

Policy Brief

Key Messages

- For the industrialization of agricultural GMOs, China will continue to push forward in line with the principles of respecting science, strict management, abiding by laws and regulations, and ensuring safety.
- Ten domestic GM crops have been issued approvals in China since 2019. These include a range of traits, predominantly herbicide tolerance and pest resistance.
- No foreign genes: MARA issued the Safety Evaluation Guideline for Gene-Edited Agricultural Plants (Provisional) on 24 January. It outlines the submission of applications for a safety evaluation based on possible risks, covering gene-edited plants that have not introduced the exogenous gene.

GMO Policies and Regulations in China

By Dr. JG

Introduction

The safety assessment and commercialization of Agricultural genetically modified organisms (GMOs) is a hot societal issue in China. Since 2009, the State Council has been approved a special science and technology fund with about 3 billion USD for China's sustainable agricultural development, which aimed to research and develop new GM crops, with the traits of high-quality, disease resistant, high yielding and resource efficient. In the Central Economic Work Conference conducted in December 2020, Chinese government emphasized the strategic importance of developing seed industry repeatedly and highlighted the necessity to protect germplasm resources and construct seed banks [1]. On 18 February 2021, the Chinese Ministry of Agriculture and Rural Affairs (MARA) issued a Notice to encourage independent innovation in research of GMOs and the transfer of biological materials [2]. The issued Notice and policy guidance is undoubtedly positive for industry, which actively encourages the research and commercialization of GMOs.

Terminology of GMOs

Chinese laws and regulations related to genetically modified organisms mainly focus on “Agricultural GMOs”. According to them, Agricultural GMOs refer to “*the animals, plants, microorganisms and their derivate products for the use in agricultural production or processing, whose genomic structure has been modified by genetic engineering technologies*”. In general, Agricultural GMOs contain transgenesis, cisgenesis, intragenesis, RNAi, and gene-edited species, since all these products were produced by transgenic transformation techniques, such as agrobacterium-mediated transformation and microparticle bombardment.

Regulatory Framework

Regulatory Structure

The agricultural biotech regulatory environment is outlined in the State Council’s “Administrative Rules for Safety of Agriculture GMOs” which are implemented by these measures:

- Administrative Measures for the Safety Assessment of Agriculture GMOs (issued on 5 January 2002, revision issued on 30 November 2017, latest revision issued on 21 January 2022)
- Administrative Measures for the Safety Assessment of Agriculture GMOs Imports (issued on 5 January 2002, latest revision issued on 30 November 2017)
- Administrative Measures on Labelling of Agriculture GMOs (issued on 5 January 2002, latest revision issued on 30 November 2017)
- Measures for the Review and Approval of Agricultural Genetically Modified Organisms for Processing (implemented on 1 July 2006)
- Technical guidance, standards and procedures released in form of MARA public notices
- AQSIQ Decree 62 “Administrative Measures of Inspection and Quarantine on Entry-Exit GM Products” (implemented on 24 May 2004, latest revision issued in April 2018)
- The Special Administrative Measures for Foreign Investment Access (latest revision issued in January 2022).

National Biosafety Committee (NBC)

The NBC was organized by the MARA, who is in charge of reviewing the domestic and foreign applications of biosafety certificates for cultivation and import.

Other Functional Departments

The General Administration of Customs (GACC) is responsible for testing the imported agricultural and food products according to the GMO administrations and labelling regulation. The National Forestry and Grassland Administration (NFGA) is responsible for the approval of forestry products for research, domestic production, and import based on its own biotech regulatory policies related to wood products. The Ministry of Ecology and Environment (MEE) is the lead agency in the negotiation and implementation of the Cartagena Biosafety Protocol. 42 MARA professional testing institutions are responsible for providing technical support on molecular

characteristics evaluation, environmental and food safety assessment. The State Administration for Market Regulation (SAMR) is the authority for comprehensive market oversight, law enforcement in respect of market supervision and administration, and the comprehensive coordination on the supervision and administration of food safety nationwide.

MARA Approval Procedure

Under the safety evaluation system, a GMO safety certificate must be obtained prior to any other examination, registration, evaluation or approval [3]. There are two types of safety certificates: one for imported foreign products and one for domestic products.

Biosafety Certificate for Agricultural Biotech Products (Import) Issued to Foreign Developers

The Administrative Measures for Safety Control in the Import of Agricultural GMOs declares the basic requirements for importing foreign biotech products. After receiving the application for biosafety certificate, MARA's GMO Biosafety Office will at first designate several domestic professional institutions to conduct safety assessment and to verify the data provided by the developer. Then, the NBC will review the validation report and compare it with those of developers. Finally, the NBC will deeply discuss this in its annual meeting and send its decision to the MARA.

