the Cartagena Protocol on Biosafety. The Coordinating Group was

established in 1993 and led by the State Environmental Protection Administration at that time. The number of members of the Coordinating Group were initiated in 13, became 20 in 1995 and extended to 22 ministries and institutions in 2004, including: the Ministry of Foreign Affairs, the State Development and Reform Commission, the Ministry of Education, the Ministry of Science and Technology, the Ministry of Public Security, the Ministry of Finance, the State Environmental Protection Administration, the Ministry of Construction, the Ministry of Agriculture, the Ministry of Commerce, State Administration of Custom, State Administration for Industry and Commerce, the General Administration of Quality Supervision, Inspection and Quarantine, the State Administration of Press, Publication, Radio, Film and Television, State Forestry Administration, State Intellectual Property Office, the Xinhua News Agency, the Chinese Academy of Sciences, State Oceanic Administration, State Administration of Traditional Chinese Medicine, People's Daily, GUANGMING Daily.

Apart from the Ministry of Agriculture and the Ministry of Environmental Protection, GMO safety management also involves National Health and Family Planning Commission (NFHPC), General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), State Forestry Administration (SFA), etc. The work of these regulatory departments of GMOs is within their own scope of authority and responsibility. For example, NHFPC is responsible for human genetic resource management, AQSIQ is responsible for the inspection and quarantine of the import/export of genetically modified products and SFA is responsible for the management of genetically modified forest trees.

IV. Risk assessment and monitoring status of GMOs in China

Biosafety Committee of Agricultural GMOs reviews agricultural GMO risk assessment report for environmental release, pre-production trials and safety certificate applications. Forestry Genetic Engineering Safety Committee

assesses the risks of genetically modified forest tree species. MEP takes part in major decision-making processes through the mechanism of the Inter-ministerial Joint Conference on Conservation of Biological Resources. It also appointed experts to participate in the safety assessment of GMOs. General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) is responsible for the inspection and quarantine of import/export GMO products. By conducting testing, AQSIQ ensures safe and successful cross-border transfer of GMOs while protecting the soundness of the environment, agriculture and forestry production and human and animal health in China.

At the same time, with the support of UNEP-backed Biosafety Project on the Implementation of National Biosafety Framework, the National Key Technology R&D Program, the R&D Special Fund from MEP and Major National Science and Technology Research Projects on Breeding New Varieties of GMOs, Chinese government has brought together experts from sectors such as agriculture, environmental protection, quality inspection, technology, education, forestry and Chinese Academy of Sciences, to study on the environmental risk assessment and monitoring of genetically modified rice, cotton, corn, wheat, soybeans, pigs, cattle and sheep. A group of testing organizations has also been set up to analyze GM component, environmental impact and food safety. Moreover, Chinese government requires competent departments to carry out casual inspections on law enforcement by themselves or together with other departments, so as to investigate and deal with the organization/individual that conducts illegal GMO research and development. R&D projects have been developed by the government to track and monitor GMOs in the long run. 25% of the fund of Major National Science and Technology Research Projects on Breeding New Varieties of GMOs has been put into biosafety researches—the first time ever for safety research to take up such a large proportion of fund in major national science and

technology projects. As a result, China is able to set up a national system for GMO safety regulation and services and train a team of skilled professionals.

V. Current status of biosafety mainstreaming

Since China joined the Cartagena Protocol on Biosafety, the country has been promoting national biosafety management and the implementation of the protocol. Chinese government has made great effort in incorporating biosafety management into biodiversity conservation. CBD Implementation Office of China and the coordination group not only aim to promote CBD implementation, but also play a significant role in promoting the implementation of the protocol. The coordination group was joined by 13 departments initially. By 2015, there were 25 departments in the group, including the Ministry of Environmental Protection, the Publicity Department of the Communist Party of China, the Ministry of Foreign Affairs, National Development and Reform Commission, the Ministry of Education, the Ministry of Commerce, the Ministry of Science and Technology, the Ministry of Public Security, Ministry of Finance, the General Administration of Customs, State Administration of Press, Publication, Radio, Film and Television, State Administration for Industry & Commerce, General Administration of Quality Supervision, Inspection and Quarantine, State Forestry Administration, State Intellectual Property Office, Xinhua News Agency, Chinese Academy of Sciences, State Oceanic Administration, State Administration of Traditional Chinese Medicine, People's Daily, Guangming Daily, etc. National-level mechanisms as such have helped to put biosafety management on the agenda of the State Council and relevant departments. Biosafety mainstreaming in China has embraced new opportunities as the 18th National Congress of the Communist Party of China proposed to build ecological civilization and made biodiversity conservation a strategic task.