Biosafety Certificate for Agricultural Biotech Products (Import) Issued to Traders

Chinese importers must obtain a "Biosafety Certificate for Agricultural Biotech products (Import)" for each consignment of biotech products they intend to import. The importer must show the MARA-issued certificate to local customs during the inspection and quarantine process. An importer is requested to prepare the following files to apply for the certificate: (1) electronic or paper copy of the Biosafety Certificate for Agricultural Biotechnology (Import) Issued to Foreign Developers; (2) Registration for Safety Management of Agricultural Biotechnology Import (Used for Processing Materials) (the application form) and (3) intended safety control measures.

Domestic Cultivation Approval Procedure

If domestic developers intend to commercialize a new agricultural biotech product in China, they also need to apply for MARA's biosafety certificate. After obtaining the certificate, developers need to apply for plant variety registration from MARA's Seed Industry Management Department. After obtaining the licence of variety registration, developers can commercially cultivate biotech products in the allowed geographical regions of variety registration licence.

Approvals

Up to data, the MARA has issued 63 safety certificates and licenses for using as raw materials or planting for foreign biotech crop events. The MARA has issued ten safety certificates for domestic biotech crop events since 2019, including three GM soybeans and seven GM maizes [4].

Outlook

To solve the problems caused by *Spodoptera frugiperda* and weed damage faced by current agricultural production, the MARA initiated an industrialization pilot program for two biotech products that received the safety certificate in 2021: (1) herbicide-tolerant GM soybean and (2) insect-resistant and herbicide-tolerant GM corn. And the pilot program was noticeably beneficial, the MARA said. In the first half of 2021, Chinese high-level officials emphasized that germplasm resource and breeding are crucial to Chinese agricultural stability and food security. According to the amended Seed Law of 2015, a total of five major crops (rice, wheat, corn, cotton, and soybean) are requested and subjected to variety registration. The Administrative Measures for Major Crops Variety Registration released by the MARA in January 2022 issued the detail requirements for variety registration of biotech crops. The administrative measures facilitate the ability of developers of biotech crop varieties to apply for seed variety registration as well as for a Production and Operation License. The Department of Science, Technology and Education of the MARA issued the Safety Evaluation Guideline for Agricultural Gene-Edited Plant (Provisional) in 24 January 2022, which outlines the application requirements of safety assessment and safety certificate for the gene-edited plant without exogenous gene introduced. Industry professionals believed that the issuance of the guideline is now moving a step closer to the industrialization of gene-edited plant.

Through the analysis of major policies in recent years, it can be seen that the strategic positioning of biotech crops has risen from a simple departmental management to a national strategy, which is also reflected in the Document No.1 of the CPC Central Committee and the General Secretary Xi's speeches. All the above has pointed to the direction for the healthy development of an agricultural biotech industry, and there is a shift from simply paying attention to scientific research to focusing on more aspects of scientific research, safety management, industrial application, and popularization of science and application.

References

- [1] http://www.xinhuanet.com/politics/leaders/2020-12/18/c_1126879325.htm
- [2] http://www.moa.gov.cn/ztl/zjyqwgz/zcfg/202102/t20210219_6361812.htm
- [3] http://www.moa.gov.cn/ztl/zjyqwgz/zcfg/201007/t20100717_1601306.htm
- [4] <https://www.moa.gov.cn/ztl/zjyqwgz/>

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This policy brief is published under the responsibility of the Sino-German Agricultural Centre (DCZ), which is funded by the German Federal Ministry of Food and Agriculture (BMEL). All views and results, conclusions, proposals or recommendations stated therein are the property of the authors and do not necessarily reflect the opinion of the BMEL.

About the project

The Sino-German Agricultural Centre is a joint initiative of the German Federal Ministry of Food and Agriculture (BMEL) and the Ministry of Agriculture and Rural Affairs of the People's Republic of China (MARA). It was established in March 2015 as a central contact and information point and for coordinating bilateral cooperation between Germany and China in the agricultural and food sector. The DCZ brings together stakeholders from the public and private sector and the scientific community. It creates forums in which agricultural issues of common interest are addressed. The spectrum of Sino-German cooperation in the agricultural sector is reflected in the three components of the DCZ: Agricultural Policy Dialogue, Agri-Food Business Dialogue and Scientific Dialogue.

Further information can be found on the project website: <https://dcz-china.org/en/the-project.html>.