VI. Challenges for biosafety mainstreaming

There are a number of problems and challenges facing biosafety mainstreaming in China, including:

i The legal system and management mechanism for biosafety are yet to be improved

China has rolled out a series of management regulations relating to biosafety, however all of them are area-specific and there is no comprehensive Law on Biosafety. Efforts are also highly needed in areas such as improving interdepartmental biosafety management coordination mechanism and the formulation of regulations and technical standards for GMO management, and the R&D, contained use, environmental release, commercialization, transfer, storage, handling and import/export of GM products.

ii Risk assessment and management capability should be improved.

Compared with developed countries, China still lags behind in risk assessment and management. The country's lack of testing, detection and emergency response capacity for GMOs and GM products leads to limited GMO safety management and supervision on law enforcement.

iii Public participation in biosafety management needs to be improved.

Although many local governments have already included biosafety into their biodiversity conservation strategy and action plan, government departments' awareness about and management capacity of biosafety still have much room to improve, so are the level of participation and supervision of the public. Relevant enterprises at the same time need to be more oriented towards risk management and law-abiding.

Strengthening GMO management is an irresistible trend, judging from both the situation of international convention negotiations and the implementation of relevant conventions at home. With countries pushing forward their work on biosafety management law enforcement and the protocol implementation,

biosafety management capacities in different countries and regions will keep enhancing, management system and public awareness in this regard will also be improved.

VII. Capacity building needed for mainstreaming biosafety

In order to address the challenges, capacity building in following areas is needed:

i. Strengthening legal and policy support

Biosafety mainstreaming involves different sectors and fields. For example, incorporating biosafety mainstreaming into economic development, land use planning or environmental impact assessment will inevitably cause changes to local economy, society, environment, cultural structure or status. It also has impacts on the interests and rights of different stakeholders. Therefore, legal and policy support is a must for biosafety mainstreaming; otherwise, there will be many difficulties, even resistance from stakeholders.

ii. Improving biosafety management institution-building

Institutional building and improvement is an important way or method to achieve biosafety mainstreaming. It also asks for a higher status and expanded mandates for existing departments responsible for biosafety management, which will promote coordination and cooperation among different stakeholder. Setting up new biosafety management departments is one of the ways to include biosafety into the work of the government.

iii. Enhancing publicity and education

For different parties, particularly the decision-makers, the first step towards accept and promote biosafety mainstreaming is to understand the importance of biosafety to biodiversity conservation and human health. Effective ways to enhance awareness in this regard include expand publicity and organize knowledge dissemination and awareness-improving trainings and campaigns.

The content of which can cover areas such as the basic knowledge of biosafety, the significance and influence of biosafety mainstreaming and also successful cases and practices from home and abroad. The implementation of biosafety projects will play a key role in this process.

iv. Developing methods and techniques for mainstreaming

Sometimes, the problem facing local governments or enterprises is not that they do not want to mainstream biosafety, but they don't know how to do it or they hardly understand the concept despite they are very enthusiastic. This will not only slow down the mainstreaming process, but also limit its effectiveness. Government is suggested to carry out relevant research and technology development to offer theory, techniques and practical experience needed for local governments, departments and enterprises.

v. Reinforcing scientific and technical support

Biosafety mainstreaming is at early stage in China. Existing theory and methodology cannot meet the needs of current work. Therefore, in order to provide necessary scientific and technical support to biosafety mainstreaming, the country needs to increase its investment in scientific research and technology development.

vi. Supporting and promoting international cooperation

Since joined the Convention on Biological Diversity and The Cartagena Protocol on Biosafety, China has been actively engaging in international negotiations and promoting the implementation of both the convention and the protocol. As for the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, now relevant departments in China are communicating and coordinating, with the hope to accelerate domestic ratification proceedings.

International projects such as capacity building project on China's biodiversity

clearing house mechanism, China national biodiversity framework implementation project and China biodiversity partnership framework project are proven successful in promoting China's GMO research and management capacity. Therefore, in the future, international organizations such as UNEP, GEF and CBD can continue to be the platform of communication and experience exchange for China, supporting China's effort in biosafety mainstreaming.